IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

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| LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., and JILL L. VIBHAKAR, M.D., | ) | 4:03CV3385 |
| Plaintiffs, | ) | |
| vs. | ) | **MEMORANDUM AND ORDER** |
| JOHN ASHCROFT, in his official capacity as Attorney General of the United States, | ) | |
| Defendant. | ) | |

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> Again and again the uterus contracts as the cervix opens up. The tiny passageway that once allowed the entrance of a single file of sperm now must widen to about four inches to accommodate a baby's head.
>
> Human births are far more dangerous than those of other mammals or even other primates. The human brain is three to four times bigger than an ape's brain. And the pelvis is narrower to allow us to walk upright. A human baby has to go through considerable contortions to make it through the narrow opening. Sometimes, there simply is not enough room.[1]

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[1] Life's Greatest Miracle (PBS television broadcast, Nov. 20, 2001), available at http://www.pbs.org/wgbh/nova/transcript/2816miracle.html.

Like giving birth to a child, when a woman ends her pregnancy during or after the second trimester, she confronts a serious problem. Her cervix will frequently be too small to allow the skull of the human fetus to pass through it. Although terminating a pregnancy in America is safer than childbirth, this "skull-is-too-large" difficulty makes the abortion of a human fetus, like the birth of a human baby, potentially very dangerous to both the life and health of the woman. Our elected representatives have decided that it is never necessary to use a specific surgical technique— "partial-birth abortion"—to deal with this concern during an abortion. On the contrary, they have banned the procedure.

After giving Congress the respectful consideration it is always due, I find and conclude that the ban is unreasonable and not supported by substantial evidence. In truth, "partial-birth abortions," which are medically known as "intact D&E" or "D&X" procedures, are sometimes necessary to preserve the health of a woman seeking an abortion. While the procedure is infrequently used as a relative matter, when it is needed, the health of women frequently hangs in the balance.

Four examples, out of many, illustrate this point:

* During the 17th week of gestation, before many physicians are comfortable inducing fetal death by injection prior to beginning a surgical abortion, one of Mr. Ashcroft's expert witnesses conceded that it would be consistent with the standard of care at the University of Michigan Medical School, where she practices, to crush the skull of the living fetus when the body was delivered intact outside the cervix and into the vaginal cavity if the skull was trapped by the cervix and the woman was hemorrhaging. (Tr. 1598-1602, Test. Dr. Shadigian.)

* Another of Mr. Ashcroft's expert witnesses, the head of obstetrics and gynecology at Yale, testified on direct examination, and confirmed again

on cross-examination, that there are "compelling enough arguments as to [the banned technique's] safety, that I certainly would not want to prohibit its use in my institution." (Tr. 1706 & 1763, Test. Dr. Lockwood.)

* Another physician, Dr. Phillip D. Darney, the Chief of Obstetrics and Gynecology at San Francisco General Hospital, a major metropolitan hospital that performs 2,000 abortions a year, provided Congress with two very specific examples of abortions at 20 weeks and after (one case presenting with a bleeding placenta previa and clotting disorder and the other with a risk of massive hemorrhage) "in which the 'intact D&E' technique was critical to providing optimal care[,]" and was the "safest technique of pregnancy termination" in those situations. (Ct.'s Ex. 9, Letter to Sen. Feinstein from Dr. Darney, at 100-01.)

* Still another doctor, who had served on the committee of physicians designated by the American College of Obstetricians and Gynecologists (ACOG) to look into this issue and who holds certifications in biomedical ethics, obstetrics and gynecology, and gynecologic oncology, Dr. Joanna M. Cain, testified that in the case "of cancer of the placenta often diagnosed in the second trimester," where "the least amount of instrumentation possible of the uterine wall is desirable[,] . . . it is much safer for the woman to have an intact D&X to remove the molar pregnancy." (Pls.' Ex. 115, Dep. Dr. Cain, at 177.)

Therefore, I declare the "Partial-Birth Abortion Ban Act of 2003" unconstitutional because it does not allow, and instead prohibits, the use of the procedure when necessary to preserve the health of a woman. In addition, I decide that the ban fails as a result of other constitutional imperfections. As a result, I will

also permanently enjoin enforcement of the ban.[2] Importantly, however, because the evidence was sparse regarding postviability, I do not decide whether the law is unconstitutional when the fetus is indisputably viable.

## *AN APOLOGY*

In advance, I apologize for the length of this opinion. I am well aware that appellate judges have plenty to do and that long-winded opinions from district judges are seldom helpful. That admitted, this case is unique.

As might be expected, the two-week trial presented numerous live witnesses and hundreds of exhibits. That evidence includes a record developed by Congress over many years. Because the parties have also submitted the testimony and evidence presented in two other similar cases, this record is bloated by that additional information. Lastly, and most importantly, since I decide the constitutionality of an Act of Congress that explicitly found a prior decision of this court to be factually unsound, and that law addresses one of the most contentious issues confronting this nation, respect for our national legislature requires more than the usual attention to detail. Nonetheless, I pity the poor appellate judge who has to slog through this thing. I am truly sorry.

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[2]Should there be any doubt that these plaintiffs are in imminent danger of prosecution, on the day the President signed the ban, Mr. Ashcroft wrote the Director of the FBI, all United States Attorneys, and all FBI Special-Agents-in-Charge announcing that the "Department of Justice will enforce vigorously the criminal provisions of the Act." (Pls.' Ex. 40, at ENF00009.) He added: "All United States Attorneys are advised to contact the task force ([telephone number redacted]) at the earliest opportunity after learning of a possible violation of the Act." (Id.)

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## *I. FACTS*

First, I give the background of this case. Second, I provide a summary of the congressional record regarding information provided by doctors, medical organizations, and statisticians. Third, I describe the medical evidence presented to me at trial.

### *A. BACKGROUND*

I first give a brief statement of the case and describe the parties. Next I set forth the law banning the procedure. After that, I reproduce the Congressional "Findings" which were published as a part of the law banning "partial-birth abortion."

#### *1. STATEMENT OF THE CASE AND THE PARTIES*

This is a challenge by four physicians to a law enacted by Congress in 2003 purporting to ban "partial-birth abortion." These physicians claim that the law is unconstitutional for four reasons. First, they claim that the law is invalid because it lacks an exception which would permit use of the banned procedure in order to preserve the health of women. Second, the doctors contend that the law bans other types of abortion procedures, not just "partial-birth abortion." Third, the physicians claim this criminal law is vague. Finally, the plaintiffs contend that the exception permitting a doctor to perform the banned procedure when necessary to preserve the life of the woman is too narrow.

Plaintiff LeRoy Carhart, M.D., practices medicine and surgery and performs abortions in Nebraska. While on active duty with the United States Air Force, Dr. Carhart received his Doctorate of Medicine from Hahnemann Medical College in 1973; completed his internship at Malcolm Grow USAF Hospital at Andrews Air Force Base, Maryland, in 1974; and completed his general surgery residency at

Hahnemann Medical College and Hospital in Philadelphia, Pennsylvania, and Atlantic City Medical Center in Atlantic City, New Jersey, in 1978. Carhart is a retired lieutenant colonel in the United States Air Force who served as Chief of General Surgery, Chief of Emergency Medicine, and Chairman of the Department of Surgery at Offutt Air Force Base in Nebraska from 1978 to 1985.

Dr. Carhart was an assistant professor from 1978 to 1986 in the surgery department of the Creighton University School of Medicine and an assistant professor in the University of Nebraska Medical Center Department of Surgery from 1982 to 1997. Since 1985, Dr. Carhart has operated the Bellevue Health and Emergency Center. He began performing abortions in an Omaha, Nebraska, clinic in 1988, and at his Bellevue clinic in 1992. He performs approximately 1,400 abortions each year in Nebraska. Dr. Carhart has never attempted to become certified by a medical specialty board. He is licensed to practice medicine in eight states. (Tr. 582-94, Test. Dr. Carhart; Ex. 111.)

Plaintiff William G. Fitzhugh, M.D., M.P.H., has practiced obstetrics and gynecology in Virginia and has served as faculty at the Medical College of Virginia since 1975. Dr. Fitzhugh received his medical degree in 1966 from the Medical College of Virginia in Richmond, Virginia, and completed a "straight medicine" internship at the Indiana University Medical Center in 1967. He then entered active duty with the United States Air Force, during which he finished his obstetrics and gynecology residency in 1972 at the Medical College of Virginia and received a master's degree in public health from the Johns Hopkins University School of Public Health in 1975. During his military tenure he was a flight surgeon for one year and Assistant Chief of the Obstetrics and Gynecology Department at the Malcolm Grow Medical Center, Andrews Air Force Base, for three years.

Dr. Fitzhugh's practice includes obstetrics and gynecology in Richmond, Virginia, and performing abortions in three Virginia cities. He estimates that he

performs 70 first-trimester abortions and 5 to 7 second-trimester abortions per week. He is a fellow of the American College of Obstetrics and Gynecology and a diplomate of the American Board of Obstetrics and Gynecology. (Tr. 203-12, Test. Dr. Fitzhugh; Ex. 92.)

Plaintiff William H. Knorr, M.D., is a board-certified obstetrician and gynecologist practicing in New York. He attended medical school from 1975 to 1979 at the Universidad Autonoma de Guadalajara in Mexico, after which he completed an additional year of clinical training at the New York Medical College in order to practice in the United States. Dr. Knorr's internship included rotations in surgery, neonatal intensive care, and obstetrics and gynecology at three different New York hospitals. Dr. Knorr is board-certified and is currently licensed to practice medicine in Alabama, South Carolina, and New York. He practices at three privately owned clinics in New York, and he owns an abortion clinic in Savannah, Georgia. Dr. Knorr estimates that he performed between 5,000 and 6,000 abortions in 2003, and 12 to 15 percent of those were second-trimester abortions. (Tr. 495-501, Test. Dr. Knorr; Ex. 98.)

Plaintiff Jill L. Vibhakar, M.D., received her medical degree from the University of Iowa College of Medicine in 1995 and was a resident in obstetrics and gynecology at the Beth Israel Medical Center in New York from 1995 to 1999. She was licensed to practice medicine in Iowa in 1999; has served as an assistant professor of clinical obstetrics and gynecology at the University of Iowa College of Medicine since 1999; and was certified by the American Board of Obstetrics and Gynecology in 2002. Dr. Vibhakar is a fellow of the American College of Obstetricians and Gynecologists. (Tr. 306-08, Test. Dr. Vibhakar; Ex. 102.)

Fifty to seventy-five percent of Dr. Vibhakar's time is spent doing didactic and clinical teaching at the University of Iowa, with the remainder of her time being spent performing a full range of obstetrical and gynecological services, including treating

women with high-risk pregnancies. Dr. Vibhakar sees private obstetrics and gynecology patients at the University of Iowa and has a variety of clinical assignments such as supervising labor and delivery, working in the ambulatory surgical center, performing outpatient procedures, and staffing the Veterans Administration Medical Center Gynecology Clinic. She also practices at the Emma Goldman Clinic, an independent, nonprofit women's clinic in Iowa City. Dr. Vibhakar estimates that she delivers between 50 and 75 babies per year; performs 1 to 3 abortions per month at the University of Iowa; and performed 264 second-trimester abortions at the Emma Goldman Clinic between 2001 and 2003. (Tr. 308-13, Test. Dr. Vibhakar; Ex. 102.)

Defendant John Ashcroft is sued in his official capacity as Attorney General of the United States of America, as are his employees, agents, and successors in office. Defendant Ashcroft is charged with enforcing the challenged provision of the Act. (Filing 29, Suppl. Compl.)

### *2. THE ACT*

The Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, provides as follows:

> (a) Any physician who, in or affecting interstate or foreign commerce, knowingly performs a partial-birth abortion and thereby kills a human fetus shall be fined under this title or imprisoned not more than 2 years, or both. This subsection does not apply to a partial-birth abortion that is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself. This subsection takes effect 1 day after the enactment.
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> (b) As used in this section—

(1) the term "partial-birth abortion" means an abortion in which the person performing the abortion—

(A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and

(B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus; and

(2) the term "physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the doctor performs such activity, or any other individual legally authorized by the State to perform abortions: Provided, however, That any individual who is not a physician or not otherwise legally authorized by the State to perform abortions, but who nevertheless directly performs a partial-birth abortion, shall be subject to the provisions of this section.

(c)(1) The father, if married to the mother at the time she receives a partial-birth abortion procedure, and if the mother has not attained the age of 18 years at the time of the abortion, the maternal grandparents of the fetus, may in a civil action obtain appropriate relief, unless the pregnancy resulted from the plaintiff's criminal conduct or the plaintiff consented to the abortion.

(2) Such relief shall include—

(A) money damages for all injuries, psychological and physical, occasioned by the violation of this section; and

(B) statutory damages equal to three times the cost of the partial-birth abortion.

(d)(1) A defendant accused of an offense under this section may seek a hearing before the State Medical Board on whether the physician's conduct was necessary to save the life of the mother whose life was endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself.

(2) The findings on that issue are admissible on that issue at the trial of the defendant. Upon a motion of the defendant, the court shall delay the beginning of the trial for not more than 30 days to permit such a hearing to take place.

(e) A woman upon whom a partial-birth abortion is performed may not be prosecuted under this section, for a conspiracy to violate this section, or for an offense under section 2, 3, or 4 of this title based on a violation of this section.

### *3. THE CONGRESSIONAL FINDINGS SET FORTH IN THE LAW*

The Congressional Findings accompanying the Act provide as follows:

The Congress finds and declares the following:

(1) A moral, medical, and ethical consensus exists that the practice of performing a partial-birth abortion—an abortion in which a physician deliberately and intentionally vaginally delivers a living, unborn child's body until either the entire baby's head is outside the body of the mother, or any part of the baby's trunk past the navel is outside the body of the mother and only the head remains inside the womb, for the purpose of performing an overt act (usually the puncturing of the back of the child's skull and removing the baby's brains) that the person knows will kill the partially delivered infant, performs this act, and then

completes delivery of the dead infant—is a gruesome and inhumane procedure that is never medically necessary and should be prohibited.

(2) Rather than being an abortion procedure that is embraced by the medical community, particularly among physicians who routinely perform other abortion procedures, partial-birth abortion remains a disfavored procedure that is not only unnecessary to preserve the health of the mother, but in fact poses serious risks to the long-term health of women and in some circumstances, their lives. As a result, at least 27 States banned the procedure as did the United States Congress which voted to ban the procedure during the 104th, 105th, and 106th Congresses.

(3) In Stenberg v. Carhart, 530 U.S. 914, 932 (2000), the United States Supreme Court opined "that significant medical authority supports the proposition that in some circumstances, [partial-birth abortion] would be the safest procedure" for pregnant women who wish to undergo an abortion. Thus, the Court struck down the State of Nebraska's ban on partial-birth abortion procedures, concluding that it placed an 'undue burden' on women seeking abortions because it failed to include an exception for partial-birth abortions deemed necessary to preserve the 'health' of the mother.

(4) In reaching this conclusion, the Court deferred to the Federal district court's factual findings that the partial-birth abortion procedure was statistically and medically as safe as, and in many circumstances safer than, alternative abortion procedures.

(5) However, substantial evidence presented at the Stenberg trial and overwhelming evidence presented and compiled at extensive congressional hearings, much of which was compiled after the district court hearing in Stenberg, and thus not included in the Stenberg trial record, demonstrates that a partial-birth abortion is never necessary to preserve the health of a woman, poses significant health risks to a woman upon whom the procedure is performed and is outside the standard of medical care.

(6) Despite the dearth of evidence in the Stenberg trial court record supporting the district court's findings, the United States Court of Appeals for the Eighth Circuit and the Supreme Court refused to set aside the district court's factual findings because, under the applicable standard of appellate review, they were not "clearly erroneous". A finding of fact is clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed". Anderson v. City of Bessemer City, North Carolina, 470 U.S. 564, 573 (1985). Under this standard, "if the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently". Id. at 574.

(7) Thus, in Stenberg, the United States Supreme Court was required to accept the very questionable findings issued by the district court judge—the effect of which was to render null and void the reasoned factual findings and policy determinations of the United States Congress and at least 27 State legislatures.

(8) However, under well-settled Supreme Court jurisprudence, the United States Congress is not bound to accept the same factual findings that the Supreme Court was bound to accept in Stenberg under the "clearly erroneous" standard. Rather, the United States Congress is entitled to reach its own factual findings—findings that the Supreme Court accords great deference—and to enact legislation based upon these findings so long as it seeks to pursue a legitimate interest that is within the scope of the Constitution, and draws reasonable inferences based upon substantial evidence.

(9) In Katzenbach v. Morgan, 384 U.S. 641 (1966), the Supreme Court articulated its highly deferential review of congressional factual findings when it addressed the constitutionality of section 4(e) of the Voting Rights Act of 1965 [42 U.S.C.A. § 1973b(e)]. Regarding Congress' factual determination that section 4(e) [42 U.S.C.A. § 1973b(e)] would assist the Puerto Rican community in "gaining nondiscriminatory

treatment in public services," the Court stated that "[i]t was for Congress, as the branch that made this judgment, to assess and weigh the various conflicting considerations * * *. It is not for us to review the congressional resolution of these factors. It is enough that we be able to perceive a basis upon which the Congress might resolve the conflict as it did. There plainly was such a basis to support section 4(e) [42 U.S.C.A. § 1973b(e)] in the application in question in this case.". Id. at 653.

(10) Katzenbach's highly deferential review of Congress' factual conclusions was relied upon by the United States District Court for the District of Columbia when it upheld the "bail-out" provisions of the Voting Rights Act of 1965 (42 U.S.C. 1973c), stating that "congressional fact finding, to which we are inclined to pay great deference, strengthens the inference that, in those jurisdictions covered by the Act, state actions discriminatory in effect are discriminatory in purpose". City of Rome, Georgia v. U.S., 472 F. Supp. 221 (D.D.C. 1979) aff'd City of Rome, Georgia v. U.S., 446 U.S. 156 (1980).

(11) The Court continued its practice of deferring to congressional factual findings in reviewing the constitutionality of the must-carry provisions of the Cable Television Consumer Protection and Competition Act of 1992 [Pub. L. 102-385, Oct. 5, 1992, 106 Stat. 1460; see Tables for complete classification]. See Turner Broadcasting System, Inc. v. Federal Communications Commission, 512 U.S. 622 (1994) (Turner I) and Turner Broadcasting System, Inc. v. Federal Communications Commission, 520 U.S. 180 (1997) (Turner II). At issue in the Turner cases was Congress' legislative finding that, absent mandatory carriage rules, the continued viability of local broadcast television would be "seriously jeopardized". The Turner I Court recognized that as an institution, "Congress is far better equipped than the judiciary to 'amass and evaluate the vast amounts of data' bearing upon an issue as complex and dynamic as that presented here", 512 U.S. at 665-66. Although the Court recognized that "the deference afforded to legislative findings does 'not foreclose our independent judgment of the facts bearing on an issue of constitutional law,'" its "obligation to exercise independent judgment when First Amendment rights are

implicated is not a license to reweigh the evidence de novo, or to replace Congress' factual predictions with our own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence." Id. at 666.

(12) Three years later in Turner II, the Court upheld the 'must-carry' provisions based upon Congress' findings, stating the Court's "sole obligation is 'to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.'" 520 U.S. at 195. Citing its ruling in Turner I, the Court reiterated that "[w]e owe Congress' findings deference in part because the institution 'is far better equipped than the judiciary to 'amass and evaluate the vast amounts of data' bearing upon' legislative questions," id. at 195, and added that it 'owe[d] Congress' findings an additional measure of deference out of respect for its authority to exercise the legislative power." Id. at 196.

(13) There exists substantial record evidence upon which Congress has reached its conclusion that a ban on partial-birth abortion is not required to contain a 'health' exception, because the facts indicate that a partial-birth abortion is never necessary to preserve the health of a woman, poses serious risks to a woman's health, and lies outside the standard of medical care. Congress was informed by extensive hearings held during the 104th, 105th, 107th, and 108th Congresses and passed a ban on partial-birth abortion in the 104th, 105th, and 106th Congresses. These findings reflect the very informed judgment of the Congress that a partial-birth abortion is never necessary to preserve the health of a woman, poses serious risks to a woman's health, and lies outside the standard of medical care, and should, therefore, be banned.

(14) Pursuant to the testimony received during extensive legislative hearings during the 104th, 105th, 107th, and 108th Congresses, Congress finds and declares that:

> (A) Partial-birth abortion poses serious risks to the health of a woman undergoing the procedure. Those risks include, among other things: An increase in a woman's risk of suffering from cervical incompetence, a result of cervical dilation making it

difficult or impossible for a woman to successfully carry a subsequent pregnancy to term; an increased risk of uterine rupture, abruption, amniotic fluid embolus, and trauma to the uterus as a result of converting the child to a footling breech position, a procedure which, according to a leading obstetrics textbook, "there are very few, if any, indications for * * * other than for delivery of a second twin"; and a risk of lacerations and secondary hemorrhaging due to the doctor blindly forcing a sharp instrument into the base of the unborn child's skull while he or she is lodged in the birth canal, an act which could result in severe bleeding, brings with it the threat of shock, and could ultimately result in maternal death.

(B) There is no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures. No controlled studies of partial-birth abortions have been conducted nor have any comparative studies been conducted to demonstrate its safety and efficacy compared to other abortion methods. Furthermore, there have been no articles published in peer-reviewed journals that establish that partial-birth abortions are superior in any way to established abortion procedures. Indeed, unlike other more commonly used abortion procedures, there are currently no medical schools that provide instruction on abortions that include the instruction in partial-birth abortions in their curriculum.

(C) A prominent medical association has concluded that partial-birth abortion is "not an accepted medical practice", that it has "never been subject to even a minimal amount of the normal medical practice development," that "the relative advantages and disadvantages of the procedure in specific circumstances remain unknown," and that "there is no consensus among obstetricians about its use". The association has further noted that partial-birth abortion is broadly disfavored by both medical experts and the public, is "ethically wrong," and "is never the only appropriate procedure".

(D) Neither the plaintiff in Stenberg v. Carhart, nor the experts who testified on his behalf, have identified a single circumstance during which a partial-birth abortion was necessary to preserve the health of a woman.

(E) The physician credited with developing the partial-birth abortion procedure has testified that he has never encountered a situation where a partial-birth abortion was medically necessary to achieve the desired outcome and, thus, is never medically necessary to preserve the health of a woman.

(F) A ban on the partial-birth abortion procedure will therefore advance the health interests of pregnant women seeking to terminate a pregnancy.

(G) In light of this overwhelming evidence, Congress and the States have a compelling interest in prohibiting partial-birth abortions. In addition to promoting maternal health, such a prohibition will draw a bright line that clearly distinguishes abortion and infanticide, that preserves the integrity of the medical profession, and promotes respect for human life.

(H) Based upon Roe v. Wade, 410 U.S. 113 (1973) and Planned Parenthood v. Casey, 505 U.S. 833 (1992), a governmental interest in protecting the life of a child during the delivery process arises by virtue of the fact that during a partial-birth abortion, labor is induced and the birth process has begun. This distinction was recognized in Roe when the Court noted, without comment, that the Texas parturition statute, which prohibited one from killing a child "in a state of being born and before actual birth," was not under attack. This interest becomes compelling as the child emerges from the maternal body. A child that is completely born is a full, legal person entitled to constitutional protections afforded a "person" under the United States Constitution. Partial-birth abortions involve the killing of a child that is in the process, in fact mere inches away from, becoming a "person".

Thus, the government has a heightened interest in protecting the life of the partially-born child.

(I) This, too, has not gone unnoticed in the medical community, where a prominent medical association has recognized that partial-birth abortions are "ethically different from other destructive abortion techniques because the fetus, normally twenty weeks or longer in gestation, is killed outside of the womb". According to this medical association, the "'partial birth' gives the fetus an autonomy which separates it from the right of the woman to choose treatments for her own body".

(J) Partial-birth abortion also confuses the medical, legal, and ethical duties of physicians to preserve and promote life, as the physician acts directly against the physical life of a child, whom he or she had just delivered, all but the head, out of the womb, in order to end that life. Partial-birth abortion thus appropriates the terminology and techniques used by obstetricians in the delivery of living children—obstetricians who preserve and protect the life of the mother and the child—and instead uses those techniques to end the life of the partially-born child.

(K) Thus, by aborting a child in the manner that purposefully seeks to kill the child after he or she has begun the process of birth, partial-birth abortion undermines the public's perception of the appropriate role of a physician during the delivery process, and perverts a process during which life is brought into the world, in order to destroy a partially-born child.

(L) The gruesome and inhumane nature of the partial-birth abortion procedure and its disturbing similarity to the killing of a newborn infant promotes a complete disregard for infant human life that can only be countered by a prohibition of the procedure.

(M) The vast majority of babies killed during partial-birth abortions are alive until the end of the procedure. It is a medical fact, however, that unborn infants at this stage can feel pain when

> subjected to painful stimuli and that their perception of this pain is even more intense than that of newborn infants and older children when subjected to the same stimuli. Thus, during a partial-birth abortion procedure, the child will fully experience the pain associated with piercing his or her skull and sucking out his or her brain.
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> (N) Implicitly approving such a brutal and inhumane procedure by choosing not to prohibit it will further coarsen society to the humanity of not only newborns, but all vulnerable and innocent human life, making it increasingly difficult to protect such life. Thus, Congress has a compelling interest in acting—indeed it must act—to prohibit this inhumane procedure.
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> (O) For these reasons, Congress finds that partial-birth abortion is never medically indicated to preserve the health of the mother; is in fact unrecognized as a valid abortion procedure by the mainstream medical community; poses additional health risks to the mother; blurs the line between abortion and infanticide in the killing of a partially-born child just inches from birth; and confuses the role of the physician in childbirth and should, therefore, be banned.

Pub. L. No. 108-105, § 2, Nov. 5, 2003, 117 Stat. 1201.

### *B. THE CONGRESSIONAL RECORD*

A focused summary of the congressional record is appropriate. By way of an introduction, I state the intended purpose of this summary. Next, I describe the limits of this summary. Lastly, I describe the method I used to prepare the summary. After that, I provide the summary in a narrative and tabular form.

The primary aim of the summary is to catalogue the informed and serious medical opinions of physicians providing information to Congress regarding the need

for and relative safety of the banned procedure for pregnant women. The overview is not intended to summarize other medical questions (like medical ethics) or the views of other interested persons or groups (like patients and nurses). Nor is the summary intended to address non-medical opinions (like legal arguments or the morality of abortion), even if the person who expressed such a non-medical view was a doctor.

To be both frank and critical, the otherwise lengthy record contains remarkably little substantive information from physicians on either side regarding the need for and safety of the banned procedure insofar as the health of pregnant women is concerned. In fact, the record contains only a few statements of physicians who appeared to have extensive and current surgical experience performing abortions.

Still further, and very troubling, the number of physicians who actually appeared before Congress and testified[3] on any medical subject (as contrasted with doctors who submitted unsworn letters or statements) was small. In this regard, and excluding anesthesiologists and other physicians who testified primarily about fetal pain, during the several years Congress considered this matter, only seven doctors who dealt primarily with women's health issues actually appeared before Congress to give live testimony. Two opposed the ban, and five supported it.[4] As we shall see,

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[3]When I use the word "testified," I mean that a witness physically appeared before Congress and was recognized as a witness by the presiding officer, and the witness then spoke orally and was subject to questioning. That said, it does not appear that Congress administered an oath to any of the witnesses who "testified."

[4]The seven doctors who testified on women's health were: (1) Courtland Robinson, who opposed the ban; (2) Pamela Smith, who supported the ban; (3) Mary Campbell, who opposed the ban; (4) Nancy Romer, who supported the ban; (5) Curtis Cook, who supported the ban; (6) Kathi Aultman, who supported the ban; and (7) Mark Neerhof, who supported the ban.

while the two who opposed the ban had relevant abortion experience, the five who supported it had no such experience.

Interestingly, there is a fair amount of medical information from doctors about whether pain medications given to the pregnant woman during the banned procedure cause fetal death, whether fetuses are physiologically capable of receiving the stimuli that would cause a pain response in human beings, and whether human fetuses perceive pain in the same sense that human beings perceive pain. While these fetal-anesthesia questions are not directly pertinent to the case-dispositive legal questions, for the sake of completeness, I have nevertheless included a summary of them.

I should also make four things clear regarding this summary. That is:

* I did not consider certain portions of the record sufficiently helpful or trustworthy so as to warrant inclusion in the summary. For example, I attempted to avoid cumulative materials, and although I carefully reviewed them, I did not summarize statements or letters from physicians which are conclusory in nature or which state primarily legal or moral views. Nor have I summarized partial transcripts of judicial hearings or trials purporting to describe the views of a doctor unless it appeared that all of the doctor's testimony on the pertinent subject was included in the congressional record at that spot. In that same vein, and as contrasted with scientific papers or statements clearly subscribed to by a physician, in most cases, and with one exception regarding Dr. Hern, I have not summarized media or third-party accounts inserted into the record purporting to quote or describe the views of a physician. Furthermore, I have summarized only the statements of the two leading national medical associations—that is, the American Medical Association (AMA) and the American College of Obstetricians and Gynecologists (ACOG)—regarding substantive medical questions, but

only to the extent the statements reflected the considered medical opinion of such groups after an apparent professional inquiry. I did not summarize the policy views of these or other associations.[5] To be precise, and seeking to avoid a cumulative and redundant description of the record, I have not recounted the views of other national or state medical organizations (like the American Medical Women's Association or the California Medical Association). For the same reason, I have not recounted the views of affiliates of medical associations (like the state sections of ACOG). Similarly, and also because they were primarily formed to lobby for or against abortion legislation, I have not summarized "form" letters bearing multiple signatures from groups of physicians, such as "Physicians' Ad Hoc Coalition for the Truth" (which supported the ban) or "Physicians for Reproductive Choice and Health" (which opposed the ban).

* Redundant statements by the same physicians are generally not summarized more than once even if the physician appeared at, or submitted information to, several different congressional hearings.

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[5]For an example of why the policy views of the AMA on this subject are suspect, see Booz-Allen & Hamilton, Management Audit of the American Medical Association Decision-Making Processes (October 13, 1998), found in the 2003 hearing record. (Ct.'s Ex. 9, at 261-64 & 267.) This highly critical report was prepared for and at the direction of the AMA and studied the AMA's support of the Partial-Birth Abortion Ban Act of 1997. (Ct.'s Ex. 9, at 246.) In the end, the report concludes that "the combined effect of AMA policies was to allow the most critical, controversial, and high-visibility policy issues to be addressed using the least democratic, least researched, and least systematic decision-making process." (Ct.'s Ex. 9, at 267.)

* Senator Frist,[6] Congressman Weldon, and Congressman Burgess supported the ban and spoke in favor of it in the floor debates. (Def.'s Ex. 517, at S3457-59 (statement of Sen. Frist); Def.'s Ex. 520, at H4918 (statement of Rep. Burgess); Def.'s Ex. 520, at H4938 (statement of Rep. Weldon); Def.'s Ex. 523, at S12947-48 (statement of Sen. Frist).) They were trained as physicians. However, because these men were acting as members of Congress and were properly pursuing their political duties, as contrasted with independent doctors giving their views to Congress on purely medical questions, I will not further summarize the views of these physician-legislators regarding the ban.

* Because of the imprecise method Congress uses to index and record information, it is difficult, at best, to locate in this record each pertinent utterance of a physician. For example, and as described more fully later, critical information submitted by one of the doctors who pioneered use of the banned procedure (Dr. McMahon) was not indexed in the pertinent congressional record as being from a physician. Therefore, and although I have spent a great deal of time reviewing the congressional record, I may have overlooked the views of a physician. If so, it was inadvertent.

There are seven three-ring notebooks that comprise the bulk of the legislative record. At the beginning of the case, Mr. Ashcroft's able counsel provided me with these books and represented that they contained most of the congressional record pertinent to this case. Those books have been received in evidence as Court's Exhibits 4 through 10. Later, during the trial, the parties agreed that I should also consider certain floor debates that had not been included in the notebooks. Those

[6]Senator Frist was the Majority Leader in the Senate when the ban passed in 2003.

debates appear in Defendant's Exhibits 502 through 523, which were also received in evidence. Following the trial, and during a period in which I allowed the parties to expand their record, they agreed to admission into evidence of Defendant's Exhibits 893 through 902, which added indexes and additional floor debates to the trial record. These exhibits (Ct.'s Exs. 4-10, Def.'s Ex. 502-523, and Def.'s Exs. 893-902 ) form the basis for the summary.

Regarding the congressional record which was received in evidence, Appendix I to this opinion gives the exhibit number, a corresponding citation in Bluebook form to the record which comprises the exhibit, and, when available, a Westlaw citation to the record which comprises the exhibit. Thus, the congressional record presented to me can more easily be located by the reader in a library or online by reference to Appendix I.

In most instances, the reference to a "page" in the summary pertains to the printed page number of the record (typically, but not always, found on the top of the page) that is summarized. Sometimes, and particularly when a printed page number is not available, a typewritten page number will be referenced. Once again, in order to avoid a cumulative presentation, not every page in the record where a doctor may have expressed some view is referred to in this summary.

The "date" reference in the summary pertains to the date of the hearing, debate or the issuance of the report, and not necessarily the date of a doctor's statement. The "name" reference in the summary pertains to the physician or, infrequently, to a record keeper or to more generalized information.

The foregoing explained, I proceed next to the summary. First, I present a narrative summary. In Appendix II to this opinion, I also provide a tabular summary for quick reference.

**Court's Exhibit 4; "1995 House Hearings"; Page: 15-21; Date: June 15, 1995; Name: Martin Haskell, M.D.**

Dr. Haskell performed abortions in an outpatient clinic setting, and he claimed to be one of the first doctors to use a variant of the procedure that the legislation would ban. He did not testify, but a copy of his professional paper entitled "Dilation and Extraction for Late Second Trimester Abortion" presented to the National Abortion Federation Risk Management Seminar on September 13, 1992, was added to the record. There are handwritten notations and underlining on the article that are not from Dr. Haskell.

The paper contains a description of the "how, when, where, what, and why" of Dr. Haskell's procedure. In particular, Dr. Haskell described the procedure, giving the following details:

DESCRIPTION OF DILATION AND EXTRACTION METHOD

Dilation and extraction takes place over three days. In a nutshell, D&X can be described as follows:

Dilation
MORE DILATION
Real-time ultrasound visualization
Version (as needed)
Intact extraction
Fetal skull decompression
Removal
Clean-up
Recovery

Day 1 - Dilation

The patient is evaluated with an ultrasound, hemoglobin and Rh. Hadlock scales are used to interpret all ultrasound measurements.

In the operating room, the cervix is prepped, anesthetized and dilated to 9-11 mm. Five, six or seven large Dilapan hydroscopic dilators are placed in the cervix. The patient goes home or to a motel overnight.

Day 2 - More Dilation

The patient returns to the operating room where the previous day's Dilapan are removed. The cervix is scrubbed and anesthetized. Between 15 and 25 Dilapan are placed in the cervical canal. The patient returns home or to a motel overnight.

Day 3 - The Operation

The patient returns to the operating room where the previous day's Dilapan are removed. The surgical assistant administers 10 IU Pitocin intramuscularly. The cervix is scrubbed, anesthetized and grasped with a tenaculum. The membranes are ruptured, if they are not already.

The surgical assistant places an ultrasound probe on the patient's abdomen and scans the fetus, located the lower extremities. This scan provides the surgeon information about the orientation of the fetus and approximate location of the lower extremities. The tranducer is then held in position over the lower extremities.

The surgeon introduces a large grasping forceps, such as a Bierer or Hern, through the vaginal and cervical canals into the corpus of the uterus. Based upon his knowledge of fetal orientation, he moves the tip of the instrument carefully towards the fetal lower extremities. When the instrument appears on the sonogram screen, the surgeon is able to open and close its jaws to firmly and reliably grasp a lower extremity.

The surgeon then applies firm traction to the instrument causing a version of the fetus (if necessary) and pulls the extremity into the vagina.

By observing the movement of the lower extremity and version of the fetus on the ultrasound screen, the surgeon is assured that his instrument has not inappropriately grasped a maternal structure.

With a lower extremity in the vagina, the surgeon uses his fingers to deliver the opposite lower extremity, then the torso, the shoulders and the upper extremities.

The skull lodges at the internal cervical os. Usually there is not enough dilation for it to pass through. The fetus is oriented dorsum or spine up.

At this point, the right-handed surgeon slides the fingers of the left hand along the back of the fetus and "hooks" the shoulders of the fetus with the index and ring fingers (palm down). Next he slides the tip of the middle finger along the spine towards the skull while applying traction to the shoulders and lower extremities. The middle finger lifts and pushes the anterior cervical lip out of the way.

While maintaining this tension, lifting the cervix and applying traction to the shoulders with the fingers of the left hand, the surgeon takes a pair of blunt curved Metzenbaum scissors in the right hand. He carefully advances the tip, curved down, along the spine and under his middle finger until he feels it contact the base of the skull under the tip of his middle finger.

Reassessing proper placement of the closed scissors tip and safe elevation of the cervix, the surgeon then forces the scissors into the base of the skull or into the foramen magnum. Having safely entered the skull, he spreads the scissors to enlarge the opening.

The surgeon removes the scissors and introduces a suction catheter into this hole and evacuates the skull contents. With the

> catheter still in place, he applies traction to the fetus, removing it completely from the patient.
>
> The surgeon finally removes the placenta with forceps and scrapes the uterine walls with a large Evans and a 14 mm suction curette. The procedure ends.
>
> Recovery
>
> Patients are observed a minimum of 2 hours following surgery. A pad check and vital signs are performed every 30 minutes. Patients with minimal bleeding after 30 minutes are encouraged to walk about the building or outside between checks.
>
> Intravenous fluids, pitocin and antibiotics are available for the exceptional times they are needed.
>
> (Id. at 17-19.)

Note that Haskell only caused a "version" of the fetus "if necessary." (Id. at 18.) In other words, if the fetus presented "feet-first" in the uterus, then manipulation of the fetus to a "feet-first" presentation in the uterus was not needed. In that case, and using a single pass into the uterus, the fetal body was pulled "feet first" through the cervix until the skull, which is normally too large to pass, lodges against the interior portion of the cervical canal.

In the paper, Haskell stated that he had "performed over 700 of these procedures with a low rate of complications." (Id. at 15.) Haskell ended his paper by stating: "In conclusion, Dilation and Extraction is an alternative method for achieving late second trimester abortions to 26 weeks. It can be used in the third trimester. Among its advantages are that it is a quick, surgical outpatient method that can be performed on a scheduled basis under local anesthesia. Among its disadvantages are that it requires a high degree of surgical skill, and may not be

appropriate for a few patients." (Id. at 21.) The copied article (at this point in the record) does not contain Dr. Haskell's footnotes.

**Court's Exhibit 4; "1995 House Hearings"; Page: 39-62; Date: June 15, 1995; Name: Pamela Smith, M.D.**

Dr. Smith did not claim to do abortions. At the time she testified, she was the Director of Medical Education at Mt. Sinai Hospital. She was board-certified in obstetrics and gynecology. She testified as the president-elect of the American Association of Pro-Life Obstetricans and Gynecologists. She stated that the "partial-birth abortion" procedure is like an intentional breech delivery and that type of delivery is dangerous. She also stated that: "Although the defenders of this technique proclaim that it is safe, they have not substantiated these claims." (Id. at 43.)

Dr. Smith concluded:

> Today, partial-birth abortions are being heralded by some as safer alternatives to D&E. But "advances" in this type of technology do not solve the problem . . . they only compound it. In part because of its similarity to obstetrical techniques that are designed to save a baby's life and not to destroy it, this procedure produces a moral dilemma that is even more acute than that encountered in dismemberment techniques. The baby is literally inches from being declared a legal person by every state in the union. The urgency and seriousness of these matters therefore require appropriate legislative action.

(Id. at 44.)

Attached to Dr. Smith's presentation are letters from Watson Bowes, M.D., a fetal and maternal medical health professor (see below for his summary), stating that he believed the fetus is alive at the time the banned procedure is performed and attesting to the accuracy of certain drawings. (Id. at 46-47.) Also attached to Dr.

Smith's presentation is a copy of Chapter 25 from Williams Obstetrics entitled "Techniques for Breech Delivery." (Id. at 48-62.) The textbook chapter does not pertain to abortion.

**Court's Exhibit 4; "1995 House Hearings"; Page: 63-67; Date: June 15, 1995; Name: J. Courtland Robinson, M.D.**

Dr. Robinson had been performing abortions, including second-trimester abortions, for about 40 years. A former medical missionary in Korea, Dr. Robinson was a full-time faculty member at Johns Hopkins University School of Medicine Department of Gynecology and Obstetrics and held a joint appointment with the Johns Hopkins School of Hygiene and Public Health.

Dr. Robinson acknowledged that during a standard D&E abortion, an intact fetus is sometimes removed, but "[i]n no case is pain induced to the fetus." (Id. at 66.) Dr. Robinson stated that the legislation would ban standard D&E abortions because doctors "would not undertake [such] a surgery if they were legally prohibited from completing it in the safest and most effective way, according to their professional judgment." (Id. at 66.) The implication of that statement is that sometimes it is necessary to deliver the fetus intact to perform the safest method of abortion. Dr. Robinson concluded that the law would interfere with his obligation to select "the most appropriate surgical technique—using my expertise, developed over years of experience and training, to determine what method is safest . . . ." (Id. at 67.)

**Court's Exhibit 4; "1995 House Hearings"; Page: 67-71; Date: June 15, 1995; Name: Robert J. White, M.D.**

Dr. White did not perform abortions. He was an "academic neurosurgeon" and a professor of surgery at the Case Western Reserve University. (Id. at 69.) The doctor was of the opinion that a fetus subjected to the banned procedure at 20 weeks of

gestation and beyond is sufficiently advanced in neurostructural organizational development to feel pain.

Later in the hearing, an article entitled "Neonatal Pain Management," authored by Constance S. Houck, M.D. (whose background is not included with the article), was added to the record. (Id. at 81.) As pertinent here, this journal article states that "[t]here is substantial evidence to show that development of the physiologic mechanisms and pathways for pain perception takes place during late fetal and neonatal life[,]" and that "[c]utaneous sensory perception . . . spreads to include all cutaneous and mucous surfaces by the 20th week." (Id.)

**Court's Exhibit 4; "1995 House Hearings"; Page 104-107; Date: June 15, 1995; Name: Watson A. Bowes, Jr., M.D.**

Dr. Bowes was described as "an internationally recognized authority on maternal and fetal medicine" and "a professor of both obstetrics/gynecology and pediatrics" at the University of North Carolina.[7] (Id. at 107.) There was no indication that Dr. Bowes performed abortions.

In a letter addressed to Chairman Canady, Dr. Bowes made the following points: (1) the language of the bill accurately described the procedure sought to be banned (specifically including those performed by Drs. Haskell and McMahon) (id. at 104-05); (2) although he had never witnessed the procedure, Dr. Bowes believed that the fetus is alive until the brain matter is removed (id. at 105); (3) although it is true that the analgesic given to the mother will reach the fetus and presumably provide some type of pain relief, the extent to which such relief is provided would be very difficult to document (id. at 106); (4) the drawings used by Congressman Canady and others to depict the banned procedure were accurate (id.); (5) banning the

[7]Dr. Bowes also testified at the trial in this case.

procedure would not prevent doctors from reducing fluid from the brain of the fetus in the case of an abnormality if the intent was to deliver a living infant (id. at 106-07); and (6) the viability of preterm infants varies widely, earlier statistics are outdated, and, as an example of more recent statistics, at 24 weeks of gestation, survival varies from a low of 10 percent to a high of 57 percent. (Id. at 107.)

**Court's Exhibit 4; "1995 House Hearings"; Page: 108-21; Date: June 15, 1995; Name: James McMahon, M.D.**

The description of a very important document in the congressional record is curiously inaccurate. It is entitled: "Appendix 3–Letter, With Enclosure, Dated June 8, 1995, to Keri D. Harrison,[8] Assistant Counsel, Subcommittee on the Constitution, From Eve Surgical Centers Medical Corp."( Id. at (III) & 108.) While the signature is somewhat difficult to read, and although it is written on letterhead bearing the name of Eve Surgical Centers Medical Corp., the handwritten letter was signed by "Jim McMahon." (Id. at 108.) Of course, Dr. McMahon was one of the pioneers of the banned procedure.

According to published sources, until his death in October of 1995, Dr. McMahon was the medical director of Eve Surgical Centers. Robert W. Lee, The Partial Birth "Choice" (April 15, 1996), available at http://www.thenewamerican.com/tna/1996/vo12no08/vo12no08_partialbirth.htm (last accessed June 17, 2004). After his death, the material, described as being from "Eve Surgical Centers," was explicitly attributed to Dr. McMahon when an opponent of the procedure testified. (Ct.'s Ex. 5, Test. Dr. Smith, at 82.) Some five years later, Congressman Canady specifically attributed this material to Dr. McMahon in a brief Mr. Canady and others submitted to the Supreme Court in Stenberg v. Carhart, 530 U.S. 914 (2000). (Br.

[8]Harrison is listed in the record as Assistant Counsel to the Majority. (Id. at (II).)

Amici Curiae Rep. Canady & Other Members of Congress Supp. Pet'rs, 2000 WL 228464 (Feb. 28, 2000).)[9] I, therefore, find and conclude that the material I next summarize was authored by Dr. McMahon, but inaccurately described by the House Judiciary Committee in its published records.

In part, Dr. McMahon's letter stated that the "additional material concerns technical matters regarding the surgery (intact D&E), fetal and maternal indications, blood loss, and major complications." (Ct.'s Ex. 4, at 108.[10]) The enclosure to the letter was a 13-page typewritten analysis (including charts, graphs, and statistics) of data derived from numerous "intact D&E" procedures performed by Dr. McMahon. (Id. at 109-21.)

Among other things, the data presented by Dr. McMahon showed that: (1) in his practice, as the length of gestation increased, the number of fetuses exhibiting significant fetal abnormalities also increased (id. at 109); (2) out of 2,000 "intact D&E" procedures, 5 women suffered major complications, but all survived (id. at 118-19); (3) blood loss increased with gestational age, but not substantially (id. at 120); and (4) a table was presented providing a general guide for surgeons as to the

[9]Contrary to the way the information is described and indexed in the congressional record, where no reference is made to Dr. McMahon as being the author, Mr. Canady's brief describes the information this way: "Appendix 3–Letter from Jim McMahon, M.D. to Keri Harrison (assistant counsel, Subcommittee on the Constitution) (June 8, 1995) (attaching charts of "Fetal Indications" for abortions he performed)." (Br. at 9.)

[10]In the letter, Dr. McMahon also inquired about protocol when testifying. (Ct.'s Ex. 4, at 108.) However, and perhaps because he died soon thereafter of cancer (Ct.'s Ex. 5, at 102), the record does not reflect that Dr. McMahon ever appeared before Congress.

average amount of cerebral spinal fluid that should be removed from the fetus before intact delivery of the calvarium (skullcap) can be expected. (Id. at 121.[11])

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 5-12; Date: November 17, 1995; Name: Martin Haskell, M.D.**

As previously indicated, Dr. Haskell performs abortions, and he was apparently one of the first doctors to use the procedure that the legislation bans. He did not testify at these Senate hearings, but, as before the House, a copy of his paper entitled "Dilation and Extraction for Late Second Trimester Abortion," presented to the National Abortion Federation Risk Management Seminar on September 13, 1992, was added to the record. Unlike the House version, this copy of the paper contains Dr. Haskell's footnotes. (Id. at 12.)

As noted, Haskell did not testify. His counsel advised the Senate that Dr. Haskell would not testify because he feared for his safety. (Id. at 15.) Among other things, counsel claimed that one of Dr. Haskell's clinics had been fire bombed.[12] (Id.)

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[11]In the trial of this case, a paper presented on April 2, 1995, to the National Abortion Federation, prepared by Dr. McMahon and entitled, "Intact D&E, The First Decade," was received in evidence as Plaintiff's Exhibit 64. This paper explains in very great detail Dr. McMahon's experience in performing the procedure he called "intact D&E" from June of 1983 through February 1995. The paper indicated that he would sometimes convert the fetus to a footling breech and sometimes take the fetus as he found it depending upon whether there was a "Longitudinal lie, calvarium presentation" (head first), "Longitudinal lie, breech presentation" (feet first), or "Transverse/oblique lie, various presentations" (at an angle or sideways). (Ex. 64, at CH0000501-02.) That paper will be discussed in more detail in a later portion of this opinion. It does not appear, however, that Congress gave this important paper much, if any, consideration.

[12]In preparing for the trial of this case, there was credible evidence presented to me under seal that showed one of the plaintiffs' witnesses had been subjected to extreme forms of violence because of his or her abortion practices.

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 28-51; Date: November 17, 1995; Name: Martin Haskell, M.D.**

This part of the record contains Dr. Haskell's testimony at the preliminary injunction hearing in Women's Medical Professional Corp. v. Voinovich, an Ohio federal case. It appears to contain the entire direct, cross, and redirect examination of Dr. Haskell as to his use of the banned procedure. It also includes questions put to the doctor by the presiding federal judge.

Among other things, Dr. Haskell testified that: (1) he used the banned procedure after the 20th week (id. at 41); (2) he had complications of 2 per 1,000 for the standard D&E during the relevant time (id.); (3) he had no complications in the 1,000 banned procedures that he performed during the relevant time (id. at 41-42); (4) he believed that "there's an enormous advantage to the woman" by using the banned procedure rather than a standard D&E (id. at 47); and (5) in response to questioning by the judge, Dr. Haskell explained why he thought the banned procedure was far better and, condensed, he gave these three reasons: (a) it minimizes trauma to the uterus; (b) it minimizes blood loss; and (c) it shortens surgical time. (Id. at 50.) Dr. Haskell, who had previously been board-certified but who was not board-certified at the time of his testimony,[13] stated that he learned the banned technique from Dr. McMahon, who Haskell regarded "as an expert amongst the peer of physicians that regularly perform abortions. [McMahon is] regarded as someone to whom the most difficult cases go." (Id. at 45.)

[13]Haskell had been board-certified in family practice for seven years, but when his practice evolved into a speciality abortion practice, he did not renew his certification. (Id. at 31-32.)

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 99-101, 122-23, 153-54, 222-24; Date: November 17, 1995; Name: Mary Campbell, M.D.**

Dr. Campbell was the Medical Director of Planned Parenthood of Metropolitan Washington. She was a fellow of the American College of Obstetrics and Gynecology and held a master's degree in public health from Johns Hopkins University. I presume Dr. Campbell performed abortions based upon her directorship of an abortion clinic and (as discussed below) her observations of Dr. McMahon's abortion practice.

Dr. Campbell spent the summer of 1995 observing Dr. McMahon perform the banned procedure. When she was questioned by Senator Specter, Dr. Campbell stated that: (1) she had observed 10 of the banned procedures; (2) all of the fetuses involved in those procedures had serious defects (such as a single-chambered heart); and (3) none of the fetuses would have survived outside the womb. (Id. at 122-23.)

According to Dr. Campbell, the ban "outlaws the safest way of ending a third trimester pregnancy[,]" and the prohibited technique "is a safe procedure—safer than induction, far safer than hysterotomy." (Id. at 103.) From Campbell's point of view, the benefits of the banned procedure to the mother include decreased dilation of the cervix and decreased risk of cervical lacerations. (Id. at 102.)

Later inserted into the record, as a part of the questioning of Dr. Campbell, was a July 1985 professional paper entitled "Morbidity and Mortality from Second-Trimester Abortions," authored by David A. Grimes, M.D., and Kenneth F. Schulz, M.B.A., published in the Journal of Reproductive Medicine. (Id. at 125-34.) Based upon an analysis of statistics compiled from 1972 to 1981, the authors concluded that the "D&E [method] appears to be the safest method of second-trimester abortion available in the United States." (Id. at 125 (abstract).)

Dr. Campbell also clarified an earlier "fact sheet" prepared by her which stated that the fetus died in the womb during the banned procedure due to anesthesia. Dr. Campbell told Senator Abraham that she no longer believed "the fetus dies of an overdose of anesthesia given to the mother intravenously." (Id. at 153.) While she continued to believe that spontaneous fetal respiration or movement was not observed in the 2,000 or so times the banned procedure was performed by Dr. McMahon, and this led her to believe that the fetus was not in pain and was, perhaps, dead, Dr. Campbell admitted that she did know the precise timing or mechanism of death. (Id.)

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 107-08, 225; Date: November 17, 1995; Name: Norig Ellison, M.D.**

Dr. Ellison testified as the president of the American Society of Anesthesiologists. His association took no position on the appropriateness of any abortion procedure (including the banned procedure) and he did not appear to speak for or against the legislation. He did not claim to do abortions.

Dr. Ellison stated that he and his association disagreed with Dr. Haskell to the extent Haskell had said that anesthesia caused fetal demise or fetal brain death.

> Although it is certainly true that some general analgesic medications given to the mother will reach the fetus and perhaps provide some pain relief, it is equally true that pregnant women are routinely heavily sedated during the second or third trimester for the performance of a variety of necessary surgical procedures [other than abortion], with absolutely no adverse effect on the fetus . . . .

(Id. at 108.)

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 144-46; Date: November 17, 1995; Name: Dru Elaine Carlson, M.D.**

Dr. Carlson was the Director of Reproductive Genetics and a perinatologist and geneticist at Cedars-Sinai Medical Center in Los Angeles. She was also an assistant professor at the UCLA School of Medicine.

Dr. Carlson did not perform abortions, but advised women carrying abnormal fetuses in the second trimester about the nature and severity of the abnormality. If a woman wished to consider termination of her pregnancy because of a serious fetal abnormality, Dr. Carlson referred her patient to Dr. McMahon because of his "unusual expertise in the termination of late in gestation flawed pregnancies." (Id. at 144.) Among other things, Dr. Carlson stated:

> The usual type of termination of pregnancy is a traumatic stretching of the cervix that then increases a woman's chance for infertility in the future. The procedure that is up for "banning" allows very passive dilatation of the cervix and allows gentle manipulation to preserve the very much desired fertility of these distraught women.

(Id.)

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 109-112, 156-57, 227-29; Date: November 17, 1995; Name: Nancy G. Romer, M.D.**

Dr. Romer was a board-certified obstetrician and gynecologist and a fellow of the American College of Obstetrics and Gynecology. She was a clinical professor in the Department of Obstetrics and Gynecology at Wright State University and chairman of the department of obstetrics and gynecology at a hospital in Dayton, Ohio, a city in which Dr. Haskell practices. Dr. Romer did not claim to do abortions. However, at her hospital there were physicians who did medically required second-trimester

abortions and Dr. Romer testified that those physicians did not use the banned procedure. (Id. at 156-157.)

Dr. Romer stated that from her review of the literature, "[t]here is simply no data anywhere in the medical literature in regards to the safety and efficacy of this procedure." (Id. at 111.) "Since these procedures are currently being done in an outpatient clinic there is no ongoing peer review of either the procedure or the physician performing it." (Id.) She emphasized that "[i]f this procedure offered significant advantages over other termination procedures, and if there were no safe alternatives, there would be more physicians performing it. Instead there are only two clinics to my knowledge performing this procedure on a routine basis." (Id.)

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 75-83, 214-21; Date: November 17, 1995; Name: Pamela E. Smith, M.D.**

Dr. Pamela Smith, who did not claim to do abortions, testified before the House. I have earlier summarized her background and testimony. Her testimony before the Senate was similar. But, in two areas, she expanded upon her views that the procedure should be banned.[14]

Dr. Smith described in greater detail why she believed the banned procedure, mimicking (she thought) an intentional breech delivery, was medically inappropriate. In particular, she was concerned that the procedure, since it requires substantial dilation of the cervix over several days, takes too long and she was also concerned that the procedure could puncture the cervix and the uterus, resulting in massive blood loss and possibly death. (Id. at 77-78.)

[14]She also submitted two letters to the Senate in December of 1995.

Apparently unaware that he submitted a detailed statement to the Senate opposing the ban and listing the potential benefits of the banned procedure, Dr. Smith referred to and relied upon part of a newspaper account that allegedly quoted Warren Hern, M.D. Dr. Smith said the following about Dr. Hern's views:

> It is also noteworthy that even leading authorities on late-term abortion methods have expressed the gravest reservations regarding this technique. Consider, for example, this excerpt from an article in the November 20 edition of American Medical News, the official newspaper of the American Medical Association.
>
> "I have very serious reservations about this procedure," said Colorado physician Warren Hern, M.D., the author of Abortion Practice, the nation's most widely used textbook on abortion standards and procedures. Dr. Hern specializes in late-term procedures *** [O]f the procedure in question he says, "You really can't defend it. I'm not going to tell somebody else they should not do this procedure. But I'm not going to do it."
>
> Dr. Hern's concerns center on claims that the procedure in late-term pregnancy can be safest for the pregnant woman and that without this procedure women would have died. "I would dispute any statements that this is the safest procedure to use," he said.
>
> Turning the fetus to a breech position is "potentially dangerous," he added. "You have to be concerned about causing amniotic fluid embolism and placental abruption if you do that."
>
> Dr. Hern said he could not imagine a circumstance in which this procedure would be safest. He did acknowledge that some doctors use skull-decompression techniques, but he added that in those cases fetal death has been induced and the fetus would not purposely be rotated into a breech position.

(Id. at 81.)

Dr. Smith also attacked two of the statistics provided by Dr. McMahon to the House earlier in 1995. She thought that McMahon's data tended to show that in 33% of 175 cases the women were already suffering from medical problems that were "contraindications" for use of the banned procedure as opposed to justifications for use of the procedure. (Id. at 82.) She also believed that in 22% of 175 cases the medical problems the women suffered from prior to the procedure (such as depression), and which allegedly persuaded Dr. McMahon to use the procedure, would have existed after the procedure—thus, the procedure was not needed to address the medical problem. (Id.)

**Court's Exhibit 5; "1995 Senate Hearings"; Page: 1-17 of "Errata" (the last 10 pages[15] of the exhibit); Date: November 17, 1995; Name: Warren Martin Hern, M.D.**

Dr. Hern performed outpatient abortions at his clinic in Colorado since 1975. He held both a master's and a Ph.D. degree in public health in addition to his medical degree. He served as Chief, Program Development and Evaluation Branch, Family Planning Division, Office of Health Affairs in the Office of Economic Opportunity, Executive Office of the President, Washington, D.C. He was an assistant clinical professor at the Department of Obstetrics and Gynecology at the University of Colorado Health Sciences Center. He was the author of a leading medical textbook on abortion and numerous other books and professional papers on abortion.

[15]This document was not separately paginated by the Senate. Morever, it was photocopied and placed into the record in a reduced, duplex form. In contrast, the document itself was paginated by Dr. Hern, and contains 17 pages. Since the congressional record contains no page numbers, citations in the text refer to Dr. Hern's typewritten page numbers which appear on the top of the document.

Another version of Dr. Hern's statement appears in Court's Exhibit 5 at 242-255. The "errata" note to the version I summarize gives the following explanation for the two statements:

> The following prepared statement of Warren M. Hern, M.D., M.P.H., Ph.D., replaces the printed version of his statement on pages 242 through 255 of the Senate Judiciary hearing entitled "Partial-Birth Abortion Ban Act of 1995", S. Hrg. 104-260, Serial No. J-104-54, held on November 17, 1995, which was inadvertently inserted in the record.

**(**Ct.'s Ex. 5, "Errata" at first unnumbered page following printed cover sheet.)

In the beginning of his paper, Dr. Hern noted that he had been asked to testify in person by Senators Hank Brown and Ben Nighthorse Campbell. However, Dr. Hern stated (without further explanation) that "I was not permitted to testify in person . . . ." (Id. at 1.) Therefore, Dr. Hern requested that his written statement "be entered into the record as per the requests by Senators Brown and Campbell." (Id.**)**

At the hearing, Senator Brown confirmed "that Dr. Warren Hern is here[,]" and "[h]e had asked to testify . . . ." (Ct.'s Ex. 5, at 150.) Senator Hatch responded that "[t]hat is the first time I have heard that he wanted to testify." (Id.) Senator Brown asked Senator Hatch "if [Dr Hern] has observations or reactions to our discussions, if I might be allowed to insert those in the record[,]" and Senator Hatch responded: "Sure; we would be happy to." (Id.**)**

Among other things, Dr. Hern made the following points in his paper: (1) the history of the banned procedure may date back as far as 1,950 years, and it is "not a new idea" (Ct.'s Ex. 5, "Errata," at 4-5); (2) "maneuvers described by the sponsors [of the law banning the procedure] are followed by attending physicians throughout the nation when the safety of the woman having the abortion is at issue" (id. at 6); (3) Dr. Hern used a variation of the banned procedure, but he first induced fetal death in the

uterus by injection and "[i]n the case of a breech presentation of a dead fetus, the [banned method] is routinely followed" (id. at 6); (4) Dr. Hern believed that the "possible advantages" to the banned procedure include "a reduction of the risk of perforation of the uterus[,]" and it "eliminates the risk of embolism of cerebral tissue into the woman's blood stream[,]" a complication which "can be almost immediately fatal" (id. at 7); (5) while fetuses have enough neurological development to permit reflexes, "[i]nterpretation of these reflexes as 'pain' is highly misleading" (id. at 8); (6) fewer than 500 abortions are performed after 26 weeks, "[t]he majority of those are now performed by [Dr. Hern or one of his] medical colleagues[,]" and "[t]hese abortions are almost always performed for the most tragic reasons of severe fetal anomaly, genetic disorder, or immediate risk to the woman's life" (id. at 8); (7) "a woman is ten or more times likely to die if she carries a pregnancy to term than if she has an abortion[,]" and, in particular, a late-term abortion is "safer in terms of mortality risk than carrying a pregnancy to term" (id. at 12); and (8) in 2 studies where the data was derived from his clinical practice and his variant of the procedure was followed, the complication rates for abortion were very low, that is, when the average length of pregnancy was 23 weeks, the major complication rate was less than 1% (1 out of 124) and when pregnancies ranged from 13 to 25 weeks, the major complication rate was 0.3% (3 out of 1,001). (Id. at 12-13.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S17890; Date: December 4, 1995; Name: James R. Schreiber, M.D.**

Dr. Schreiber was professor and head of obstetrics and gynecology at the Washington University Medical Center in St. Louis, Missouri. Dr. Schreiber did not claim to perform abortions. He was responding to written questions from Senator Simon.

He opposed the ban. He thought the procedure might be necessary in two circumstances, that is: (1) "when the life of the woman is in danger and the most

expeditious delivery of the fetus would be the safest method for her[,]" as the banned "method allows for that, since the fetus can be delivered through a partially dilated cervix" or (2) when, between 20 and 22 weeks, "a fetus that is doomed to die after delivery or has a series of severe malformations" is presented, since "this technique of abortion can be safest for the mother because it can be performed when the cervix is not fully dilated." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S17891; Date: December 4, 1995; Name: David W. Cromer, M.D.**

Responding to written questions from Senator Simon, Dr. Cromer indicated that he was a member of the Department of Obstetrics and Gynecology at the Evanston Hospital in Illinois. He did not claim to perform abortions and he had never seen the banned procedure. Nevertheless, Dr. Cromer opposed the ban, and he stated that in "proper hands (i.e., a qualified physician) the procedure does have a place in the armamentarium of termination procedures." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S17891-92; Date: December 4, 1995; Name: Laurence I. Burd, M.D.**

Responding to questions from Senator Simon, Dr. Burd indicated that he was an associate clinical professor of obstetrics and gynecology at the University of Illinois. He did not claim to perform abortions.

Dr. Burd opposed the ban. He stated that he referred patients to a surgeon who "is adept at surgically removing a fetus of late gestation (24 weeks or less) either intact or with only minimal distortion[,]" and "[t]his has great benefit for the patient because we are able to perform an autopsy on the fetus and confirm any of the suspected abnormalities for which the patient was referred." (Id. at S17891.)

With respect to the need for and safety of the banned procedure, "one can hypothesize that there is less trauma to the mother's cervix from further opening which would be required to deliver the fetal head without decompression." (Id.) He added that: "Greater trauma to the cervix has been implicated as a cause of an 'incompetent cervix' which results in repeated pregnancy loss." (Id.) As a result, Dr. Burd believed that evaluation of the procedure "must be left to the process of peer review[,]" because "[i]t is only by this method that those procedures which have the greatest benefit and carry the least risk to the patient can be identified." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S17892; Date: December 4, 1995; Name: Antonio Scommegna, M.D.**

Dr. Scommegna was responding to written questions from Senator Simon. The doctor was on the staff of the University of Illinois at Chicago College of Medicine in its Department of Obstetrics and Gynecology. It is not clear whether the doctor performed abortions.

The doctor opposed the ban. He could "vividly recall" a situation when a woman presented in labor, suffering a high fever and infection, and with "her premature fetus partially expelled in the vagina through an incompletely dilated cervix." (Id.) "Thus, a head decompression measure such as the one described in the partial-birth abortion bill was used." (Id.)

The doctor stated that "[i]f the proposed legislation was in effect," then his patient "would have had to be exposed to a Cesarean Section for a non-viable fetus." (Id.) Such an "invasive" procedure would have "increased significantly" the risk of "spreading infection, affecting her future fertility and perhaps compromising her life." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S17892; Date: December 4, 1995; Name: Donald M. Sherline, M.D.**

Like several other doctors, Dr. Sherline was responding to written questions from Senator Simon. Dr. Sherline was on the staff of the Cook County Hospital in the Department of Obstetrics and Gynecology. It is not clear whether the doctor performed abortions.

He opposed the ban. He stated: "If we were to only judge the procedure on its medical merits and compared to the other methods of late second trimester abortion, it would be judged the safest method for the mother when carried out by an experienced operator." (Id.) But, he cautioned, because the procedure was not an "esthetically 'clean'" one, no "caring physician" would perform the procedure "except in the most demanding medically indicated situation." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S18192; Date: December 7, 1995; Name: Samuel Edwin, M.D.**

Dr. Edwin was a practicing obstetrician and gynecologist from Michigan. It is unclear whether he performed abortions.

Dr. Edwin opposed the ban. He stated that "it will prevent me from providing the best possible care for my patients in emergency situations. The D&X procedure is the safest option for many women faced with medical emergencies during pregnancy." (Id.) He added that the procedure was used "only in extreme situations, such as when a woman's life is in danger or when a fetus has severe abnormalities that are incompatible with life." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S18197; Date: December 7, 1995; Name: L. Laurie Scott, M.D.**

Dr. Scott was a maternal-fetal medicine specialist and she was on the faculty in the Department of Obstetrics and Gynecology at the University of Texas Southwest Medical Center. She did not claim to do abortions. She supported the ban. She stated "unequivocally that there is no maternal medical indication 'for late term abortions.'" (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S18197; Date: December 7, 1995; Name: Margaret Nordel, M.D.**

Dr. Nordel was a practicing obstetrician and gynecologist from North Dakota. She did not claim to do abortions. She supported the ban and believed that the "'partial-birth abortion'" procedure is "unnecessary to protect either the life or the health of women in this country." (Id.)

**Defendant's Exhibit 901; "Fall of 1995 Senate Debate"; Page: S18197; Date: December 7, 1995; Name: Karen E. Shinn, D.O.**

Dr. Shinn was a practicing obstetrician and gynecologist from New York. She did not claim to do abortions. She supported the ban and believed that the "partial birth abortion procedure is very dangerous and absolutely unnecessary to protect either the life or the health of women in America." (Id.)

**Court's Exhibit 6; "1996 House Hearings; Page: 17; Date: March 21, 1996; Name: Mary Campbell, M.D.**

Dr. Campbell's earlier testimony has been summarized previously. Inserted into the record was an undated letter from Dr. Campbell to Senator Boxer. Among other things, Dr. Campbell wrote:

> In the case of late-term D&X abortion, the drug combination most frequently used has been intravenous Versed (10-40 mg, given in 1-2 mg increments) and Fentanyl (900-2500 ug, given in 100-150 ug increments) over a 1-3 hour period. The total dose and timing vary with the woman's weight and condition. These drugs have been documented to cross the placental circulation to the fetus. Though these total doses are high, the incremental administration of the drugs minimizes the probability of negative outcomes for the mother. In the fetus, these dosage levels may lead to fetal demise (death) in a fetus weakened by its own developmental anomalies. In other cases these drugs prevent the perception of pain by the fetus; they cause depression of fetal respiration before the extraction procedure and preclude fetal respiration afterward.

(Id.)

**Court's Exhibit 6; "1996 House Hearings"; Page: 130; Date: March 21, 1996; Name: William K. Rashbaum, M.D.**

Dr. Rashbaum was a professor of obstetrics and gynecology at the Albert Einstein College of Medicine and the Cornell School of Medicine. He "started performing and teaching Dilation and Evacuation techniques in 1978." (Id.)

Dr. Rashbaum and his colleagues have completed over 19,000 abortion procedures. "We have done the D&X method that is under consideration [in the then-proposed legislation] routinely since 1979. This procedure is only performed in cases of later gestational age." (Id.)

"To ban the D&X would only be making a very safe procedure more dangerous." (Id.) As contrasted with the banned procedure, "Dilation and Evacuation requires surgical instruments that could result in rare but severe damage" to the pregnant woman. (Id.) "The D&X procedure does not require the use of these instruments." (Id.)

"Outlawing the D&X will result in higher maternal health risks and mortality. The result to the fetus is the same—unfortunate but merciful termination regardless of method." (Id.)

**Court's Exhibit 6; "1996 House Hearings"; Page: 132; Date: March 21, 1996; Name: Herbert C. Jones, M.D.**

Dr. Jones was a fellow of the American College of Obstetricans and Gynecologists. He operated a clinic for reproductive and sexual health and performed abortions.

Dr. Jones indicated that in 1956 he was trained to perform, and has since then used, "basically the technique which is being legislated against." (Id.) He concluded that: "This approach has been utilized for years and was advocated for the aftercoming head when undeliverable. The decompression of the cranium by needle or trocar[16] certainly is better than cesarean section or a hysterotomy." (Id.) He added that "[t]here have been two or three cases over the years that without knowledge of the ability to perform such a procedure would have left my patient in jeopardy[,]" particularly because "a change in type of delivery may have to be instantaneous." (Id.)

**Court's Exhibit 6; "1996 House Hearings"; Page: 140-43; Date: March 21, 1996; Name: David J. Birnbach, M.D.**

Like Dr. Ellison, whose 1995 testimony was summarized earlier,[17] Dr. Birnbach was an anesthesiologist. Dr. Birnbach was the Director of Obstetric Anesthesiology

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[16]A "trocar" is an instrument "for withdrawing fluid from a cavity" and it "consists of a metal tube (cannula) into which fits an obturator with a sharp three-cornered tip, which is withdrawn after the instrument has been pushed into the cavity." Stedman's Medical Dictionary 1878 (27th ed. 2000).

[17]Dr. Ellison also gave similar testimony in 1996.

at St. Luke's-Roosevelt Hospital Center, a teaching hospital at Columbia University College of Physicians and Surgeons in New York City. He was president-elect of the Society for Obstetric Anesthesia and Perinatology when he testified. He did not claim to perform abortions.

Dr. Birnbach testified "to take issue with the previous testimony before committees of the Congress that suggests that anesthesia causes fetal demise." (Id. at 141.) He was particularly concerned that testimony regarding the banned procedure and the use of anesthesiology during that procedure might be misconstrued in the lay press such that pregnant women would fear that they could not have pain medication during normal delivery or surgery without killing the living fetus they wished to deliver. He was of the opinion that safe doses, and even massive doses, of pain medication would not cause fetal demise.

Commenting on Dr. McMahon's use of analgesics during the use of the banned procedure as allegedly described by persons other than Dr. McMahon (such as Dr. Campbell), Dr. Birnbach, who acknowledged that Dr. McMahon could not be questioned on the subject (due to his death), was of the opinion that the quantity of medication used by McMahon was excessive. Dr. Birnbach stated: "Although there is no evidence that this massive dose will cause fetal demise, there is clear evidence that this excessive dose could cause maternal death." (Id. at 142.[18])

[18]There is no indication that Dr. Birnbach or any of the other anesthesiologists who questioned Dr. McMahon's use of pain medication and its impact upon the pregnant woman during performance of the banned procedure were aware that Dr. McMahon had provided the House with data which allegedly showed that Dr. McMahon's major complication rate was far less than 1% (5 out of 2,000) and which also allegedly showed that the few patients who suffered major complications all survived.

**Court's Exhibit 6; "1996 House Hearings"; Page: 143-46; Date: March 21, 1996; Name: David H. Chestnut, M.D.**

Dr. Chestnut was Chairman of the Department of Anesthesiology at the University of Alabama at Birmingham. He did not claim to perform abortions. He gave testimony similar to that given by Dr. Birnbach. That is:

> In summary, these false claims regarding the effects of maternal anesthesia on the fetus may cause some pregnant women to delay necessary and perhaps even life-saving surgery during pregnancy. Further, these false claims may prompt other women to deny themselves adequate pain relief during labor and vaginal or cesarean delivery. In almost all cases, anesthesia does not kill the fetus unless the mother is killed or seriously injured first. Clinical administration of local anesthetic drugs has negligible effect on the fetus. Administration of either small or large doses of Versed™ and fentanyl does not result in fetal death or fetal neurologic injury. I am skeptical that any physician in the United States would knowingly administer 10 to 40 mg of Versed™ and 900 to 2500 ug of fentanyl for an abortion procedure. Finally, it is unlikely that these doses consistently abolish all fetal pain.
>
> (Id. at 146.)

**Court's Exhibit 6; "1996 House Hearings"; Page: 146-50; Date: March 21, 1996; Name: Jean A. Wright, M.D.**

Dr. Wright was an associate professor of pediatrics and anesthesia at Emory School of Medicine. She was board-certified in pediatrics, anesthesia, and critical care medicine. She did not claim to do abortions.

Dr. Wright concluded that:

> The scientific literature reviewed above and my clinical experience in the delivery of general anesthesia, systemic analgesia, conscious

sedation, local and regional anesthesia to a wide variety of patients lead me to believe that:

> 1. The anatomical and functional processes responsible for the perception of pain have developed in human fetuses that may be considered for "partial birth abortions." (At this stage of neurologic development, human fetuses respond to the pain caused by needle puncture in utero in a similar manner as older children or adults, within the limits of their behavioral repertoire).
>
> 2. It is likely that the threshold for such pain is lower than that of older preterm newborns, full-term newborns, and older age groups. Thus, the pain experienced during "partial birth abortions" by the human fetus would have a much greater intensity than any similar procedures performed in older age groups.
>
> 3. Current methods for providing maternal anesthesia during "partial birth abortions" are unlikely to prevent the experience of pain and stress in the human fetuses before their death occurs after partial delivery.

(Id. at 150 (emphasis in original).)

Attached to Dr. Wright's statement were numerous articles from medical journals. These articles dealt with pain and anesthesia from the viewpoint of newborn children and fetuses. (Id. at 151-282.) Perhaps the most informative of these articles came from a leading British medical journal. It concluded:

> Since the mechanisms involved in pain perception are not fully understood, it is not possible to conclude that the fetus experiences pain [but] . . . [o]ur study shows that, as with neonates, the fetus mounts a similar hormonal response to that which would be mounted by older children and adults to stimuli which they would find painful. . . .

> Just as physicians now provide neonates with adequate analgesia, our findings suggest that those dealing with the fetus should consider making similar modifications to their practice. This applies not just to diagnostic and therapeutic procedures on the fetus, but possibly also to termination of pregnancy, especially by surgical techniques involving dismemberment.

(Id. at 282 (Xenophon Giannakoulopoulos, et al., Fetal plasma cortisol and *B*-endorphin response to intrauterine needling, Lancet 77 & 80 (July 9, 1994).)

**Court's Exhibit 6; "1996 House Hearings"; Page: 289-90; Date: March 21, 1996; Name: Mitchell Creinin, M.D.**

Dr. Creinin was an assistant professor and Director of Family Planning Research at the Magee-Women's Hospital. The hospital was a part of the University Health Center of Pittsburgh. From this record, it was not clear whether Dr. Creinin performed abortions.

Dr. Creinin was of the opinion that fetuses do not suffer pain. That is, because pain "is only experienced at a conscious level" and a "fetus in the uterus has no level of consciousness," fetuses suffer no pain. (Id. at 289.) Furthermore, Dr. Creinin was of the opinion that researchers who propose that fetuses suffer pain are mistaking an autonomic reflex that does not involve the conscious brain for a perception of pain that does involve the conscious brain.

**Defendant's Exhibit 901; "1996 Senate Debate"; Page: S11387; Date: September 26, 1996; Name: Albert W. Corcoran, M.D.**

Dr. Corcoran was a practicing obstetrician and gynecologist. He did not claim to perform abortions, and he supported the ban. He thought the banned procedure was dangerous because "forceful dilation . . . creates a site for infection and excessive bleeding[,]" particularly because the "placenta is not ready for delivery [so] it may [be]

deemed necessary to manually deliver it[,]" which "may cause even more bleeding." (Id.)

**Court's Exhibit 7; "1997 Joint Hearings"; Page: 9-12; Date: March 11, 1997; Name: Edward J. Sondik, Ph.D.**

Dr. Sondik was senior advisor to the Secretary of Health and Human Services on health statistics. He also served as the Director of the National Center for Health Statistics, which is a part of the Centers for Disease Control and Prevention.

He stated that "[b]ecause the term 'partial-birth abortions' is not a medical term," doctors do not use it when submitting data on abortions. (Id. at 9.) The banned procedure (variously described by doctors as a D&X or intact D&E procedure) "is one of several abortion methods included under the general category of curettage." (Id.) Attached to Dr. Sondik's statement were two tables, one showing the number of procedures by weeks of gestation and the other showing an estimate of the numbers of abortion by more detailed gestational distribution. (Id. at 9 & 11-12.) Dr. Sondik was "unaware of credible data to address use of [the banned] procedure." (Id. at 10.)

**Court's Exhibit 7; "1997 Joint Hearings"; Page: 120-124, 132-35; Date: March 11, 1997; Name: Curtis Cook, M.D.**

Dr. Cook did not claim to do abortions. He was a board-certified obstetrician and gynecologist and a maternal-fetal medicine specialist. He was an assistant clinical professor at the Michigan State University College of Human Medicine. He was the founding member of Physicians' Ad Hoc Coalition for Truth About Partial Birth Abortion (PHACT), a group of doctors who intended to "educate the population on this single issue."(Id. at 123.[19])

[19]Dr. Cook provided Congress with similar testimony in 2003. Dr. Cook also testified at the trial in this case.

Dr. Cook stated: (1) partial-birth abortion is mostly performed in the fifth and sixth months of pregnancy (id.); (2) the procedure takes days due to the need for cervical dilation and thus it takes longer than an induction abortion which takes about 12 hours (id. at 123-24); (3) internal rotation of the fetus to the breech position during the banned procedure places the woman at greater risk for bleeding, infection, and weakening of the cervix (id. at 123); (4) there is no record of the banned procedure in the medical literature (id.)[20]; (5) there is no advantage to the banned procedure even in situations involving fetal abnormalities and there are other procedures (like induction) that would suffice (id. at 124); and (6) he believed that even five- to six-month-old fetuses suffer pain, and he had witnessed fetuses of this age withdraw from needles and the like while the doctor was performing life-saving measures on the fetuses while in the uterus. (Id.)

**Court's Exhibit 7; "1997 Joint Hearings"; Page: 165-67; Date: March 11, 1997; Name: Sheila Lynn Kuzmic, M.D.**

Dr. Kuzmic was a board-certified pediatrician. She was on maternity leave from private practice at the time she provided her statement.

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[20]This assertion is incorrect. As Dr. Hern told Congress, the procedure or some variant of it has been around for nearly 2,000 years. Procedures similar to the banned procedure were discussed in American medical literature at least as early as 1866. (Pls.' Ex. 51, at 27 (Hugh L. Hodge, M.D., The Principles and Practice of Obstetrics 268 (1866) (discussing "Embryotomy," "Craniotomy" and "Cephalotomy"; calling these types of procedures "probably the most ancient of obstetric operations"; referring to a "Craniotomy or Cephalotomy," and stating: "Delivery by this operation implies perforation of the head, diminution of its size, and then its deliverance.").) A procedure similar to the banned procedure has also been mentioned in popular American fiction for at least 50 years. See Henry Morton Robinson, The Cardinal 77-78 (Simon & Schuster 1949) ("'If the birth is started, and the infant's skull gets wedged in the pelvis [sic][,]'" the "'[r]outine practice among non-Catholic doctors calls for a craniotomy—that is, crushing of the infant's skull.'")

Dr. Kuzmic was of the opinion that fetuses suffer pain from as "young as 24 weeks gestational age and up." (Id. at 166.) In particular, she relied upon her clinical experience in the resuscitation of infants (both premature and full-term) and the previously described journal article entitled "Fetal plasma cortisol and *B*-endorphin response to intrauterine needling." (Id. at 166-67.)

**Defendant's Exhibit 899; "May of 1997 Senate Debate"; Page: S4521; Date: May 15, 1997; David Grimes, M.D.**

From other portions of the congressional record, it appears that Dr. Grimes was board-certified in obstetrics and gynecology, had been Chief of the Department of Obstetrics, Gynecology and Reproductive Sciences at the San Francisco General Hospital, and had served as Chief of the Abortion Surveillance Branch of the Centers for Disease Control. (Def.'s Ex. 902, "November of 1995 House Debate," at H11610; Def.'s Ex. 901, "November of 1995 Senate Debate," at S16776.) He was a prolific author on the subject of abortion. (See Pls.' Ex. 44 (David A. Grimes, et al., Mifepriston and mioprostotol versus dilation and evacuation for midtrimester abortion: a pilot randomized controlled trial, 111 Br. J. Obstet. Gynaecol. 148 (2004) (in a pilot study intended to determine the feasibility of a randomized controlled trial comparing certain medically induced abortions (labor) as compared to a particular type of surgical abortions (D&E), most women, when provided with "informed consent" information, choose the surgical abortion (D&E) rather than "randomization," thus making a trial impossible).)

Dr. Grimes gave the Senate an example of when and why he used the banned procedure to save a patient's life. The woman was seriously ill from preeclampsia, a disease the doctor described as "toxemia of pregnancy." (Def.'s Ex. 899, at S4521.) This illness manifested itself as "a dangerous and extreme form" known as "HELLP syndrome" involving liver failure and an abnormal blood-clotting ability. (Id.) The gestational age of the fetus was 24 weeks.

Over several days, attempts were made, unsuccessfully, to induce labor. The woman's medical condition continued to get worse. Out of "desperation," the attending physician then called Dr. Grimes to assist. (Id.) Grimes used the banned procedure, completing the procedure rapidly and with little blood loss. Dr. Grimes told the Senate that "[i]n this instance, an intact D&E was the fastest and safest option available to me and to the patient." (Id.)

**Defendant's Exhibit 899; "May of 1997 Senate Debate"; Page: S4565; Date: May 15, 1997; C. Everett Koop, M.D.**

Former Surgeon General Dr. Koop wrote that it was "never necessary" to perform an abortion on a viable fetus to preserve the health of the mother. (Id.) Although he could not think of an example, "if it were deemed beneficial for the mother to be without the fetus, it could be delivered by induction or C-section." (Id.)

**Court's Exhibit 8; "2002 House Hearings"; Page: 6-14, 32-33; Date: July 9, 2002; Name: Kathi Aultman, M.D.**

Dr. Aultman was a board-certified gynecologist and a fellow of the American College of Obstetricians and Gynecologists. She was in private practice. She was on the Ethics Commission of the Christian Medical and Dental Association and a member of PHACT, the group founded by Dr. Cook to ban the procedure. Although she had not performed abortions since 1982, Dr. Aultman had previous experience performing D&E abortions when she worked for a local Planned Parenthood clinic as a medical director in the early 1980s.

Among others, Dr. Aultman rendered the following opinion about the differences between a standard D&E and the banned procedure:

> Both the American Medical Association and the American College of Obstetricians and Gynecologists clearly distinguish D&X and D&E. The difference between D&E, or dilation and evacuation, and D&X,

dilation and extraction, is that, in the D&E, the cervix is dilated just enough to allow passage of the forceps and the removal of fetal parts. By grasping an extremity and pulling, the part can be detached because the rest of the body can't pass through the cervix. Once the smaller parts have been removed, the physician can crush the thorax and head and remove them.

In the D&E, the fetus dies in the uterus as it is dismembered or crushed. In D&X, the cervix is dilated to a much larger degree so that everything but the head can pass through. The head is then decompressed and the fetus is delivered.

In D&X, the fetus is still alive when everything but the head is delivered into the vagina, but then dies when the head is crushed or the brains are suctioned.

D&E can be performed from about 13 to 22 weeks and, rarely, until 24 weeks' gestation, early to mid second trimester. Past that point, the tissues become too tough to break apart easily. D&X is generally performed from about 20 to 22 weeks' gestation and beyond and has been done as late as 40 weeks, full term.

(Id. at 7.)

Dr. Aultman also believed that the banned procedure was unnecessary to preserve a pregnant woman's health. She said:

The ban on partial-birth abortion would not endanger a woman's health because it isn't medically necessary and there are standard alternative methods available at every gestational age. There's also an exception if her life is truly threatened.

Obstetricians regularly handle medical complications of pregnancy that may threaten a woman's health or life without having to resort to partial-birth abortion. In an emergency situation, when immediate delivery is necessary, D&X would not be used because it would take too long. In its report on late-term pregnancy termination techniques, the

> AMA stated: Except in extraordinary circumstances, maternal health factors which demand termination of the pregnancy can be accommodated without sacrifice of the fetus, and the near certainty of the independent viability of the fetus argues for ending the pregnancy by appropriate delivery.
>
> They also stated that according to the scientific literature, there does not appear to be any identified situation in which intact D&X is the only appropriate procedure to induce abortion and ethical concerns have been raised by intact D&X.

(Id. at 8.)

Additionally, she thought there were health risks with using the banned procedure insofar as the pregnant woman was concerned:

> These would include hemorrhage; infection from retained products; DIC, which is a condition where a woman can just start bleeding and can't stop because of her clotting factors being used up; embolus, where fluid or tissue can enter the mother's circulation. I think that one of the biggest things that we see or that there's a concern of is incompetent cervix, because the cervix is dilated so much more in this procedure than it is in the D&E. And there's some suggestion that, as you dilate the cervix larger, that there's more chance of incompetence. And I think Dr. Cook has actually seen that in his practice, where he's had women come in with cervical incompetence.

(Id. at 33.)

Although Dr. Aultman believed that a physician would never need to use the banned procedure, Dr. Aultman stated that if something unusual happened that might cause a physician to consider use of the banned procedure, a legal variant of the technique would suffice. That is, the fetus could be killed in the uterus using an injection or the cord could be cut at the beginning of the procedure and then the

remainder of the banned procedure could be effectuated on the then-dead fetus. (Id. at 12.**)**

**Court's Exhibit 8; "2002 House Hearings"; Page: 186-87, 189-221; Date: July 9, 2002; Name: American Medical Association (AMA).**

To advise its House of Delegates on the question of late-term abortions, the AMA caused a study to be done by a committee of doctors. The committee submitted a report to the AMA in June of 1997. The report was presented by Nancy W. Dickey, M.D. (Her qualifications and that of the other doctors are not readily evident.)

Among the most pertinent findings of the report were these: (1) the D&E method of abortion appears to be the safest at the relevant gestational ages for maternal mortality, but at 20 weeks and beyond the rates for induction and D&E abortions are similar (id. at 199); (2) the banned procedure is a variant of the D&E procedure (id. at 196); (3) relying upon the American College of Obstetricians and Gynecologists, the banned procedure "may minimize trauma to the woman's uterus, cervix, and other vital organs" (id. at 196); (4) from a review of the "scientific literature, there does not appear to be any identified situation in which [the banned procedure] is the only appropriate procedure to induce abortion" (id. at 203); and (5) the procedure should be avoided "unless alternative procedures pose materially greater risk to the woman[,]" and the report emphasized that "[t]he physician, must, however, retain the discretion to make that judgment, acting within standards of good medical practice and in the best interests of the patient." (Id.)

On April 5, 2000, Dr. Dickey, on behalf of the AMA, issued a public statement. In that statement, Dr. Dickey stated that the banned procedure was "broadly disfavored—both by experts and the public[,]" the banned procedure "is never the only appropriate procedure[,]" and it "has no history in peer reviewed medical literature or in accepted medical practice development." (Id. at 186.)

**Court's Exhibit 8; "2002 House Hearings"; Page: 220-21, 231, 233; Date: July 9, 2002; Name: American College of Obstetricians and Gynecologists (ACOG).**

ACOG convened a select panel of its doctor-members to study the use of the banned procedure. (The qualifications of the select panel are not evident from the congressional record.) The report of the panel was approved by Executive Board of ACOG on January 12, 1997.

The panel defined the banned procedure this way:

> The American College of Obstetricians and Gynecologists (ACOG) believes the intent of such legislative proposals is to prohibit a procedure referred to as "Intact Dilatation and Extraction" (Intact D & X). This procedure has been described as containing all of the following four elements:
>
> 1. deliberate dilatation of the cervix, usually over a sequence of days;
> 2. instrumental conversion of the fetus to a footling breech;
> 3. breech extraction of the body excepting the head; and
> 4. partial evacuation of the intracranial contents of a living fetus to effect vaginal delivery of a dead but otherwise intact fetus.
>
> Because these elements are part of established obstetric techniques, it must be emphasized that unless all four elements are present in sequence, the procedure is not an intact D & X.

(Id. at 231.)

The panel indicated that when "abortion is performed after 16 weeks, intact D&X is one method of terminating a pregnancy." (Id.) However, it was unknown how many of these procedures are actually performed. (Id.) The panel "could identify no circumstances under which this procedure . . . would be the only option to save the life or preserve the health of the woman." (Id. at 232.) On the other hand, the panel

stated, "[a]n "intact D&X . . . may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman. . . ." (Id.)

In October of 1999, Stanley Zinberg, M.D., Vice President of Clinical Activities of ACOG, wrote the Senate. He said that "there are rare occasions when Intact D&X is the most appropriate procedure[,]" and "[i]n these instances, it is medically necessary." (Def.'s Ex. 897, at S12982.)

On February 13, 2002, ACOG reaffirmed its position. Although "a select panel convened by ACOG could identify no circumstances under which intact D&X would be the only option to protect the life or health of a woman, intact D&X 'may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman. . . .'" (Ct.'s Ex. 8, at 233 (quoting its 1997 report) (emphasis in the original).)

**Defendant's Exhibit 516; "March 10, 2003 Senate Debate"; Page: S3385-86; Date: March 10, 2003; Name: Natalie E. Roche, M.D. and Gerson Weiss, M.D.**

Dr. Weiss was Professor and Chair of the Department of Obstetrics and Gynecology and Women's Health at New Jersey Medical College. Dr. Roche was an assistant professor of obstetrics at that school. Both actively practiced.

Among other things, the doctors stated that the D&E method is the standard and preferred approach to abortions in the second trimester and is safer than induction abortions. They believed the legislation could be used to ban the use of the D&E procedure because the "D&X is merely a variant of [the] D&E." (Id. at 3385.)

Acknowledging that there is a "dearth of data" regarding the banned procedure, the doctors believed that the procedure "is sometimes a physician's preferred method of termination" because: (1) "it offers a woman the opportunity to see the intact

outcome of the abortion of a desired pregnancy thus speeding the grieving process"; (2) "it provides a greater chance of acquiring valuable information regarding hereditary illness and fetal anomaly"; and (3) it "involves less use of sharp instruments in the uterus, providing a lesser chance of uterine perforations or tears and cervical lacerations." (Id. at S3385-86.)[21]

**Defendant's Exhibit 517; "March 11, 2003 Senate Debate"; Page: S3471-72; Date: March 11, 2003; Name: Lorne A. Phillips, Ph.D.**

From the Kansas Department of Health and the Center for Health and Environmental Statistics, a letter dated March 24, 2000, addressed to "Dear Interested Party" and authored by Lorne A. Phillips, Ph.D., together with an attachment, was inserted into the record by Senator Brownback, a supporter of the ban.[22] Among other things, the letter and the related attachment presented a "preliminary analysis" of "selected" abortion statistics regarding the use of an undefined surgical abortion method, called by the State of Kansas, the "Partial Birth" procedure. It presented other abortion statistics for that same year as well.

In 1999, of the 12,421 abortions reported to the state agency, 841 (5.8%) were done between 13 and 16 weeks, 564 (4.5%) were done between 17 and 21 weeks, and 574 (4.6%) were done 22 weeks and after. (Id. at S3472.) The vast majority of the abortions (about 84%) were done at 12 weeks or earlier.

In terms of the methods of abortion, a large majority (about 86%) were completed by suction curettage. (Id.) "D&E" abortions accounted for 7.5% (929) of

[21]This letter appears similar to another letter sent by numerous doctors under the letterhead "Physicians for Reproductive Choice." (Def.'s Ex. 519, at S3657.)

[22]The trial evidence indicated that Dr. Carhart sometimes performed abortions in Kansas. (Tr. 595, Test. Dr. Carhart.)

the total; there were no hysterotomies or hysterectomies; "Digoxin-Induction" abortions accounted for 3.0% (366) of the total; and "'Partial Birth' Procedure[s]" accounted for 1.5% (182) of the total. (Id.)

In every one of the 182 "partial-birth abortions" conducted in 1999 in Kansas, the physician certified that "there is a reasonable probability that this pregnancy may be viable." (Id.) In every "partial-birth abortion" conducted in 1999, the physician also certified that the abortion was necessary to "[p]revent substantial and irreversible impairment of a major bodily function," that in every case the impairment was "mental" rather than "physical," and that certification was based upon the patient's history and physical examination. (Id.) It was also based upon the "referral and consultation by an unassociated physician," such that "the attending physician believes that continuing the pregnancy will constitute a substantial and irreversible impairment of the patient's mental function." (Id.)

**Defendant's Exhibit 519; "March 13, 2003 Senate Debate"; Page: S3657; Date: March 13, 2003; Felicia H. Stewart, M.D.**

Dr. Stewart was a former Deputy Assistant Secretary for Population Affairs for the United States Department of Health and Human Services. She had represented the United States at an international conference on population control. She was an adjunct professor in the Department of Obstetrics and Gynecology and Reproductive Sciences at the University of California, San Francisco, where she served as Co-Director of the Center for Reproductive Health Research and Policy. She previously served as the Director of the Reproductive Health Program of the Henry J. Kaiser Family Foundation.

She opposed the legislation because she believed it would force women in the second trimester to have more dangerous procedures, most particularly hysterectomies. Due to the criminal penalties in the law, Dr. Stewart believed that doctors would start

using hysterectomies or hysterotomies because they would fear criminal prosecution if they performed safer D&E or D&X abortions even when women suffer "grievous underlying medical conditions." (Id. at S3657.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 6-10, 40-43; Date: March 25, 2003; Name: Mark Neerhof, D.O.**

Dr. Neerhof was trained as an osteopathic physician. He was an associate professor of obstetrics and gynecology at Northwestern University Medical School and was an attending physician in the Department of Obstetrics and Gynecology, division of Maternal-Fetal Medicine, at Evanston Northwestern Health Care in Evanston, Illinois. He had been practicing for 14 years. Dr. Neerhof did not claim to do abortions.

Among other things, Dr. Neerhof stated the banned procedure is neither safe nor necessary. He gave the following reasons: (1) there are no credible medical studies that attest to the safety of the procedure (id. at 9); (2) the banned procedure increases the risk of uterine rupture and other associated and serious problems because of the need to convert the fetus to a footling breech (id.); (3) the use of scissors to puncture the fetal skull is "blind" to the surgeon, and the procedure increases the risk of laceration and bleeding (id.); and (4) other procedures are available to terminate pregnancy at later stages, so the risks of the banned procedure are unnecessary. (Id.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 100-01; Date: March 25, 2003; Name: Phillip D. Darney, M.D.**

Dr. Darney was a professor and Chief of Obstetrics, Gynecology and Reproductive Sciences at San Francisco General Hospital and at the University of California, San Francisco. Dr. Darney performed abortions in hospitals. The department he supervised performed about 2,000 abortions a year, particularly for poor women.

In a detailed letter, he described his use of the banned procedure and why he believed that the procedure was both safe and needed. The letter, addressed to Senator Feinstein, was first referenced in the March 12, 2003, floor debate in the Senate. (Def.'s Ex. 518, at S3600.) It was quoted by Senator Feinstein to explicitly rebut Senator Santorum's assertion that he had never been provided with a specific example of a situation where the banned procedure "'would be the best, this would be appropriate, this would be medically indicated.'" (Id. at S3600 (Sen. Feinstein quoting Sen. Santorum).)

Because of its significance and the fact that it generated several critical responses from other doctors, I reproduce the substance of Dr. Darney's letter regarding the safety of and need for the banned procedure:

> I write to provide examples of the need for a "medical exemption" to the proposed restriction of use of the so-called "partial birth abortion" technique which is now before the Senate. (The medical term for the technique is "intact D&E").
>
> I am Chief of Obstetrics and Gynecology at San Francisco General Hospital (SFGH), where my department provides about 2,000 abortions yearly to poor women from throughout Northern California. Patients who are in the second trimester and who have special medical problems are referred to SFGH for treatment because our staff has special competence in second trimester abortion and because we can provide specialized care for women who are more likely to have a complicated pregnancy termination. Although I have not reviewed medical records in order to count the number of times we have employed intact D&E, I will provide examples of cases in which the technique was critical to safe conduct of our surgery:
>
> > • A 25 year old with two previous vaginal deliveries and bleeding placenta previa and a clotting disorder at 20 weeks was referred for termination of pregnancy. After checking her coagulation parameters and making blood available for

transfusion, we dilated the cervix overnight with Laminaria and planned uterine evacuation when adequate dilation was achieved or bleeding became too heavy to replace. Within 12 hours cervical dilation was 3 cm and heavy bleeding had begun. We removed the placenta quickly and used the "intact D&E" approach to complete the abortion and accomplish quick control of blood loss. The patient required a transfusion of two units of whole blood and was discharged the next day in good health.

- A 38 year old with three previous cesarean deliveries and evidence of placenta accreta was referred for pregnancy termination at 22 weeks because her risk of massive hemorrhage and hysterectomy at the time of delivery was correctly estimated at about 75%. After SFGH sonographic studies confirmed placenta previa and likely accreta we undertook cervical dilation with laminaria and made blood available in case transfusion was required. To reduce the 75% probability of emergency hysterectomy in the situation of disseminated intravascular coagulation (DIC is quite likely with accreta) we decided to empty the uterus as quickly as possible with the intact D&E procedure and treat hemorrhage, if it occurred, with uterine artery embolization before our patient lost too much blood and hysterectomy was our only option. This approach succeeded and she was discharged in good health two days later.

These two patients provide examples from my memory of situations in which the "intact D&E" technique was critical to providing optimal care. I am certain that a review of our hospital records would identify cases of severe pre-eclampsia, for example, in which "intact D&E" was the safest technique of pregnancy termination.

(Ct.'s Ex. 9, at 100-01.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 102; Date: March 25, 2003; Name: Daniel J. Wechter, M.D.**[23]

Dr. Wechter was a board-certified specialist in maternal-fetal medicine. He was an assistant professor in obstetrics and gynecology at the Michigan State College of Human Medicine and Co-Director of Maternal-Fetal Medicine in Saginaw, Michigan. Dr. Wechter did not claim to do abortions.

He disagreed with Dr. Darney that use of the banned procedure is ever necessary or safe. In particular, he believed that the second patient described by Dr. Darney could have carried the fetus longer and delivered a healthy child by repeat cesarean section followed by hysterectomy.

**Court's Exhibit 9; "2003 House Hearings"; Page: 104; Date: March 25, 2003; Name: Watson A. Bowes, Jr., M.D.**

I have previously described Dr. Bowes' background. In this letter, he confirmed that he did not perform abortions.

Dr. Bowes acknowledged "that there can be differences of opinion on this matter." (Id.) But, he believed that the "important point is that if the technique of partial-birth abortion ('intact D&E') were not available there would be alternative methods available to terminate the pregnancies described by Dr. Darney with comparable levels of risk to the patients." (Id.)

[23]The doctor's letter was also discussed in the Senate floor debate. (Def.'s Ex. 519, at S3654.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 105; Date: March 25, 2003; Name: Steve Calvin, M.D.**[24]

Dr. Calvin was a specialist in maternal-fetal medicine with 23 years of experience. He taught and did research at the University of Minnesota, where he was co-chair of the Program in Human Rights in Medicine. Although rarely, Dr. Calvin did abortions and he used the banned procedure when necessary to preserve the life (but not the health) of the pregnant woman.

"In the rare circumstances when continuation of pregnancy is life-threatening to a mother I will end the pregnancy." (Id.) "If an emergent life-threatening situation requires emptying the uterus before fetal viability then I will utilize a medically appropriate method of delivery, including intact D&E." (Id.)

"Though they are certainly complicated, the two cases described by Dr. Darney describe situations that were not initially emergent." (Id.) Because the law banning the procedure contains "an exemption for situations that are a threat to the life of the mother[,]" and because "an additional medical exemption [regarding maternal health] is redundant[,]" Dr. Calvin did not believe the law threatened the "provision of excellent medical care to pregnant women and their unborn children." (Id.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 106; Date: March 25, 2003; Name: Nathan Hoeldtke, M.D.**

Dr. Hoeldtke was a board-certified obstetrician and gynecologist. He was the Medical Director for Maternal-Fetal Medicine at Tripler Medical Center in Hawaii. Dr. Hoeldtke did not claim to do abortions.

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[24]Dr. Calvin's letter was also discussed in the Senate floor debate. (Def.'s Ex. 519, at S3653.)

Dr. Hoeldtke disagreed with Dr. Darney. In particular, (1) in both cases described by Dr. Darney, "a standard D&E could have been performed without resorting to the techniques encompassed by the intact D&X procedure[,]" (id.); and (2) regarding the second case described by Dr. Darney, "[t]he good outcome described by Dr. Darney" could have been accomplished by "a near term delivery in this kind of patient[.]" (Id.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 107-08; Date: March 25, 2003; Name: Byron C. Calhoun, M.D.**[25]

Dr. Calhoun was a board-certified obstetrician and gynecologist. He had served as a visiting clinical professor or an adjunct professor at various academic hospitals. He had written many peer-reviewed articles and presented over 100 papers. Dr. Calhoun did not claim to do abortions himself.

Dr. Calhoun did not agree with Dr. Darney. Dr. Calhoun not only disagreed with Dr. Darney's use of the banned procedure, but he did "not understand why he was performing the abortions" at all. (Id. at 107.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 109-10; Date: March 25, 2003; Name: T. Murphy Goodwin, M.D.**[26]

Dr. Goodwin was the Chief of the Division of Maternal-Fetal Medicine at the Department of Obstetrics and Gynecology at the University of Southern California. He had published numerous papers and book chapters regarding pregnancy complications. He directed the obstetrics service at the Los Angeles County Women's

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[25]The doctor's letter was also discussed in the Senate floor debate. (Def.'s Ex. 519, at S3653.)

[26]The doctor's letter was also discussed in the Senate floor debate. (Def.'s Ex. 519, at S3654.)

and Children's Hospital, the major referral center for complicated cases among indigent and under-served women in Los Angeles. He did not perform abortions.

"Mindful of Dr. Darney's broad experience with surgical abortion," Dr. Goodwin strongly disagreed with him. Initially, the cases described by Dr. Darney "are infrequent" and "there is no[] single standard for management" of those cases. (Id. at 109.) According to Dr. Goodwin, "the vast majority of physicians confronting either of these cases would opt for careful hysterotomy as the safest means to evacuate the uterus." (Id. at 110.) In fact, Dr. Goodwin had never encountered "a case in which what has been described as partial birth abortion is the only choice, or even the better choice among alternatives, for managing a given complication of pregnancy." (Id.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 111-12; Date: March 25, 2003; Name: Susan E. Rutherford, M.D.**[27]

Dr. Rutherford was board-certified in maternal-fetal medicine. She had 17 years of experience in maternal-fetal medicine. Dr. Rutherford did not claim to do abortions.

She believed that Dr. Darney was lucky that the women he described had good outcomes and that those women were "at extremely high risk for catastrophic life-threatening hemorrhage with any attempt at vaginal delivery." (Id. at 111.) She did "not agree that D&X was a necessary option." (Id.)

[27]The doctor's letter was also discussed in the Senate floor debate. (Def.'s Ex. 519, at S3653-54.)

**Court's Exhibit 9; "2003 House Hearings"; Page: 113-16; Date: March 25, 2003; Name: Camilla C. Hersh, M.D.**

Dr. Hersh was a board-certified obstetrician and gynecologist with 13 years of experience. She had served as a clinical assistant professor of obstetrics and gynecology at Georgetown University. She was a member of PHACT and she did not claim to do abortions.

She believed the banned procedure was dangerous. In particular, she believed the forced dilation of the cervix over a number of days may lead to an incompetent cervix and that such a time requirement is likely to make the banned procedure irrelevant to saving the life of a pregnant woman in the case of an emergency. Furthermore, she believed the banned procedure risks serious infection.

**Court's Exhibit 9; "2003 House Hearings"; Page: 117; Date: March 25, 2003; Name: Lewis J. Marola, M.D.**

Dr. Marola, together with his partner, claimed 60 years of "ob-gyn" practice experience. His statement was addressed to the New York legislature although it was included in the House record. Dr. Marola did not claim to do abortions.

Dr. Marola was of the view that the procedure was dangerous because of the conversion of the fetus to the breech position. That action may cause a dangerous condition, that is, "an abruption of the placenta and amniotic fluid embolism." (Id.) He believed that an induction abortion would be "far safer." (Id.)

**Court's Exhibit 9; "2003 House Hearings"; Page 186-88; Date: March 25, 2003; Name: Vanessa Cullins, M.D.**

Dr. Cullins was a board-certified obstetrician and gynecologist. She received her medical degree and master's degree in public health from Johns Hopkins

University. She received her MBA from the University of Pennsylvania, Wharton School. She previously served as an assistant professor at Johns Hopkins University School of Medicine and was an attending physician in obstetrics and gynecology at the institution. She had published extensively and made numerous presentations in the area of obstetrics and gynecology. At the time her testimony was presented to the House, she was Vice President of Medical Affairs for Planned Parenthood Federation of America. Although there are indications in her submission to Congress that she probably performed abortions, it is not entirely clear from her statement whether she had in fact performed those procedures.

Dr. Cullins believed the banned procedure is both safe and needed and that the Congressional Findings to the contrary are incorrect. In particular, she stated:

> D&X abortions offer a variety of potential safety advantages over other procedures used during the same gestational period.
>
> First, compared to D&E abortions, D&X involves less risk of uterine perforation or cervical laceration because it requires fewer passes into the uterus with sharp instruments.
>
> Second, there is considerable evidence that D&X reduces the risk of retained fetal tissue, a serious complication that can cause maternal death or injury.
>
> Third, D&X may be safer than available alternatives for women with particular health conditions. As ACOG has concluded, D&X may be "the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman." D&X may also be the most appropriate method in the presence of certain fetal indications. For example, D&X "may be especially useful in the presence of fetal abnormalities, such as hydrocephalus" because it entails reducing the size of the fetal skull "to allow a smaller diameter to pass through the cervix, thus reducing risk of cervical injury." In addition, "intactness allows unhampered evaluation of structural abnormalities" in the fetus and can

thus aid in diagnosing fetal anomalies. Finally, an intact fetus can "aid . . . patients grieving a wanted pregnancy by providing the opportunity for a final act of bonding."

Fourth, D&X procedures usually take less time than other abortion methods used at a comparable stage of pregnancy, which can have significant health advantages.

Based on my clinical experience and knowledge of this field, there is no reliable medical evidence to support the claim in H.R. 760's Findings that D&X endangers maternal health. (Finding Number (14)(A).) The Findings claim that the amount of cervical dilatation involved in D&X procedures heightens the risk of cervical incompetence or cervical trauma. Many D&E procedures, however, involve similar amounts of dilatation, and of course childbirth involves even more dilatation. The concern stated in the Findings about the risks posed by the physician repositioning the fetus into a footling breech, is similarly misplaced. Some clinicians recommend repositioning the fetus in some D&Es, depending on how the fetus initially presents. Moreover, the Findings suggest that the use of sharp instruments to collapse the head in a D&X is more dangerous than repeated instrument passes into the uterus in a D&E. But the physician can visualize and feel the surgical field during a D&X and therefore the instrument can be carefully guided, thus minimizing risk to the woman.

Finally, H.R. 760's sponsors attempt to rely on the lack of comparative studies or peer-reviewed articles relating to the D&X procedure. (Finding Number (14)(B).) However, the development and medical acceptance of safe surgical procedures is not always achieved by orderly and controlled testing. For example, the most common abortion procedures used today were all developed years ago by physicians who slightly varied their technique to achieve greater safety for their patients, found that the variation did improve the safety, and then taught the new technique to their colleagues. Similarly, open heart surgery (as an example) was not tested in a randomized, controlled way. Rather, physicians figured out how to perform the surgery, and did so. As patients lived, physicians kept doing it, and got better at it.

(Id. at 187-88 (footnotes omitted).)

**Court's Exhibit 9; "2003 House Hearings"; Page 191-95; Date: March 25, 2003; Name: Anne R. Davis, M.D.**

Dr. Davis, a member of ACOG, was an assistant professor in clinical obstetrics and gynecology at Columbia University. In addition, she provided direct patient care. She had published in the area of obstetrics and gynecology and was board-certified. It is not clear whether Dr. Davis had performed abortions.

Dr. Davis was of the opinion that the banned procedure is safe and needed and that the Congressional Findings to the contrary are incorrect. Her statement mirrored Dr. Cullin's statement. (Id. at 194.)

**Court's Exhibit 10; "2003 House Report"; Page 14-23, 107-08, 127, 151-53; Date: April 3, 2003; Name: None.**

Among other things, this House report purports to summarize, from the viewpoint of the majority and minority, the information before Congress regarding the need for and relative safety of the banned procedure. References to some of the findings of the various district courts that have considered the need for and safety of the procedure are sprinkled throughout the two opposing summaries. The report also contains two briefs presented to the Supreme Court in Stenberg v. Carhart, one from ACOG and the other from the Association of Physicians and Surgeons and others, on the need for and safety of the procedure.

The majority summary may contain a significant factual error regarding the views of Dr. Warren Hern, the author of a leading textbook on abortion, as it concerns the need for and safety of the banned procedure. For example, the majority summary states that: "Dr. Warren Hern has testified that he had 'very serious reservations about

this procedure[’] and that ‘he could not imagine a circumstance in which this procedure would be the safest.’” (Id. at 18 & n.90.)

As previously described in this summary, Dr. Hern did not testify although he was present in the hearing room, and apparently ready and willing to do so. The supposed views of Dr. Hern were recounted by another doctor who read from a newspaper published by the AMA which in turn purported to quote Hern’s views. As contrasted with this third-party account, Dr. Hern submitted a detailed written statement which, among other things, opposed the ban and listed the possible advantages to the pregnant woman of the banned procedure. Indeed, Hern used a variant of the banned procedure, but he first killed the fetus using an injection.

### *C. MEDICAL EVIDENCE PRESENTED AT TRIAL*

#### *1. THE PROCEDURES*

Out of a total of 23 physician-witnesses who testified, 18 of them testified primarily about the need for and safety of the procedure.[28] The testimony of those 18 witnesses is summarized below.

[28]Of the five others, Dr. Cain testified as a spokesperson for ACOG. She, too, testified about the need for and safety of the procedure. Dr. Baergen testified on pathology issues. Drs. Howell and Mazariegos testified on the development of surgical techniques. Dr. Anand testified about fetal-pain issues. The views of these five additional physician-witnesses are summarized in a later portion of this opinion.

### *a. MECHANICS*

### *I. PLAINTIFF DR. LEROY CARHART*

Dr. Carhart has performed abortions since 1988, and he estimates that he provides approximately 1,400 abortions per year. He performs medical abortions, as well as abortions using vacuum aspiration, D&E, and intact D&E techniques. (Tr. 593-94, Test. Dr. Carhart.)

#### *(a) DILATION*

Dr. Carhart testified that he generally begins performing his D&E procedure at 12 to 14 weeks. From 12 through 15 weeks, he uses misoprostol,[29] a medication that is placed in the patient's cheek cavity, to dilate the patient's cervix before the procedure is performed later that same day. From 16 weeks to the end of the 19th week, Dr. Carhart uses laminaria[30] to dilate the cervix, a two-day process in which laminaria are placed in the cervix, the patient is sent home overnight to resume normal activities with some minor restrictions, and the patient returns the next day for the procedure. After 19 weeks, the laminaria-dilation process is repeated for two days,

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[29]Misoprostol is a medication originally designed for the treatment of peptic ulcers, but it also induces uterine contractions and serves as a cervical ripening agent—that is, the cervix becomes soft and dilates due to a chemical process in which the protein content of the cervix breaks down and the water content of the cervix increases. (Tr. 1672, Test. Dr. Lockwood.)

[30]A "laminaria" is a "[s]terile rod made of kelp . . . which is hydrophilic, and, when placed in the cervical canal, absorbs moisture, swells, and gradually dilates the cervix." Stedman's Medical Dictionary 964 (27th ed. 2000). Laminaria range from 1/8 to 1/4 of an inch in thickness; the amount of expansion in each laminaria is variable; and the same number and size of laminaria inserted in many different women would yield many different amounts of dilation. (Tr. 221-22, Test. Dr. Fitzhugh.)

with the procedure being performed on the third day. Dr. Carhart has not detected any long-term threat to his patients by using this "slow-dilation" method. (Tr. 602, 604-07, 609-11, 683, Test. Dr. Carhart.)

According to the plaintiffs and their expert, there are three aspects to dilation: (1) ripening, or the softening of the tissue such that it will stretch rather than tear; (2) the degree of relaxation or amount of opening of the cervix; and (3) the length of the cervix. (Tr. 748, Test. Dr. Carhart.) The amount of dilation that occurs is not predictable and depends upon the initial firmness, length, and degree of opening of the cervix; the amount of fluid in the patient's cervix; the patient's age; whether the patient has previously had vaginal deliveries; gestational age of the fetus; and the patient's pain tolerance. (Tr. 608-09, Test. Dr. Carhart; Tr. 222-23, Test. Dr. Fitzhugh; Tr. 504-05, Test. Dr. Knorr; Tr. 334, Test. Dr. Vibhakar; Tr. 40, Test. Dr. Doe.)

At 14 weeks and later, Dr. Carhart's goal "is to remove the fetus intact, or as intact as possible," so he seeks to achieve cervical dilation in the amount of two-thirds of the biparietal[31] diameter of the fetus. (Tr. 608, Test. Dr. Carhart.) While Dr. Carhart attempts to achieve maximum dilation in every case—that is, enough dilation to deliver the entire fetus, including the head—the "law of diminishing returns" prevents him from extending the laminaria-dilation process an extra day for his patients who are 17 weeks or less because of the risks of infection occurring overnight, bleeding, and because the fetal skin begins to break up. (Tr. 608-09 & 734-35, Test. Dr. Carhart.)

[31]"Biparietal" means "[r]elating to both parietal bones of the skull." Stedman's Medical Dictionary 207 (27th ed. 2000).

### *(b) REMOVAL OF FETUS*

After sufficient dilation is achieved in his 12- to 13-week patients, Dr. Carhart uses a cannula[32] to remove the amniotic fluid, fetus, and placenta, and then uses a curette[33] to ensure that all fetal tissue has been removed from the patient's uterus. With 12- to 13-week patients who have previously delivered children, dilation is such that the "membranes are bulging" before the procedure begins and the fetus "expel[s] in total or in part" when the membranes are ruptured, requiring Dr. Carhart to "remove that part and then complete the abortion." "[V]ery, very frequently" the fetus has a heartbeat at the time the fetus, or part of it, "expels." (Tr. 614-15, Test. Dr. Carhart.) The fetal heartbeat can be detected by constant ultrasound observation, which Dr. Carhart uses from 5 to 24 weeks. (Tr. 616, Test. Dr. Carhart.)

For patients who have achieved sufficient dilation with laminaria, Dr. Carhart performs the procedure by first removing the laminaria. He then uses a speculum[34] and tenaculum[35] to pull the cervix down further into the vaginal cavity, thereby decreasing the length of the "tunnel you're looking through" and giving Dr. Carhart

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[32]A "cannula" is a "tube that can be inserted into a cavity, usually by means of a trocar filling its lumen; after insertion of the [cannula], the trocar is withdrawn and the [cannula] remains as a channel for the transport of fluid." Stedman's Medical Dictionary 278 (27th ed. 2000).

[33]A "curette" is an "[i]nstrument in the form of a loop, ring, or scoop with sharpened edges attached to a rod-shaped handle, used for curettage." Stedman's Medical Dictionary 436 (27th ed. 2000).

[34]A "speculum" is an "instrument for exposing the opening of any canal or cavity in order to facilitate inspection of its interior." Stedman's Medical Dictionary 1665 (27th ed. 2000).

[35]A "tenaculum" is a "surgical clamp designed to hold or grasp tissue during dissection, commonly used to grasp the cervix." Stedman's Medical Dictionary 1793 (27th ed. 2000).

a better "field of vision." The distance Dr. Carhart is able to achieve between the cervix and the vaginal introitus[36] ("opening") varies anywhere from six centimeters to the cervix actually being outside the vaginal opening, the latter of which occurs five to ten times per year. (Tr. 612-14, Test. Dr. Carhart.)

Dr. Carhart then ruptures the membranes and removes the fetus with forceps, using a twisting motion in an attempt to remove the fetus intact or as intact as possible. (Tr. 616-19, Test. Dr. Carhart.) Patients' cervixes respond differently as the fetus is removed, which affects whether Dr. Carhart may remove the fetus intact or in pieces. (Tr. 749, Test. Dr. Carhart.)

Per year, Dr. Carhart estimates that he delivers four to six fetuses[37] that are between 13 and 18 weeks of gestation intact or to the point where the fetal body, save for the head, is in the patient's vaginal cavity or outside her body. (Tr. 726-29, Test. Dr. Carhart.) Because these deliveries occur before 18 weeks—the point at which Dr. Carhart induces fetal demise before performing an abortion—Dr. Carhart has observed the existence of a "very slow" fetal heartbeat[38] in these fetuses, but has never seen signs of movement because these fetuses are "probably unconscious" from administration of anesthesia and misoprostol to the patient that causes "enough constr[i]ction of the uterus on the fetus to minimize circulation and at least obtund the

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[36]"Introitus" means "[t]he entrance into a canal or hollow organ, as the vagina." Stedman's Medical Dictionary 918 (27th ed. 2000).

[37]Dr. Carhart also testified that during his 14- to 17-week procedures, fetuses "come[] out intact up to the level of the calvarium" on an average of once a month, but Dr. Carhart is successful at actually removing fetuses completely intact less than 5% of the time at these gestational ages. (Tr. 617 & 619-20, Test. Dr. Carhart.) "Calvarium" is a term "[i]ncorrectly used for calvaria," which is the "upper domelike portion of the skull." Stedman's Medical Dictionary 271 (27th ed. 2000).

[38]Dr. Carhart testified that the fetuses of his 16- and 17-week patients are normally "alive at the time of the final delivery." (Tr. 617, Test. Dr. Carhart.)

fetus." In this gestational age range, Dr. Carhart attempts to cause fetal demise by cutting the umbilical cord if the cord prolapses after he ruptures the membranes and if the cord is accessible. Dr. Carhart believes that the cause of death in fetuses he has delivered intact between 13 and 18 weeks of gestation was oxygen deprivation, although Dr. Carhart can never be sure which step during an abortion will cause fetal demise. (Tr. 726-27, 729-31, 746, Test. Dr. Carhart.)

Beginning at 18 weeks, Dr. Carhart performs what he calls a "combination of induction techniques and surgical D&E techniques. He begins by injecting the fetus with lidocaine and digoxin anywhere from 24 to 36 hours prior to the time the procedure is scheduled to be completed in order to kill the fetus before he begins the procedure. For his 18- and 19-week patients, Dr. Carhart removes the laminaria that were placed the prior day. If dilation in the amount of 65 "French"[39] has not been achieved by that point, Dr. Carhart mechanically dilates the patient's cervix as far as he can "without feeling resistance" and then ruptures the membranes. Dr. Carhart then places four Cytotec[40] tablets in the patient's rectum; administers sedation and pitocin or oxytocin intravenously; and waits for the patient to deliver the fetus intact, which happens approximately 75% of the time at 18 and 19 weeks of gestation. If the patient has not delivered the fetus within three to four hours, Dr. Carhart removes it using the D&E technique he uses for 14- and 15-week patients. If the patient delivers the fetus and placenta intact, Dr. Carhart finishes by performing a D&C to remove retained tissue that is subject to infection and to check the condition of the cervix, repairing tears if necessary. If the patient has delivered only the fetus, Dr. Carhart will remove the remaining placenta and perform a D&C. (Tr. 607-08, 620-24, 643, 696, Test. Dr. Carhart.)

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[39]"French" in this context refers to a scale "for grading sizes of sounds, tubes, and catheters as based on a diameter of 1/3 mm equaling 1 F on the scale (e.g., 3 F = 1 mm)." Stedman's Medical Dictionary 1596 (27th ed. 2000).

[40]Cytotec is also known as misoprostol. (Tr. 536, Test. Dr. Knorr.)

Dr. Carhart does not normally convert the fetus to a footling breech during his abortion procedures; rather, he "take[s] the fetus as it's presenting." (Tr. 657-60 & 662, Test. Dr. Carhart.) If Dr. Carhart cannot deliver an intact fetus pursuant to his normal procedures, he must remove the fetus from the patient in a piecemeal fashion; that is, he uses his hands and forceps to grasp individual fetal parts, pulls them down through the cervical os,[41] and uses a rotating motion to dismember various parts from the fetus. Dr. Carhart testified that the dismemberment procedure gets more difficult as gestational age increases due to the increasing toughness of the fetal tissue. (Tr. 691, 694-95, 697-98, Test. Dr. Carhart; Tr. 1276, Test. Dr. Cook (before 20 weeks, fetal tissue is much more fragile than at 24 weeks; skin is more easily disrupted, fetus bruises more easily, and disarticulation or trauma can occur more easily).)

It is "extremely rare" for Dr. Carhart to use an instrument to remove the fetus in patients who are past 20 weeks and who are not adequately dilated on the third day of the process. Instead, Dr. Carhart prefers to "do things to get better dilation and do things to get a little better uterine contraction so that it does, indeed, go ahead and complete spontaneously." (Tr. 722-23, Test. Dr. Carhart.) Most (90%) of Dr. Carhart's patients who are beyond 20 weeks will expel their fetuses without the need for any instrumentation by Dr. Carhart during the D&E procedure. (Tr. 702-04, Test. Dr. Carhart.)

### ***(c) COMPRESSION OF FETAL SKULL***

When Dr. Carhart performs his "combination of induction techniques and surgical D&E techniques," described above, 10% of his patients over 20 weeks expel the fetus up to its skull, at which point Dr. Carhart must "open the back of the skull and drain it" or compress the fetal skull in some manner to facilitate delivery. Dr.

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[41]"Os" is a "[t]erm applied . . . to an opening into a hollow organ or canal." Stedman's Medical Dictionary 1279 (27th ed. 2000).

Carhart performs the same techniques when the fetal skull becomes lodged in the patient's cervical os after he has attempted to extract the fetus with instruments. Dr. Carhart rarely uses a cannula or suction to assist him in compressing the fetal skull. (Tr. 623, 689-91, 704-05, 707, Test. Dr. Carhart.) As described by Dr. Carhart:

> Very often when the head is tightly impacted into the cervix, there is going to be a chance of causing damage to try to put forceps around the skull to grab ahold of it to bring it out. If, indeed, enough of the posterior nuchal[42] region of the head is exposed, assuming that we are talking about a foot-first presentation, that I can safely and adequately drain the cavity of the fetus, then if I'm fairly sure by ultrasound and other pelvic evaluation it's not going to come out on its own, then I would elect to open the skull. If, on the other hand, if the cervix is relaxed enough which I can get around the skull and I can grasp it which obviously wouldn't be too often, it might just pass if it was relaxed enough, but if I could do that I would prefer to do that.
>
> (Tr. 706, Test. Dr. Carhart.)

### *(d) MANNER OF PERFORMING PROCEDURES*

In his 13- to just-before-18-week D&Es, Dr. Carhart's hand movements and use of instruments are the same, whether the doctor ultimately performs an intact D&E or a dismemberment D&E. "I still try to take small bites, I still try to progress the fetus through the canal. I try to be as gentle as possible whether or not it's going to be intact." (Tr. 731-32, Test. Dr. Carhart.) Even if Dr. Carhart has removed multiple pieces of the leg and abdomen areas of a fetus, he still attempts to keep the remainder of the fetus as intact as possible to avoid a "floating head"; that is, the fetal head

[42]The "nuchal" region is the area at the back, or nape, of the neck. Stedman's Medical Dictionary 1231 (27th ed. 2000).

becomes separated from the fetus and becomes lodged in the upper part of the uterus and is "virtually impossible to get out." (Tr. 733, Test. Dr. Carhart.)

At 12 through 17 weeks, Dr. Carhart "can normally remove" "two, three pieces" and "[he] can often get up to the base of the skull, then go back and remove the skull" or "[he] can often get both lower extremities and divide somewhere at the upper part of the spinal cord, removing abdominal organs and some even thoracic organs on the very first removal." (Tr. 627, Test. Dr. Carhart.) During this gestational age range, Dr. Carhart has encountered the situation "where the fetus has been not intact, partially dismembered," but "part of the fetal trunk [past] the umbilicus has come outside the body of the mother." (Tr. 618, Test. Dr. Carhart.) In these situations, Dr. Carhart has torn the fetus apart at the level of the elbow, shoulder, scapula, and chest wall. (Tr. 618, Test. Dr. Carhart.) Approximately 25 to 40 times per year, Dr. Carhart extracts the fetus "up to the shoulders where [he has] to go in and do something else"—that is, tear that portion of the fetal body below the shoulders from that part of the body above the shoulders. (Tr. 728, Test. Dr. Carhart.)

Because abortions may not be performed in eastern Nebraska hospitals, Dr. Carhart maintains monitoring equipment, supplies, and experienced staff in his clinic in an attempt to provide hospital-like care. (Tr. 738-40, Test. Dr. Carhart.)

### *ii. PLAINTIFF DR. WILLIAM G. FITZHUGH*

Dr. Fitzhugh has performed abortions since 1969, and he estimates that he provides approximately 70 abortions per week on patients who are in their first trimester and 5 to 7 abortions per week on second-trimester patients. He performs D&Cs, D&Es, and unintentional intact D&Es. (Tr. 212, 214, 270-71, Test. Dr. Fitzhugh.)

### *(a) DILATION*

Dr. Fitzhugh testified that he generally accomplishes adequate dilation with one round of laminaria, combined with occasional use of mechanical dilators after the laminaria are removed if greater dilation is necessary. He recalls only two cases in 24 years in which he inserted a second round of laminaria and instructed the patient to return the following day. (Tr. 231-32 & 273-74, Test. Dr. Fitzhugh.)

The number and size of laminaria that Dr. Fitzhugh uses to dilate his patients vary for each patient, depending upon gestational age, size of the cervix, comfort level of each patient, and condition of the cervix. (Tr. 229-30, Test. Dr. Fitzhugh.) Dr. Fitzhugh does not use "serial" laminaria—that is, multiple insertions of laminaria over two to three days—nor does he use Cytotec, misoprostol, or other prostaglandins[43] in conjunction with his dilations because he has learned in his medical career that "the least that you do safely is the best." (Tr. 232-33 & 272, Test. Dr. Fitzhugh.)

### *(b) REMOVAL OF FETUS*

Dr. Fitzhugh breaks the amniotic sac and removes the amniotic fluid with a suction cannula, which shrinks the uterus and may lessen the risk of amniotic fluid emboli,[44] a condition in which amniotic fluid enters maternal circulation, causing sudden shock. (Tr. 239-40, Test. Dr. Fitzhugh.) After Dr. Fitzhugh uses suction to remove the amniotic fluid, either the umbilical cord or another part of the fetus will

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[43]Prostaglandins cause uterine contractions and uterine activity. They can be used to prepare the cervix for a surgical abortion procedure by utilizing the physiologic process of uterine contractions which lead to gradual cervical change. (Tr. 1359, Test. Dr. Cook.)

[44]Amniotic fluid embolism is a condition in which amniotic fluid enters the bloodstream of the mother, causing cardiovascular collapse and a breathing abnormality. (Tr. 1724-25, Test. Dr. Lockwood.)

come through the cervix. When Dr. Fitzhugh begins to remove the fetus during a D&E procedure, the fetus is usually alive. (Tr. 251-52 & 254, Test. Dr. Fitzhugh.) If the umbilical cord presents itself first, Dr. Fitzhugh detaches it; otherwise, he grasps various fetal parts with ring forceps, using a twisting motion to remove as much tissue as possible at once. This procedure may lead to detachment of the fetal part that has passed through the cervix from the rest of the fetus, which is still inside the uterus. In order to accomplish dismemberment of the fetus entirely inside the uterus, Dr. Fitzhugh would be required to insert both a stabilizing instrument and a pulling instrument in the uterus at one time, which is generally not possible. (Tr. 240-42, Test. Dr. Fitzhugh.)

In typical cases, the placenta will then deliver, followed by the fetal head. Dr. Fitzhugh cleans the uterus with suction, rather than a curette, because he is concerned about removing too much of the myometrium.[45] (Tr. 243, Test. Dr. Fitzhugh.) Suction alone is sufficient for Dr. Fitzhugh to remove fetuses up to 15 to 16 weeks, after which forceps must be used to grasp the fetus and remove it piece-by-piece from the uterus. (Tr. 272, Test. Dr. Fitzhugh.)

Dr. Fitzhugh estimates that when he begins to remove the fetus during a second-trimester abortion, the distance between the cervix and vaginal opening is less than two centimeters in one of every three patients, whereas such distance occurs in one in seven of his first-trimester patients. (Tr. 236, Test. Dr. Fitzhugh.)

Because it is difficult to gain access to ultrasound machines and additional staff in the hospitals[46] in which Dr. Fitzhugh performs abortions, he does not generally use

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[45]The "myometrium" is the "muscular wall of the uterus." Stedman's Medical Dictionary 1175 (27th ed. 2000).

[46]As is required by state law, Dr. Fitzhugh performs second-trimester abortion procedures in a hospital. The state and private hospitals at which Dr. Fitzhugh

ultrasound during his abortion procedures. (Tr. 238, 243, 294, Test. Dr. Fitzhugh.) While Dr. Fitzhugh does not convert the fetus to a footling breech before performing an abortion, he sometimes manipulates the position of the fetus to facilitate the fetus's head passing through the patient's cervix. (Tr. 239 & 294, Test. Dr. Fitzhugh.)

Ever since Dr. Fitzhugh learned to perform the D&E method of abortion in 1975, he has intended to remove the fetus as intact as possible in each procedure because he has learned that "the quicker I got done, the easier it was and the safer it was." (Tr. 251, Test. Dr. Fitzhugh.) While Dr. Fitzhugh thinks it would be "nice" to remove intact fetuses in his abortions, he does not "expect" the fetus to deliver intact because "it doesn't happen often," and he does not "take any special steps to ensure that [the fetus] comes out intact." In order for intact removal to occur on a regular basis, Dr. Fitzhugh would have to dilate his patients with a second round of laminaria. (Tr. 276-77, Test. Dr. Fitzhugh.)

Dr. Fitzhugh does not characterize as separate and distinct the D&E procedure in which the fetus is disarticulated and the D&E procedure in which the fetus is delivered intact up to the head, followed by fetal skull compression. "I just do the same procedure all the time, and I don't categorize things. So to me, I just terminate a pregnancy." (Tr. 256, Test. Dr. Fitzhugh.)

Per year, Dr. Fitzhugh estimates that one aborted fetus delivers past the vaginal opening entirely intact without further assistance from him, and two to three fetuses deliver intact up to the fetal head, which become lodged in the cervix. (Tr. 245-46, Test. Dr. Fitzhugh.) The earliest gestational age Dr. Fitzhugh has observed delivery of an intact fetus up to the head is 16 weeks. (Tr. 253, Test. Dr. Fitzhugh.)

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practices have mortality and morbidity committees. (Tr. 303-05, Test. Dr. Fitzhugh.)

Dr. Fitzhugh does not induce fetal demise before beginning an abortion procedure. (Tr. 254, Test. Dr. Fitzhugh.) However, Dr. Fitzhugh takes various actions during a D&E procedure that could be fatal to the fetus: separation of the umbilical cord, which occurs in 25% of his cases; disarticulation of fetal parts in the uterus; and compression of the fetal skull. (Tr. 253-54, Test. Dr. Fitzhugh.) Dr. Fitzhugh has "no idea" which one of these actions would be immediately fatal in any given case. (Tr. 253, Test. Dr. Fitzhugh.)

Dr. Fitzhugh refers patients who want to abort a live fetus beyond 22 weeks to clinics in Atlanta, New York, and Kansas. (Tr. 285, Test. Dr. Fitzhugh.)

### *(c) COMPRESSION OF FETAL SKULL*

In the two to three cases per year in which fetuses deliver intact up to the fetal head, which becomes lodged in the cervix, Dr. Fitzhugh uses forceps to compress the fetal skull in order to reduce its size and to ensure that the fetus is dead when it is removed. (Tr. 245-47, Test. Dr. Fitzhugh ("The one thing that I want—and I don't want the staff to have to deal with is to have a fetus that you remove and have some viability to it, some movement of limbs, because it's always a difficult situation."); Tr. 294-95, Test. Dr. Fitzhugh (some of operating room staff gasp when fetus delivers intact during D&E).)

Dr. Fitzhugh is not aware of a workable alternative to compressing the fetal skull when it becomes lodged in the cervix. He does not know whether various drugs work; he could damage the patient's cervix by cutting it; and detaching the fetal body from the head and retrieving the head from the uterus at the end of the procedure is difficult. (Tr. 247-48, Test. Dr. Fitzhugh.) Dr. Fitzhugh was once called to the operating room at the Medical College of Virginia to assist a physician who had unsuccessfully tried to medically induce labor the prior day in a patient who was miscarrying. The patient had ruptured membranes, a 103˚ temperature, and was

"really sick." When Dr. Fitzhugh arrived in the operating room, another physician had already removed the fetus up to the head, which was lodged in the patient's cervix, and the fetus showed signs of life. Dr. Fitzhugh was required to crush the fetal skull in order to remove the fetus from the patient. (Tr. 262-63, Test. Dr. Fitzhugh.)

### (*d) MANNER OF PERFORMING PROCEDURES*

The manner in which Dr. Fitzhugh can remove the fetus is affected by the amount of cervical dilation, the patient's response to anesthesia used to contract the uterus, the size of the patient, and the amount of sleep Dr. Fitzhugh has had. (Tr. 250-51, Test. Dr. Fitzhugh.)

## *iii. PLAINTIFF DR. WILLIAM H. KNORR*

Dr. Knorr has performed abortions since the early 1980s. He estimates that he performed 5,000 to 6,000 abortions in 2003. Dr. Knorr performs D&Cs, medical abortions, and D&Es, and he performs intentional intact D&Es during the second trimester in rare instances. (Tr. 500-01 & 565, Test. Dr. Knorr.)

### *(a) DILATION*

Dr. Knorr testified that from 12 to 16 weeks, he uses a mechanical dilator to achieve enough dilation (43 Pratt[47]) to accommodate a 14-millimeter suction cannula. Between 16 and 20 weeks, Dr. Knorr administers Cytotec—a medication which softens the cervix—to his patients in the morning. Three to five hours later, Dr. Knorr uses a mechanical dilator up to 63 Pratt (2.1 centimeters) or larger, followed by the D&E procedure. (Tr. 502-03 & 535, Test. Dr. Knorr.)

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[47]"Pratt" dilators are "cylindrical metal rods of graduated sizes used to dilate the cervical canal." Stedman's Medical Dictionary 503 (27th ed. 2000).

As compared to laminaria, Dr. Knorr has observed several advantages to dilating with Cytotec in his 12- to 16-week patients: laminaria inserted the day prior to the procedure cause cramping and pain overnight; Cytotec significantly reduces the time of the abortion process; Cytotec both softens and dilates the cervix; and dilation with Cytotec occurs not with contractions every three to five minutes during labor, but with tetanic contractions at the level of the uterus in which the uterus contracts down, but does not relax. (Tr. 504 & 538-39, Test. Dr. Knorr.)

Dr. Knorr characterized the side effects of Cytotec as chills, fever, nausea, vomiting, and diarrhea and the side effects of laminaria as infection, hemorrhage, and uterine perforation. (Tr. 539-40, Test. Dr. Knorr.)

For his patients who are 20 weeks and beyond, Dr. Knorr pre-dilates the cervix with mechanical dilators to a size 63 Pratt, and then inserts three jumbo laminaria and three large laminaria in the patient's cervix, where they remain overnight. The following morning, the patient is given 600 milligrams of Cytotec orally, and after three to five hours, the abortion is performed. (Tr. 505, Test. Dr. Knorr.) Dr. Knorr's use of Cytotec with laminaria allows the laminaria to absorb more water and expand more freely, avoiding the "dumbelling" effect of laminaria—that is, where the expanded ends of the laminaria would be inside the internal cervical opening and outside the cervix, with a smaller diameter in the middle of the cervix. (Tr. 506, Test. Dr. Knorr.)

Dr. Knorr began using Cytotec approximately six years ago after being advised by a European doctor that Cytotec was more efficient, it caused less discomfort for the patient, and abortions up to 21 weeks could be successfully performed using Cytotec and dilation alone. Before Dr. Knorr began using Cytotec, he used laminaria to dilate his patients who were beyond 16 weeks. (Tr. 503 & 505-06, Test. Dr. Knorr.)

Typically, Dr. Knorr's patients are dilated at least four centimeters. Dr. Knorr does not believe that his methods of dilation cause cervical incompetence, a condition in which the cervix will not hold a pregnancy. (Tr. 506-07 & 516, Test. Dr. Knorr.) Dr. Knorr considers his method of dilation to be "atypical" for abortions through 24 weeks because he uses a technique that results in "greater dilation over a shorter period of time." Between 20 and 24 weeks of gestation, it generally takes Dr. Knorr approximately 24 hours to dilate the patient's cervix and remove the fetus. (Tr. 537, Test. Dr. Knorr.)

### ***(b) REMOVAL OF FETUS***

All of Dr. Knorr's second-trimester abortions are done under general anesthesia and with ultrasound guidance. Beginning at 16 weeks, Dr. Knorr places a speculum in the vagina after the patient is asleep and gently pulls forward on the cervix to straighten the cervical canal with a tenaculum or, when exceptional dilation occurs with Cytotec, with sponge forceps. The tenaculum not only straightens the cervical canal, but provides counter-traction for the mechanical dilators Dr. Knorr uses. (Tr. 508-09 & 514, Test. Dr. Knorr.)

Use of the tenaculum can shorten the distance between the vaginal opening and the outer cervix, especially as pregnancy advances and the cervix and ligaments relax in preparation for childbirth. In four to six percent of his second-trimester abortion patients, Dr. Knorr sees second-, third-, and fourth-degree descensus[48] in which the cervix is within a centimeter of the hymen at the opening of the vagina (second-degree); part of the cervix and possibly part of the uterus extend out of the vagina (third-degree); or the uterus and cervix are completely outside of the cavity in which they belong (fourth-degree). The distance between the cervix and vaginal opening is

[48]"Descensus" means to fall away from a higher position. "Descensus uteri" means "prolapse of the uterus." Stedman's Medical Dictionary 483 (27th ed. 2000).

sometimes short enough that if Dr. Knorr brings the fetus out through the cervix feet-first, the fetus past the navel can be past the vaginal opening with the fetal head still in the cervix. (Tr. 509-11, Test. Dr. Knorr.)

Before removing the fetus, Dr. Knorr suctions out as much amniotic fluid as possible in order to decrease the risk of amniotic embolus. After the speculum is in the vagina and the tenaculum is on the cervix, Dr. Knorr inserts the speculum into the uterine cavity and manually extracts the fetus. Because Dr. Knorr does not convert the fetus to any particular position, he begins removing whatever fetal part presents itself first. (Tr. 513-15 & 549, Test. Dr. Knorr.) Dr. Knorr testified that the "predominant characteristic" of second-trimester D&Es is dismemberment of the fetus. (Tr. 540-41, Test. Dr. Knorr.)

If the fetal head presents itself first, Dr. Knorr applies forceps around the head and performs a "crushing technique . . . to decrease the cerebral volume so that it will pass through the cervical canal." However, in most cases, Dr. Knorr "disarticulate[s] limbs and the fetus in utero . . . . that is my goal. Because of the dilatation technique that I use, we gain . . . a significant amount of dilatation, and therefore I remove fewer pieces of fetal tissue than the average person doing this procedure." In his 16- to 24-week patients, Dr. Knorr removes the fetus in 10 to 20 minutes. (Tr. 514-15, Test. Dr. Knorr.)

After Dr. Knorr removes the fetus, he, with sonographic guidance, uses forceps to remove the placenta, a large sharp curette to ensure that the cavity is empty, and a suction curette to finish the procedure. (Tr. 518, Test. Dr. Knorr.) Because Dr. Knorr performs his D&E procedures under sonographic guidance for all D&Es after 12.1 weeks, he is able to see whether the patient's uterus is empty at the end of the procedure and whether uterine perforation has occurred. (Tr. 532-33, Test. Dr. Knorr.)

Because Dr. Knorr does not, except in rare cases, induce fetal demise before performing an abortion, the majority of fetuses Dr. Knorr removes during a D&E procedure are alive. (Tr. 511, Test. Dr. Knorr.) Dr. Knorr has also had patients who are in the process of miscarrying their pregnancies and the fetus is alive in, or partly in, the uterus. (Tr. 522, Test. Dr. Knorr.)

Although not a "common occurrence," Dr. Knorr has had fetuses deliver entirely intact. Dr. Knorr delivers a fetus intact up to the fetal head that is too large to pass through the cervix approximately 10 times per year in his 20- to 24-week patients, and much less than that for his 16- to 20-week patients. These instances are related to the amount of dilation Dr. Knorr has been able to accomplish. (Tr. 515-16 & 573-75, Test. Dr. Knorr.) Before each abortion procedure, Dr. Knorr expects that, most likely, the fetus will be removed in large parts, but realizes that intact removal of a fetus can, and does, happen because of his dilation technique. (Tr. 517, Test. Dr. Knorr.)

Dr. Knorr has attempted, albeit rarely, to remove fetuses intact in the second trimester upon a referring physician's request so that anatomical studies on a malformed fetus can be performed or so pictures of the fetus can be taken for teaching purposes. Dr. Knorr also attempts intact removal of second-trimester fetuses upon a patient's request. When Dr. Knorr is attempting to remove a second-trimester fetus intact, he must achieve greater dilation than would be necessary to perform a dismemberment D&E. (Tr. 541-43 & 558, Test. Dr. Knorr.)

Dr. Knorr does not perform second-trimester induction abortions because he does not "really have the ability to do that. I cannot put a woman in the hospital where I have privileges and admit her for an elective abortion beyond 12 weeks[49] of

[49]Shortly after Dr. Knorr "came on board" at the hospital, the hospital's bylaws changed the 20-week limit to 12 weeks. (Tr. 520, Test. Dr. Knorr.) Dr. Knorr does not have privileges at the Manhattan-area hospital that allows abortions up to 24 weeks. (Tr. 568-69, Test. Dr. Knorr.)

gestation, and even if I wanted to do 12 weeks and under, I can usually never find a nurse that will accompany me to the [operating room] to do it." (Tr. 519-20, Test. Dr. Knorr.)

### *(c) COMPRESSION OF FETAL SKULL*

In "almost all of [Dr. Knorr's] cases, the [fetus's] head gets stuck" during removal of the fetus. (Tr. 538, Test. Dr. Knorr.) As mentioned above, if the fetal head presents itself first, Dr. Knorr applies forceps around the head and performs a "crushing technique . . . to decrease the cerebral volume so that it will pass through the cervical canal." (Tr. 514, Test. Dr. Knorr.) If the fetus has come through the cervix except for the head, Dr. Knorr proceeds as follows:

> I first evaluate the cervix to see if I have enough room to slip a finger between the cervix and the fetal head, and if I can do that, I can then insert my crushing forcep around the head, crush the head and extract it. If the cervix is very tight, I can't do that, I will use a craniotomy procedure, will turn the fetus so the back is up and find the area that I want to open, and either with a finger, a dilator or a scissor will open that area and gently pull down. That pressure alone is enough to empty the cranium and extract the head.

(Tr. 516, Test. Dr. Knorr.) Dr. Knorr has never used a suction cannula with the above-described procedure. (Tr. 516-17, Test. Dr. Knorr.) When the fetus comes through the patient's cervix except for the head, the fetus could be alive prior to Dr. Knorr's compression or puncturing of the skull. (Tr. 518, Test. Dr. Knorr.) These living fetuses are "grossly obtunded, meaning that they have a lack of oxygen due to the tetanic contraction. They have some oxygen, there will be a fetal heartbeat, but they are generally limp." (Tr. 558, Test. Dr. Knorr.)

Dr. Knorr would rather not remove a fetus completely intact—that is, without collapsing the fetal skull—because he is attempting to perform "an abortion procedure

and not a live delivery" and because "that head coming through the cervix without collapsing it first will cause damage to the cervix. It is the largest diameter you're removing from the uterine cavity." (Tr. 544-46, Test. Dr. Knorr.)

Dr. Knorr does not wait to see if the fetal head will eventually pass through the cervix on its own because his patients are under general anesthesia and are not intubated[50] during this procedure, and "adding dose upon dose of this [anesthesia] medication would eventually become toxic." (Tr. 517, Test. Dr. Knorr.)

The earliest gestation at which Dr. Knorr has observed a fetus coming out intact except for the head, which remains inside the patient's cervix, is 16 weeks. (Tr. 518, Test. Dr. Knorr.)

Dr. Knorr does not view an abortion procedure in which he able to remove the fetus intact but for the head as a separate, distinct procedure from a D&E where he must dismember the fetus in order to remove it. (Tr. 519, Test. Dr. Knorr.) Dr. Knorr's medical charts do not note whether a fetus is removed intact but for the head or in pieces because it is not medically relevant in his opinion. (Tr. 570, Test. Dr. Knorr.)

### *(d) MANNER OF PERFORMING PROCEDURES*

Dr. Knorr would consider a "delivery" to include the situation in which the fetus is in a vertex position and the fetal head comes outside the body of the mother. In such a case, Dr. Knorr would not deem it appropriate to kill the fetus and he would "do

[50]"Intubation" is "[i]nsertion of a tubular device into a canal, hollow organ, or cavity; specifically, passage of an oro- or nasotracheal tube for anesthesia or for control of pulmonary ventilation." Stedman's Medical Dictionary 918 (27th ed. 2000).

everything in [his] power to keep that fetus alive if it is resuscitatable." (Tr. 555-56, Test. Dr. Knorr.)

### *iv. PLAINTIFF DR. JILL L. VIBHAKAR*

Dr. Vibhakar performs medical abortions, suction procedures, D&Es, and induction terminations. Dr. Vibhakar performs D&Es up to 23 weeks and up to 24 weeks to save the life or health of the mother. (Tr. 314 & 362, Test. Dr. Vibhakar.)

Dr. Vibhakar performs abortions at the Emma Goldman Clinic, an independent, nonprofit facility, and the University of Iowa Hospital and Clinic. The University of Iowa discourages elective abortions at its facility, but will allow patients who do not fit within the admission criteria at the Emma Goldman Clinic or Planned Parenthood to obtain an abortion there. This includes patients who have severe cardiac disease, uncontrolled diabetes, uncontrolled seizure disorders, uncontrolled asthma, and large uterine fibroids, among other conditions. (Tr. 400-09, Test. Dr. Vibhakar.)

#### *(a) DILATION*

Dr. Vibhakar testified that for her patients with 13- and 14-week pregnancies, she uses misoprostol bucally (in the cheeks or oral cavity without swallowing) the morning of the procedure. At 15 to 16 weeks, she inserts one set of laminaria the day prior to the D&E, and at 17 weeks, two sets of laminaria are used. The number of laminaria contained in each set varies with each patient. (Tr. 331-35, Test. Dr. Vibhakar.) For her laminaria patients, Dr. Vibhakar will also administer misoprostol the morning of the procedure. (Tr. 329-30, Test. Dr. Vibhakar.)

At 13 to 14 weeks, Dr. Vibhakar attempts to achieve 12 to 14 millimeters of dilation; at 15 and 16 weeks, she attempts to dilate to 15 or 16 millimeters (1½ centimeters); and at 17 weeks, Dr. Vibhakar prefers to dilate from 2 to 4 centimeters.

Dr. Vibhakar uses metal dilators if adequate dilation is not achieved by use of misoprostol and/or laminaria. (Tr. 330-33, Test. Dr. Vibhakar.) Dr. Vibhakar does not use a third round of laminaria when adequate dilation has not been achieved because it makes the procedure more expensive and burdensome for her patients who do not live in the area, and an additional day of laminaria does not "gain[] that much more medically." (Tr. 334-35, Test. Dr. Vibhakar.)

Larger dilation makes Dr. Vibhakar's abortion procedures faster, safer, easier to perform, and less uncomfortable for the patient. Dr. Vibhakar believes that increased dilation results in less blood loss and reduces the chance of having to remove the fetus in small pieces which can increase the chance of cervical injury and uterine perforation. (Tr. 333-34 & 345, Test. Dr. Vibhakar.) If enough dilation is achieved so that Dr. Vibhakar can remove the fetus "predominantly intact up to the level of the calvarium . . . that procedure then just involves . . . one or two passes into the uterus, no small fragments. It's faster, shorter, it's less uncomfortable to the patient, and there is less chance of uterine injury." (Tr. 397-98, Test. Dr. Vibhakar.)

### *(b) REMOVAL OF FETUS*

The length and position of a woman's vagina, location of the cervix, a patient's parity, and gestational age affect the distance between the cervix and vaginal opening after Dr. Vibhakar uses a tenaculum to straighten the cervix. It is "[n]ot very common" for the cervix to be at the vaginal opening; whereas the distance between the cervix and the vaginal opening is four centimeters approximately 10% of the time. (Tr. 336-38, Test. Dr. Vibhakar.)

Dr. Vibhakar first uses a suction cannula to evacuate the amniotic fluid from the uterus and to bring the products of conception closer to the cervix. (Tr. 338, Test. Dr. Vibhakar.) Dr. Vibhakar does not manipulate the fetus into a certain position before beginning the extraction procedure with the forceps. (Tr. 375, Test. Dr. Vibhakar.)

She uses forceps to remove as much pregnancy tissue as possible at one time. To facilitate removing large pieces of the fetus, Dr. Vibhakar grasps fetal parts that start coming through the cervix, and then regrasps or twists those parts at a higher level in the cervix or uterus, rather than continuing to pull on the part such that it disarticulates. When a part of the fetus is too large to fit through the cervix, it separates from the rest of the fetus's body, causing "multiple passes" to be made to remove the entire fetus. Larger pieces of the fetus may be extracted when a greater degree of dilation occurs before the procedure begins. (Tr. 338-41, Test. Dr. Vibhakar.)

Dr. Vibhakar uses suction—and sometimes a sharp or blank curette—to remove remaining pieces of tissue after the large parts of the fetus are removed. If she is unsure whether she has retrieved all the major parts of the fetus during the procedure, Dr. Vibhakar uses ultrasound to check for retained tissue and physically checks the fetal tissue that has been removed during the procedure to be sure she has an adequate amount. (Tr. 376-77, Test. Dr. Vibhakar.)

While she learned to perform a procedure similar to what ACOG has described as an intact D&X in her residency training, Dr. Vibhakar does not perform that procedure because she typically does not get the amount of dilation necessary to perform the procedure and she is now more experienced at doing dismemberment D&Es. When Dr. Vibhakar begins a D&E, she cannot predict whether it will come out largely intact or in pieces. (Tr. 343-46, Test. Dr. Vibhakar.) Dr. Vibhakar testified that 100% of her second-trimester D&E procedures involve fetal dismemberment. (Tr. 362, Test. Dr. Vibhakar.)

Before Dr. Vibhakar begins a second-trimester D&E, the fetus is likely alive, as documented by an ultrasound performed either a day or a few weeks before the procedure. Dr. Vibhakar does not know when fetal demise occurs during her

procedures, nor is there any clinical significance to when demise occurs in her opinion. (Tr. 346, Test. Dr. Vibhakar.)

### *(c) COMPRESSION OF FETAL SKULL*

Dr. Vibhakar has had two cases at 18 or 19 and 21 weeks where the fetus has delivered intact up to the head, after which she disarticulated the body from the head, used forceps to compress the fetal head, and extracted the head. In the 18- or 19-week case, the patient had been dilated with two sets of laminaria, and both laminaria and misprostol were used in the 21-week case. (Tr. 341-42 & 381-83, Test. Dr. Vibhakar.)

Whether the fetus delivers intact up to the fetal head, or whether Dr. Vibhakar has disarticulated the fetus in some fashion in the course of removing the fetus, she must compress the head in some fashion in order to fit through the cervix. Such compression can create skull fragments that can cause lacerations. (Tr. 383-84 & 399, Test. Dr. Vibhakar ("Can't think of a time when it's come out without being compressed.").)

### *(d) INDUCTION*

Dr. Vibhakar estimates that of all second-trimester abortion procedures performed in the United States, only five percent are induction abortions. Dr. Vibhakar provides induction abortions because after counseling regarding the risks and benefits of induction compared with D&E, some patients opt to have an induction. There are other patients who are carrying a fetus with an anomaly who wish to have an induction termination resulting in an intact fetus so photographs may be taken to assist in the grieving process. (Tr. 325-26, Test. Dr. Vibhakar.)

In cases where neither a D&E nor an induction termination is contraindicated for an abortion patient, deciding which procedure will be performed is a matter of

informed consent for the patient and a matter of staff and facility availability. For example, Dr. Vibhakar does not offer induction abortions at the clinic where she works on a monthly basis because it does not have a facility and staff available 24 hours a day. (Tr. 391-92, Test. Dr. Vibhakar.)

### *v. DR. DOE*

The identity and curriculum vitae of Dr. Doe are subject to a protective order and are sealed. Suffice it to state that Dr. Doe has been practicing medicine for over 40 years, is board-certified in the United States and other countries, is a member of ACOG, has practiced medicine in major metropolitan hospitals, and is currently a clinical associate professor at a medical school and director of a women's clinic in a major metropolitan area. In 2003, Dr. Doe performed 1,130 abortions, of which 280 were second-trimester abortions for maternal indications, 92 were second-trimester abortions for fetal anomalies, and the remainder were first-trimester procedures. Dr. Doe performed approximately 950 abortions in both 2001 and 2002.

#### *(a) DILATION*

Dr. Doe testified that from 13 through 15 weeks, he or she uses laminaria to dilate the patient's cervix the day prior to performing the termination procedure. Beginning at 16 weeks, Dr. Doe dilates the patient's cervix over two days. The first day, Dr. Doe inserts one or two Dilapan, a synthetic osmotic dilator, into the cervix, along with a gauze sponge in the vagina to keep the Dilapan in place, after which the patient leaves the clinic to resume normal activities, with some minor restrictions. The dilation process causes severe discomfort in some women, and no discomfort whatsoever in others. (Tr. 37-39, Test. Dr. Doe.)

Dr. Doe attempts to get a "generous dilatation" before performing a D&E procedure. At 16 weeks, Dr. Doe strives for 1½ to 2 centimeters of dilation for

maternal indications and 3 centimeters for fetal indications; at 18 weeks, 3 to 4 centimeters of dilation for maternal indications and 4 to 5 centimeters for fetal indications; and at 20 weeks, 4 to 5 centimeters for maternal indications, with 5 being the goal for fetal indications. (Tr. 41-42, Test. Dr. Doe.) In fetal-indication cases in which Dr. Doe seeks to achieve more generous dilation in order to obtain an intact fetus, he or she uses more laminaria—up to 25 Dilapan in the second insertion—sometimes over the course of three days. (Tr. 50, Test. Dr. Doe.)

Dr. Doe uses misoprostol in maternal-indication cases where additional softening and dilation of the cervix are needed because Dr. Doe has been unable to insert as many laminaria or Dilapan as he or she wishes. (Tr. 139-40, Test. Dr. Doe.)

### *(b) REMOVAL OF FETUS*

In the first trimester of Dr. Doe's patients' pregnancies, Dr. Doe uses the suction curettage and manual vacuum aspiration methods of abortion. He or she performs these methods by administering intravenous sedation and analgesia; examining the abdominal area manually and by ultrasound to measure the size, shape, and position of the uterus and size of the fetus; inserting a speculum into the vagina and administering local anesthesia to the anterior lip of the cervix; grasping the anterior lip of the cervix with a tenaculum to hold it steady while he or she injects more local anesthetic; dilating the cervix according to the size of the fetus with long, slim, metal rods ("metal dilators"); inserting a suction cannula into the uterus; using either electrical suction or suction created by a 50 cc syringe to remove the uterine contents; and cleaning the uterine cavity with a curette. (Tr. 35-37, Test. Dr. Doe.)

Before performing a second-trimester abortion in cases in which fetal demise has not been induced, Dr. Doe does not know if the fetus is alive before he or she

begins the abortion.[51] Further, before he or she begins the abortion, Dr. Doe does not wait for the fetus to die after he or she has ruptured the membranes, removed the amniotic fluid, or cut the cord. In such cases, Dr. Doe sometimes detects fetal movement after the fetus is outside the patient's body, but he or she takes no steps to confirm that the fetus is dead or alive because it is of "no clinical importance." (Tr. 127-29, Test. Dr. Doe.)

In his or her second-trimester D&E procedures, Dr. Doe administers pain sedation, inserts a speculum into the vagina, removes the vaginal packs and Dilapan, and grasps the anterior lip of the anesthetized cervix with a tenaculum to stabilize and manipulate the cervix so that local anesthetic can be administered and Vasopressin can be injected. According to Dr. Doe, this injection causes the uterus to contract and constricts the smaller blood vessels so the uterus is more contracted and there is less bleeding. At this point, the distance between the cervix and vaginal opening is usually three inches, but can be one inch or, infrequently, the cervix and vaginal opening can meet. The distance depends on the degree of relaxation of the pelvic structures and the position of the cervix. (Tr. 43-45, Test. Dr. Doe.)

Dr. Doe then removes the amniotic fluid either by rupturing the membranes or using a 14-millimeter suction curette. Dr. Doe then uses Bierer forceps to grasp and extract with a slow, rotating motion the presenting fetal part that is lowest in the uterus, trying to remove as much of the fetus as possible with each pass. (Tr. 43 & 46-48, Test. Dr. Doe.) If the fetus is in a transverse position, Dr. Doe occasionally converts the fetus to a breech position with instruments or his or her hand before attempting to remove the fetus from the patient. (Tr. 91-92, Test. Dr. Doe (procedure is called "internal podalic version").)

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[51]Dr. Doe only performs an ultrasound if he or she is seeing the patient for the first time or if the patient has not had a previous ultrasound examination. (Tr. 126-27, Test. Dr. Doe.)

Dr. Doe generally removes the fetus in pieces, but approximately one to three fetuses per month come out completely intact. (Tr. 46-49, Test. Dr. Doe.) Dr. Doe does not know whether the fetus will deliver intact or dismembered when he or she starts the procedure because he or she cannot predict how much dilation will be achieved. (Tr. 83-84, Test. Dr. Doe.) Whether the fetus will deliver intact is "a function of the size of the fetus and of the degree of cervical dilatation and also of the fragility of the fetus." (Tr. 86, Test. Dr. Doe.) In 2003, Dr. Doe estimates that of the 92 abortions he or she performed for fetal anomalies in which he or she intended to remove the fetus intact, he or she successfully did so in 25 cases. Dr. Doe estimates that of the 280 second-trimester abortions performed in 2003 for maternal indications,10 fetuses were removed intact to the fetus's head. (Tr. 130-31, Test. Dr. Doe.)

Dr. Doe stated that dismembering a fetus is more difficult after 20 weeks of gestation because the fetal tissue is tougher and larger at that stage of development. (Tr. 87, Test. Dr. Doe.)

When attempting to remove a fetus intact because of fetal indications, Dr. Doe performs the abortion in a hospital under general anesthesia. Using a procedure similar to that described above, Dr. Doe uses Bierer forceps to grasp a foot, which aligns the fetus vertically in preparation for extraction of the fetus. Dr. Doe then attempts to grasp the second foot and pulls down on both legs simultaneously, as well as the pelvis, in order to extract the fetus. (Tr. 49-52, Test. Dr. Doe.)

### *(c) COMPRESSION OF FETAL SKULL*

When a fetus delivers intact up to the head in a maternal-indication case, and the fetal head has become lodged in the cervical opening, Dr. Doe exerts traction on the fetal body in an attempt to allow the head to pass. Depending upon the size of the head and the resistance of the cervix, Dr. Doe either continues to exert traction so that

the head separates from the rest of the fetal body and is separately retrieved with forceps, or Dr. Doe places forceps around the fetal head inside the cervix and uterus and compresses the head enough "so that it will squeeze through the cervix." Dr. Doe believes the latter procedure is the easier of the two to perform. (Tr. 49, Test. Dr. Doe.)

In a fetal-indication case where Dr. Doe attempts to extract the fetus intact and the head becomes lodged in the patient's cervix, Dr. Doe tries to push the cervix up over the head in order to get the head to deliver intact. If he or she cannot dislodge the head in that manner, Dr. Doe decompresses the head by inserting scissors into the back of the fetal head and perforating the skull. He or she makes a large enough hole to allow the fetus's brain tissue to "exude" in the patient's vaginal area as he or she exerts continued traction on the fetal shoulders and head so that the head can pass. (Tr. 53 & 93, Test. Dr. Doe.) Dr. Doe prefers to perform this skull-compression procedure, rather than let uterine contractions result in delivery, because:

> [T]he patient is under a general anesthetic at this time, and the longer the patient is under a general anesthetic, the more likely she is to develop uterine relaxation and increased bleeding. And the longer she's under a general anesthetic, the longer it will take her to recover from the general anesthetic after the procedure is finished, so under a general anesthetic, I would not delay the procedure more than a minute or two. And if the head doesn't come using the measures I described, I would decompress the head so it comes through.

(Tr. 54, Test. Dr. Doe.)

Dr. Doe characterizes the intact procedure he or she uses to abort fetuses with abnormalities as the "dilatation and extraction procedure" ("D&X") because it is "a modification of the D&E procedure . . . [and] we are trying to remove the fetus, to extract the fetus in as intact a manner as possible." (Tr. 58, Test. Dr. Doe.) Dr. Doe began performing the D&X procedure in the late 1980s or early 1990s. (Tr. 64, Test.

Dr. Doe.) Dr. Doe began attempting to extract fetuses in a more intact manner in approximately 2000 when he or she began seeing more patients carrying fetuses with anomalies. (Tr. 64-65, Test. Dr. Doe.)

In the hypothetical case of a 17-week maternal-indication patient, Dr. Doe would prefer to deliver the fetus intact, as opposed to piecemeal, because "it comes out in one piece, and you know you've completed a procedure, and it's just a matter of removing the placenta and then it's over." (Tr. 152, Test. Dr. Doe.)

Dr. Doe has not published a review of his or her D&X procedures so independent review could occur, nor does Dr. Doe routinely follow up with his or her patients after a midtrimester abortion and two-day dilation process. (Tr. 94-95, Test. Dr. Doe.)

### *vi. DR. STEPHEN T. CHASEN*

Dr. Chasen is a board-certified physician in obstetrics and gynecology and maternal-fetal medicine, a member of ACOG, and a fellow of the Society for Maternal-Fetal Medicine.[52] Dr. Chasen has an active patient-care practice, supervises an antepartum inpatient service, and directs the High-Risk Obstetric Clinic at the New York Weill/Cornell Medical Center. He is a member of that care facility's Obstetric Patient Safety Committee and the Obstetric and Gynecology Quality Assurance

[52]Maternal-fetal medicine is a subspecialty of obstetrics and gynecology that endeavors to have healthy mothers deliver healthy babies. The maternal aspect of this subspecialty focuses on medical complications experienced by the mother during pregnancy, whether those problems arise due to the mother's underlying and pre-existing medical condition or as a pregnancy-related medical complication. The fetal aspect of maternal-fetal medicine assesses the fetus's health and identifies fetuses that may benefit from therapy or by a timed delivery. (Ex. 121, Test. Dr. Chasen 1545-47.)

Committee. Dr. Chasen is an associate professor of obstetrics and gynecology at the Weill Medical College of Cornell University, with 80% of his teaching performed in a clinical setting. His clinical instruction includes teaching surgical abortion methods, including the D&E and intact D&E procedures. He is involved in clinical research involving antepartum care, obstetric complications, and prenatal diagnosis and has written or co-authored over 20 peer-reviewed and published articles. (Ex. 121, Test. Dr. Chasen 1540-44, 1547-50, 1555-57.)

### *(a) ABORTION TRAINING AND EXPERIENCE*

Dr. Chasen received training to perform first-trimester D&Cs during his residency between 1992 and 1996. He was trained to perform second-trimester D&Es during his fellowship at the New York Hospital beginning in 1996. (Ex. 121, Test. Dr. Chasen 1553-54.)

Over the course of his career, Dr. Chasen has performed 200 to 300 D&Cs, 200 to 300 D&Es, and 50 to 75 intact D&Es. He estimates he has supervised 50 second-trimester abortions over the past year. (Ex. 121, Test. Dr. Chasen 1551-52 & 1555.) The D&E is the only method of second-trimester abortion Dr. Chasen has performed over the last year. (Ex. 121, Test. Dr. Chasen 1553.) Dr. Chasen performs D&Cs before 14 weeks and D&Es from 13 to 23 weeks and six days, and possibly later in cases of fetal demise. (Ex. 121, Test. Dr. Chasen 1552-53.)

### *(b) DISMEMBERMENT AND INTACT D&E COMPARED*

Dr. Chasen views the dismemberment version of the D&E and the intact D&E as variations of the D&E procedure. Dr. Chasen believes both are dilation and evacuation procedures in which the cervix is in most cases deliberately dilated and the fetus and placenta are removed; however, one involves dismemberment of the fetus

with forceps, while the other is accomplished by a breech extraction. (Ex. 121, Test. Dr. Chasen 1560-61).

To perform a D&E, Dr. Chasen first provides the patient with a detailed informed consent. Dr. Chasen advises his patients that the D&E presents a small risk (1%) of hemorrhage, a very small risk of uterine perforation (less than 1%), and a small risk (5%) of infection. He then inserts laminaria into the patient's cervix and administers prophylactic antibiotics. (Ex. 121, Test. Dr. Chasen 1681-82.)

Dr. Chasen strives for the maximum cervical dilation that can be obtained. Depending on the gestational size and fetal age, Dr. Chasen inserts laminaria one or two days before the D&E surgical procedure. At 20 weeks or greater, he generally inserts laminaria for two consecutive days. The day after the last insertion of laminaria, the patient comes to the operating room, receives anesthesia, is placed in stirrups, the laminaria are removed, and the patient receives a sterile wash and drape. Once the patient is under anesthesia, Dr. Chasen examines the dilation of the cervix and, based on the proximity of the cervix to the vagina and the position of the fetus as determined by palpation or ultrasound, determines the most appropriate way to evacuate the fetus from the uterus. (Ex. 121, Test. Dr. Chasen 1571-72, 1635, 1673.)

Dr. Chasen stated that the two methods of performing a D&E both involve the use of forceps. In most cases, he dismembers or disarticulates the fetus. However, the fetus may come out intact to the level of the head. If this occurs, Dr. Chasen performs an intact D&E. Dr. Chasen delivers a breech-presentation fetus intact to the level of the umbilicus or higher, and when the head reaches the cervical os, he uses forceps to make an incision at the base of the skull. Dr. Chasen aspirates the skull contents by suction, thereby collapsing the fetal head, and he then delivers the fetus intact. In some cases, Dr. Chasen aborts the fetus intact without the use of forceps or collapsing the skull. (Ex. 121, Test. Dr. Chasen 1572-73, 1597, 1675.)

When an intact D&E is feasible, Dr. Chasen performs the procedure much like a breech delivery after viability, with the exception of decompressing the fetal skull. One leg is delivered and when it is almost out, the second leg is swept out. Dr. Chasen wraps a small sterile towel around the fetus and pulls the legs out to the sacrum (lower portion of the spine). When the fetus is out to the level of the umbilicus, Dr. Chasen wraps a second towel around the first small towel and pulls the fetus down to the level of the shoulder blades. With his hands on the fetus's back, Dr. Chasen twists the fetus to rotate the shoulder and the arm in front is swept out. Dr. Chasen then rotates the fetus to the other side, sweeping the other arm out. At that point, the head is at the cervical os and Dr. Chasen must decide if the head can be delivered without suctioning. If lowering the chin will permit the fetal head to be removed, Dr. Chasen does so, places the removed fetus on a table, and then delivers the placenta. If the head cannot be removed by lowering the chin, Dr. Chasen uses a clamp to grasp the cervix and elevate it. As a surgical assistant pulls the fetus's legs, Dr. Chasen visually and by palpation locates the base of the fetal skull, punctures the skull with scissors, and suctions out the contents. Dr. Chasen removes the fetal head and suction cannula simultaneously. (Ex. 121, Test. Dr. Chasen 1674-78.)

With a vertex (head-first) presentation, when the fetal skull is flush against the internal cervical os, Dr. Chasen uses suction on the skull and then delivers the fetus. (Ex. 121, Test. Dr. Chasen 1678-79.)

Since Dr. Chasen believes that the intact D&E is safer than the dismemberment D&E, Dr. Chasen's goal is to perform an intact D&E every time. However, the ultimate choice between the two methods of D&E depends on the degree of cervical dilation, the proximity of the cervix to the vagina, and the position of the fetus by palpation or ultrasound. Dr. Chasen makes a general determination of which method will be used when he first examines the extent of cervical dilation. In some cases the doctor believes at the outset that disarticulation will be required, but in the first pass

he grasps a fetal leg and continues to attempt an intact D&E by breech extraction. (Ex. 121, Test. Dr. Chasen 1572-74 & 1612.)

Dr. Chasen testified that an intact D&E by breech extraction is typically more likely after 20 weeks of gestation because it is easier to achieve a higher degree of cervical dilation and the fetus is less likely to be dismembered or torn apart by manual traction. Intact delivery may be possible before 20 weeks when Dr. Chasen obtains advanced degrees of cervical dilation. (Ex. 121, Test. Dr. Chasen 1574-75 & 1675.) Dr. Chasen estimates that fetuses deliver intact up to their head approximately 12 times per year. (Ex. 121, Test. Dr. Chasen 1655.)

According to Dr. Chasen, the distance between the vaginal opening and the cervical os is usually eight to ten centimeters. However, a history of prior vaginal deliveries or the administration of general anesthesia at the time of the surgical abortion relaxes the pelvic muscles. In such circumstances, Dr. Chasen has observed that the cervix may be at or within one or two centimeters of the level of the vaginal opening, and during the D&E procedure, parts of the fetus may be in the cervix and uterus while other parts of the fetus may be in the vaginal opening. (Ex. 121, Test. Dr. Chasen 1575-77.)

Dr. Chasen's goal in performing D&Es is to remove the fetus as intact as possible to minimize the risk of trauma to the maternal tissues, including the uterus and cervix. (Ex. 121, Test. Dr. Chasen 1561). For Dr. Chasen, the method of abortion chosen is not dependent on the medical condition that requires termination of the pregnancy. Rather, he attempts an intact D&E in all second-trimester abortions. (Ex. 121, Test. Dr. Chasen 1683-85.)

### *vii. DR. FREDRIK FRANCOIS BROEKHUIZEN*

Dr. Broekhuizen is a board-certified physician in obstetrics and gynecology. Twenty percent of his professional employment is committed to international health consulting and teaching in maternal and neonatal health and cervical cancer prevention. The remainder of his professional time is spent at the Medical College of Wisconsin in Milwaukee, Wisconsin, where he is a professor and maintains a clinical practice in general obstetrics and gynecology, which includes working in the division of internal fetal medicine managing high-risk obstetrical care, ultrasound, and prenatal diagnosis. Thirty percent of his medical school employment is devoted to being the medical director for Planned Parenthood of Wisconsin. Dr. Broekhuizen was a plaintiff in a suit challenging Wisconsin's partial-birth abortion act. Dr. Broekhuizen has extensive experience in performing abortions for maternal- and fetal-health reasons. (Ex. 120, Test. Dr. Broekhuizen 482-84, 488-89, 493.)

Dr. Broekhuizen performs D&Cs, second-trimester D&Es up to 20 weeks, and second-trimester inductions up to 24 weeks, the legal limit in Wisconsin. (Ex. 120, Test. Dr. Broekhuizen 490.) D&Es have been a "regular" part of Dr. Broekhuizen's practice for the past 20 years, having performed a total of 400 to 500 over his career, with 90 to 95% of those involving dismemberment. (Ex. 120, Test. Dr. Broekhuizen 491 & 571.) Dr. Broekhuizen also considers induction abortions to be a "regular" part of his practice for the past 20 years. Although the total number of induction abortions performed by Dr. Broekhuizen is unknown, he estimates that he has completed more labor inductions than D&Es. (Ex. 120, Test. Dr. Broekhuizen 491 & 579.)

#### *(a) D&E*

Dr. Broekhuizen's objective in performing an abortion procedure is to evacuate the contents of the uterus with the least possible trauma to the mother in the shortest

period of time. A shortened time period avoids prolonged bleeding. Dr. Broekhuizen attempts to lessen trauma by using laminaria and misoprostol to obtain sufficient dilation so that instruments can pass through the cervix without causing damage and to keep the number of instrument passes at a minimum. He may also administer oxytocin to promote uterine contractions as needed. (Ex. 120, Test. Dr. Broekhuizen 518-19.)

Up to 18 weeks of gestation, Dr. Broekhuizen uses only misoprostol to promote cervical dilation. After 18 weeks, he uses a combination of misoprostol and laminaria. (Ex. 120, Test. Dr. Broekhuizen 510.) The number of laminaria Dr. Broekhuizen uses is determined by how many can safely be placed into the woman's cervix. Dr. Broekhuizen has inserted as many as 20 to 25 dilators into a woman's cervix at one time. (Ex. 120, Test. Dr. Broekhuizen 511 & 615.) Dr. Broekhuizen only uses serial dilation with laminaria when he intends at the outset of the procedure, for medical reasons, to deliver the fetus intact up to the head. (Ex. 120, Test. Dr. Broekhuizen 588-89.)

Dr. Broekhuizen administers misoprostol vaginally to soften and dilate the cervix and prompt uterine activity. He believes that using misoprostol avoids use of mechanical dilators and promotes sufficient cervical dilation to permit a D&E without numerous instrument passes. However, Dr. Broekhuizen cannot predict the extent of misoprostol's effect on a particular woman. (Ex. 120, Test. Dr. Broekhuizen 511-13.) For a 22-week D&E, Dr. Broekhuizen attempts to achieve three to four centimeters of dilation. (Ex. 120, Test. Dr. Broekhuizen 544.)

Since his objective is to evacuate the uterus in the simplest and safest way possible, if sufficient dilation exists, Dr. Broekhuizen removes the fetus up to the head. (Ex. 120, Test. Dr. Broekhuizen 582.) The amount of cervical dilation influences whether Dr. Broekhuizen delivers the fetus intact, but a prediction on whether intact delivery may be accomplished cannot occur until Dr. Broekhuizen

removes the laminaria and evaluates the extent of the woman's response to the misoprostol and laminaria. For maternal-care reasons, Dr. Broekhuizen will not dismember the fetus and expose the woman to multiple passes through the cervix and other risks of a dismemberment D&E if the extent of dilation accomplished permits an intact D&E. (Ex. 120, Test. Dr. Broekhuizen 522.)

Dr. Broekhuizen testified that the distance between the vaginal opening and the cervical os varies depending on the patient. In the D&E procedure, Dr. Broekhuizen places a clamp on the anterior or posterior lip of the cervix and pulls the clamp to straighten the cervix. Depending on the woman, the cervix may come to the level of the vaginal opening and, on rare occasions, may be pulled out of the vaginal opening. (Ex. 120, Test. Dr. Broekhuizen 514-15.)

Dr. Broekhuizen uses forceps in his D&Es as a grabbing instrument with serrated surfaces that can crush and hold onto tissue. He uses forceps to pull the fetus, sometimes in combination with a twisting motion, out of the uterus through the cervix. (Ex. 120, Test. Dr. Broekhuizen 519-20 & 569-70.)

Dr. Broekhuizen's second-trimester D&Es normally involve removing the fetuses in parts. (Ex. 120, Test. Dr. Broekhuizen 566-67.) In a D&E procedure, Dr. Broekhuizen testified that disarticulation can occur in the vagina and, depending on the distance between the cervix and the vaginal introitus, part of the extremity may be outside the woman's body when disarticulation occurs. (Ex. 120, Test. Dr. Broekhuizen 520-21.)

Dr. Broekhuizen stated that in a D&E procedure, a doctor may accomplish pulling a living fetus through the cervix intact to a point where the fetal umbilicus is outside the vaginal opening and the fetal head is lodged at the internal cervical os. He testified that this can happen as early as 12 to 13 weeks of gestation and is more common with the use of misoprostol. Dr. Broekhuizen observed that disarticulation

can occur in the vagina and, depending on the distance between the cervix and the vaginal opening, part of the extremity may be outside the woman's body when disarticulation occurs. (Ex. 120, Test. Dr. Broekhuizen 521.)

Dr. Broekhuizen testified that if the fetal head is lodged at the cervical os, compression or decompression of the head may be accomplished by crushing the skull, or sometimes traction at the base of the skull will release the brain fluids. Dr. Broekhuizen may use a trocar if the fetal head is enlarged due to a fetal anomaly. (Ex. 120, Test. Dr. Broekhuizen 523-24.) Once the fetal contents are removed, Dr. Broekhuizen uses suction and a sharp curette to remove the placenta, as retained placenta or fetal parts may cause infection and bleeding. (Ex. 120, Test. Dr. Broekhuizen 525-26.)

After 18 weeks of gestation, Dr. Broekhuizen uses ultrasound to perform D&Es. Prior to 18 weeks, he uses ultrasound if, due to the lack of cervical dilation with laminaria or other observations made during his examination, he believes the fetus will be dismembered in the D&E procedure and he anticipates problems identifying whether all the parts have been removed. (Ex. 120, Test. Dr. Broekhuizen 515.)

Dr. Broekhuizen does not intentionally convert the fetus to a breech position before its removal, but believes his method of performing the D&E may result in a conversion. Before he begins the D&E procedure, he uses a large suction curette to remove the amniotic fluid, and sometimes parts of the placenta will also be removed in that process. He then introduces an instrument to grab and pull on a fetal part, the effect of which may be conversion of the fetus to a breech position. (Ex. 120, Test. Dr. Broekhuizen 516 & 566.) In Dr. Broekhuizen's experience, at least one-half of second-trimester fetuses will, without conversion, be in the uterus in a breech position. (Ex. 120, Test. Dr. Broekhuizen 516.)

A D&E usually takes Dr. Broekhuizen 15 to 20 minutes to complete, but it can take as little as 5 and as many as 40 minutes. (Ex. 120, Test. Dr. Broekhuizen 524.)

In Dr. Broekhuizen's opinion, the only fundamental difference between a dismemberment D&E and an intact D&E is that larger cervical dilation is attempted for intact D&Es. (Ex. 120, Test. Dr. Broekhuizen 544.) Dr. Broekhuizen testified that while an intact D&E is preferred over disarticulation to avoid multiple passes, bony fragments, and resulting damage to the cervix, uterine wall, and bleeding, the doctor cannot always accomplish that and must accept the situation encountered. (Ex. 120, Test. Dr. Broekhuizen 520 & 611-12.)

### *(b) LABOR INDUCTION*

Dr. Broekhuizen prefers labor induction over the D&E after 20 weeks of gestation. (Ex. 120, Test. Dr. Broekhuizen 578.)

Dr. Broekhuizen described medical induction as an inpatient procedure performed in the hospital that takes as little as eight hours and as long as three days. Dr. Broekhuizen begins this procedure by starting the woman on an IV and placing misoprostol in her vagina every four to six hours to induce labor. The medication used for a labor-induction abortion is more potent than what is administered to induce delivery at term because the medicine must override the body's natural mechanisms for retaining the fetus to term. Cramping and labor pain that may be stronger than that experienced at a term delivery occur because the body has not produced natural pain suppressants in preparation for a term delivery. Dr. Broekhuizen offers the patient an epidural, IV morphine, dilaudid, or demerol for pain relief.

A surgical evacuation by D&E may be necessary if complications, especially infection, arise. After Dr. Broekhuizen delivers the fetus, he administers high doses of oxytocin to deliver the placenta. Dr. Broekhuizen will wait up to four hours for the

placenta to deliver, but in 20 to 30% of his second-trimester labor-induction abortions, he must perform a D&C-type procedure (instrumental removal) to deliver the placenta, either because delivery was not occurring or because the woman began bleeding. (Ex. 120, Test. Dr. Broekhuizen 526-31 & 580.)

Dr. Broekhuizen testified that six to seven centimeters of cervical dilation would be sufficient for delivery of a 22-week fetus by labor induction, whereas ten centimeters of dilation is required at term. (Ex. 120, Test. Dr. Broekhuizen 544-45.)

### *viii. DR. MARILYNN FREDERIKSEN*

Dr. Frederiksen is a 1974 graduate of Boston University Medical School. She completed her pediatrics residency program at the University of Maryland in 1976 and her obstetrics and gynecology residency program at Harvard University in 1979. She has also completed fellowship programs at Northwestern University in maternal-fetal medicine in 1981 and clinical pharmacology in 1983. She is a member of ACOG, the American Society of Clinical Pharmacology and Therapeutics, and the Society for Maternal Fetal Medicine. Dr. Frederiksen is board-certified in obstetrics and gynecology, maternal-fetal medicine, and clinical pharmacology. For the past two and one-half years, she has been a private practitioner for Northwestern Perinatal Associates in Chicago, Illinois, specializing in general obstetrics and gynecological care of high-risk pregnancies, prenatal diagnosis, and pregnancy terminations by medical induction, D&E, and intact D&E. Prior to her current position, she maintained a similar full-time practice and faculty position at Northwestern University Medical School. In her full-time faculty position, she managed that institution's abortion services and supervised resident education in abortion practices. She has taught at Northwestern University since 1981 and remains a clinical associate professor of obstetrics and gynecology, providing lectures on pathology in pregnancy, contraception, abortion, and antenatal care of the pregnant patient. She has been a

member of Northwestern University's Institutional Review Board for the last 12 years. (Ex. 123, Test. Dr. Frederiksen 1037-42, 1046 & Sub-Ex. 123A).

Dr. Frederiksen was a plaintiff who challenged the Illinois partial-birth abortion act, and was an expert witness in cases challenging Colorado's and Idaho's parental-notification statutes. She has been described as "a critical medical expert in many of the ACLU's challenges to anti-choice legislation," and, along with Dr. Carhart, serves on the board of directors of Physicians for Reproductive Choice and Health. (Ex. 123, Test. Dr. Frederiksen 1165-68.)

Dr. Frederiksen has performed D&C, D&E, intact D&E, and medical-induction abortion procedures. She has performed thousands of D&Es over the course of her career, approximately 100 to 125 procedures per year. The latest gestational age at which Dr. Frederiksen has performed elective abortions is 23 and 5/7 weeks, but she has performed induction abortions at 20 to 24 weeks. She provides induction abortions after 24 weeks only for lethal fetal anomalies. (Ex. 123, Test. Dr. Frederiksen 1043-44, 1163-64, 1176, 1235.)

***(a) D&E***

Dr. Frederiksen characterizes the intact D&E as a variation of the D&E. (Ex. 123, Test. Dr. Frederiksen 1065.) She testified that a D&E can easily become an intact version of the D&E if the fetus can be delivered without dismemberment. (Ex. 123, Test. Dr. Frederiksen 1233-34.) Dr. Frederiksen's intent in performing a D&E is to empty the uterus quickly. Therefore, her intent at the outset of a D&E is to deliver the fetus as intact as possible. (Ex. 123, Test. Dr. Frederiksen 1234.)

Dr. Frederiksen uses the same dilation method for an intact D&E and a dismemberment D&E. (Ex. 123, Test. Dr. Frederiksen 1140.) For D&Es performed at 20 to 23 5/7 weeks, Dr. Frederiksen attempts to achieve as much dilation as possible

and sometimes achieves 5 to 6 centimeters of dilation. (Ex. 123, Test. Dr. Frederiksen 1185 & 1187.)

Dr. Frederiksen places serial laminaria in the cervix over time to provide adequate dilation for extraction of the fetus relatively intact. (Ex. 123, Test. Dr. Frederiksen 1044-45.) For D&Es performed at 20 to 23 weeks of gestation, the cervix is dilated over a 24-hour period. Dr. Frederiksen uses three to four sets of laminaria; the first set is inserted at 8:30 a.m., the second at noon, and the third at 5:00 or 5:30 p.m. Each time, she inserts as many laminaria as possible. Dr. Frederiksen administers vaginal misoprostol the next morning approximately three hours before the surgery. (Ex. 123, Test. Dr. Frederiksen 1185-87.)

Dr. Frederiksen does not use metal dilating rods. Dr. Frederiksen testified that forcible dilation of the cervix with an instrument is the most common cause of uterine perforation and can cause bleeding at the internal os. (Ex. 123, Test. Dr. Frederiksen 1191 & 1210-12.) Dr. Frederiksen stated that Dilapan is a synthetic osmotic dilating rod which achieved maximum cervical dilation in four hours, but it was removed from the market in the United States and is no longer used in this country. According to Dr. Frederiksen, Dilapan provided superior dilating power, but sometimes fragmented and caused a risk of infection. (Ex. 123, Test. Dr. Frederiksen 1187-89.)

Dr. Frederiksen administers paracervical blocks in the mother's cervix along with medications to provide pain relief and amnesia, but Dr. Frederiksen does not place the patient under general anesthesia. (Ex. 123, Test. Dr. Frederiksen 1075.)

In preparation for removal of the patient's uterine contents, Dr. Frederiksen places a Graves speculum in the vagina and prepares the cervix with betadine and a

lidocaine injection.[53] (Ex. 123, Test. Dr. Frederiksen 1222.) Dr. Frederiksen then uses a tenaculum or ring forceps to grasp the cervix, places a paracervical block, and infuses 5cc's of lidocaine. (Ex. 123, Test. Dr. Frederiksen 1222-23.)

Dr. Frederiksen then places a cannula within the patient's uterus to suction the amniotic fluid. She severs the cord if it comes down with the fluid during this suctioning. Dr. Frederiksen uses further suctioning to pull the placenta or fetal parts close to the cervix. (Ex. 123, Test. Dr. Frederiksen 1207 & 1223-24.) She then uses a Hern or Sopher forceps to grasp fetal parts and bring them through the cervix. Dr. Frederiksen testified that the forceps is not sharp and does not pose a risk of cervical laceration. (Ex. 123, Test. Dr. Frederiksen 1207, 1209-10, 1224.)

When an intact D&E is performed and the fetus presents in a breech position, Dr. Frederiksen grasps the fetal foot and carefully manipulates the fetus to deliver it to the fetal trunk until the fetal head is lodged inside the cervix. (Ex. 123, Test. Dr. Frederiksen 1225.) Dr. Frederiksen does not convert the fetus to a breech position due to the discomfort to the woman and the lack of sufficient anesthesia. Dr. Frederiksen can perform an intact D&E if the fetus is in the breech or vertex position. (Ex. 123, Test. Dr. Frederiksen 1225-26.)

Dr. Frederiksen may deliver the fetal head by using scissors to make an incision at the base of the skull and a finger to disrupt the cranial contents. Dr. Frederiksen does not use suction and does not always remove the cranial contents. Under some circumstances, Dr. Frederiksen believes it is easier to use a grasping forceps and crush the skull to compress it. (Ex. 123, Test. Dr. Frederiksen 1140-41 & 1224-25.) Dr. Frederiksen stated that the scissors is a sharp instrument and potentially more dangerous to the woman than a forceps. (Ex. 123, Test. Dr. Frederiksen 1210.)

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[53]Lidocaine hydrochloride is a "local anesthetic with antiarrhythmic and anticonvulsant properties." Stedman's Medical Dictionary 996 (27th ed. 2000).

Dr. Frederiksen testified that if the fetal head becomes lodged at the internal os of the cervix, the fetal body past the level of the navel may be outside the woman's body. The traction of the ring forceps on the cervix may deliver the cervix to the level of the entrance to the vagina, and if the woman has a prolapsed uterus, the cervix can be outside the body. (Ex. 123, Test. Dr. Frederiksen 1139.)

Dr. Frederiksen then delivers the placenta by administering oxytocin intravenously to cause the uterus to contract, and by using a suction curette to assure that the uterus is empty. (Ex. 123, Test. Dr. Frederiksen 1207 & 1224.) Dr. Frederiksen stated that ultrasound can be used to determine if all the fetal tissue has been removed during a D&E, but this lengthens the procedure and is not reliable because the amniotic fluid is lost during the D&E procedure and therefore cannot provide contrast for the ultrasound. Moreover, fetal parts and blood clots sometimes have the same density and can lead to misidentification of the ultrasound image. (Ex. 123, Test. Dr. Frederiksen 1064.)

### *(b) LABOR INDUCTION*

As part of her protocol, Dr. Frederiksen may perform labor inductions at 20 to 24 weeks. She views labor induction as a safe method of late second-trimester abortion. (Ex. 123, Test. Dr. Frederiksen 1176.)

Dr. Frederiksen performs a fetal intracardiac injection of potassium chloride the day prior to performing the induction. She uses laminaria, and sometimes serial laminaria every six hours, to soften the cervix and misoprostol to induce contractions. (Ex. 123, Test. Dr. Frederiksen 1182-83.)

### *ix. DR. MITCHELL CREININ*

Dr. Creinin is a physician at the University of Pittsburgh hospital and is board-certified in obstetrics and gynecology. He attended medical school at Northwestern University, and he completed a residency program in obstetrics and gynecology, a fellowship in family planning, and a fellowship in clinical research at the University of California at San Francisco in 1993. A family-planning fellowship provides specialized training in clinical care and research related to abortion and contraceptive services. There are currently 24 family-planning fellows in the nation, and Dr. Creinin was the first. The fellowship program provides training in performing abortions between 4 and 24 weeks of gestation. (Ex. 122, Test. Dr. Creinin 647-49.)

Dr. Creinin spends 40% of his professional time doing clinical research; 20% as an administrator and teacher, which includes training residents and two family-planning fellows in abortion procedures; 20% in private practice; and 20% as the medical and laboratory director of Planned Parenthood. In all these roles, he works with patients, and 90% of his practice is devoted to seeing patients and providing patient care. Dr. Creinin is also a faculty member of the University of Pittsburgh's Department of Epidemiology. (Ex. 122, Test. Dr. Creinin 648-56.)

Patients are either referred to Dr. Creinin or they contact him directly for abortion services. Due to a lack of providers, Dr. Creinin performs abortion services for patients from a geographic area extending to southern New York, eastern Ohio, northern Virginia, and to the middle of Pennsylvania—a geographical radius of approximately a three-hour drive. Dr. Creinin performs research in contraception, abortion, ectopic pregnancy, and miscarriage, and is the author of approximately 70 publications in peer-reviewed journals and a chapter on inductions in the textbook Gynecology and Obstetrics. Dr. Creinin has never been a party or expert in a case challenging legislation regulating abortion. (Ex. 122, Test. Dr. Creinin 651-56.)

Dr. Creinin provides medical abortions, D&Cs, D&Es, and intact D&Es. He has not performed an induction abortion in the last 10 years. (Ex. 122, Test. Dr. Creinin 653 & 710-11.) He has performed approximately 5,000 abortions in his career, or 500 per year. In 99% or more of the D&Es Dr. Creinin has performed at 20 weeks and later, disarticulation of the fetus has resulted to some extent. He has performed three intact D&Es, as defined by ACOG, over the course of his career. (Ex. 122, Test. Dr. Creinin 731-32 & 735-36.)

Dr. Creinin performs medical abortions through 9 weeks of gestation, D&Cs through 14 to 15 weeks, and D&Es from 14 to 15 weeks through 23 and 6/7 weeks, limited to 56 millimeters biparietal diameter. (Ex. 122, Test. Dr. Creinin 650-51.) Dr. Creinin performs abortions up to 18 weeks at a Planned Parenthood clinic and at the Magee-Women's Hospital for patients at 18 weeks of gestation and beyond. (Ex. 122, Test. Dr. Creinin 650-51 & 663.)

### *(a) D&E*

Dr. Creinin's intent in performing D&Es is to empty the uterus. (Ex. 122, Test. Dr. Creinin 681.) Dr. Creinin's objective at the outset of the D&E is not to remove the fetus intact, but he prefers to remove the fetus as intact as possible. (Ex. 122, Test. Dr. Creinin 739 & 766.) Dr. Creinin does not attempt, at the outset, to perform an intact D&E because he believes that in his hands, a dismemberment D&E is safer than an intact D&E. (Ex. 122, Test. Dr. Creinin 744.) Dr. Creinin explains to his patients that the fetus will come out in pieces and not intact. (Ex. 122, Test. Dr. Creinin 739-40.)

Dr. Creinin testified that the D&E he performs and the intact D&E as defined by ACOG are different procedures because, among other things, the ACOG intact D&E involves multiple days of dilation. (Ex. 122, Test. Dr. Creinin 736.) Dr. Creinin stated that the intact D&E requires more cervical dilation than he generally

provides. (Ex. 122, Test. Dr. Creinin 738-39.) The number of dilators Dr. Creinin administers increases as gestational age increases. (Ex. 122, Test. Dr. Creinin 734-35.)

Dr. Creinin's objective is to obtain the minimal amount of dilation necessary to perform the D&E, but the woman's response to dilators cannot be predicted. (Ex. 122, Test. Dr. Creinin 661-62.) Between 14 and 18 weeks, Dr. Creinin uses Lamicel to dilate the cervix. Dr. Creinin described Lamicel as a firm dilator which is impregnated with magnesium and softens when moistened. The magnesium activates enzymes present in the cervix to soften the cervix. Softening can occur in as little as 2 hours and as much as 24 hours, depending on the gestational age of the fetus, the history of the patient, and other factors. (Ex. 122, Test. Dr. Creinin 657-58.)

Beyond 18 weeks, Dr. Creinin uses Dilapan or Lamicel to soften the cervix. Dr. Creinin inserts an average of 5 Dilapan at 20 weeks of gestation and leaves them in place for an average of 24 hours. The number of Dilapan Dr. Creinin places is determined by estimating the amount needed to obtain the minimal necessary dilation to empty the uterus without causing undue discomfort to the woman or inducing labor and delivery. Dr. Creinin explained that Dilapan, Lamicel, and laminaria are not the same, but they are all osmotic dilators. Dilapan and laminaria perform the same function, but Dr. Creinin believes using Dilapan is more effective and reduces the likelihood of needing multiple insertions of osmotic dilators to obtain adequate cervical dilation. In Dr. Creinin's view, Dilapan is also more reliable in providing dilatation. (Ex. 122, Test. Dr. Creinin 658-59, 662, 735, 743, 787.)[54]

[54]This April 5, 2004, testimony is difficult to reconcile with Dr. Frederiksen's. She stated that Dilapan was a synthetic osmotic dilating rod with superior dilating power which achieved maximum cervical dilation in four hours, but it was removed from the market in the United States and is no longer available in this country. She acknowledged using it in the past, and stated she experienced no problems with this product, but Dilapan was reportedly prone to fragment which caused a risk of infection. (Ex. 123, Test. Dr. Frederiksen 1187-89.)

Dr. Creinin performs dismemberment D&Es with minimal cervical dilation to perform the procedure as safely as possible. (Ex. 122, Test. Dr. Creinin 740.) Dr. Creinin believes that inserting more dilators may induce labor and result in delivering the fetus when the patient is not under a doctor's supervision. Further, using more dilators may increase the level of pain the woman experiences. (Ex. 122, Test. Dr. Creinin 743-44.)

Dr. Creinin tries to achieve a minimum of 1.75 to 2 centimeters of dilation at 18 to 19 weeks of gestation, and 2 to 2.5 centimeters of dilation at 20 weeks of gestation and thereafter, but he cannot predict the actual extent of dilation for individual women. The extent of dilation varies based on the patient's parity and past medical history. (Ex. 122, Test. Dr. Creinin 661-62 & 742-43.)

Once Dr. Creinin inserts the Dilapan, the patient is allowed to go home. Most women are able to resume their normal activities. Dr. Creinin provides his patients with instructions which state that they may experience mild cramping, can use over-the-counter pain medications, and should call the doctor if they experience severe cramps. They are told to return the following day for surgery. Dr. Creinin receives about one call per year from women requesting stronger pain medication. (Ex. 122, Test. Dr. Creinin 660.)

If adequate dilation does not occur within a day, Dr. Creinin may insert more Dilapan and delay the patient's surgery until later in the day or until the next day. (Ex. 122, Test. Dr. Creinin 660-61.) In unusual circumstances, Dr. Creinin administers vaginal misoprostol. (Ex. 122, Test. Dr. Creinin 661.)

Dr. Creinin performs procedures beyond 18 weeks of gestation in an operating room under deep sedation with the assistance of an anesthesiologist or anesthetist. In rare circumstances, he may administer a spinal block or general anesthesia. (Ex. 122, Test. Dr. Creinin 663.) According to Dr. Creinin, for those D&Es he performs in an

operating room, the woman is placed in stirrups (a lithotomy position), a speculum is inserted, and the dilators are removed. The cervix and vagina are cleansed, and a local anesthetic with Vasopressin (which constricts the blood vessels in the cervix and lower uterus) is injected into the cervix. (Ex. 122, Test. Dr. Creinin 663.)

Dr. Creinin uses a tenaculum to grasp and pull the cervix to stabilize and position the uterus. Dr. Creinin testified that the uterus sits at an angle to the vagina, especially at gestational ages of 18 weeks or more. According to Dr. Creinin, aligning the uterus with the vagina reduces the need to maneuver instruments at an angle and lowers the risk of uterine perforation. (Ex. 122, Test. Dr. Creinin 663-64.) Dr. Creinin testified that depending on the woman's parity, grasping the cervix with the tenaculum may lower it to the level of the vaginal opening, which may push the speculum completely or partially out. (Ex. 122, Test. Dr. Creinin 665.)

Dr. Creinin stated that unless the membranes have already ruptured, he ruptures the amniotic sac and suctions out the fluid using a cannula under direct visualization with ultrasound. If the cannula does not break the amniotic sac, a ring forceps can be used. Dr. Creinin finds that when the amniotic fluid is suctioned out, the uterus compresses and the fetal parts migrate toward the cervix. (Ex. 122, Test. Dr. Creinin 665-66.)

Dr. Creinin then inserts forceps into the lower uterus to grab whatever fetal part presents itself. Dr. Creinin's goal is to grab a lower extremity or a body part other than the fetal head, as it is very difficult to grasp and pull the fetal head first. Dr. Creinin uses ultrasound to locate, grasp, and pull a lower limb to maneuver the fetus and convert it to a breech position. (Ex. 122, Test. Dr. Creinin 666-69.) Dr. Creinin uses ultrasound guidance for all abortion procedures where instruments (other than a suction cannula) are placed in the uterus. (Ex. 122, Test. Dr. Creinin 667-68.)

Dr. Creinin then pulls the fetus, or whatever part has been grabbed, through the cervix until there is resistance from the lower uterine segment or the internal os of the cervix. This resistance or traction while pulling on the grasped fetal part causes dismemberment. (Ex. 122, Test. Dr. Creinin 667-68.) When there is resistance or traction, Dr. Creinin minimally rotates the fetus to try to ease it through the cervix to reduce the number of instrument passes. The fetus may dismember during this process. (Ex. 122, Test. Dr. Creinin 678.)

Dr. Creinin's goal is to remove the fetus as intact as possible, with fewer instrument passes and increased safety for the woman. (Ex. 122, Test. Dr. Creinin 667.)

Dr. Creinin has observed that a fetus may have a heartbeat and pass through the cervix intact or substantially intact past the level of the fetal umbilicus. In Dr. Creinin's experience, this occurs at least once per month. (Ex. 122, Test. Dr. Creinin 678-79 & 681.)

Dr. Creinin testified that a fetal body may pass through the cervix intact or relatively intact to the level of the calvarium, with the fetal head stuck at the internal cervical os. This has occurred about 50 times over Dr. Creinin's career. When it occurs, Dr. Creinin usually pulls until the fetus comes apart at the neck. On occasion he inserts scissors into the fetal head and uses a cannula to suction the brain tissue and collapse the skull. (Ex. 122, Test. Dr. Creinin 680 & 744-47.)

On five to ten occasions over Dr. Creinin's career, the cervical dilation was so extensive that the fetus could be removed intact without collapsing the skull. If the fetus is less than 24 weeks of gestation, Dr. Creinin holds the fetus in the mother and collapses the fetal skull while it is still in the uterus to avoid delivering a living fetus. (Ex. 122, Test. Dr. Creinin 747-48.)

If Dr. Creinin dismembers the fetus, as with the other body parts, the fetal head is grasped, crushed, and removed through the cervix. (Ex. 122, Test. Dr. Creinin 679.) Once Dr. Creinin removes the fetal parts, he removes the placenta. He then uses a cannula to suction the uterine lining, and with ultrasound assistance, uses a curette to feel the lining to assure that the uterus is empty. (Ex. 122, Test. Dr. Creinin 679-80.) Dr. Creinin then checks the level of bleeding, removes the tenaculum, and inspects the cervix for lacerations or tears. The speculum, if any, is removed, and the procedure is then complete. (Ex. 122, Test. Dr. Creinin 680.)

Dr. Creinin estimates that the extraction portion of the D&E procedure takes approximately five minutes. (Ex. 122, Test. Dr. Creinin 741.)

Dr. Creinin's patients may go home approximately two hours after the D&E is completed. Most of his patients do not return for follow-up care. (Ex. 122, Test. Dr. Creinin 682-83 & 751.)

### *(b) LABOR INDUCTION*

While Dr. Creinin views labor induction as safe, he does not perform this method of abortion. The vast majority of women at his institution who are seeking an elective abortion or an abortion for maternal and fetal indications choose the D&E. As such, he does not have significant experience with labor-induction abortion, believes that in his hands a D&E is a safer procedure, and he refers patients to other physicians if they choose to abort by induction. (Ex. 122, Test. Dr. Creinin 710-12 & 767-68.)

## *x. DR. MAUREEN PAUL*

Dr. Paul is a physician who is board-certified in obstetrics and gynecology and in occupational and environmental medicine. She completed residencies in obstetrics

and gynecology at the University of Washington in 1981 and at Tufts University Medical School in 1984. She completed her residency in occupational medicine at the University of Massachusetts in 1987. She is a fellow of ACOG. Dr. Paul is the chief medical officer of Planned Parenthood Golden Gate, which includes eight treatment sites located throughout the San Francisco Bay area. In her capacity with Planned Parenthood, she oversees the quality of that facility's medical care, provides direct clinical services, participates in strategic planning, hires physicians, supervises the physicians and advanced practice clinicians providing care at that facility, and develops clinical protocols. In addition to general gynecological care, Planned Parenthood Golden Gate provides abortion care at all eight of its facilities. Dr. Paul is an associate professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences at the University of California at San Francisco ("UCSF") and the Director of Training at the UCSF Center for Reproductive Health Research and Policy. In both of these capacities, she teaches abortion techniques to residents and medical care providers. (Ex. 125, Test. Dr. Paul 5-11 & Sub-Ex. 125A.)

Dr. Paul has authored several peer-reviewed and published articles and was the editor-in-chief of the 1999 textbook publication, A Clinician's Guide to Medical and Surgical Abortion, which Dr. Paul described as the standard reference text on abortion care. (Ex. 125, Test. Dr. Paul 11-12.) Dr. David Grimes was a co-editor of this textbook. (Ex. 125, Test. Dr. Paul 26.)[55]

Dr. Paul performs early medical abortions, D&Cs, and D&Es at Planned Parenthood outpatient clinics. Although she was trained in residency to perform D&Es to 23 weeks, the latest gestational age she performs D&Es is 18 and 6/7 weeks. Dr. Paul estimates that in "1 to 10 to 1 to 20" of the D&Es she performs, the fetus delivers intact up to the head. (Ex. 125, Test. Dr. Paul 7, 9, 71.)

[55]Dr. Westhoff co-authored the "Procedure Selection" chapter of this textbook.

### *(a) UNITED STATES ABORTION PRACTICE*

Based on statistics from the Centers for Disease Control (Ex. 32, at 16)[56] for the year 2000, 88% of abortions were performed at less than 13 weeks of gestation, 6.2% were performed between 13 and 15 weeks of gestation; 4.3% were performed between 16 and 20 weeks of gestation; and 1.4% (or approximately 18,000) were performed after 20 weeks of gestation. (Ex. 125, Test. Dr. Paul 38-42.)

Dr. Paul testified that a shortage of abortion providers exists in the United States, with about 87% of the counties having no abortion provider. Of the available abortion providers, most are trained to perform only first-trimester abortions. Dr. Paul stated that those trained to do second-trimester abortions are likely trained to do induction abortion rather than D&E. (Ex. 125, Test. Dr. Paul 43.)

Dr. Paul testified that most D&Es are done in outpatient clinics, while induction abortions, which require medications administered over several hours and perhaps for two days with associated pain and side effects, are generally done in a hospital. (Ex. 125, Test. Dr. Paul 45-46.)

Based on CDC data for the year 2000 (Ex. 32, at 32, tbl. 18), 95% of all second-trimester abortions at 16 to 20 weeks of gestation were performed by D&E. After 20 weeks of gestation, 85% were performed by D&E, with the remainder performed by labor induction. As used by the CDC, the D&Es reported include the intact D&E variation. (Ex. 125, Test. Dr. Paul 47-49.)

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[56]This article, the CDC MMWR dated November 28, 2003, was received into evidence without objection.

### *(b) D&E*

Dr. Paul testified that the goal of any abortion is to get something larger, the fetus, out of something smaller, the cervix, without causing injury to the cervix. (Ex. 125, Test. Dr. Paul 51-52.)

Dr. Paul acknowledged that a D&E abortion can occur by dismemberment or intact removal of the fetus. Dr. Paul characterizes the intact D&E as a variant of the D&E. (Ex. 125, Test. Dr. Paul 44-45.) According to Dr. Paul, the level of cervical dilation determines whether an intact or dismemberment D&E is performed, and Dr. Paul cannot predict which will occur at the outset of performing the D&E. (Ex. 125, Test. Dr. Paul 71 & 121.)

From the 14th to the beginning of the 16th week of gestation, Dr. Paul uses misoprostol alone to dilate the cervix. (Ex. 125, Test. Dr. Paul 61.) Dr. Paul testified that misoprostol tablets can be administered vaginally, orally, buccally, or sublingually to prepare the cervix; that the cervix is composed of collagen fibers that are cross-linked; and that the effect of misoprostol on these fibers, along with the contractions of the uterus initiated by using misoprostol, is to dilate and soften the cervix. (Ex. 125, Test. Dr. Paul 58-59.) Dr. Paul administers misoprostol buccally between 90 minutes and 3 hours before the D&E surgery. Once misoprostol is administered, Dr. Paul does not allow the woman to leave the clinic due to the risk of induced contractions leading to spontaneous abortion. (Ex. 125, Test. Dr. Paul 59.)

At 16 weeks of gestation and thereafter, Dr. Paul places laminaria into the cervix. According to Dr. Paul, the laminaria absorb fluid from the cervix and vagina, expand, and gradually stretch the cervix open. The laminaria remain inserted overnight. (Ex. 125, Test. Dr. Paul 52, 55, 57, 61.)

To insert the laminaria, Dr. Paul places a speculum into the vagina to open it up and permit visualization of the cervix. She then cleans the cervix with antiseptic and anesthetizes the cervix. Dr. Paul places the laminaria in the external os, through the cervical canal, and a little past the internal os. The laminaria vary in width. Dr. Paul inserts as many laminaria as will comfortably fit without forcing them into the cervix. However, the minimum used by gestational age is 3 at 16 to 17 weeks of gestation, and 4 at 17 to 18 weeks of gestation. Once the laminaria are inserted, the woman is allowed to return to her normal life. In Dr. Paul's practice, a second insertion of laminaria occurs only rarely. (Ex. 125, Test. Dr. Paul 53-55 & 60.)

At 17 weeks of gestation or greater, Dr. Paul uses laminaria and misoprostol in combination. (Ex. 125, Test. Dr. Paul 61-62.) Dr. Paul cannot predict the amount of dilation that will be achieved because women respond differently to the laminaria and misoprostol. (Ex. 125, Test. Dr. Paul 55.) Enough dilation is needed to permit the instruments to be inserted with some extra room to maneuver the instruments. In Dr. Paul's opinion, greater cervical dilation is better because the D&E is easier to perform with greater dilation. (Ex. 125, Test. Dr. Paul 55 & 57.)

Before the surgical portion of the D&E begins, Dr. Paul performs a pelvic examination to check the size and position of the uterus. If laminaria were inserted, she may be able to remove them at this time with her fingers. The uterus sits at an angle to the cervix, and as the pregnancy progresses and the uterus grows, that position changes. However, Dr. Paul testified that the position of the uterus in an individual woman is not predictable and must be assessed before inserting instruments which could damage the uterus. (Ex. 125, Test. Dr. Paul 62-64.)

Dr. Paul then inserts a speculum into the vagina to visualize the cervix and uses a tenaculum to grasp the cervix, stabilize it, and allow the doctor to remove the laminaria, move the cervix toward the vaginal opening, and move the cervix around during the evacuation procedure. The cervix is then anesthetized. (Ex. 125, Test. Dr.

Paul 64-65.) The patient is not under general anesthesia, but pain medications and sedation are administered through an intravenous line. (Ex. 125, Test. Dr. Paul 64.)

Dr. Paul stated that without the tenaculum in place, the cervix may be within a couple inches of the vaginal opening. With the tenaculum in place, the angle between the cervix and uterus is straightened, the cervix is moved closer to the vaginal opening, and the doctor's ability to see while using instruments is improved. (Ex. 125, Test. Dr. Paul 65-66.)

Dr. Paul then breaks the amniotic sac and drains or suctions the remaining fluid. (Ex. 125, Test. Dr. Paul 66-67.) Dr. Paul inserts forceps through the cervical opening while the doctor continues to pull on the cervix with the tenaculum to straighten the angle. Sometimes the fetus dismembers and Dr. Paul removes it in pieces, and sometimes she removes the fetus as a whole, at least to the level of the fetal head. (Ex. 125, Test. Dr. Paul 67-68.)

If the level of dilation permits, rather than using her forceps to firmly grasp the fetal parts, Dr. Paul uses forceps to gently draw the fetal tissue out of the cervix in an attempt to deliver the fetus as intact as possible. (Ex. 125, Test. Dr. Paul 70-71.) With Dr. Paul's administration of osmotic dilators and misoprostol, the living fetus may be completely or partially expelled past the level of the umbilicus and outside the woman's body before the surgical portion of the D&E begins. If this occurs, or if the fetal body is removed intact during the D&E to the level of the calvarium, Dr. Paul may disarticulate the fetal body at the neck. However, it is Dr. Paul's preference, and she is more likely, to use her forceps to collapse the fetal skull and deliver the fetus intact. In either case, she believes she has performed a lethal act on a vaginally delivered living fetus. (Ex. 125, Test. Dr. Paul 60-61, 69-70, 79.)

If the head is lodged at the cervical os, the fetus can be disarticulated at the neck, or, as is Dr. Paul's preference, the doctor can reach in with the forceps, collapse

the skull, and remove the fetus intact. (Ex. 125, Test. Dr. Paul 69-70 & 110.) Dr. Paul testified that it would be very unusual to perforate the uterus by collapsing the skull with forceps because most perforations occur at the top of the uterus while searching for fetal parts, and not at the lower area of the uterus near the cervix. (Ex. 125, Test. Dr. Paul 111.)

Once the fetus is removed, Dr. Paul removes the placenta by suction curettage. (Ex. 125, Test. Dr. Paul 74.) Dr. Paul believes that a D&E results in the deliberate and intentional vaginal delivery of a living fetus. (Ex. 125, Test. Dr. Paul 76.)

Many of Dr. Paul's D&E procedures, especially those done at (and presumably after) 16 weeks of gestation, are performed under ultrasound guidance. (Ex. 125, Test. Dr. Paul 67.)

### *xi. DR. CAROLINE WESTHOFF*

Dr. Westhoff is a 1977 graduate of the University of Michigan medical school who is board-certified in obstetrics and gynecology. She is employed at Columbia University College of Medicine as a professor of obstetrics and gynecology, and as a professor of epidemiology and of population and family health for the School of Public Health. She is an attending physician at New York Presbyterian Hospital, the medical director of the hospital's family-planning clinic, and the director of the Special GYN Service at its Allen Pavilion.[57] Approximately 20,000 patients are seen per year at the family planning clinic, and between 2,000 and 3,000 patients are seen at the Special GYN Service per year to obtain tubal ligation, abortion care, or care for miscarriages. Dr. Westhoff is an attending physician at these facilities two days per

[57]There is no real description of whether the Allen Pavilion is a hospital or a clinic, but it has operating rooms and access to general anesthesia. The facility serves a predominantly "Medicaid population." (Ex. 126, Test. Dr. Westhoff 986-91 & 1018-20.)

week, supervises and manages all care provided at that these facilities, and personally sees approximately 500 patients per year at each of these facilities. Her private practice through Columbia University focuses on miscarriage and abortion care, and in that capacity, she sees slightly less than 500 patients a year. She has been performing abortions since 1978, and currently performs abortions in her private practice and at the Special GYN Service. (Ex. 126, Test. Dr. Westhoff 731-43 & Sub-Ex. 126A.)

Dr. Westhoff is a fellow of ACOG, a member of the board of directors for the Association of Reproductive Health Professionals and the American Medical Women's Association, and a member of the American Public Health Association and the National Abortion Federation. She has authored several peer-reviewed and published articles, primarily in the areas of contraception, ovarian cancer epidemiology, and first-trimester medical abortions. She co-authored the "Procedure Selection" chapter of A Clinician's Guide to Medical and Surgical Abortion, a medical textbook published in 1999 used for teaching in the field of abortion practice. The "Procedure Selection" chapter discusses the intact D&E abortion method. Dr. Westhoff was a five-year member of the United States Preventative Services Task Force, has participated in study sections or initial review groups for the National Institutes of Health, and was an advisor to the National Institute of Child Health and Human Development. She has been an expert witness in Michigan and New Jersey cases challenging legislation banning partial-birth abortions. (Ex. 126, Test. Dr. Westhoff 754-57, 761-64 & Sub-Ex. 126A.)

Since 1978, Dr. Westhoff has performed several thousand abortions. (Ex. 126, Test. Dr. Westhoff 742.) She performs medical abortions up to 9 weeks, D&Cs up to 12 or 13 weeks, D&Es from 14 weeks through 23 and 6/7 weeks, and she has performed several hundred labor-induction abortions in the past. In 1997, she performed 400 out of 500 second-trimester abortions by labor induction. Since the Special GYN Services at the Allen Pavilion opened in 2001, Dr. Westhoff now refers

those who choose labor induction. (Ex. 126, Test. Dr. Westhoff 744-45 & 985-86.) Dr. Westhoff performed a total of 250 D&Es, 50 of which were intact D&Es, at the special GYN Service for 2003, and around 750 for the years 2001 through 2003. Dr. Westhoff personally performed or supervised students performing 50 D&Es, including the intact version, in 2003. (Ex. 126, Test. Dr. Westhoff 750-51 & 979.)

### *(a) D&C*

Dr. Westhoff begins a D&C procedure by positioning the patient on a procedure table in the manner used for a gynecologic examination and administering antiseptics and analgesics. Dr. Westhoff grasps the cervix with a tenaculum, stretches the cervical opening to an appropriate diameter with a mechanical dilator, inserts a suction cannula into the uterus through the cervical os, and removes the uterine contents by vacuum aspiration. (Ex. 126, Test. Dr. Westhoff 771-72.)

Dr. Westhoff testified that the uterus lies suspended by ligaments in the woman's pelvic cavity. She explained that the tenaculum is an instrument used to grasp the cervix in order to pull down on the uterus and this traction stabilizes the uterus so that it does not move when instruments are inserted. (Ex. 126, Test. Dr. Westhoff 772.)

Dr. Westhoff stated that a D&C can be used from the earliest time that a pregnancy is diagnosed throughout the first trimester and perhaps in the very early part of the second trimester, but usually a D&E is required in the second trimester. (Ex. 126, Test. Dr. Westhoff 773.)

### *(b) D&E*

Based on CDC data, Dr. Westhoff testified that 95% of all second-trimester abortions are performed by D&E. This statistic includes the intact D&E variation. (Ex. 126, Test. Dr. Westhoff 778-80.)

For Dr. Westhoff's D&E procedures, the patient is seen one or two days prior to the D&E to obtain a routine history, physical examination, and an additional sonogram to confirm the fetus's gestational age. This information is used to determine which abortion options should be discussed with the patient. (Ex. 126, Test. Dr. Westhoff 780-81 & 993.)

Unless Dr. Westhoff's patients ask for additional information, they are generally not told their fetus may be dismembered or the fetal head crushed or aspirated. Dr. Westhoff's patients are advised that the fetus and placenta will be removed from the uterus as safely as possible, but exactly how that will occur proceeds differently with each patient. (Ex. 126, Test. Dr. Westhoff 797.)

For Dr. Westhoff's patients who wanted a child but must have a second-trimester abortion, the woman may want to hold the fetus as part of the grieving process. For these women, Dr. Westhoff explains that labor may be induced or an intact D&E attempted, but an intact D&E cannot be guaranteed. The woman is also told the fetal skull will be empty if she chooses an intact D&E. (Ex. 126, Test. Dr. Westhoff 830-31 & 833-34.)

Dr. Westhoff inserts osmotic dilators once or twice under local anesthesia. (Ex. 126, Test. Dr. Westhoff 785.) Once the laminaria are inserted, Dr. Westhoff allows the woman to go home or return to work. (Ex. 126, Test. Dr. Westhoff 814.)

Dr. Westhoff's assessment of whether dilators are inserted serially over two days depends on the fetus's gestational age and the woman's anatomy and history. If inserted over two days, the woman returns after the first day to have the first set of dilators removed and a second set inserted. Occasionally misoprostol is administered a few hours before the procedure to further soften the cervix. Dr. Westhoff testified that the amount of dilation needs to be greater as the pregnancy progresses. (Ex. 126, Test. Dr. Westhoff 785-86 & 998-99.)

According to Dr. Westhoff, the cervical dilation the woman presents with, and the woman's response to dilation procedures, varies widely. Some women present with three to four centimeters of dilation before any dilation procedure is started. (Ex. 126, Test. Dr. Westhoff 788.)

Dr. Westhoff's goal with every D&E is to remove the fetus as intact as possible, so her dilation process does not differ between intact and dismemberment D&Es. (Ex. 126, Test. Dr. Westhoff 795.)

Dr. Westhoff stated that dilation of the cervix with mechanical dilators, as opposed to osmotic dilators, can tear and scar the cervix, but whether that leads to problems in subsequent pregnancies is unknown. (Ex. 126, Test. Dr. Westhoff 996-98.)

In a hospital operating room, Dr. Westhoff administers general anesthesia to the woman, removes the cervical dilators, ruptures the amniotic sac, and allows the sac to drain. (Ex. 126, Test. Dr. Westhoff 786.) Dr. Westhoff uses a tenaculum to grasp the cervix. She inserts a finger or instrument into the uterine cavity through the cervix to begin pulling down fetal parts. (Ex. 126, Test. Dr. Westhoff 786).

According to Dr. Westhoff, although 95% of term fetuses present in the vertex position, second-trimester fetuses are in a variety of positions because of the additional

room available in the uterus. One-third of second-trimester fetuses are vertex; one-third breech; and one-third transverse. Therefore, the part of the fetus Dr. Westhoff initially grabs during second-trimester D&Es varies. (Ex. 126, Test. Dr. Westhoff 788.)

Dr. Westhoff removes the fetus by pulling fetal parts with instruments or digits. If the fetus is dismembered, she examines the parts to assure that all parts have been removed, and then delivers the placenta with a combination of suction curettage and a sharp curette. (Ex. 126, Test. Dr. Westhoff 787.)

Dr. Westhoff prefers to minimize the number of instrument passes into the uterine cavity, and therefore, prefers to remove the fetus as intact as possible. However, whether she performs a dismemberment or an intact D&E depends on individual circumstances encountered as the procedure evolves. Dr. Westhoff cannot accurately predict at the outset of the procedure which variation of D&E will actually be performed. (Ex. 126, Test. Dr. Westhoff 794.)

Dr. Westhoff testified that for any fetal part that is too large to pass through the cervix, including the fetal head, she reduces the diameter of the part by severing, crushing, or collapsing it. Dr. Westhoff must crush or collapse the fetal head in the vast majority of D&Es. (Ex. 126, Test. Dr. Westhoff 798.)

In a dismemberment D&E, Dr. Westhoff cannot directly visualize the fetal head, so sonography must be used. Dr. Westhoff uses a long forceps to grasp the skull and crush it to drain the skull contents and reduce its size. Dr. Westhoff described this as difficult, requiring several instrument passes to accomplish. (Ex. 126, Test. Dr. Westhoff 799 & 801.)

In Dr. Westhoff's intact D&E procedures, a hole is placed in the base of the fetal skull under direct visualization. The contents drain spontaneously in most cases,

and if not, the contents are suctioned. The skull bones will then collapse inward without any external application of force and Dr. Westhoff can remove the skull from the uterus. (Ex. 126, Test. Dr. Westhoff 799-800 & 1004-05.)

In Dr. Westhoff's experience, the intact D&E occurs more commonly (but in less than half the cases) at 18 to 20 weeks of gestation or later, but it can occur earlier in the second trimester. (Ex. 126, Test. Dr. Westhoff 801-02.)

Dr. Westhoff estimates that the surgical portion of the D&E lasts, on average, about 20 minutes, but can be as short as 10 minutes and as long as an hour (or more if there are complications). (Ex. 126, Test. Dr. Westhoff 813-14.)

Dr. Westhoff generally performs her D&Es under ultrasound guidance. (Ex. 126, Test. Dr. Westhoff 786-87.)

### *(c) LABOR INDUCTION*

Dr. Westhoff remains familiar with the current medical literature and has prepared a teaching tape on behalf of ACOG for use by physicians learning about the use of prostaglandins for performing abortions. (Ex. 126, Test. Dr. Westhoff 744.)

Based on CDC data, Dr. Westhoff testified that labor induction is used in about 5% of all second-trimester abortions. (Ex. 126, Test. Dr. Westhoff 802.)

According to Dr. Westhoff, using osmotic dilators prior to starting an induction abortion will shorten the procedure. (Ex. 126, Test. Dr. Westhoff 790-91.)

### *xii. DR. CASSING HAMMOND*

Dr. Hammond received his medical degree from the University of Missouri in Kansas City in 1988 and completed his residency in obstetrics and gynecology at the University of Rochester in Rochester, New York, in 1992. He became board-certified in obstetrics and gynecology in 1994. He is a diplomate of the National Board of Medical Examiners. Dr. Hammond is employed as a physician by the Northwestern Medical Faculty Foundation at the Northwestern University Medical School, and is an assistant professor in Northwestern University's Department of Obstetrics and Gynecology. He teaches medical students, residents, and fellows; administers policy regarding the general and high-risk obstetric and gynecologic care provided through the Prentice Ambulatory Care Clinic for low-income women; and directs the obstetrics and gynecology rotational training for third-year medical students at the Prentice Women's Hospital. Within his faculty-based practice, 60% of his professional time is spent treating patients as a general OB/GYN physician. He delivers approximately 100 babies per year. The remainder of his time is spent providing OB/GYN patient care to women with severe disabilities at the Rehabilitation Institute of Chicago, providing OB/GYN care to women with AIDS at Northwestern Memorial's Comprehensive Women's AIDS Center, and supervising and performing first- and second-trimester pregnancy terminations. (Ex. 124, Test. Dr. Hammond 517-27 & Sub-Ex. 124B.)

Dr. Hammond supervises and performs pregnancy terminations from very early in gestation through 24 weeks. He provides abortion services approximately two days a week at Northwestern's family-planning center, and he supervises Northwestern's two-year fellowship program in family planning and contraceptive research, which includes teaching abortion procedures. Dr. Hammond is a fellow of ACOG. He has offered testimony challenging Illinois and Ohio partial-birth abortion statutes. (Ex. 124, Test. Dr. Hammond 517-25, 527, 536, 539-40 & Sub-Ex. 124A.)

Dr. Hammond has been performing abortions for 15 years and performs medical abortions in the first trimester with medications that induce miscarriage, D&Cs, labor induction, and D&Es up to 24 weeks. Over the course of his career, he has performed at least 3,000 abortions, including at least 1,000 D&Es. At 20 to 24 weeks of gestation, 95% of the abortions Dr. Hammond performs are D&Es, with the remainder being labor induction. Dr. Hammond estimates that at least three times per month a fetus will deliver intact to the level of the fetal calvarium, and in about half of his D&Es from 20 to 24 weeks, he is able to remove the fetus intact to the level of the fetal navel or above. (Ex. 124, Test. Dr. Hammond 526-28, 530, 533, 668, 675.)

### *(a) D&E*

Dr. Hammond characterizes the intact D&E as a variation of the D&E. For every D&E performed, Dr. Hammond tries to remove the pregnancy as intact and as expeditiously as possible. (Ex. 124, Test. Dr. Hammond 531-32.)

In Dr. Hammond's practice, for most women at 20 to 24 weeks of gestation, the pregnancy is being terminated to preserve the mother's health or because of a fetal anomaly. The patient's psychological condition is fragile. By the time Dr. Hammond sees these patients, they have usually been counseled by maternal-fetal medicine specialists concerning D&E and labor-induction abortion. Nonetheless, Dr. Hammond re-advises them of their options and explains that the fetus may be dismembered and, in some cases (depending on the patient's desire to know and psychological state), he explains that the skull will be collapsed with the forceps. Most of the women he sees have already been advised of their abortion options and were referred to him because they chose D&E. Dr. Hammond believes these women choose D&E based on a personal need and desire to avoid the pain and length of labor when they are already losing a wanted pregnancy. (Ex. 124, Test. Dr. Hammond 544-46 & 656-61.)

Dr. Hammond testified that some women are now choosing D&E and requesting that it be done as intact as possible because they want the control and predictability of the D&E, but want the ability to hold the fetus afterward. Dr. Hammond tells such patients that an intact D&E cannot be guaranteed, and that the fetus may need to be dismembered, but the doctors will do their best. (Ex. 124, Test. Dr. Hammond 551-52.) Dr. Hammond stated that fetal tissue dismembers more easily at 20 weeks of gestation than at 24 weeks of gestation. (Ex. 124, Test. Dr. Hammond 671.)

For Dr. Hammond, the D&E is a two-day procedure involving dilation of the cervix followed by surgical removal of the uterine contents. (Ex. 124, Test. Dr. Hammond 530-31.) Dr. Hammond's dilation protocol for D&Es is based on the gestational age of the fetus, with the goal being to obtain sufficient dilation to perform an intact D&E in every case. (Ex. 124, Test. Dr. Hammond 597.)

At 20 to 24 weeks of gestation, Dr. Hammond typically inserts 2 to 3 sets of laminaria, and for late second-trimester abortions, he may insert as many as 15 to 20 laminaria. (Ex. 124, Test. Dr. Hammond 672-73.) Laminaria are inserted 24 hours before the scheduled D&E surgery. (Ex. 124, Test. Dr. Hammond 673.) For women with an especially tight cervix, Dr. Hammond may administer a combination of misoprostol and a third set of laminaria the morning of the D&E. (Ex. 124, Test. Dr. Hammond 673.) Dr. Hammond administers general anesthesia to those patients beyond 16 to 18 weeks of gestation. (Ex. 124, Test. Dr. Hammond 573.)

In the operating room, Dr. Hammond inserts a suction curette into the uterus and suctions out the amniotic fluid. (Ex. 124, Test. Dr. Hammond 676.) In the majority of Dr. Hammond's cases, suctioning the amniotic fluid will cause the umbilical cord to come out. Dr. Hammond cuts the cord and the fetus eventually dies. (Ex. 124, Test. Dr. Hammond 676.)

Dr. Hammond may use forceps to grasp a fetal part, pull it down, and re-grasp the fetus at a higher level—sometimes using both his hand and a forceps—to exert traction to retrieve the fetus intact until the head is lodged in the cervical os. (Ex. 124, Test. Dr. Hammond 679.)

Dr. Hammond testified that a breech extraction D&E refers to reaching into the uterus and, if the fetus is presenting in a breech or buttocks-first position, grasping the lower extremity and gradually delivering the fetus to the level of the fetal head or calvarium. (Ex. 124, Test. Dr. Hammond 532.) A breech presentation allows for delivery of the fetus intact up to the level of the fetal navel or above. (Ex. 124, Test. Dr. Hammond 533-34.) Dr. Hammond occasionally converts the fetus to a breech position. (Ex. 124, Test. Dr. Hammond 686.)

Sometimes another physician assists Dr. Hammond in performing D&Es by pressing on the woman's abdomen to put pressure on the uterus to expel the fetus. (Ex. 124, Test. Dr. Hammond 680.)

As Dr. Hammond is removing the fetus, it is rotated so the abdomen faces downward. With help from his surgical assistant, Dr. Hammond raises the anterior lip of the cervix to allow the doctor to insert a forceps and, under direct visualization or by sense of feel, to permit the forceps to be inserted into the base of the fetal skull to collapse the skull. (Ex. 124, Test. Dr. Hammond 680-81.) At 20 weeks of gestation or later, Dr. Hammond usually uses a scissors at the base of the fetal skull to collapse it. At less than 20 weeks, Dr. Hammond can usually use his finger because the skull is softer. (Ex. 124, Test. Dr. Hammond 606-07.)

Dr. Hammond uses ultrasound occasionally, but not routinely, to assist in determining if all fetal parts have been removed. He testified that routine use of ultrasound would lengthen the procedure and the patient's exposure to anesthesia. (Ex. 124, Test. Dr. Hammond 572-73.)

### *(b) LABOR INDUCTION*

Dr. Hammond induces labor by administering vaginal misoprostol suppositories periodically until the woman delivers the fetus. If the fetus is dead at the start of the procedure, the induction abortion lasts 12 to 24 hours in 90% of cases. If the fetus is alive, 12 to 24 hours is the lower limit of time needed for an induction abortion. (Ex. 124, Test. Dr. Hammond 668-69.)

## *xiii. DR. WATSON A. BOWES, JR.*

Dr. Watson A. Bowes, Jr., is an obstetrician and gynecologist who is currently Professor Emeritus of Obstetrics and Gynecology at the University of North Carolina in Chapel Hill. Dr. Bowes is board-certified in obstetrics, gynecology, and maternal-fetal medicine. Dr. Bowes graduated from the University of Colorado Medical Center in 1959, after which he completed an internship at a hospital associated with the Dartmouth Medical School. He then completed residencies in general practice, obstetrics, and gynecology, as well as a fellowship in fetal physiology at the University of Colorado. In 1965, he entered private OB/GYN practice and served as part-time faculty at the University of Colorado. Beginning in 1967, Dr. Bowes spent two years in the Army Medical Corps, after which he took a faculty position in the Department of Obstetrics and Gynecology at the University of Colorado until 1982. He then became a faculty member in the Department of Obstetrics and Gynecology at the University of North Carolina, where he remained until his 1999 retirement. Dr. Bowes still serves on the institutional review board of the University of North Carolina medical school, is an editor-in-chief of a medical journal related to obstetrics and gynecology, and is a peer reviewer for two medical journals. Dr. Bowes is a fellow of ACOG and has served on the committee on ethics for five years. (Ex. 525; Tr. 897-903, Test. Dr. Bowes.)

Dr. Bowes has performed D&Cs for incomplete miscarriages; suction curettage; and induction of labor for fetal death in the second trimester of pregnancy. He has supervised D&Es on demised fetuses. His experience with these procedures is predominantly in situations in which the fetus has died in utero before the procedure begins, although he has supervised "some number" of induction abortions on live fetuses in both the first and second trimesters. Over the course of his career, Dr. Bowes has supervised or assisted in performing D&Es on live fetuses in two or three cases and he has performed approximately 150 procedures on demised fetuses, 40 to 80 of those being inductions and the remainder D&Es that he supervised. He has never observed or supervised an intact D&E. He has had no formal training on abortion techniques or procedures since 1965. (Tr. 903-05, 920-21, 944-45, 948, 952-53, Test. Dr. Bowes.)

Dr. Bowes first became aware of the so-called "partial-birth abortion" in 1995 when Congressman Canady asked him to critique statements that had been submitted supporting use of the procedure. Dr. Bowes submitted letters to the House and Senate commenting on specific questions posed by Congressman Canady and Senator Santorum regarding the banned procedure. Dr. Bowes has been involved in six lawsuits dealing with state laws that purported to ban the procedure, uniformly testifying in support of the constitutionality of these bans. (Tr. 914-15, 950-51, 993, Test. Dr. Bowes.) Dr. Bowes has also testified in support of other state statutes imposing restrictions on abortions. (Tr. 951-52, Test. Dr. Bowes.) Dr. Bowes agrees that "because [he] believe[s] that the intact D&E procedure has comparable risk to other available procedures, [his] support for the partial-birth abortion act is not based on any concerns for protecting maternal health"; rather, he is ethically opposed to abortion in general, would support a ban on all abortions as long as the law contained an exception for when the woman's life was at risk, would personally not perform an abortion to save his patient's life unless the likelihood that the patient will die is over 50%, and would favor banning abortions of pregnancies resulting from rape and incest. (Tr. 960-61, Test. Dr. Bowes.)

Dr. Bowes understands the "partial-birth abortion" procedure to mean the technique variously described by Drs. Haskell and McMahon and ACOG which "involves . . . partial delivery of a fetus who, at the time of that delivery, is still alive, and then some procedure or some act is performed by the physician that not only ends the delivery but also kills the fetus." Specifically, Dr. Bowes understands the procedure to involve dilating with laminaria; converting the fetus to a breech presentation when possible; delivering the fetus up to the head, at which point the cervix is not fully enough dilated to allow the head to pass; making an incision in the fetal skull; and inserting a suction device into the fetal skull to suction out the brain of the fetus in order to diminish the size of the fetus's skull and to kill the fetus. (Tr. 915-16, Test. Dr. Bowes.)

Based on his limited abortion experience and his review of the Haskell and McMahon papers, the ACOG statement, and approximately 20 expert reports submitted by the plaintiffs in the nationwide litigation regarding the Partial-Birth Abortion Ban Act of 2003, Dr. Bowes opined that he has never "seen any situation where [he] perceived the need to use an intact D&E" or where he "perceived any advantage to using an intact D&E over other methods of abortion." (Tr. 919-20, Test. Dr. Bowes.)

### *xiv. DR. M. LEROY SPRANG*

Dr. Sprang is a fellow of ACOG, the American College of Surgeons, and the American Society for Colposcopy and Cervical Pathology. He currently practices obstetrics and gynecology with a large private practice that is affiliated with the Northwestern University Medical School in Chicago. He has served as an instructor, associate professor, or assistant professor in clinical obstetrics and gynecology at Northwestern since 1975 and has been active in professional organizations since completion of his residency in obstetrics and gynecology in 1975. He earned his medical degree from Loyola Medical School in 1969. Dr. Sprang has delivered over

3,000 babies in his medical career and has handled 450-500 spontaneous abortions (or miscarriages) during all trimesters of pregnancy. He has performed D&Es and induction abortions in cases of fetal demise. Dr. Sprang recalls performing one abortion on a live fetus during a hysterotomy which was necessary to save the life of a mother who was bleeding into her abdomen due to a placenta percreta, a condition in which the placenta grows through the uterine wall. (Tr. 1098-1106, Test. Dr. Sprang; Ex. 530.)

Dr. Sprang testified that he does not perform abortions on live fetuses because he went into medicine to preserve life and is uncomfortable causing fetal death. "In my office, patients [wanting an abortion of a live fetus] are referred. They go have the abortion, they come back and see me." (Tr. 1128, Test. Dr. Sprang.)

Dr. Sprang testified that after 20 weeks of gestation, every physician in his institution uses the induction method of abortion. (Tr. 1112, Test. Dr. Sprang.) Dr. Sprang uses misoprostol or laminaria for inductions through the 40th week of pregnancy. The shortest time period Dr. Sprang has observed for completion of a second-trimester induction abortion using misoprostol is four to six hours. (Tr. 1115, 1130, 1184, Test. Dr. Sprang.)

During his term as chairman of the board of the Illinois State Medical Society, Dr. Sprang became involved in the "[p]artial intact D&X" issue and collected information on the issue from physicians across the United States and in foreign countries. The Society introduced a resolution in the Illinois House to ban the "intact D&X" and, as an Illinois delegate to the American Medical Association ("AMA"), Dr. Sprang served on an AMA committee assigned to review the issue. Following issuance of the committee's report, the AMA "went to Congress in Washington" in support of HR 1122, which was a prior version of the Partial-Birth Abortion Ban Act of 2003 now before this court. (Tr. 1116-22, Test. Dr. Sprang.) According to Dr. Sprang, who is currently the chairman of the Illinois delegation to the AMA, the AMA

does not support the version of the law now before the court due to the AMA's traditional position of not supporting legislation that potentially criminalizes a physician's actions. (Tr. 1123-24, Test. Dr. Sprang.)

Dr. Sprang understands the intact D&X procedure to be that described by ACOG; that is, gradually dilating the cervix; performing an internal podalic version of the fetus from a vertex presentation to a breech presentation; extracting the fetus up to the head; piercing the fetal skull with scissors; removing the intracranial contents with a suction cannula; and then delivering the dead, but otherwise intact, fetus. Dr. Sprang understands that all physicians do not perform the procedure in the same way. (Tr. 1142-44, Test. Dr. Sprang.)

As Dr. Sprang interprets the medical literature and information he has gained through his work with the AMA, the intact D&E, or D&X, differs from the traditional disarticulation D&E in that more cervical dilation with repeated insertion of laminaria is required for the intact procedure and the intact procedure requires an internal podalic version which is a rarely used and seldom-recommended technique. (Tr. 1145-47, Test. Dr. Sprang.)

### *xv. DR. CURTIS COOK*

Dr. Cook is a board-certified maternal-fetal medicine specialist who is also board-certified in obstetrics and gynecology. Dr. Cook graduated from the Indiana University School of Medicine in 1989; completed his four-year OB/GYN residency in Michigan in 1993; and in 1995 finished a fellowship in maternal-fetal medicine at the University of Louisville School of Medicine where he completed additional training to learn to care for complicated pregnancies that may include fetal or maternal complications. In addition to his current position as associate director for maternal-fetal medicine at a large health care organization in western Michigan, Dr. Cook serves as an associate clinical professor in the Department of Obstetrics and

Gynecology at the Michigan State College of Human Medicine. Dr. Cook's clinical practice is mainly comprised of referrals from other physicians, including women with surgical and medical complications, multiple gestation, and fetuses with abnormalities. Dr. Cook delivers between 100 and 200 babies per year and has delivered "[s]everal thousand" babies over the course of his career. (Tr. 1254-62, Test. Dr. Cook; Ex. 527.)

Dr. Cook is a member of the Association of Pro-Life OB/GYNs and has been involved in PHACT, Physicians' Ad Hoc Coalition for Truth, a group primarily operated by academic physicians with expertise in management of complicated pregnancies for the purpose of issuing "some factual and supported documents for educational purposes regarding specifics of [the intact D&E or D&X] procedure" in response to "medical misinformation that was being put forward regarding this procedure." (Tr. 1291-92, Test. Dr. Cook.)

As a maternal-fetal specialist, Dr. Cook treats both the mother and the fetus as patients. Part of Dr. Cook's practice involves performing medical procedures on living fetuses, including removing fluid or tissue from various fetal cavities for examination; inserting shunts into fetuses to bypass obstructions; and performing transfusions for anemia. (Tr. 1263, Test. Dr. Cook.)

Dr. Cook performs suction curettage up to 12 weeks for spontaneous miscarriages; he has in "rare instances" performed D&Es on expired fetuses in the second trimester; and he has not performed a D&E on a living fetus. Dr. Cook does not typically perform D&Es on living fetuses because "it's not [his] treatment of choice . . . . But if the case arose where [he] felt that it was in the mother's best health interest to end the pregnancy, and [he] could not do it safely as in the manner of a labor induction, then [he has] experience doing the D&E technique and would do that, if the clinical situation necessitated that, in order to preserve the health of the mother."

Dr. Cook performs D&Es on fetuses that have already expired approximately once a year or less. (Tr. 1265 & 1270-75, Test. Dr. Cook.)

Dr. Cook testified on cross-examination that he has performed between three and five D&Es on expired fetuses and he has supervised under 20 D&Es. Of those 20 D&Es, less than 10 involved a living fetus at the beginning of the procedure. (Tr. 1375-76, Test. Dr. Cook.)

Dr. Cook does not perform elective abortions. Dr. Cook refers his patients to other physicians for D&Es when a fetus has been diagnosed with a nonlethal fetal abnormality and the patient wishes to terminate the pregnancy. If one of Dr. Cook's patients is carrying a fetus with a lethal fetal anomaly, but with no maternal medical complications related to the anomaly, Dr. Cook refers the patient to one of his partners for delivery and Dr. Cook handles aftercare and management of complications. (Tr. 1270, 1281, 1332-33, Test. Dr. Cook.) Dr. Cook does treat patients for complications related to abortion, such as perforation, bleeding, and infection. (Tr. 1283-84, Test. Dr. Cook.)

When pregnancy terminations prior to term are necessary after 16 weeks of gestation, Dr. Cook predominantly uses medical induction for several reasons. First, lethal fetal abnormalities are usually diagnosed via second-trimester ultrasound and are not presented to Dr. Cook's office until 16 to 20 weeks of gestation, and often later, and the D&E is a much more complicated and possibly riskier procedure beyond 20 weeks. Second, in fetal-abnormality cases, "we frequently want to have a complete fetus for pathologic evaluation after delivery," including an intact central nervous system, in order to gather information that may be relevant for family members or future pregnancies. Third, many of his patients have underlying medical complications that require delivery in "as controlled a situation as possible, using as normal a process as possible for the delivery." Finally, "many of the patients that we see are devastated by the unexpected outcomes of the fetuses, and want to be able to

have whatever period of time they can with their baby, which would include generally being able to hold a baby that[] is intact as and normal appearing as possible." (Tr. 1264-65, 1271, 1278-79, Test. Dr. Cook.)

By using prostaglandins, Dr. Cook claims that physicians can "get medical inductions down to pretty reliable 12-hour, on average, interval of time or less and do it in a manner that minimizes risk for both maternal complications and still allows, if it's appropriate, adequate outcome for the fetus." (Tr. 1369, Test. Dr. Cook.)

Dr. Cook estimates that he performs inductions for fetuses less than 23 weeks one to two times per month and inductions after 23 weeks once per week. (Tr. 1281-82, Test. Dr. Cook.) Dr. Cook has performed inductions prior to viability on living fetuses that either die at some point during the process or are "born with signs of life but [are] not able to survive, ultimately, just because of the early gestational age." (Tr. 1282-83, Test. Dr. Cook.) Dr. Cook has never injected a fetus with digoxin or KCl in the course of an induction procedure. (Tr. 1429-30, Test. Dr. Cook.) Dr. Cook agrees that women with viral diseases like hepatitis and HIV would face greater risks with such injections. (Tr. 1431, Test. Dr. Cook.)

When Dr. Cook terminates a pregnancy for maternal health reasons previability, he may not monitor the fetus and he is less concerned about how well the fetus may tolerate vaginal delivery. For such pregnancy terminations involving viable fetuses, "it is always our preference to try to deliver vaginally by utilizing . . . a normal laboring process because it's most physiologic and generally best tolerated by the mother." If the fetus has complications that would prevent it from tolerating a vaginal delivery, Dr. Cook "would then do an operative delivery such as a cesarean delivery in order to facilitate maternal recovery and to allow the least traumatic method of delivery of the fetus." (Tr. 1302-03, Test. Dr. Cook.)

Dr. Cook became aware of the intact D&E, or D&X, procedure when it was "proposed through the U.S. Congress as a procedure that would be worthy of being evaluated and potentially banned, if, indeed, it turned out to have some of the potential risk or concerns that subsequently have come to light." As Dr. Cook understands it, the procedure—also referred to as "partial-birth abortion"—consists of the following:

> I understand it to refer to the procedure basically described by Dr. Haskell as a D&X procedure; Dr. McMahon, as an intact D&E procedure, and others as the intact D&X procedure, the hallmark of which is overt dilation of the cervix, potentially internal podalic version or turning a fetus to a breech position, grasping the fetus, pulling it down through the dilated cervix to the level of the after[-]coming head, such that all the fetus is delivered but the head. And then doing some sort of destructive and decompression procedure on the fetal head to allow passage of the remainder of the baby.

(Tr. 1284-85, Test. Dr. Cook.) Dr. Cook understands that the intact D&E procedure may vary in how the cervix is dilated, how much the cervix is dilated, whether or not the fetus is converted to a breech position, and how the fetal skull is decompressed. (Tr. 1297, Test. Dr. Cook.)

Dr. Cook views the intact D&E, or D&X, procedure to be distinct from the D&E because the intact D&E is performed at a later gestational age (after 20 weeks) on a larger fetus; involves much more cervical dilation and more intrauterine manipulation of the fetus; and it involves a "decompression procedure of the fetal head that is unique in its form of aspirating out the brain contents." (Tr. 1286-87, Test. Dr. Cook.) In contrast, the D&E involves dismembering the fetus inside the uterus with instruments and removing the pieces through an adequately dilated cervix. (Tr. 1294-95, Test. Dr. Cook.)

Dr. Cook was asked to, and did, testify before Congress regarding the potential banning of the intact D&E or D&X procedure during a special joint hearing of the

House and Senate Judiciary Committees in 1997 and before a House Subcommittee in 2003. (Tr. 1289, Test. Dr. Cook.) Dr. Cook "was asked . . . to give advice on how we could write a better Bill [after Carhart], how we could most narrowly define the procedure, and so [he] put forward several recommendations, some of which became incorporated, some of which did not." (Tr. 1447, Test. Dr. Cook.) In an effort to narrow the scope of the Act, Dr. Cook recommended that the Act be limited to procedures performed after 20 weeks. He also suggested including anatomic landmarks and "intentional or volitional destructive procedures" and excluding normal vaginal deliveries. (Tr. 1447-48 & 1451, Test. Dr. Cook.) Dr. Cook has also testified or submitted declarations in support of statutes limiting partial-birth abortions in litigation in Michigan, Missouri, Wisconsin, and Alaska. (Tr. 1448 & 1450, Test. Dr. Cook.)

### *xvi. DR. ELIZABETH SHADIGIAN*

Dr. Shadigian is a board-certified obstetrician and gynecologist who is also a full-time faculty member at the University of Michigan. She received her medical degree from the Johns Hopkins School of Medicine in 1990, completed her OB/GYN residency at the Franklin Square Hospital Center in Baltimore and Johns Hopkins in 1994, and became a full-time clinical assistant professor of obstetrics and gynecology at the University of Michigan that same year. She is a fellow of ACOG and is a reviewer for several national medical journals. (Tr. 1486-90, Test. Dr. Shadigian; Ex. 529.)

Dr. Shadigian has performed D&Cs, D&Es, and medical induction of labor to terminate pregnancies prior to full term. Dr. Shadigan testified that with the exception of some pregnancy terminations that were necessary to treat maternal health complications, "all the babies that . . . [Dr. Shadigian has] . . . performed abortions on were dead by the time" she performed the procedure. (Tr. 1493-94, Test. Dr. Shadigian.) Dr. Shadigian does not perform abortions on live fetuses unless "it's [her]

belief the mother will die," a situation that has occurred approximately 20 to 40 times in her career. (Tr. 1564-65, Test. Dr. Shadigian.) In those cases, she used the induction method of abortion to terminate the pregnancy. (Tr. 1565, Test. Dr. Shadigian.)

Dr. Shadigian performs D&Cs from approximately 5 to 12 weeks of pregnancy, a procedure which involves dilating the cervix and using sharp or suction curettage to remove the uterine contents, including the fetus, placenta, and fluid. (Tr. 1493, Test. Dr. Shadigian.) She has performed "hundreds" of D&Cs on expired fetuses and has observed the procedure being performed on living fetuses. (Tr. 1495, Test. Dr. Shadigian.) Dr. Shadigian uses mechanical dilation of the cervix for her D&C and vacuum-aspiration procedures. (Tr. 1574, Test. Dr. Shadigian.)

Dr. Shadigian testified that she performs D&Es in the second trimester, a procedure which involves dilation of the cervix over a series of days with laminaria or osmotic dilators; use of medicine such as misoprostol to dilate and prepare the cervix; removal of the laminaria and possible use of additional dilators at that time; placement of traction onto the cervix to straighten it out; and use of instruments inside the uterus to facilitate the fetus's disarticulation and removal. (Tr. 1493-94, Test. Dr. Shadigian.) Dr. Shadigian has assisted with 30 to 50 D&Es on expired fetuses during residency, performed 10 to 20 D&Es on expired fetuses since she came to the University of Michigan in 1994, and has observed D&E procedures being performed on live fetuses up to 20 or 22 weeks of gestation. Of the D&Es she has performed, Dr. Shadigian has completed approximately 8 to 10 D&Es on 17- to 19-week fetuses at the University of Michigan and on 20-week fetuses during residency. Under normal circumstances, Dr. Shadigian estimates that surgical removal of a fetus during a D&E procedure takes approximately 30 minutes to 2 hours. (Tr. 1495-96, 1565, 1580-81, Test. Dr. Shadigian.)

Dr. Shadigian most commonly uses medical induction at 20 weeks of gestation and up. Dr. Shadigian performs medical inductions on fetuses prior to term on a weekly basis, but it is "more rare" for her to use induction prior to viability. Dr. Shadigan testified that medical induction involves placement of medications in the woman's uterus, vagina, or mouth to induce contractions and begin the physiological process of labor. (Tr. 1493-97 & 1499, Test. Dr. Shadigian.) Dr. Shadigian has most commonly used the induction method to terminate pregnancies prior to viability for chorioamnionitis[58] and preeclampsia. (Tr. 1499-1500, Test. Dr. Shadigian.)

Dr. Shadigian treats abortion complications such as infection, blood loss, uterine scar tissue, and premature births following induced abortions. She has developed an interest in treating such complications because "[i]t has been estimated up to 43% of American women will have an elective abortion or a medically necessary abortion by the time they are age 45." (Tr. 1505-07, Test. Dr. Shadigian.)

Dr. Shadigian has performed a systematic literature review regarding the intact D&E or D&X, defined as dilation of the cervix over several days to accomplish an adequate amount of dilation; instrumental conversion of the fetus to a breech presentation; delivery of the fetus up to its head; admission of instruments into the base of the fetal skull; and extraction of the contents of the fetal skull in order to facilitate delivery of the head. After her review of the Act, various definitions of the intact D&E procedure, and expert declarations, Dr. Shadigian thinks there are "several

[58]"Chorioamnionitis" is an "[i]nfection involving the chorion, amnion, and amniotic fluid; usually the placental villi and decidua are also involved." Stedman's Medical Dictionary 343 (27th ed. 2000). See also Ex. 124, Test. Dr. Hammond 588-89 (chorioamnionitis is "an infection of the fetal membranes and also the amniotic fluid"). Dr. Shadigan defines chorioamnionitis, perhaps more broadly, as "an infection of the membranes, the placenta, the baby, the uterus, and . . . any variation thereof." (Tr. 1499-1500, Test. Dr. Shadigan.)

variations" of the procedure, and instrumental conversion of the fetus is not a necessary part of the definition. (Tr. 1510-12, Test. Dr. Shadigian.)

### *xvii. DR. STEVEN CLARK*

Dr. Clark is a maternal-fetal medicine specialist for the Inner Mountain Health Care facility ("LDS Hospital"), a private LDS community hospital in Salt Lake City, Utah. He is a professor of obstetrics and gynecology at the Utah School of Medicine, and in addition to didactic teaching, provides clinical training to medical students, residents, and fellows at the Inner Mountain Health Care facility and the University Hospital. Currently, half his professional time is devoted to the care and treatment of women with complicated pregnancies, with the remainder spent in formal teaching, chairing the quality assurance committee of the LDS Hospital, and performing research. (Ex. 891, Test. Dr. Clark 2270-71, 2275 & Sub-Ex. A.)

Dr. Clark graduated from the University of Wisconsin Medical School in 1979, completed a residency in obstetrics and gynecology in 1983, and completed a fellowship in maternal-fetal medicine in 1985, both at the University of Southern California. He is board-certified in obstetrics and gynecology and in the subspecialty of maternal-fetal medicine. He is a member of ACOG and the Society of Maternal Fetal Medicine, is a grant application reviewer for the National Institutes of Health, and has served on several professional committees in the area of maternal complications during pregnancy. Dr. Clark has published 173 articles (more than half of which were peer-reviewed), including several book chapters, and was the lead editor of Critical Care Obstetrics, a textbook initially published in the late 1980s and currently in its fourth edition. His research is focused on caring for the critically ill pregnant woman and her fetus, complications of pregnancy, and vaginal birth after cesarean section. He has never written or researched the methods or techniques of performing abortions. Although he is ethically and morally opposed to elective abortion, Dr. Clark has not previously been involved in cases challenging statutes

banning partial-birth abortion. Dr. Clark has testified or given a deposition as a medical expert in malpractice cases 160 times over the last four years. None of these depositions involved abortion techniques. (Ex. 891, Test. Dr. Clark 2270-90, 2397, 2399-2402 & Sub-Ex. 891A.)

Dr. Clark performs D&Cs in the first trimester, labor induction to term, and dismemberment D&Es up to 20 weeks. He performs abortions only when medically necessary. (Ex. 891, Test. Dr. Clark 2297-98.)

Over the course of his career, Dr. Clark has performed a dozen first-trimester abortions on live fetuses; less than 20 labor-induction abortions; and "[a]t most, a dozen" D&Es on live fetuses up to 20 weeks of gestation due to lack of experience. Dr. Clark characterizes the instances where an abortion of a live fetus was necessary for the mother's sake as "very, very rare." The last D&E Dr. Clark performed on a live fetus was one to two years ago. In cases of spontaneous abortion (miscarriage or fetal death), Dr. Clark has performed hundreds of procedures, with D&C being the most common and labor induction the second most common. (Ex. 891, Test. Dr. Clark 2299, 2302, 2399.)

### *(a) D&E*

Dr. Clark describes the D&E as a process involving cervical dilation, introducing an instrument into the uterus, pulling the fetus out in pieces, and removing the placenta with forceps. (Ex. 891, Test. Dr. Clark 2301.)

In his practice, abortion is so infrequent that Dr. Clark has no experience performing D&Es after 20 weeks of gestation, and all women at that gestational age who choose D&E are referred to the same colleague so that a doctor in their group can acquire some base of experience. (Ex. 891, Test. Dr. Clark 2407.)

Dr. Clark testified that when the mother is going to die unless the fetus is aborted, the mother is advised that if a D&E is performed, the fetus will be pulled out in pieces and will die. (Ex. 891, Test. Dr. Clark 2302-03.)

To dilate the cervix prior to performing a D&E, Dr. Clark uses two sequences of laminaria, and each time he places as many laminaria in the cervix as he can without causing trauma. In his opinion, laminaria are a gentler method of cervical dilation than the use of mechanical dilators and appropriate use of laminaria does not increase the risk of pregnancy loss. Dr. Clark has used mechanical dilators in addition to laminaria. (Ex. 891, Test. Dr. Clark 2413-14.)

Dr. Clark has "read about" intact D&E in the McMahon and Haskell articles, the pre-publication Chasen article, and the expert disclosures given in this litigation, but he has never seen it performed, talked to anyone who performs them concerning the technique, and has never performed an intact D&E. He understands the intact D&E to include cervical dilation, breech presentation and removal of the fetus until the head is lodged at the cervical os, putting a hole in the fetus's head, suctioning out the fetal brain, removing the fetus intact, and removing the placenta. (Ex. 891, Test. Dr. Clark 2307-08, 2310, 2399.)

### *(b) LABOR INDUCTION*

According to Dr. Clark, prostaglandins can be used to induce labor. There are two classes of prostaglandins: E prostaglandins and F prostaglandins. Dr. Clark testified that some patients experience complications from prostaglandin administration, but even when one class of prostaglandin causes problems, the other class of prostaglandin can be safely used. Misoprostol is an E prostaglandin and is commonly used for labor-induction abortion. (Ex. 891, Test. Dr. Clark 2304-05.)

Dr. Clark stated that misoprostol was developed to treat ulcers, but is widely used to induce preterm and term labor and delivery. It has replaced ritadrin for inducing preterm labor. Ritadrin has not been used for about 10 years. (Ex. 891, Test. Dr. Clark 2305-06.)

### *xviii. DR. CHARLES LOCKWOOD*

Dr. Charles Lockwood is a maternal-fetal medicine specialist who has been the Chairman of the Department of Obstetrics, Gynecology and Reproductive Services at the Yale University School of Medicine since 2002. Part of Dr. Lockwood's duties at Yale include maintaining the quality of clinical care at the Yale New Haven Hospital. From 1995 to 2002, Dr. Lockwood served as Chairman of the Department of Obstetrics and Gynecology at the New York University School of Medicine where he chaired or directed the obstetrics and gynecology departments at two hospitals. (Ex. 528; Tr. 1639-42, Test. Dr. Lockwood.) In his last year at NYU, approximately 900 abortions were performed there, approximately one-third of which were second-trimester procedures. Of those second-trimester abortions, approximately 25 to 35% were intact D&Es. While Dr. Lockwood did not know intact D&Es were being performed in his department during his time at NYU, he would have allowed the procedure to be performed if he had known. It would have been a "violation of [his] obligation" to have allowed any unsafe procedures to be performed in his department at NYU. (Tr. 1666, 1744-45, 1764-65, Test. Dr. Lockwood.)

Dr. Lockwood received his medical degree from the University of Pennsylvania School of Medicine in 1981; finished his residency in obstetrics and gynecology at Pennsylvania Hospital in 1985; completed a fellowship in maternal-fetal medicine at the Yale University School of Medicine in 1987; and concluded his postdoctoral fellowship in coagulation at the Mount Sinai School of Medicine in New York in 1991. He is board-certified in obstetrics and gynecology with a special certification

in maternal-fetal medicine[59] and is currently licensed to practice medicine in New Jersey, New York, and Connecticut. Dr. Lockwood currently maintains an active medical practice in maternal-fetal medicine and conducts research on a variety of topics. Approximately 150 of Dr. Lockwood's studies have been peer-reviewed and he has served as a peer reviewer for many medical journals. (Ex. 528; Tr. 1642-45, Test. Dr. Lockwood.)

Dr. Lockwood was responsible for creating a "reproductive choice service" at New York University and Bellevue Hospital that would train residents in abortion techniques and would conduct research in abortion and contraception. (Tr. 1661-63, Test. Dr. Lockwood.) The program director had significant discretion regarding what abortion procedures would be performed at NYU, but as viability approached in any given case, the ethics committee at Bellevue Hospital was involved in "adjudicating whether the abortion would be appropriate." (Tr. 1661-64, Test. Dr. Lockwood.) Currently, NYU provides medical abortions by methotrexate, manual vacuum aspiration, dilatation and aspiration, suction curettage, D&E, and D&X. (Tr. 1664, Test. Dr. Lockwood.) Dr. Lockwood is planning to develop a family planning and reproductive choice program at Yale University that will conduct academic research and publish peer-reviewed studies. If the director of that program wishes, Dr. Lockwood will allow the intact D&E procedure to be performed and taught at Yale. (Tr. 1666-67 & 1746, Test. Dr. Lockwood.)

Dr. Lockwood does not perform abortions on live fetuses. (Tr. 1647, Test. Dr. Lockwood.) He has observed approximately ten D&Es up to 20 weeks of gestation

[59]Dr. Lockwood describes this specialty as "the field of study and clinical activity in obstetrics and gynecology that deals with complicated obstetrical cases, including pregnancies complicated by maternal medical illnesses and obstetrical complications such as premature labor, recurrent miscarriage, preeclampsia, and a variety of other conditions as well as the fetus. And that includes providing diagnosis and therapy for the fetal patient." (Tr. 1642-43, Test. Dr. Lockwood.)

during his residency, three to four per year during his fellowship, and one to two per year at Mt. Sinai, NYU, and Yale. Dr. Lockwood performs dilation and aspiration or suction curettage after fetal death up to 12 to 13 weeks of gestation; has managed many patients with complications of surgical and medical abortion; and has performed ultrasounds during abortions in an effort to avoid maternal injury. (Tr. 1652-53 & 1658, Test. Dr. Lockwood.) Dr. Lockwood performed medical-induction abortions more than 40 times during residency and he continues to do so in cases of nonliving fetuses. (Tr. 1658-59, Test. Dr. Lockwood.) He has treated women for complications after an abortion, including retained placental fragments, uterine perforation, and chorioamnionitis. (Tr. 1660-61, Test. Dr. Lockwood.)

Dr. Lockwood's suction curettage procedure includes premedicating the patient, generally with Motrin; placing a sterile speculum in the vagina; sterilizing the cervix; placing a tenaculum on the cervix; administering a paracervical block; inserting a suction curette in the uterus; and evacuating the contents of the uterus. Dr. Lockwood confirms with ultrasound that the uterus contains no residual products and sends the patient home with pain relief and antibiotics if necessary. The tissue removed from the uterus is often then sent for karyotypic analysis to evaluate whether a chromosomal abnormality caused the miscarriage. (Tr. 1653-54, Test. Dr. Lockwood.)

Dr. Lockwood describes the D&E procedure as placement of laminaria, with or without prostaglandin or misoprostol, for two to three days depending upon the gestational age of the fetus; use of premedication and a paracervical block or general anesthesia; manual examination to determine the position of the cervix; insertion of a speculum; additional mechanical dilation if needed; optional ultrasound to determine the fetus's length; rupture of the membranes if necessary; and removal of the fetus. The fetus is removed in parts by placing a clamp or forcep on a fetal part and "achieving counter-traction by the cervix so that there is pressure, there is a vector force in that direction . . . . And that, in turn, creates a point of fracture . . . in the fetal tissue." Ultrasound may then be used to determine if residual parts remain in the

uterus. The placenta is then removed by suction curettage in most cases and pitocin is used to minimize bleeding. After counseling on contraception, the patient is then released with antibiotics, pain relief, and instructions for follow-up care. (Tr. 1654-57, Test. Dr. Lockwood.)

According to Dr. Lockwood, ultrasound-guided imaging during D&E procedures is "very, very important" because "any time we manipulate anything inside the uterus, if we don't use ultrasound imaging, it makes it a more complicated procedure, potentially a more risky procedure." In the case of D&Es, "[r]ather than blindly trying to identify fetal parts, and hoping that you're not clamping the uterus, the use of ultrasound allows one to carefully place various clamps directly on the fetus and remove the fetus with some assurety that you are not grasping the uterus." (Tr. 1670-71, Test. Dr. Lockwood.)

Dr. Lockwood understands there are "multiple definitions" of the intact D&E or D&X, but he defines it as cervical ripening for some time, perhaps for several days; internal podalic version[60] unless the fetus is already in a breech position; delivery of the fetus until the head abuts the cervix; and evacuation of the uterine contents, which often will require "the intracranial . . . tissue to be removed to collapse the [fetal] skull to allow delivery." As compared with the traditional D&E procedure, the intact D&E involves "a greater degree of cervical dilatation, and, therefore, serial placement of laminaria and/or . . . Cytotec or Misoprostol" are used. (Tr. 1664-65 & 1673-74, Test. Dr. Lockwood.)

Dr. Lockwood testified that both the intact D&E and traditional D&E involve dilation of the cervix. In some cases, the cervix will dilate more than in others, even with the same cervical preparation. (Tr. 1757, Test. Dr. Lockwood.)

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[60]Dr. Lockwood interprets the Act to prohibit procedures that do not involve conversion of the fetus to a breech position. (Tr. 1751, Test. Dr. Lockwood.)

Dr. Lockwood stated that second-trimester labor induction for termination of pregnancy has "changed dramatically over the last 25 years," going from intraamniotic injections of hypertonic saline to use of laminaria and misoprostol or Cytotec. According to Dr. Lockwood, modern labor-induction abortions often involve the use of laminaria, followed by admission to the hospital and removal of the laminaria. Some physicians administer antibiotics at that point and most give an epidural for pain relief. Misoprostol suppositories are then used for two to four hours. Depending upon the dose of misoprostol used, the induction procedure usually lasts from 12 to 24 hours with a 5% risk of retained placenta. (Tr. 1676 & 1710, Test. Dr. Lockwood.)

Dr. Lockwood noted that abortion procedures that begin as inductions sometimes fail. Specifically, in performing a previability induction abortion, the fetus sometimes partly expels in a breech position, but the patient experiences excess bleeding before the head is delivered. In that case, one of the options in the physician's armamentarium "would be to compress the calvarium with forceps," even after the fetus has shown signs of life. Dr. Lockwood believes that the physician performing an induction abortion knows at the outset of the procedure that such circumstances may occur and might necessitate such instrumentation. (Tr. 1758-59, Test. Dr. Lockwood.)

Dr. Lockwood testified that when a physician begins a previability D&E, intending to remove the fetus in large pieces but not specifically intending to do an intact D&E, the fetus may be pulled through the cervix until the after-coming head is obstructed. According to Dr. Lockwood, one of the physician's options in this circumstance "would be to compress the calvarium with forceps in order to remove the fetus just as in the induction," even though the fetus had shown signs of life before such compression. The physician performing the D&E may know at the outset of the procedure that these circumstances may occur and might necessitate such instrumentation. (Tr. 1759, Test. Dr. Lockwood.)

Dr. Lockwood believes that patient preference regarding length of the procedure and comfort level are important considerations in choosing an abortion procedure, and barring contraindications to a certain procedure, a woman should be given the option of having an induction abortion or a surgical abortion after 20 weeks and before viability. (Tr. 1747-48, Test. Dr. Lockwood.)

### *xix. ACOG*

A Statement of Policy issued by the executive board of the American College of Obstetricians and Gynecologists defines the "intact dilatation and extraction" procedure as containing all four of the following elements:

1. deliberate dilatation of the cervix, usually over a sequence of days;
2. instrumental conversion of the fetus to a footling breech;
3. breech extraction of the body excepting the head; and
4. partial evacuation of the intracranial contents of a living fetus to effect vaginal delivery of a dead but otherwise intact fetus.

(Ex. 5, at 2.) The policy describes the "intact D&X" as one method of terminating a pregnancy after 16 weeks, but one's "physician, in consultation with the patient, must choose the most appropriate method based upon the patient's individual circumstances." (Ex. 5, at 2.)

## *b. INDICATIONS AND CONTRAINDICATIONS*

Many of the doctors also testified regarding maternal and fetal conditions that, in their opinion, may or may not necessitate an abortion or a particular type of abortion. That testimony is described below.

## *I. MATERNAL INDICATIONS AND CONTRAINDICATIONS*

Dr. Chasen testified that a second-trimester abortion may be required to protect a woman's health or save her life. For example, a dilated cervix or ruptured membranes in the second trimester pose a substantial risk of infection. Continuing the pregnancy can lead to infection throughout the body (sepsis) and death. (Ex. 121, Test. Dr. Chasen 1609.) Dr. Broekhuizen stated that sometimes the issue faced is not the woman's life, but her long-term health, and the Act does not include an exception for a mother's health. (Ex. 120, Test. Dr. Broekhuizen 558.)

According to Dr. Clark, it is rare that terminating a pregnancy is necessary for the mother's health, averaging less than 1 in 50,000 cases per year during the second trimester. (Ex. 891, Test. Dr. Clark 2314-15.) Dr. Doe performs a "very small percentage" of abortions for maternal physical health reasons, characterizing such pregnancy terminations as "rare." Dr. Doe does not recall terminating a pregnancy for maternal health reasons in 2003 or 2004. (Tr. 103-04, Test. Dr. Doe.) Similarly, only a small number of Dr. Westhoff's second-trimester patients seek abortions for maternal health reasons. (Ex. 126, Test. Dr. Westhoff 805-07.)

In contrast to Dr. Clark's testimony, Dr. Lockwood stated that approximately 1 to 5 per 1,000 pregnancies must be terminated prior to viability due to a physical health condition of the mother. (Tr. 1682-87, Test. Dr. Lockwood.)

If the mother's health is truly at risk, Dr. Clark stated that the need to terminate the pregnancy generally arises in the first trimester, although preeclampsia may very rarely arise in the second trimester. (Ex. 891, Test. Dr. Clark 2316-18.) Dr. Paul testified that abortions for maternal or fetal indications are more likely after the first trimester of pregnancy. (Ex. 125, Test. Dr. Paul 21-22.)

According to physicians who testified at trial, some of the "maternal indications" for which abortions are performed include the physical and mental health condition of the mother, such as cancer; left or right heart failure and other heart conditions; thromboembolism and pulmonary embolism (blood clots in the legs and lungs, respectively); hyperemesis gravidarum (serious nausea and vomiting induced by pregnancy); hypertension or severe preeclampsia[61]; HELLP syndrome, a severe complication of preeclampsia[62]; intracranial hemorrhage; infection; severe, uncontrolled diabetes; renal conditions; liver disease; substance abuse; mental retardation; depression; and schizophrenia. (Tr. 31-32, Test. Dr. Doe; Tr. 600, Test. Dr. Carhart; Tr. 213, Test. Dr. Fitzhugh; Tr. 501, Test. Dr. Knorr; Tr. 315, Test. Dr. Vibhakar; Tr. 1301-02, Test. Dr. Cook; Tr. 1514-15, Test. Dr. Shadigian (maternal health conditions potentially necessitating termination of previable pregnancy include chorioamnionitis and severe preeclampsia); Tr. 1677-78 & 1688-89, Test. Dr. Lockwood; Ex. 121, Test. Dr. Chasen 1609-10 (woman may develop preeclampsia, which may be life-threatening, or heart disease, which may be life- or health-threatening); Ex. 120, Test. Dr. Broekhuizen 495-96 (health problems existing before a pregnancy that may prompt a woman to choose to end her pregnancy include cardiopulmonary disease (e.g., pulmonary hypertension where pregnancy is associated with a 30 to 40% mortality rate), coronary heart disease, end-stage renal disease, and liver disease; health problems arising during pregnancy that may cause a woman to end the pregnancy include cancer, the treatment for which may be less effective during pregnancy or may cause birth defects or developmental problems in the fetus); Ex. 125, Test. Dr. Paul 12-13 & 15-16; Ex. 891, Test. Dr. Clark 2318-19, 2362-63, 2367-

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[61]"Preeclampsia" is "[d]evelopment of hypertension with proteinuria or edema, or both, due to pregnancy." Stedman's Medical Dictionary 1437 (27th ed. 2000).

[62]HELLP syndrome is "a variation of preeclampsia or toxemia which HELLP stands for hemolysis, breakdown of red blood cells, low platelet count, elevated liver function test, putting it in that order. It's very serious. You can have liver failure. You can have hemorrhage, seizures, and it's frequently associated with small fetuses . . . ." (Tr. 1694-95, Test. Dr. Lockwood.)

68 (most common medical condition requiring termination of pregnancy is heart disease; cancer, hypertension, and disorders of other organ systems can also be life-threatening but are much less common; thromboembolism is common complication of pregnancy and in most patients, the pregnancy need not be terminated, but in some circumstances terminating the pregnancy may be required to save the woman's life; if the woman has been placed on anticoagulants to treat thromboembolism, risk of bleeding makes labor induction the preferred second-trimester abortion procedure).)

Dr. Paul identified maternal health conditions specific to or more common in pregnancy which she believes provide a basis for choosing or needing an abortion: preeclampsia, chorioamnionitis, thromboembolism, and pulmonary embolism. (Ex. 125, Test. Dr. Paul 12-13 & 15-16.) According to Dr. Paul, underlying maternal health conditions which are exacerbated by pregnancy and provide a basis for choosing or needing an abortion include diabetes and heart conditions. Specifically, as pregnancy progresses, hormonal changes make it very difficult to control blood sugar levels. Dangerously low blood sugars can lead to seizures, and dangerously high blood sugar levels may cause coma. (Ex. 125, Test. Dr. Paul 17; see also Ex. 891, Test. Dr. Clark 2375-76 (proliferative retinopathy is complication of diabetes characterized by changes in retina which can cause blindness; for unknown reasons, in some pregnant women with underlying retinopathy, the condition of retina rapidly deteriorates during pregnancy; woman may elect to terminate pregnancy to stop this deterioration and prevent permanent blindness; if the woman so elects, either labor induction or dismemberment D&E are appropriate second-trimester abortion techniques).) Dr. Paul testified that as a pregnancy progresses, the woman's blood volume nearly doubles, her heart rate accelerates, and the heart is working harder. She stated that these physiological changes of pregnancy are very taxing on women with underlying heart conditions, and the increased pressures in the heart can back up into

the lungs, causing pulmonary edema (fluid in the lungs) or heart failure. (Ex. 125, Test. Dr. Paul 16-17.)[63]

Dr. Clark testified that lung disease is not a maternal health condition requiring pregnancy termination. According to Dr. Clark, the predominant lung disease in pregnant women is asthma, and asthma is not a reason to terminate a pregnancy. (Ex. 891, Test. Dr. Clark 2337-38.) "All other forms of lung disease are so small as to be essentially not worth considering." (Ex. 891, Test. Dr. Clark 2334-35.) In Dr. Clark's opinion, F prostaglandins may cause bronchiospasm in a woman with asthma, but E prostaglandins (such as misoprostol and oxytocin) do not cause bronchiospasm. Therefore, Dr. Clark concluded that either labor induction with misoprostol or oxytocin or a dismemberment D&E can be safely performed to terminate a second-trimester pregnancy in a woman with asthma. (Ex. 891, Test. Dr. Clark 2335-38.)

Dr. Clark also believes that auto-immune disorders and prior organ transplantation (except in the case of toxemia of pregnancy) are not reasons to terminate a pregnancy. (Ex. 891, Test. Dr. Clark 2349.)

Some of the witnesses before the court testified that hospitalization is preferable for some abortions involving certain maternal health conditions. According to Dr. Doe, hospitalization would be advisable for abortions performed for maternal health reasons when the patient has a systemic illness requiring hospital management like a bleeding, pulmonary, or heart problem; a severe psychiatric or psychological illness that prevents the patient from traveling back and forth during the course of the procedure; or an obstetrical or gynecological complication such as placenta previa or

[63]Dr. Clark opined that while it is true that women in the second trimester of pregnancy have a higher overall blood volume than non-pregnant women, this change in volume is not relevant in deciding whether labor induction or a D&E is the safer abortion procedure. (Ex. 891, Test. Dr. Clark 2326-28.)

placenta previa accreta. Hospitalization in such circumstances would allow more rapid access to consultants and facilities, such as blood transfusion equipment and supplies. (Tr. 109-10, Test. Dr. Doe.) Dr. Knorr sometimes refers his patients to a hospital for an abortion if the patient has an unstable medical condition like hyperthyroidism, a heart condition, or uncontrolled diabetes or hypertension for which the patient has not been medically cleared by an outside doctor to have the abortion performed in Dr. Knorr's clinic. (Tr. 550-51, Test. Dr. Knorr.)

Dr. Lockwood testified that when a maternal complication necessitates early termination of a pregnancy, the method used to terminate the pregnancy varies depending upon whether the fetus is previable or postviable. (Tr. 1678, Test. Dr. Lockwood.) For example, if the fetus is viable and the mother or fetus is gravely ill, a cesarean section would be used. In the absence of grave illness, a fetus that is vertex would be delivered by labor induction. (Tr. 1680, Test. Dr. Lockwood.) According to Dr. Lockwood,

> cesarean section is a procedure done over a million times a year in the United States. We have enormous experience with it. It is remarkably safe, and is a very reasonable approach to delivery, particularly near term. And we have also got extensive experience with induction of labor, and those are very safe and reasonable alternatives for terminating the pregnancy.

(Tr. 1681, Test. Dr. Lockwood.)

Several physicians testifying in this case expressed preferences in abortion method for various maternal health conditions. Dr. Frederiksen believes that pregnancy termination is necessary for women with chorioamnionitis and severe preeclampsia, and an abortion by either induction or D&E may be performed. (Ex. 123, Test. Dr. Frederiksen 1228-29.) Dr. Frederiksen also opined that pregnancy termination may be necessary for women with pulmonary hypertension, and either an

intact or a dismemberment D&E may be performed. (Ex. 123, Test. Dr. Frederiksen 1229.) However, Dr. Clark testified that when the mother's blood pressure cannot be controlled, barring any associated clotting problems, D&E is the preferred second-trimester abortion method because it is faster. (Ex. 891, Test. Dr. Clark 2408-09.) An induction or D&E abortion may be performed on a woman with renal disease, according to Dr. Frederiksen. (Ex. 123, Test. Dr. Frederiksen 1229-30.) In Dr. Clark's opinion, either a dismemberment D&E or labor induction can be performed to abort a fetus when the woman is experiencing a maternal medical complication in the second trimester. He stated that in some cases, one procedure may be preferred over the other, but both are generally safe. (Ex. 891, Test. Dr. Clark 2313-14.) If a woman with a transplanted organ elects to have an abortion, either labor induction or dismemberment D&E are appropriate second-trimester abortion techniques in Dr. Clark's opinion. (Ex. 891, Test. Dr. Clark 2349 & 2374-75.)

### *ii. FETAL INDICATIONS*

#### *(a) TYPES OF ANOMALIES*

Rebecca Baergen, M.D., is a board-certified clinical pathologist, professor of clinical pathology and laboratory medicine, attending pathologist, and chief of perinatal and pediatric pathology at the Joan and Sanford I. Weill Medical College and Graduate School of Cornell University. She specializes in perinatal, placental, and gynecological pathology which includes the study of fetal, placental, and female reproductive organ abnormalities. (Ex. 119, Test. Dr. Baergen 1089-92, 1093 & Sub-Ex. 119A.)

Dr. Baergen defines a fetal anomaly as an external or internal abnormality of the fetus. According to Dr. Baergen, a fetal syndrome is characterized by a collection of specific abnormalities that typically occur together and, when seen in combination, suggest a particular disease process or etiology. (Ex. 119, Test. Dr. Baergen 1098-99.)

Dr. Broekhuizen testified that the diagnosis of chromosomal abnormalities is often performed early in pregnancy with chorionic villus sampling or DNA analysis, especially when there is a known increased risk of fetal genetic problems, and structural fetal anomalies are often diagnosed by ultrasound later in the pregnancy.[64] In the geographic area of Wisconsin, for example, most fetal anomalies are diagnosed after 16 weeks. (Ex. 120, Test. Dr. Broekhuizen 498-99; see also Ex. 125, Test. Dr. Paul 18-19 (abortions for chromosomal and structural fetal anomalies generally performed after first trimester because that is when diagnosis is most likely to occur; some anomalies and abnormalities do not appear on ultrasound until second or third trimester, and some genetic testing cannot be performed before second trimester); Ex. 126, Test. Dr. Westhoff 807-09 (some chromosomal abnormalities diagnosed in first trimester, but for most patients, fetal genetic and chromosomal abnormalities not diagnosed until second-trimester amniocentesis performed; abnormal heart most likely detected at or after 20 weeks of gestation, and hydrocephalus diagnosed around 18 to 20 weeks).)

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[64]Dr. Paul stated that ultrasound is the most common way to assess fetal health; is usually performed between 13 and 20 weeks; and is very good, but not 100% accurate, at diagnosing apparent birth defects such as anencephaly and the absence of kidneys. (Ex. 125, Test. Dr. Paul 19-20.) Dr. Chasen testified that invasive tests to detect genetic conditions include chorionic villus sampling at the end of the first trimester and amniocentesis in the second trimester (typically at 15 to 20 weeks of gestation). (Ex. 121, Test. Dr. Chasen 1550-51.) According to Dr. Paul, the latter two procedures are not routinely performed on pregnant women because there are medical risks associated with the procedures which must be balanced against the very low incidence of fetal anomalies in the general population. However, women with a family history of genetic abnormality, older women, and women whose ultrasounds reveal the presence of excessive or insufficient amniotic fluid have a higher risk of genetic abnormality in the fetus. Dr. Paul also testified that for women at risk, an amniocentesis is usually performed at approximately 16 to 18 weeks of gestation and the results are not available until a week thereafter. Amniocentesis may also be performed in the third trimester. (Ex. 125, Test. Dr. Paul 20-21.)

According to several of the physicians offering testimony in this case, some of the "fetal indications" for which abortions are performed include genetic abnormalities in the fetus (trisomy 13, 18, and 21[65] and monosomy X) that can be incompatible with life, as well as structural abnormalities such as fetal hydrops, a generalized swelling of the fetus; head abnormalities like anencephaly,[66] holoprosencephaly,[67] and hydrocephalus[68]; serious cardiac anomalies; absent or polycystic kidneys; non-development of the fetal lungs; abdominal wall abnormalities; abnormalities of the limbs; Fabry's disease; spina bifida; and cleft palate. (Tr. 34-35, Test. Dr. Doe; Tr. 501, Test. Dr. Knorr; Tr. 315, Test. Dr. Vibhakar; Ex. 120, Test. Dr. Broekhuizen 498.)

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[65]Dr. Clark testified that an abortion to terminate a fetus with trisomy 21 (Down's Syndrome) is an elective abortion in that the pregnancy does not pose a risk to the mother's health. However, unlike elective abortions where the woman simply chooses not to be pregnant, Down's Syndrome is an example of an unfortunate circumstance which requires the woman to make an important personal decision regarding abortion of an otherwise wanted child. If the woman elects to abort the fetus, either labor induction or dismemberment D&E are appropriate second-trimester abortion techniques in Dr. Clark's opinion. (Ex. 891, Test. Dr. Clark 2383-85.)

[66]"Anencephaly" means "[c]ongenital defective development of the brain, with absence of the bones of the cranial vault and absent or rudimentary cerebral and cerebellar hemispheres, brainstem, and basal ganglia." Stedman's Medical Dictionary 76 (27th ed. 2000).

[67]"Holoprosencephaly" is the "[p]resence of a single forebrain hemisphere or lobe; cycloplia occurs in the severest form. It is often accompanied by a deficit in median facial development." Stedman's Medical Dictionary 827 (27th ed. 2000).

[68]"Hydrocephalus" is a "condition marked by an excessive accumulation of cerebrospinal fluid resulting in dilation of the cerebral ventricles and raised intracranial pressure; may also result in enlargement of the cranium and atrophy of the brain." Stedman's Medical Dictionary 839 (27th ed. 2000).

Drs. Chasen and Broekhuizen characterized some of these fetal anomalies as incompatible with life, including anencephaly, trisomy 13 or 18, triploidy, and severe cardiac anomalies. (Ex. 121, Test. Dr. Chasen 1600; Ex. 120, Test. Dr. Broekhuizen 496-97.) Dr. Broekhuizen pointed out that when an anomalous fetus delivers until the head is lodged against the cervical os, the doctor may see the fetus move. Even in cases of anencephaly, a lethal fetal anomaly, the fetus may be living and may survive after birth for a few months. (Ex. 120, Test. Dr. Broekhuizen 607.)

According to Dr. Cook, lethal[69] fetal anomalies that can cause maternal complications include nonimmune hydrops, which is similar to congestive heart failure in the fetus and can cause a "mirror syndrome" in the mother creating a preeclamsia-like condition; fetal conditions that cause increased amniotic fluid volume which can impair maternal breathing and normal respiration; partial molar gestation, which can lead to maternal hypertensive disease and significant bleeding; and conjoined fetuses which necessitate abdominal delivery. (Tr. 1377-79, Test. Dr. Cook.)

In Dr. Broekhuizen's view, there are also fetal anomalies which have a direct effect on the mother's ability to deliver the infant because the infant is too large to pass through the birth canal. Examples of such conditions include macrocephaly, where the head is too big to deliver, and immune hydrops or fetal ascites, where fluid and edema accumulate in the abdomen or all the fetal tissues and the fetal body is too large to deliver. In such cases, Dr. Broekhuizen believes induction after 24 weeks is appropriate to avoid the necessity of surgical procedures for delivery that are associated with higher morbidity and mortality rates, including cesarean section or hysterotomy. (Ex. 120, Test. Dr. Broekhuizen 499-500.)

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[69]Dr. Broekhuizen testified that a lethal fetal anomaly exists when there is no long-term meaningful life expectancy and death would be expected within hours and sometimes weeks of birth. (Ex. 120, Test. Dr. Broekhuizen 485.)

Dr. Clark opined that for the most part, fetal anomalies have nothing to do with the mother's health and do not require termination of the pregnancy. Exceptions include extreme cases of hydrocephalus or possibly conjoined twins. (Ex. 891, Test. Dr. Clark 2378-79.)

In fetal-indication cases, Dr. Doe makes "a much more determined effort to deliver the fetus as intact as possible," that is, with "no marks at all and the head completely intact" and not compressed. (Tr. 50, Test. Dr. Doe.) Dr. Doe attempts to achieve more generous dilation when performing a D&E for fetal indications, allowing him or her to remove the fetus with less trauma.

> In the fetal indication procedure, it's much more important to be able to get an accurate pathological diagnosis to verify the abnormality. And, also, these are pregnancies, generally, that were planned and very much wanted, and the patient and family are going through a very stressful time and frequently want the opportunity to say good-bye to the fetus, to be able to hold it and examine it. So I make a special effort to deliver the fetus with as little trauma as possible, so they can hold the fetus and examine it.

(Tr. 42-43 & 56-58, Test. Dr. Doe (many patients aborting wanted pregnancies for fetal anomalies wish to see, touch, and hold the aborted fetus "and cry, and say good-bye"; some patients wish to have a burial or memorial service).)

### *(b) PATHOLOGICAL TESTING*

According to Dr. Baergen, the most important characteristic of a specimen for making an accurate pathological diagnosis of a fetal anomaly or syndrome is having an intact specimen. (Ex. 119, Test. Dr. Baergen 1109.) The more intact the fetal specimen received, the greater the pathologist's ability to analyze that specimen and correctly diagnose fetal anomalies, identify specific fetal abnormalities, and determine

a diagnosis of what disease or disease process caused the anomalies or abnormalities. (Ex. 119, Test. Dr. Baergen 1098.)

Examples of fetal anomalies or syndromes where intact specimen evaluation is particularly useful to Dr. Baergen include congenital heart abnormalities, where the heart and lungs must be intact to evaluate the vessels of organ structure; laterality syndrome, where the abdomen must be intact to determine if the fetus had two left sides (e.g., two spleens and no heart) or two rights sides (e.g., two hearts and no spleen); and VATER, a fetal syndrome involving multiple organ defects. (Ex. 119, Test. Dr. Baergen 1107-09.)

Dr. Baergen explained that a pathologist's examination of a fetal specimen begins with a gross examination looking for abnormalities visible to the naked eye. Following the gross examination, the pathologist performs a microscopic examination on specific sections of the fetal tissue. A third method of evaluation uses x-rays or radiographs to determine and identify specific bony abnormalities. Dr. Baergen stated that regardless of the age of the fetus, when a fetus is removed in pieces or with significantly disrupted tissues as a result of an abortion procedure, it is difficult for pathologists to perform a reliable gross examination of the specimen or to identify particular organs or tissues for microscopic evaluation. Moreover, the microscopic assessment of the tissue architecture for diagnosing certain organ abnormalities is limited if the organs themselves are disrupted. When the fetal tissue is disarticulated, pathologists are unable to assess the interrelationship or layout of the fetus's bony structure and may be unable to identify bones that were broken or disrupted. Once the joints are disarticulated or disconnected, the structure of the fetal joints cannot be evaluated. The more disrupted the fetus, the less information the pathologist can obtain from a pathological examination. (Ex. 119, Test. Dr. Baergen 1099-1103.)

Dr. Baergen testified that analyzing specimens obtained through amniocentesis and chorionic villus sampling ("CVS"—that is, removing a sample of the chorionic

villi of the placenta) can assist with the diagnosis of chromosomal and genetic fetal abnormalities such as cystic fibrosis, Tay Sachs, and trisomy 13, 18, or 21. However, amniocentesis and CVS samples cannot feasibly be used to screen for the majority of the known fetal abnormalities and syndromes. In addition, Dr. Baergen stated that fetal chromosomal analysis is not often done on second-trimester fetuses because chromosomal anomalies usually lead to spontaneous abortion in the first trimester. (Ex. 119, Test. Dr. Baergen 1103-06 & 1132-36.)

Dr. Baergen cautioned that ultrasound examination cannot replace pathological examination of the fetus because ultrasounds are not completely accurate, and for specific diagnosis, ultrasound imaging of a fetus in a certain plane cannot replace the information gained from a three-dimensional and microscopic evaluation of the fetal tissue. (Ex. 119, Test. Dr. Baergen 1106-07 & 1131.)

According to Dr. Baergen, an accurate diagnosis of a fetal anomaly or syndrome is important to determine if the problem sporadically occurs or if it was inherited and therefore presents a recurrent risk in future pregnancies. Such a diagnosis is used to counsel patients on the recurrence risk based on previous experience with a particular fetal anomaly or syndrome. (Ex. 119, Test. Dr. Baergen 1109.)

Dr. Baergen testified that delivery of an intact fetus correlates with an intact placenta; if the fetus is disrupted, the placenta is also likely to be disrupted. Some fetal developmental problems initially appear to be fetal anomalies when the real cause is a placental abnormality. In such cases, Dr. Baergen believes an accurate diagnosis of the placental abnormality can assist physicians in treating the underlying condition in the mother and permit her to have a subsequent pregnancy and a normal baby. (Ex. 119, Test. Dr. Baergen 1114-15, 1118-19, 1136.)

Drs. Baergen and Broekhuizen testified that an intact brain assists in the pathological diagnosis of abnormalities of the brain such as Arnold-Chai malform-

ation, agenesis of corpus callosum, Dandy-Walker syndrome, holoprosencephaly, cerebral ventriculomegaly, cisterna magna cyst, and porencephalic cyst. Brain anomalies represent only a minority of the total fetal anomalies. The intact D&E procedure makes it more difficult to diagnose brain abnormalities. (Ex. 119, Test. Dr. Baergen 1123-26 & 1136; Ex. 120, Test. Dr. Broekhuizen 581-82; Ex. 123, Test. Dr. Frederiksen 1220-21 (intact D&Es produce intact fetuses for pathological evaluation, but this procedure cannot be used to confirm diagnosis that fetus had intracranial defect; fetuses delivered by induction are fully intact and can be fully evaluated).)

Dr. Baergen believes an intact fetal face may be useful in diagnosing fetal anomalies such as osterogenesis imperfecta and encephaly. The intact D&E procedure may, but usually does not, impact the facial structure of the fetus. (Ex. 119, Test. Dr. Baergen 1126-28 & 1136; Ex. 126, Test. Dr. Westhoff 831-32 (intact D&E involves suctioning intracranial contents of fetal head through incision at base of skull, but facial structures are not disturbed by the process).) Dr. Baergen also believes having the rear of the fetal head intact may assist in diagnosing anomalies involving the base of the skull and spine, such as encephalocele and spina bifida. (Ex. 119, Test. Dr. Baergen 1128-29.)

Dr. Baergen does not routinely know what abortion procedures were used to terminate the pregnancies that resulted in the fetuses she examines. Only 30% of the fetuses Dr. Baergen receives for pathological evaluation are completely intact. (Ex. 119, Test. Dr. Baergen 1121-22.) There are no studies or literature comparing the method of abortion with the ability to diagnose fetal anomalies, according to Dr. Baergen. (Ex. 119, Test. Dr. Baergen 1122.)

Dr. Baergen said that the labor-induction method of abortion generally results in a completely intact fetus. (Ex. 119, Test. Dr. Baergen 1129.) However, if the fetus dies in utero and is retained for a period of time, the fetus undergoes degenerative changes, autolytic change, and maceration of the fetal tissue, which hampers the

pathological interpretation and diagnosis of fetal anomalies and abnormalities. (Ex. 119, Test. Dr. Baergen 1136.)

### *(c) PHYSICIANS' PRACTICES IN FETAL-ANOMALY CASES*

With his fetal-indication patients, Dr. Doe intends to deliver an intact fetus so that the preoperative diagnosis can be confirmed and patients can be appropriately counseled regarding future pregnancies. He believes that while genetic abnormalities almost always can be confirmed by analysis of fetal tissue, structural abnormalities may require testing of an intact fetus, and "[o]n occasion, [pathologists] are not able to confirm the diagnosis because there is too much fetal disruption." (Tr. 54-56, Test. Dr. Doe.)

While Dr. Doe does not believe that the intact D&E procedure is "necessary" for pregnancy terminations involving certain fetal anomalies, he believes the intact D&E would be "preferable" for pathological and grieving reasons. (Tr. 110-11, Test. Dr. Doe.)

Dr. Chasen stated that for abnormalities not involving the brain, the intact D&E procedure maximizes the pathologist's opportunity to correctly identify a fetal anomaly and, in turn, permits appropriate counseling to the parents because the tissues and organs are preserved and are not disrupted. (Ex. 121, Test. Dr. Chasen 1603.) However, Dr. Chasen believes that genetic abnormalities can be diagnosed on any fetal tissue, even a dismembered fetus. (Ex. 121, Test. Dr. Chasen 1686.)

Dr. Cook testified that if an intact fetus is deemed necessary or desirable for purposes of pathological testing, a safe alternative to the intact D&E procedure is induction of labor or cesarean delivery. (Tr. 1336, Test. Dr. Cook.)

Dr. Lockwood testified that if chromosomal analysis of a fetus is necessary, "a piece of placenta or amniotic fluid sample would be sufficient." If anatomic analysis of the fetal brain or central nervous system is necessary, Dr. Lockwood opined that a medical-induction abortion would be more appropriate in order to obtain an intact fetus, barring any contraindications to that procedure. The intact D&E procedure might "allow better diagnostic information" of the thorax and fetal extremities, which could be damaged during a D&E involving dismemberment. However, "in point of fact, there are very rare circumstances in which [Dr. Lockwood] will tell a patient she should have a medical abortion rather than a D&E to terminate an anomalous fetus." (Tr. 1726-27, Test. Dr. Lockwood.)

If delivery of an intact fetus for pathological purposes is necessary, Dr. Lockwood thinks that the use of digoxin or potassium chloride to ensure fetal demise at the outset of the procedure would not negatively affect a physician's ability to make a pathological assessment, as long as the interval between the injection and delivery was "not too long." (Tr. 1728, Test. Dr. Lockwood.)

### *c. INDUCING FETAL DEMISE*

Several witnesses testified that a physician could induce fetal demise before an abortion procedure to avoid performing an intact D&E on a living fetus. They explained that two main drugs are used to induce fetal demise prior to an abortion procedure. KCl, or potassium chloride, is injected directly into the fetal heart using ultrasound control. Digoxin, a heart medication, can be injected into the umbilical cord, heart, the muscle or body cavity of the fetus, or in the amniotic fluid, with or without ultrasound guidance. (Tr. 66-67, Test. Dr. Doe; Tr. 1702-03, Test. Dr. Lockwood.)

In Dr. Lockwood's opinion, it requires "significant skill" to inject digoxin into the umbilical cord, less skill to inject the fetal heart, still less skill to inject the fetal

body, and "very little" skill to inject the amniotic fluid. (Tr. 1703, Test. Dr. Lockwood.)

Beginning in the eighteenth week, Dr. Carhart injects the fetus with lidocaine and digoxin through the abdominal and uterine walls of the patient. Dr. Carhart stated that he is able to do intracardiac injections 95% of the time and intrafetal injections 5% of the time. The lidocaine anesthetizes the fetus and the digoxin causes fetal demise. According to Dr. Carhart, inducing fetal demise in this manor carries "a significant mortality morbidity risk," as well as risk of infection, intrauterine and intra-amniotic bleeding if "you happen to hit an artery vessel in the placenta," and bleeding in the uterine and abdominal cavities and in the abdominal walls. However, Dr. Carhart has never had a complication in performing this procedure. (Tr. 607-08, 629-31, 632, 637, 671, Test. Dr. Carhart.)

Dr. Carhart testified that inducing fetal demise prior to performing an abortion causes the patient's uterus to contract, making it easier to insert the second round of laminaria to achieve greater dilation. He explained that fetal demise also stops the blood flowing through the placenta, thereby causing the placenta to "shrivel," loosening the connection between the placenta and the uterine wall, softening fetal tissue, and enabling Dr. Carhart to remove the placenta and fetus intact with only minimal cleanup required in the subsequent D&C. When Dr. Carhart induces fetal demise on the first day and performs the abortion two days later after two rounds of laminaria, he sees a two-week decrease in the size of the fetal cranium that must ultimately be delivered. (Tr. 634-37, Test. Dr. Carhart.)

Dr. Carhart has had "a few" patients for whom his method of inducing fetal demise was contraindicated. While Dr. Carhart has attempted to induce fetal demise prior to 18 weeks, he "quit very soon" because the "risks and the benefits did not weigh out in the patient's favor." It was much harder for Dr. Carhart to locate the fetus earlier than 18 weeks because the smaller the uterus, the deeper it lies within the

pelvis and the more likely it is to be obstructed by the ovaries, "tubes," bowel, and bladder. (Tr. 630 & 637-38, Test. Dr. Carhart.)

For Dr. Carhart's 18- to 24-week patients to whom he administers digoxin to kill the fetus before its expulsion, he was unable to cause fetal demise in one case involving a 21-week twin pregnancy. In that case, Dr. Carhart performed the fetal injection and began inserting laminaria when the patient began bleeding with increasing severity. Dr. Carhart administered a number of medications in an attempt to slow the blood flow, which gave him 20 minutes to complete the abortions with two centimeters or less of dilation. Because of the extent of the patient's bleeding, Dr. Carhart felt he could not wait the 30 to 90 minutes it would take for the injection to cause fetal death. (Tr. 740-43, Test. Dr. Carhart.)

Dr. Fitzhugh does not induce fetal demise before beginning an abortion procedure. He testified that he is uncomfortable administering the injections necessary to induce fetal demise; he has little experience performing amniocentesis, as all such procedures are performed by maternal-fetal specialists in Dr. Fitzhugh's hospital; he prefers not to decide whether such an injection is necessary; and the advantages of inducing fetal demise before abortion procedures have "not been shown" to him. (Tr. 251-52 & 254-56, Test. Dr. Fitzhugh.)

When Dr. Fitzhugh has aborted pregnancies in which fetal demise has occurred naturally, he described the D&E procedure as easier because the fetal ligaments at the joints were easier to disarticulate because fetal death had occurred prior to the abortion. (Tr. 284-85, Test. Dr. Fitzhugh.)

From operating an abortion practice in Alabama, Dr. Knorr is experienced at administering injections to cause fetal demise. Alabama law at the time he practiced there required that digoxin be used to induce fetal demise after 18 weeks of gestation. Therefore, while the use of digoxin was within the standard of care in Alabama after

18 weeks LMP, it is not Dr. Knorr's current practice to do so on all patients because it would "subject [his] patients to unnecessary discomfort and medical risk." Dr. Knorr does not believe that this standard of care necessarily applies outside of Alabama. (Tr. 559-61 & 566-67, Test. Dr. Knorr.)

Prior to performing an abortion, Dr. Knorr currently "[v]ery rarely" induces fetal demise. When he does so, his patients are beyond 22 weeks of gestation. He does not "believe in it" because it is an "extra procedure, and, . . . [h]arm . . . can be accomplished in the most benign type of procedure." Specifically, it concerns Dr. Knorr to administer lanoxin, KCl, or digoxin when patients have had prior surgery or pelvic inflammatory disease with adhesions in the pelvis. While such injections can puncture a bowel or maternal vessel, cause sepsis or drug reactions, and can be frightening and expensive for patients, Dr. Knorr has not caused a bowel or vessel puncture or sepsis from such an injection. (Tr. 511-12 & 561-62, Test. Dr. Knorr.)

When he does induce fetal demise prior to performing an abortion and when there is a presenting fetal part at the lowest point of the uterus, Dr. Knorr numbs the patient's vagina and then, with sonographic guidance, delivers digoxin through the vagina. Dr. Knorr testified that this procedure spares the patient from seeing a needle being inserted into her abdomen and the patient will feel only a small pinch on her numbed vaginal skin. (Tr. 562-63, Test. Dr. Knorr.)

Dr. Vibhakar does not induce fetal demise prior to performing abortions with intrauterine or intrafetal injections of digoxin or KCl because "[i]t's not deemed necessary, and it would add an increased burden to the girl/woman with an additional procedure and small risk associated with that, and more anxiety and discomfort and expense and time involved." Such injections, like amniocentesis, can very rarely result in "infection, bleeding and even death." (Tr. 347-49, Test. Dr. Vibhakar.) However, it is the policy of the University of Iowa where Dr. Vibhakar is employed

to induce fetal demise after 22 weeks prior to performing induction abortions to avoid delivery of a live fetus.

> Even if it's truly 22 weeks and nonviable, it involves less, might be less traumatic on the mother, and then if it is, if the dating is off, there is poor dating or because ultrasound dating can be off by 20%, then it avoids confusion on the part of the staff in regard to resuscitation issues.

(Tr. 393-94, Test. Dr. Vibhakar.)

Two days before Dr. Doe performs an abortion in his or her maternal-indication cases, Dr. Doe injects digoxin starting at 18 weeks in order to soften fetal tissues and to make it easier and safer to remove fetal parts through the cervix, even with inadequate dilation. Dr. Doe testified that prior to 18 weeks, the fetus is small and soft and dilation is usually adequate enough such that inducing fetal demise is not necessary. Further, the patient's uterus is smaller, making it technically difficult to correctly position the needle and avoid injecting maternal structures such as the bowel, which, prior to 18 weeks, are located between the patient's abdominal wall and uterus. Dr. Doe testified that perforating a bowel may cause no damage, or it could cause the patient's bowel contents to spill, creating a significant risk of a severe life-threatening infection such as peritonitis, an infection of the lining of the abdominal cavity. (Tr. 67-69, Test. Dr. Doe.)

Dr. Doe estimates that out of the 50 to 100 digoxin injections performed in his or her career, he or she has not caused any infections or perforated any blood vessels or internal organs. Dr. Doe thinks the risks of intrauterine injection of digoxin are "very low" after 18 weeks, and that the skills necessary to inject digoxin can be learned by a clinical practitioner. (Tr. 118-19, Test. Dr. Doe; Ex. 123, Test. Dr. Frederiksen 1154-55 (Dr. Frederiksen learned how to perform fetal intracardiac injections during maternal-fetal medicine training; this skill is specialized and not routinely taught to obstetricians and gynecologists).)

Dr. Doe has tended to patients whose diagnostic amniocentesis caused intrauterine fetal demise, rupture of membranes, and infection necessitating evacuation of the uterus. Dr. Doe stated that long-term complications such as infertility can result from such an infection that spreads outside the uterus. (Tr. 147-48, Test. Dr. Doe.) Dr. Cook testified that injections into a woman's abdomen create potential risks for infection and maternal sepsis, but "the risks are fairly small." (Tr. 1458, Test. Dr. Cook.)

Dr. Doe believes that KCl and digoxin injections are, in skilled hands, generally safe for the patient, but they are of no medical benefit to the patient. (Tr. 71 & 124, Test. Dr. Doe; Tr. 972, Test. Dr. Bowes (no medical benefit to woman to inject substances to cause fetal demise in second trimester; injections cannot be given to all women in all circumstances; all physicians are not skilled enough to perform the injection).) However, Dr. Doe observed that inducing fetal demise in this manner prior to performing an abortion does provide a "psychological benefit to the patient, family and medical and nursing staff in knowing that . . . [the] 'fetus does not feel any pain,' and in the event of a premature . . . delivery . . . induced by the osmotic dilator insertions, there is no possibility there will be any sign of life, fetal life, which, if it occurs, can be very distressing." (Tr. 123-24 (statement in letter attributed to Dr. Doe that accurately reflects Dr. Doe's views); Tr. 151, Test. Dr. Doe.)

Dr. Doe does not induce fetal demise in fetal-indication cases because hospital perinatologists are responsible for performing KCl injections at 22 weeks and up. Some injections are performed prior to 22 weeks if requested by a patient. Before 22 weeks, "you can be very certain that there will be fetal demise during the extraction or induction procedure, and after that, there may be some signs of fetal life which is very disturbing to the patient and to the nursing staff." (Tr. 69-70, Test. Dr. Doe.)

Dr. Doe testified that the longer a fetus remains in the uterus following the perinatologist's KCl injection, the greater the amount of fetal tissue softening and

fragility, making it more difficult for Dr. Doe to remove the fetus in large pieces or intact. (Tr. 70-71, Test. Dr. Doe.) Dr. Lockwood agreed: "The longer the interval of fetal death, the more the tissue would become macerated and softer, and more compliant, and presumably the less risky the procedure would be for a D&E." (Tr. 1703, Test. Dr. Lockwood.)

Dr. Chasen does not routinely induce fetal demise because he believes: (1) in utero fetal death may interfere with the pathologist's review of the fetus since fetal death prompts the maceration and decay process, and (2) the procedure causes patient discomfort, there are rare medical complications, and it is difficult and occasionally impossible to do. (Ex. 121, Test. Dr. Chasen 1636 & 1638.)

However, Dr. Chasen will induce fetal demise upon patient request. In cases where the fetus is at 23 weeks of gestation and there is no lethal abnormality, Dr. Chasen warns the patient that inserting laminaria can prompt labor and the delivery of a live baby, and the patient is allowed to choose whether fetal demise should be induced. Dr. Chasen stated that he induces fetal demise prior to inserting laminaria and performing the abortion procedure in some patients by injecting a needle directly into the fetal heart and administering potassium. (Ex. 121, Test. Dr. Chasen 1570-71 & 1636-37.)

Dr. Broekhuizen has never induced fetal demise before performing a D&E. However, he has introduced digoxin into the amniotic fluid when he has induced fetal demise during an induction abortion. He has performed this procedure approximately 30 to 40 times and has never seen any maternal complications, but on two occasions, the procedure failed to induce fetal demise. (Ex. 120, Test. Dr. Broekhuizen 607, 634-35, 641.)

Drs. Chasen and Frederiksen testified that injecting potassium chloride into the fetal heart may not be an available option if the woman is obese, the uterus is distorted

by benign fibroid tumors, the fetal heart and umbilical cord are not close to the surface of the maternal abdomen, or the woman is afraid of needles and will not remain still for the procedure. Moreover, the mechanics of ultrasound depend on the presence of fluid and, for some fetal abnormalities or where the woman's membranes have ruptured, there is no amniotic fluid. In these cases, ultrasound cannot be used to assist in locating and injecting the fetal heart. (Ex. 121, Test. Dr. Chasen 1638-39; Ex. 123, Test. Dr. Frederiksen 1149-52 & 1181 (inducing fetal demise by injecting fetal heart with KCl or digoxin cannot always be accomplished, such as when the mother is very obese, the fetus is in a position which hinders access to the fetal heart, the fetal heart is difficult to visualize by ultrasound, or there is no interface between the fetal and maternal tissue due to the lack of amniotic fluid; in such cases, digoxin can be injected into the muscle of the fetus, but this is not always successful).)

According to Dr. Chasen, a doctor may induce fetal demise by cutting the umbilical cord, but this introduces a forceps into the woman's uterus, posing the risk of complications that may accompany that procedure. The fetal death is not instantaneous and can take several minutes, which prolongs the operative time and increases the risk of bleeding and infection. (Ex. 121, Test. Dr. Chasen 1639-41; see also Ex. 891, Test. Dr. Clark 2417 (Dr. Clark has never induced fetal demise with injection or asphyxiation before performing an abortion; if the cord is clamped, it may take fetus 10 to 15 minutes to die from lack of oxygen).)

Dr. Lockwood stated that KCl injections are used at Yale University for "multifetal reductions"—for example, KCl may be injected into three out of six embryos that are being carried by one woman. (Tr. 1702, Test. Dr. Lockwood.) The risks of digoxin or KCl injections are "presumably negligible," but "not zero." Dr. Lockwood would "certainly not want to do [such injections] in a patient with HIV or hepatitis." (Tr. 1757, Test. Dr. Lockwood.)

Dr. Broekhuizen testified that while inducing fetal demise may avoid delivery of a live fetus as referenced in the Act, inducing fetal demise is a very personal decision. The doctor explained that some patients do not want to induce fetal demise because they do not want to undergo the procedure. Some patients whose fetuses have lethal anomalies desire a live birth, allowing the fetus to die in their arms. For religious reasons, perhaps based on the distinction between blessing and baptizing a child, others will not permit fetal demise to be induced. Others believe inducing fetal demise provides comfort in the pregnancy-termination procedure. (Ex. 120, Test. Dr. Broekhuizen 561-62.)

When appropriate, Dr. Frederiksen induces fetal demise in both first- and second-trimester abortions. (Ex. 123, Test. Dr. Frederiksen 1179.) When inducing fetal demise, Dr. Frederiksen generally uses potassium chloride and injects the fetal heart under ultrasound guidance. (Ex. 123, Test. Dr. Frederiksen 1177.)

When induction is used to terminate a pregnancy, Dr. Frederiksen routinely induces fetal demise because she believes there is a medical benefit in doing so. That is, studies indicate that delivery of the fetus by induction with misoprostol takes less time if the fetus is dead. (Ex. 123, Test. Dr. Frederiksen 1151, 1177, 1183.) In contrast, unless the patient requests it, Dr. Frederiksen does not induce fetal demise before D&E procedures because there is no medical benefit in doing so. (Ex. 123, Test. Dr. Frederiksen 1151 & 1179.)

Dr. Frederiksen views the risks associated with inducing fetal demise as:

* Infecting the tissues of the peritoneal[70] cavity and subcutaneous tissue by placing a needle through the abdominal wall into the uterus and withdrawing fluid through these abdominal tissues overlying the uterus. (Ex. 123, Test. Dr. Frederiksen 1152-53.) For a healthy woman, the risk of infection associated with inducing fetal demise is comparable to that of amniocentesis—1 in 1,000 patients. (Ex. 123, Test. Dr. Frederiksen 1177-78.) In Dr. Frederiksen's view, amniocentesis and fetal intracardiac injection should not be performed on women with sepsis because these procedures place a needle in an infected area of the body and withdraw it through maternal tissues. (Ex. 123, Test. Dr. Frederiksen 1181 & 1236-37; Ex. 121, Test. Dr. Chasen 1648-49 (in rare instances, injecting potassium chloride into the fetal heart precipitates infection; further, the procedure is uncomfortable, requiring the insertion of a needle into the abdomen, and can take five to ten minutes or perhaps longer).)

* With a prior incision into the abdomen, the patient may have scar tissue in the peritoneal cavity or bowel between the abdominal wall and uterus. A needle passing through the abdomen may perforate these tissues and increase the risk of infection. (Ex. 123, Test. Dr. Frederiksen 1153.)

* In women with bleeding disorders, such as disseminated intravascular coagulation, a low platelet count, or leukemia, passing a needle through the abdomen increases the risk of hemorrhage, especially in the subcutaneous tissues and peritoneal cavity. (Ex. 123, Test. Dr. Frederiksen 1153.)

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[70]"Peritoneal" relates to the peritoneum, which is the "serous sac, consisting of mesothelium and a thin layer of irregular connective tissue, that lines the abdominal cavity and covers most of the viscera contained therein." Stedman's Medical Dictionary 1353 (27th ed. 2000).

* If the needle is inadvertently placed in maternal rather than fetal tissue, injecting potassium chloride or digoxin places the mother at risk of experiencing cardiac arrythmia. (Ex. 123, Test. Dr. Frederiksen 1154.) This risk does not exist with amniocentesis, which involves only the removal of fluid, and not injection of fluid into the woman. (Ex. 123, Test. Dr. Frederiksen 1235-36.)

Dr. Westhoff usually does not induce fetal demise by injecting the fetus or the amniotic fluid with potassium chloride or digoxin because the procedure offers no benefit to the woman, can be difficult, has associated risks, and can fail. (Ex. 126, Test. Dr. Westhoff 877.) In addition, Dr. Westhoff believes that inducing fetal demise results in softened fetal tissue, requires additional instrument passes to evacuate the uterus, and presents a greater risk of retained fetal tissue and infection. (Ex. 126, Test. Dr. Westhoff 879.)

Dr. Hammond has not been trained to induce fetal demise with either an intraamniotic or intrafetal injection of a chemical agent, so he chooses not to do it. According to Dr. Hammond, fetal demise is not routinely induced because there is no proven maternal benefit and there are some low risks associated with the procedure. (Ex. 124, Test. Dr. Hammond 614-15.)

### *d. FETAL PAIN*

Dr. Kanwaljeet Anand is a diplomate of the American Board of Pediatrics specializing in the care of critically ill children and infants who has researched neonatal and fetal pain for the past 20 years. He completed his medical degree, internship, and one year of a post-graduate pediatrics program in India. He then went to the University of Oxford on a Rhodes Scholarship for three years, after which he received a Doctor of Philosophy under the faculty of clinical medicine. At Oxford, Dr. Anand performed research showing that newborn infants "mount a massive hormonal

and metabolic response to surgery, and that this response can be suppressed, to some extent, by giving adequate anesthesia during the operative procedure." Dr. Anand then went to Harvard Medical School to complete a post-doctoral fellowship in the school's Department of Anesthesia, followed by a residency in pediatrics and fellowship training in neonatal and pediatric critical care. Dr. Anand then became an assistant professor of pediatrics, anesthesiology, psychiatry, and behavioral sciences at Emory University School of Medicine in Atlanta where he continued his studies on the physiology of pain and stress in early life. Currently, Dr. Anand is a professor of pediatrics, anesthesiology, pharmacology, and neurobiology at the University of Arkansas for Medical Sciences. He has published extensively in the areas of development of the pain system, the interaction between pain and stress in early life, pain management, and fetal pain and consciousness. He has never performed an abortion procedure. (Tr. 1000-08 & 1044, Test. Dr. Anand; Ex. 524.)

Dr. Anand believes there is an 80% probability that fetuses are sensitive to pain from about 20 weeks of gestation and thereafter because at 20 weeks, all of the anatomical structures necessary to experience pain are present, connected, and functional. These anatomical structures include skin receptors, sensory nerves, the dorsal horn of the spinal cord, brain stem, thalamus, several subcortical structures, the cortex, and the insula. (Tr. 1014-24, 1032-33, 1068, Test. Dr. Anand.) By 20 weeks, the fetus has sensitivity to touch and sound and can exhibit physiological indicators of pain such as the secretion of stress hormones, changes in heart rate and blood flow, changes in electrical activity of the brain, and deep inspiration and expiration of the diaphragm similar to crying activity. (Tr. 1025-30 & 1034-35, Test. Dr. Anand.)

Dr. Anand testified that there exists a greater sensitivity to pain earlier in development. Because of the lack of descending inhibitory fibers that block incoming painful stimuli, the number of receptors in the skin, and the level of expression of various chemicals, Dr. Anand believes that a fetus is most sensitive to pain between 20 and 30 weeks of gestation, and that performance of the banned procedure on a fetus

in that age range would cause "severe and excruciating pain" to the fetus. Dr. Anand believes that disarticulation would cause "severe pain" to the fetus in that gestational range, and a fetal injection of digoxin or KCl would also cause pain.[71] (Tr. 1036-38 & 1044-46, Test. Dr. Anand.) While he has not performed studies measuring the effects of anesthesia on fetuses, Dr. Anand opined that in order to anesthetize the fetus against such pain, "toxic amounts" of anesthesia would have to be given to the mother. (Tr. 1049-52, Test. Dr. Anand.)

Dr. Anand admitted that none of the studies on which he relied in forming his opinion that a fetus can experience pain at 20 weeks "directly establish fetal pain at 20 weeks." Rather, Dr. Anand's opinion that a fetus can experience pain at 20 weeks is based on "inference and extrapolation" drawn from those studies, as well as from the existence, connectivity, and functionality of a fetus's anatomical structures at 20 weeks. However, "until the fetus is able to report to us, we don't know what it is experiencing." (Tr. 1032-35 & 1075-76, Test. Dr. Anand.)

Dr. Anand explained that "[t]here is disagreement in the medical community on the issue of whether fetuses, at 20 weeks and later, are able to feel pain." Specifically, there is a consensus in the medical community that is familiar with research in the anatomical development area that, at 20 weeks, the physical structures are in place that would allow a fetus to experience pain. However, others in the "relevant medical community" believe that fetuses do not have the mechanisms in place to transmit painful stimuli and perceive pain at 20 weeks. (Tr. 1059-68, Test. Dr. Anand.)

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[71]Dr. Anand explained that a newborn infant at full term has levels of endorphins that are "about 1,000-fold higher than the highest levels ever recorded in the adult human bloodstream. So the release of beta endorphin or other . . . chemicals that block the painful stimuli [produced by the birth process] would protect the newborn infant at full term." These protective mechanisms do not begin developing until about 32 to 34 weeks of gestation and are fairly well developed at full term. (Tr. 1047-48, Test. Dr. Anand.)

According to Dr. Anand, a fetus must have some level of consciousness to experience pain, and consciousness cannot be measured, even in adults. (Tr. 1069, Test. Dr. Anand.) There is "no consensus in the medical community about when fetal consciousness occurs, if at all." (Tr. 1072-73, Test. Dr. Anand.) Despite the "intense controversy in this area," Dr. Anand believes that a fetus experiences consciousness "around the time that the pain system is completely developed," or about 20 weeks of gestation, as suggested by observed fetal responses—independent of its mother's responses—to sound, touch, light, taste, and pain. (Tr. 1038-41, Test. Dr. Anand.)

Other physicians appearing as witnesses before the court offered the following opinions regarding fetal pain:

* Dr. Sprang believes that both the intact D&E and traditional D&E procedures would be "excruciatingly painful for a fetus." (Tr. 1240, Test. Dr. Sprang.)

* Dr. Lockwood believes that between 20 and 24 weeks, the physician should "do everything they can possibly do while respecting a woman's reproductive choices and autonomy to minimize trauma and pain to the fetus as long as it doesn't endanger the mother's health." (Tr. 1757, Test. Dr. Lockwood.)

* Dr. Creinin is not a fetal pain expert, but he advises patients that, based on the best data available, fetuses are unable to feel pain in the way humans do until 26 weeks of gestation. Based on studies by the Royal College of Obstetrics and Gynecology, Dr. Creinin explained that second-trimester fetuses may have pain receptors and reflexive movements, but they do not have conscious brains and are not aware of pain or their automatic reflexive acts in response to stimuli, similar to

patients who are under general anesthesia. (Ex. 122, Test. Dr. Creinin 722-27.)

* Dr. Westhoff does not know if the second-trimester fetus experiences fetal pain. She notes that the fetus pulls away or reacts during the needle injection of amniocentesis, but does not similarly respond during the D&E procedure. In her practice, the fetus is limp throughout the D&E, showing no responsive or spontaneous motion. She believes the fetus does not respond during the D&E because intravenous analgesics and anesthesia have been administered to the mother. (Ex. 126, Test. Dr. Westhoff 783-85 & 800.)

* When Dr. Hammond performs D&Es after 16 to 18 weeks of gestation, the mother is placed under deep sedation which he believes may confer some pain relief to the fetus. Under the current state of the literature, it is difficult for Dr. Hammond to say whether the fetus feels pain at all, and if it does, there is no information comparing the relative levels of pain a fetus may experience from puncturing the fetal skull and severing the spinal cord, intracardiac fetal injection, toxic amniotic fluid, dismemberment, or asphyxiation. (Ex. 124, Test. Dr. Hammond 662-64.)

* In about 70% of Dr. Frederiksen's cases, the umbilical cord comes down when the amniotic fluid is suctioned from the uterus. The cord can then be cut, which leads to death. Dr. Frederiksen testified that this is one way of attempting to reduce any possibility of fetal pain, but it cannot be accomplished in every circumstance. (Ex. 123, Test. Dr. Frederiksen 1075.)

### *e. VIABILITY*

Many of the witnesses appearing before the court testified regarding their definitions of fetal "viability."

Dr. Paul explained that based on medical definitions, a living fetus is a fetus at 10 weeks of gestation that has a heartbeat. Before 10 weeks of gestation, the products of conception are known as an embryo. A living fetus is not synonymous with a viable fetus. (Ex. 125, Test. Dr. Paul 76.)

According to Dr. Lockwood, viability is both a legal and clinical concept. Legally, viability varies by state—some states set viability at 26 weeks, many set it at 24 weeks, and in some states, "it's well beyond that." (Tr. 1679, Test. Dr. Lockwood.) From a practical and clinical perspective, viability means "that point at which there is a meaningful probability of survival of the fetus" outside the body of the mother. Dr. Lockwood believes that 23 and 6/7 weeks is generally the point of viability, depending upon the condition of the fetus. (Tr. 1650 & 1679, Test. Dr. Lockwood (fetus that is infected, growth-retarded, small, and in extremis is probably not viable at 23 and 6/7 weeks).)

Many of the physician witnesses in this case testified that available data indicates that a fetus is viable at 24 weeks of gestation, meaning 24 weeks after the first day of the last menstrual period. (Ex. 125, Test. Dr. Paul 14-15; Ex. 120, Test. Dr. Broekhuizen 606 (fetal viability begins at "around 24 weeks"); Ex. 123, Test. Dr. Frederiksen 1162-63 (normal fetus viable at 24 weeks; there is data indicating that 24-week fetus has 50% chance of surviving delivery room); Ex. 126, Test. Dr. Westhoff 765-66 (fetal viability occurs when fetus is capable of sustained life outside the uterus; with excellent neonatal care, substantial number of fetuses will be viable after 24 weeks of gestation).)

Dr. Fitzhugh estimates viability to be 23 or 24 weeks based on his hospital's practice of trying to save babies that have a capability of life, such as those exhibiting breathing activity, at 23 weeks. (Tr. 283-84, Test. Dr. Fitzhugh.) Dr. Fitzhugh normally does not perform abortions after 22 weeks, except in occasional cases in which fetal demise has occurred naturally. (Tr. 284-85, Test. Dr. Fitzhugh.)

Dr. Knorr thinks a fetus is able to survive outside the mother late in the 23rd week of gestation. (Tr. 561, Test. Dr. Knorr.)

Defense witness Dr. Bowes has observed "wide interinstitutional variations" in "neonatal viability." (Tr. 960, Test. Dr. Bowes.) At Dr. Sprang's institution in Chicago, a fetus's chance of survival outside the womb is 1% at 22 weeks of gestation and 80% at 25 weeks. Dr. Sprang believes that viability is 23.0 weeks right now, but "[a]s modern medicine advances, the number keeps going down." (Tr. 1117, 1173, 1239, Test. Dr. Sprang; Tr. 1266-67 & 1432-33, Test. Dr. Cook (viability means the "ability to survive as a neonate, separate from the mother, while still availing itself of all the current medical technology that is available" and is 23.0 weeks and beyond, with national survival rates of 30 to 40% at 23 weeks).)

Dr. Carhart does not intentionally perform abortions after viability, a date which he says cannot be calculated purely by gestational age, but only by considering the overall health of the mother and fetus. "[W]hat's viable for one 23-week infant may not even be remotely possible . . . with another 23-week infant." If Dr. Carhart thinks a fetus is viable, he refers the patient elsewhere. (Tr. 736-38, Test. Dr. Carhart.)

Dr. Vibhakar testified that the gestational age of a fetus can be determined by ultrasound dating, last-menstrual-period dating (LMP), or in-vitro-fertilization dating. Depending upon the type of dating used, determining the gestational age of a fetus can be imprecise and could be off by up to two weeks. (Tr. 394, Test. Dr. Vibhakar.) Drs. Cook and Lockwood explained that the error range of ultrasound dating in the first

trimester is plus or minus one week; plus or minus up to two weeks of gestation in the second trimester; and plus or minus up to three weeks in the third trimester. It is conventional in clinical management of pregnancies to use LMP dating, but viability is more accurately measured by ultrasound dating. (Tr. 1268-69, Test. Dr. Cook; Tr. 1679-80, Test. Dr. Lockwood.)

Dr. Doe does not attempt to determine viability as a condition of his or her medical practice. If defined as ability to survive outside the mother, Dr. Doe believes that viability is variable because the measure of gestation is "always an estimate" that depends upon the method used to measure the length of gestation, the length of a woman's menstrual cycle, and variability in measurements done by ultrasound. The ability of a fetus to survive outside the womb also depends upon its health, the health of the mother, and whether delay or trauma has occurred during delivery. (Tr. 149-151, Test. Dr. Doe.)

### *2. COMPARATIVE SAFETY AND NECESSITY OF PROCEDURES*

The parties presented to the court a large number of witnesses and medical journal articles that expressed opinions on the comparative safety and necessity of various abortion procedures and established the existence of a medical debate regarding the safety and necessity issues. I shall describe that evidence next.

#### *a. WITNESSES' EXPERIENCE*

#### *I. RISK OF ABORTION PROCEDURES GENERALLY*

Statistics from the Centers for Disease Control ("CDC") for 1973 through 1999 reflect that 90% of all abortions are performed in the first trimester; 10% of abortions occur in the second trimester; and 1.5% of those second-trimester abortions occur after 20 weeks of gestation. (Ex. 126, Test. Dr. Westhoff 767-68.)

Dr. Paul testified that carrying a fetus to term is riskier than having an abortion as established by data from the CDC set forth in the JPSA study and the morbidity and mortality reports from 1972 through 1987 (see JPSA and Lawson article discussion, infra). (Ex. 125, Test. Dr. Paul 22 & 37-38.) Specifically, Dr. Paul testified that:

* Pregnancy-related mortality occurs in approximately 7 per 100,000 live births, with higher rates seen in older and African-American women. The risk of death for women over 40 is 5 times that of women under 20. (Ex. 125, Test. Dr. Paul 23 & 24.)

* Twelve hospitalizations per 100 deliveries result from pregnancy-related complications. (Ex. 125, Test. Dr. Paul 23-24.)

* Overall, the risk of death from childbirth is about 10 times greater than death from abortion. Under 16 weeks of gestation, the risk of abortion-related death is clearly less than the risk of death from carrying a pregnancy to term. At 16 weeks of gestation and higher, the risk of death associated with abortion and carrying a pregnancy to term are generally about equal. However, for older women, the risk of death from second-trimester abortion at 16 weeks or greater is lower than the risk of death from pregnancy. (Ex. 125, Test. Dr. Paul 37-38; Ex. 126, Test. Dr. Westhoff 804-05 (abortion safer than continuing pregnancy to term; risk of abortion complications increases with gestational age).)

* Based on the rate of complications, abortion is "hands down" a safer option than carrying a pregnancy to term. (Ex. 125, Test. Dr. Paul 37-38.)

Drs. Shadigian and Bowes believe that the safest and most appropriate abortion procedure for a particular woman depends upon the stage of pregnancy; the woman's

health; medical contraindications of the woman; the training, skill, and experience of the physician; the woman's prior surgical history; and whether the woman or her doctor wish to remove the fetus intact for pathological testing. Even if two abortion procedures are statistically similar in terms of risk, the safety for each particular woman depends upon her individual circumstances. With respect to any medical emergency exception to a procedure ban, "a physician should be permitted to rely on his or her own best medical judgment to determine if there is an emergency." (Tr. 975-78, Test. Dr. Bowes; Tr. 1563-64, Test. Dr. Shadigian.)

According to Dr. Lockwood, the skill of the physician performing the abortion procedure and the setting in which the abortion takes place both play a role in assessing the risk of various abortion procedures. Residents have higher complication rates than do senior, more experienced practitioners. And "one would assume that [a hospital] would be a safer environment" than a clinic that does not have access to "critical care specialists, rapid transfusions, superb anesthesia." (Tr. 1722-23, Test. Dr. Lockwood.)

Dr. Broekhuizen explained that a woman decides which method of abortion is to be carried out after receiving information from her physicians. For example, as part of this informed consent, Dr. Broekhuizen always advises his patients that cesarean section poses higher risks than either D&E or medical-induction abortion. (Ex. 120, Test. Dr. Broekhuizen 503-04.) However, the woman may choose a procedure with higher complication rates (such as cesarean section or hysterotomy) based on personal beliefs, even when a D&E is the safer option. (Ex. 120, Test. Dr. Broekhuizen 543-44.)

Dr. Lockwood testified that after 20 weeks of gestation, D&Es, intact D&Es, and medical-induction abortions are comparable in terms of safety. However, most abortions performed at or after 21 weeks are surgical abortions, as opposed to medical-induction abortions. (Tr. 1747, Test. Dr. Lockwood; Tr. 1407, Test. Dr. Cook

("[W]hen you look at various methods of doing a surgical procedure or emptying a uterus, and you get beyond 18 weeks [of] gestation, all the methods are of similar risk.").)

For each week of gestation beyond eight weeks, there is a "38% risk of increased risk of mortality." (Tr. 1708, Test. Dr. Lockwood.)

The leading complication in second-trimester abortion procedures is hemorrhage. (Ex. 123, Test. Dr. Frederiksen 1217.)

### *ii. DILATION*

When performing his version of the D&E, Dr. Carhart tries to achieve as much dilation as possible to enable him to remove the fetus in as few pieces as possible. In his experience, this technique requires fewer instrument passes; inflicts less damage on the uterus and cervix such as perforation or developing a "false passage, which means you have somehow gotten out of the cervical canal and you're creating a new tunnel through the cervix or through the uterus"; decreases risk of infection; and reduces problems with uterine bleeding and hemorrhage. (Tr. 626-28, Test. Dr. Carhart.)

Dr. Vibhakar is aware of evidence that suggests that a slower preparation or dilation of the cervix decreases the risk of uterine injury in general. She is also aware that misoprostol can result in side effects such as allergic reaction, chills, nausea, diarrhea, and fever. She describes these side effects as frequent, but mild. (Tr. 366, Test. Dr. Vibhakar.)

The "generous dilation" Dr. Doe uses for his or her D&E and D&X procedures allows Dr. Doe (a) to move and manipulate the forceps in a gentle manner so he or she can accurately locate the fetal part he or she intends to grasp; and (b) to more easily,

and with fewer passes, remove fetal parts through the cervix in large pieces, which reduces the likelihood of cervical damage from sharp, bony fragments and uterine perforation, allows Dr. Doe to more easily identify fetal parts so he or she can be sure the uterus has been completely emptied, and shortens procedure time, thereby reducing bleeding time. (Tr. 59-60, Test. Dr. Doe.) Dr. Doe testified that if fetal tissue is left inside the uterus, it will cause continued bleeding and possible infection, which, in turn, would require antibiotic treatment and another curettage procedure to remove the residual tissue. (Tr. 60-61, Test. Dr. Doe.)

As compared with D&E and D&X procedures using less dilation, Dr. Doe thinks that generous dilation "makes the procedure much safer and more comfortable. . . . the serious uterine injury complications that have occurred in my department over the years can almost always be linked to inadequate cervical preparation." These serious complications include uterine perforations, injury to intraabdominal organs like the bowel or bladder, and cervical lacerations, especially those that penetrate the full thickness of the cervix and extend into uterine blood vessels. Based on regular post-operative examination of patients who had extensive dilation with laminaria and based on his or her obstetrics work with patients who had incompetent cervix, Dr. Doe does not believe that generous dilation in his or her second-trimester procedures causes cervical incompetence in later pregnancies. Dr. Doe has "had patients who had severe cervical lacerations following Prostin induction and complications secondary to that, but [he or she hasn't] seen it following a D&E procedure." (Tr. 61-63, Test. Dr. Doe.)

In Dr. Doe's experience, there is no clinically significant difference in blood loss between an intact D&E and a nonintact D&E where significant dilation of the cervix has been obtained. (Tr. 98 & 141, Test. Dr. Doe.)

Dr. Cook believes that forced mechanical dilation of the cervix in a short time frame—as opposed to dilation of the cervix caused by the normal physiologic process

of uterine contractions—disrupts the "normal integrity of . . . the . . . cellular matrix or the collagenous cellular matrix of the cervix, which . . . makes up the normal architecture of the cervix." (Tr. 1356-60, Test. Dr. Cook.) However, Dr. Cook is not aware of any peer-reviewed scientific data analyzing the effects of slow, generous cervical dilation using osmotic dilators like laminaria or the use of prostaglandins to induce uterine contractions. (Tr. 1361, Test. Dr. Cook.)

Dr. Cook maintains that there "is an increasing body of evidence" that shows that people who have had first-trimester "induced" abortions—as opposed to spontaneous abortions or miscarriages—have "a higher risk for pre-term delivery and possibly low birth weight with subsequent pregnancies." In later-term abortion procedures where there is a greater amount of cervical manipulation, Dr. Cook is concerned there would be an even greater risk for preterm labor related to cervical weakness in subsequent pregnancies, and Dr. Cook claims that "there is data to suggest this." (Tr. 1361-64 & 1433-34, Test. Dr. Cook.) To his knowledge, Dr. Cook has never cared for a woman with cervical incompetence who has previously had an intact D&E procedure. (Tr. 1434, Test. Dr. Cook.)

Dr. Creinin testified that the cervix is 80% connective tissue and 20% muscle, and the uterus is a muscle. The cervix is generally very strong, but an incompetent cervix is unable to maintain its structure under the pressure of a growing pregnancy and painlessly dilates. (Ex. 122, Test. Dr. Creinin 690-91.) In a D&E, the cervix is dilated less and over a longer period of time than with a term labor and delivery. Dr. Creinin believes there is no physiological basis for concluding that the dilation in a D&E causes cervical incompetence. He testified that there are no medical studies to support a finding that D&E dilation increases the risk of cervical incompetence, and there is no common-sense reason to expect that it should. (Ex. 122, Test. Dr. Creinin 691-92.)

Dr. Shadigian understands the intact D&E procedure to involve two days of dilation with laminaria, as well as misoprostol in some cases. Placing dilators in the wrong place can create a false tract and manipulation of a woman's body to achieve dilation over two days can cause "longer-term effects," according to Dr. Shadigian. Dilation in a medical-induction procedure is not potentially as harmful as dilation with laminaria because, except in rare cases, "only medications that actually have the woman's body start a physiological process of contraction" are used in induction procedures. (Tr. 1530-32, Test. Dr. Shadigian.)

According to Dr. Broekhuizen, serial use of laminaria will likely increase the risk of infection due to prolonged exposure, and the insertion of laminaria may rupture the amniotic membrane and cause infection. Further, serial use of osmotic dilators may cause uterine cramping and may initiate labor. Dr. Broekhuizen believes that misoprostol causes more cramping than laminaria. (Ex. 120, Test. Dr. Broekhuizen 625-26 & 628.)

Dr. Westhoff testified that laminaria may cause uterine cramping and vaginal bleeding, similar to a menstrual period. In some cases, the patient cannot return to work and her normal daily activities. In rare cases, the woman's membranes may rupture. (Ex. 126, Test. Dr. Westhoff 999-1000). Dr. Westhoff testified that dilation with osmotic dilators is substantially slower and less than what occurs during delivery at term, thus, cervical dilation with osmotic dilators does not harm the cervix. (Ex. 126, Test. Dr. Westhoff 789-90.)

In Dr. Broekhuizen's opinion, up to 20 weeks of gestation, there is no increased risk of cervical incompetence caused by using gradual osmotic dilation and misoprostol to prepare the cervix. After 20 weeks, based on conflicting studies, Dr. Broekhuizen believes there may be a risk (albeit very low) of cervical incompetence created by the use of mechanical dilators. He stated that the level of risk after 20 weeks, if the risk exists at all, does not render the D&E procedure unsafe in

comparison with other procedures for terminating pregnancy or when weighed against the patient's reason for deciding to terminate the pregnancy. (Ex. 120, Test. Dr. Broekhuizen 545-47, 614, 624-25.)

### *iii. D&E BY DISMEMBERMENT*

Aside from his concerns about dilation, Dr. Cook believes that the extraction portion of second-trimester D&Es and intact D&Es performed on fetuses of the same gestational age create "comparable risk[s]." (Tr. 1424, Test. Dr. Cook.)

Dr. Lockwood testified that "prior to 20 weeks, there seems reasonable evidence that D&Es are associated with fewer complications than medical abortions, and that [at] 20 weeks, medical abortions appear to be associated with fewer significant complications than D&Es." (Tr. 1746, Test. Dr. Lockwood.) Consistent with Dr. Lockwood's testimony, Dr. Frederiksen opined that beyond 22 or 23 weeks of gestation, dismemberment of the fetus is more difficult. (Ex. 123, Test. Dr. Frederiksen 1222.)

Dr. Cook pointed out that "there are some situations where the surgical method may be the preferred method" of pregnancy termination for up to 20 weeks of gestation "if the medical situation warrants it." (Tr. 1279 & 1281, Test. Dr. Cook.) For instance, Dr. Cook had a patient with an abdominal cerclage (a stitch around the cervix) who had a fetal loss and the stitch was constricting the dilation of her cervix. Dr. Cook believed that his only options were a D&E on the nonliving fetus or a laparotomy and hysterotomy. After discussion with the patient, Dr. Cook chose the D&E because it would avoid another major abdominal surgery for the mother. (Tr. 1280, Test. Dr. Cook.)

Dr. Fitzhugh has safely performed his disarticulation D&E in the same fashion on patients and fetuses having a wide variety of health conditions and anomalies. (Tr.

286-88, Test. Dr. Fitzhugh.) He has never perforated a patient's uterus in a second-trimester procedure, but he has ruptured a patient's cervix. (Tr. 289-90, Test. Dr. Fitzhugh.) The majority of Dr. Fitzhugh's patients do not return for follow-up examinations after an abortion. (Tr. 292-93, Test. Dr. Fitzhugh.)

Dr. Knorr considers the dismemberment D&E to be a safe procedure from 20 to 24 weeks of gestation. He has rarely perforated a patient's uterus during a dismemberment D&E, and his complication rate is "very small." (Tr. 534, Test. Dr. Knorr.)

Dr. Vibhakar believes her D&E procedures are "low[-]risk." (Tr. 350, Test. Dr. Vibhakar.) Based on her experience and her understanding of the medical literature, the likelihood of encountering a complication like infection, hemorrhage, uterine perforation, or cervical laceration in performing a D&E is 1% or less. (Tr. 377-78, Test. Dr. Vibhakar.) To her knowledge, Dr. Vibhakar has not caused uterine perforation or infection by performing a second-trimester D&E, but she has had one case involving a suspected surgical laceration that caused a hemorrhage and may have required a blood transfusion. (Tr. 378-80, Test. Dr. Vibhakar.)

In Dr. Chasen's opinion, the dismemberment D&E presents a higher risk of retained fetal tissue. Even if ultrasound is used, this risk cannot be eliminated. Dr. Chasen testified that retained fetal tissue interferes with shrinkage of the uterus which presents a risk factor for hemorrhage, and retained fetal tissue also presents the risk of infection which, on a long-term basis, may scar the uterus and result in future infertility. (Ex. 121, Test. Dr. Chasen 1590 & 1592-94.)

Dr. Doe believes that the dismemberment D&E procedure is low-risk both before and after 20 weeks. (Tr. 95, Test. Dr. Doe.) Dr. Doe has perforated a uterus in a second-trimester nonintact D&E procedure only once in his or her entire career; similarly, he or she has had only one cervical laceration requiring suture. (Tr. 97, Test.

Dr. Doe.) Dr. Doe believes that, as compared with each other, the nonintact and intact D&E procedures are both low-risk. (Tr. 104, Test. Dr. Doe.)

Dr. Broekhuizen has never perforated a uterus, but has, on two occasions, been required to suture the cervix due to a cervical laceration occurring during a D&E procedure. These are the only medical injuries or complications he is aware of that were caused by the D&E procedures he has performed. In both cases, the D&E required disarticulation due to a disproportion between the size of the fetus and the limited dilation of the cervix. (Ex. 120, Test. Dr. Broekhuizen 524-25 & 578.) Dr. Paul has perforated a woman's uterus during dismemberment on two occasions. (Ex. 125, Test. Dr. Paul 73.)

Dr. Westhoff characterizes both D&E and labor induction as safe second-trimester abortion techniques with less morbidity and mortality than carrying a pregnancy to term. She believes that in the early part of the second trimester, up to 16 weeks of gestation, the uterus is less likely to respond to induction medications and the D&E is substantially safer because it is more likely to be successful. For the later part of the second trimester, and depending on access to skilled physicians, D&E and labor induction appear to be quite similar in terms of safety, but because of the infrequency of women choosing labor induction, there is less data available to assess its safety. (Ex. 126, Test. Dr. Westhoff 809-10.)

To her knowledge, Dr. Westhoff has never perforated a uterus during a D&E. However, she has lacerated a patient's cervix and has left fetal tissue in the uterus. (Ex. 126, Test. Dr. Westhoff 792 & 879.) Over the last three years at New York Presbyterian Hospital where Dr. Westhoff is an attending physician, D&E complications included one cervical laceration and three uterine perforations. Each case involved a dismemberment D&E. (Ex. 126, Test. Dr. Westhoff 793-94.) New York Presbyterian Hospital reviews complications of procedures routinely. Although all major complications of the D&E occurred with dismemberment D&E and not intact

D&E (Ex. 126, Test. Dr. Westhoff 886), the complication rates for dismemberment D&E remained well within the institution's accepted complication rates for a surgical procedure. (Ex. 126, Test. Dr. Westhoff 980-84.)

Dr. Frederiksen testified that uterine perforation, cervical laceration, and blood loss are all possible complications of the D&E. (Ex. 123, Test. Dr. Frederiksen 1192.) Further, Dr. Westhoff stated that although the grasping end of the forceps is smooth, uterine perforation may occur during a D&E if the end of the forceps punctures the uterine wall, which is very soft, or if the doctor inadvertently grasps uterine tissue with the forceps and that tissue is then torn from the rest of the uterus. (Ex. 126, Test. Dr. Westhoff 826.)

According to Dr. Clark, while risks of the D&E include perforation of the uterus,[72] cervical laceration, infection, and bleeding, the D&E is a very safe procedure, even safer than he realized before preparing to testify in this case. (Ex. 891, Test. Dr. Clark 2387, 2404-05 & 2410-11.) Further, when comparing the dismemberment D&E to the intact D&E, the purported need for less instrument passes with the intact D&E does not necessarily make the procedure safer. "[O]n a theoretical basis, yes, less passes, doesn't it make some sense that less passes might cause less problems or less jaggedy bones . . . might make it safer, I guess in some sense it makes sense. But if I drive in and out of my driveway a hundred times, if I do it properly, that really doesn't increase the risk that I am going to hit the side of the garage." (Ex. 891, Test. Dr. Clark 2387-88.)

[72]However, Dr. Clark also testified that there is no data proving jagged bony parts pose a risk of injury when performing a D&E. (Ex. 891, Test. Dr. Clark 2394.)

Dr. Cook believes that performing a D&E between 22 and 24 weeks poses a more significant risk of maternal mortality than performing the procedure at earlier gestational ages. (Tr. 1418, Test. Dr. Cook.)

Dr. Lockwood is not convinced that the intact D&E is safer than the traditional D&E procedure and he believes the intact D&E procedure may have potential long-term safety concerns. (Tr. 1667-68, Test. Dr. Lockwood.) Dr. Lockwood characterizes the D&E method of abortion as relatively safe and notes that advances like cervical ripening agents and ultrasound-guided imaging have improved the performance of D&Es. He also observed that textbook descriptions and articles on the procedure have "allowed people to have a more uniform approach to the procedure." (Tr. 1669-71, Test. Dr. Lockwood.)

Based on 30 years of published medical data and 15 years of experience, Dr. Hammond believes that in skilled hands, the D&E is a very safe procedure for terminating second-trimester pregnancies up to 24 weeks, and is likely the safest abortion procedure through approximately 20 weeks of gestation. (Ex. 124, Test. Dr. Hammond 541-42.) According to Dr. Hammond, some of the slight risks of the D&E include uterine perforation and infection. Specifically, Dr. Hammond testified that:

* Laminaria may cause pain and cramping. (Ex. 124, Test. Dr. Hammond 673.)

* Uterine perforation is very uncommon when performing a D&E, but it is more common than some may realize. In most cases, a small perforation causes no harm. A large perforation at the top of the uterus can cause bleeding, but it can be repaired with no long-term consequences. However, a perforation on the side of the uterus where the blood supply comes into the uterus can result in catastrophic hemorrhage. Where the

hemorrhage cannot be controlled, a hysterectomy is required. (Ex. 124, Test. Dr. Hammond 567-68 & 677-78.)

* The risk of infection arising from D&Es is less than one percent due to the prophylactic use of antibiotics. (Ex. 124, Test. Dr. Hammond 688.)

* The risk associated with puncturing the fetal skull and with an additional instrument pass into the uterus are both very low. However, they are not equal and Dr. Hammond believes the physician should be entitled to choose which option is the safest for his patient. (Ex. 124, Test. Dr. Hammond 682-84.)

In Dr. Cook's opinion, terminations of pregnancy for maternal conditions that are either unique to pregnancy or exacerbated by pregnancy simply require that "the fetus and the mother are separated from one another, and that the placenta is delivered in order to facilitate the recovery process for the mother"; "[i]t doesn't require that we destroy the fetus." (Tr. 1301-02 & 1306, Test. Dr. Cook.) Similarly, Dr. Shadigian believes it is "never" necessary to "take a destructive act directly against the fetus in order to protect the health interests of the mother" when a pregnancy must be terminated previability for maternal health reasons. "The most important thing is ending the pregnancy which means delivering the baby and the placenta. Once that's accomplished, then the mom will get well spontaneously." (Tr. 1517, Test. Dr. Shadigian; Tr. 1680-81 & 1737, Test. Dr. Lockwood (death of the fetus after viability is never required to preserve the health or life of the mother because there is "no circumstance where physically killing the fetus is required to somehow magically improve the mother's health. What is required is terminating the pregnancy."); Ex. 120, Test. Dr. Broekhuizen 610-11 (not medically necessary from the standpoint of the mother to kill the fetus); Ex. 891, Test. Dr. Clark 2314-15 (first goal when woman is pregnant and ill is to treat the illness, stabilize mother's condition, and assist her in carrying fetus to term).)

Dr. Lockwood stated that there "may be an incredibly rare circumstance" in which it "would be necessary to take a destructive act against the fetus, after viability, in order to preserve the life of the mother," but he has never seen such a situation. (Tr. 1682, Test. Dr. Lockwood.) If such a situation did develop, "[t]here are methods of inducing feticide, of causing the fetus to no longer be living, that would then allow the procedure to be done." (Tr. 1688, Test. Dr. Lockwood.)

If a woman was 22 weeks pregnant with unstable bleeding in her brain and a vaginal hemorrhage that cannot be stabilized and the physician has decided that the woman's uterus must be emptied, "the approach [Dr. Cook] would think is the safest is to go and do an operative procedure to empty her uterus [abdominally] in the most expeditious manner possible which would be a cesarean delivery or hysterotomy." Performing a D&E in this situation would not be appropriate because "if a patient is having vaginal bleeding, we don't want to make a bad situation worse by doing more vaginal surgery on her." (Tr. 1404-06, Test. Dr. Cook.)

Despite never having performed an intact D&E, Dr. Cook opined that performing a D&E or intact D&E without ultrasound guidance is "not practicing contemporary obstetrics" and is "not performing [the procedure] as safely as you could." Dr. Cook believes that ultrasound "should be utilized in any procedures where you are doing intrauterine manipulations." (Tr. 1366-67, Test. Dr. Cook.)

Dr. Broekhuizen believes that the use of ultrasound reduces the risk of injuring the patient during insertion of instruments. Dr. Broekhuizen has not, to his knowledge, left fetal parts in the uterus after a D&E. With careful procedure and inspection, and the use of ultrasound, the incidence of retained fetal or placental parts should be minimal, but it is never zero, stated Dr. Broekhuizen. (Ex. 120, Test. Dr. Broekhuizen 571-77.)

### *iv. INTACT D&E*

#### *(a) TESTIMONY ESTABLISHING THAT INTACT D&E HAS SAFETY ADVANTAGES AND MAY BE MEDICALLY NECESSARY IN SOME CASES*

Dr. Carhart identified some of the benefits of performing a D&E by puncturing and draining the fetal skull: avoiding injury caused by sharp, bony fragments that can be exposed when rupturing the fetal skull; avoiding contamination of the patient's internal uterine cavity with the fetus's brain contents; and reducing trauma to the cervix. (Tr. 720, Test. Dr. Carhart.)

Dr. Fitzhugh would prefer to remove the fetus intact, rather than in pieces, because it is "relatively safer" in his experience; however, intact removal rarely happens in Dr. Fitzhugh's practice, and he would be required to dilate his patients with a second round of laminaria in order for intact removal to occur on a regular basis. (Tr. 248-49 & 277, Test. Dr. Fitzhugh.) With his disarticulation procedure, Dr. Fitzhugh has been required to tend to three of his former patients who found a piece of bone in their uterus via passing or ultrasound. Comparing the faster intact delivery with his routine disarticulation procedure, Dr. Fitzhugh believes that the more time a procedure takes, the more anesthesia is required, increasing the risks of aspiration, some other anesthetic risk, and bleeding. Dr. Fitzhugh does not believe that intact removal of a fetus followed by skull compression poses serious risks to women's health. (Tr. 248-50 & 256-57, Test. Dr. Fitzhugh; see also Ex. 122, Test. Dr. Creinin 682 (there is nothing unsafe about removing fetus intact to the umbilicus or inserting scissors into fetal head to remove contents under direct visualization; Dr. Creinin has never had a patient who was injured or experienced a medical complication from fetus being removed intact to the calvarium); Ex. 125, Test. Dr. Paul 102-03 (although dismemberment D&E is safe, based on clinical experience and experience of colleagues, Dr. Paul believes intact D&E is safer).)

Dr. Vibhakar believes her D&E procedures are "less uncomfortable to the patient when the fetus is removed predominantly intact." (Tr. 350, Test. Dr. Vibhakar.)

When Dr. Knorr is able to bring the fetus out largely intact, the procedure is "a bit faster" than the disarticulation procedure, thereby shortening general anesthesia time. (Tr. 517-18, Test. Dr. Knorr.) Dr. Knorr does not believe that D&E procedures involving removal of the fetus intact but for the fetal skull, followed by either puncture or compression of the skull, pose serious risks to women's health. (Tr. 519, Test. Dr. Knorr.) Rather than removing a fetus in parts, Dr. Knorr's preference would be to perform a D&E with the fetus delivering intact up to the head followed by compression of the fetal head because "[i]t's easier, it goes quickly, and there is far fewer chance that you're going to be pulling sharp shards of skull through the cervix which can sometimes cause a laceration. . . . [B]ut since we are in a world where abortion is restricted in most hospitals in the United States, . . . I don't have the ability to keep the woman in the hospital overnight." (Tr. 572-73, Test. Dr. Knorr.)

Dr. Chasen believes that the intact D&E is a safer method for aborting fetuses with certain anomalies. For example, with hydrocephalus, the fluid in the fetal brain can be aspirated and the head reduced to a size that can easily pass through the uterus. (Ex. 121, Test. Dr. Chasen 1600-01.) However, the brain of a hydrocephalic fetus can also be drained by cephalocentesis[73] to facilitate a vaginal delivery. (Ex. 121, Test. Dr. Chasen 1687-88.) For patients with cardiac disease, Dr. Chasen identified D&E as the recommended second-trimester abortion technique. (Ex. 121, Test. Dr. Chasen 1586-87.)

[73]"Cephalocentesis" is the "[p]assage of a hollow needle or trocar and cannula into the brain to drain or aspirate . . . the fluid of a hydrocephalus." Stedman's Medical Dictionary 321 (27th ed. 2000).

Although there are no studies to confirm this conclusion, Dr. Broekhuizen believes that since the intact D&E takes less time to perform than the dismemberment D&E, the intact D&E presents less risk of complications from anesthesia. Similarly, although there are no studies supporting his conclusion, Dr. Broekhuizen believes that since the intact D&E requires less instrument passes and takes less time to perform than the dismemberment D&E, the intact D&E results in less blood loss. (Ex. 120, Test. Dr. Broekhuizen 612-13.)

Dr. Lockwood testified that when a physician sets out to perform a D&E, he or she intends to make as few passes into the uterus as possible with instruments. By definition, the intact D&E involves fewer passes of instruments into the uterus. Fewer passes with instruments would mean less risk of uterine perforation, laceration, and infection. In an intact D&E procedure, the patient's uterus and cervix are less likely to be exposed to sharp fetal bone and skull fragments. (Tr. 1750-51, Test. Dr. Lockwood; Ex. 124, Test. Dr. Hammond 564, 567-70, 656, 678 (intact D&E involves fewer instrument passes and reduces likelihood of cervical laceration from removing sharp bony fragments through cervical opening; although it is logical to believe there is less risk of perforating the uterus if there are fewer instrument passes, there is no medical data to support this belief; Dr. Hammond has perforated a uterus during a D&C and a dismemberment D&E, and has lacerated a patient's cervix performing an intact D&E).)

Dr. Chasen believes that the intact D&E "offers safety advantages" over the dismemberment D&E. (Ex. 121, Test. Dr. Chasen 1588-89.) The use of grasping forceps poses the risk of grasping the uterine wall and uterine perforation, even when performed with ultrasound guidance. Dr. Chasen testified that dismemberment D&E requires multiple passes and therefore multiple exposures to the risk of uterine perforation. Uterine perforation can cause hemorrhage or infection, and if it is not recognized, the forceps may pass through the perforation, and the bowel and bladder

may be injured. Uterine perforation poses a risk of death. (Ex. 121, Test. Dr. Chasen 1590-91 & 1606.)[74]

Dr. Paul stated that an intact D&E avoids the risk of having the fetal calvarium trapped in the uterus, a circumstance which requires the doctor to search the uterus with a forceps to retrieve the fetal head, thereby presenting a risk of uterine perforation. (Ex. 125, Test. Dr. Paul 123-25.)

Dr. Hammond believes the intact D&E is a very safe procedure and the safest variant of the D&E. (Ex. 124, Test. Dr. Hammond 563.) He testified regarding the following advantages of the intact D&E:

* The intact D&E provides for more surgical control due to more direct visualization of the fetus during the procedure. The risk of perforating the uterus and injuring the cervix is less if the doctor is not required to grope blindly in the uterus with a forceps to remove dismembered fetal parts, particularly the dismembered fetal head. Dismembered fetal parts can be pushed by the forceps or something else in the uterus through the uterine wall. (Ex. 124, Test. Dr. Hammond 568-69 & 592.)

* There is less likelihood of retained fetal parts with the intact D&E. When Dr. Hammond removes an intact fetus, he is confident that the fetal parts are removed. When the fetus is dismembered, he must exercise his best judgment to determine if he has removed all the fetal parts. He will

[74]Dr. Chasen has been sued for malpractice in connection with uterine perforation occurring during a dismemberment D&E procedure. Upon review by the hospital quality assurance committee, uterine perforation was considered a statistically occurring event even with no deviation from the standard of medical care. The case was settled. (Ex. 121, Test. Dr. Chasen 1591 & 1595.)

generally investigate the fetal parts removed to determine if he has retrieved the sentinel parts: all four limbs and the fetal head. However, in cases of fetal anomalies, the fetus may lack anatomical landmarks commonly used by the doctor to determine if the fetus is completely extracted. Retained fetal tissue increases the risk of infection and hemorrhage. (Ex. 124, Test. Dr. Hammond 566, 570-71, 671-72.) Ultrasound is occasionally used as an adjunct to assist in determining whether all fetal parts have been removed, but it is not a definitive tool. The primary way of assuring the uterus is empty is for the operator to know how an empty uterus should feel and knowing when it feels like something has been retained. (Ex. 124, Test. Dr. Hammond 572.)

* The intact D&E decreases the time in the operating room because the doctor is not required to make several instrument passes to complete removing the fetus. A shorter operating time decreases the patient's exposure to anesthesia, the risk of anesthesia-related complications, and the risk of bleeding. A shorter evacuation time causes less bleeding. Once the uterus is empty, it can contract and stop the bleeding, but while the dismemberment D&E proceeds, bleeding is often occurring. (Ex. 124, Test. Dr. Hammond 566-67 & 574-75.) The risk of excessive bleeding in all D&E procedures is 1% or less. The majority of bleeding that occurs in a D&E is caused by removing or detaching the placenta, though bleeding may rarely be caused by cervical laceration or uterine perforation. (Ex. 124, Test. Dr. Hammond 687-88.)

In Dr. Chasen's view, it is much easier and safer to collapse the fetal head using the intact D&E procedure than to crush the skull with forceps, as required in the dismemberment D&E procedure. The intact D&E procedure poses no risk of hitting the bowel with the scissors used to puncture the skull, and fetal dismemberment and crushing the skull may create sharp bony edges that may damage the cervix when

expelled. Dr. Chasen observed that it is possible to use nitroglycerin to enable the forceps to fit around the head and eliminate the need to crush the fetal skull, but in Dr. Chasen's practice, the woman's uterus is already relaxed by sedation and anesthesia. Further significant relaxation of the uterus with nitroglycerin is doubtful, and if it does occur, it could persist after the abortion and expose the woman to a risk of hemorrhage. Moreover, nitroglycerin can affect the cardiovascular system and make the mother's pulse race and blood pressure drop. (Ex. 121, Test. Dr. Chasen 1590, 1592, 1597, 1599-1600.)

Dr. Chasen views the intact D&E procedure as quicker with less risk of hemorrhage. Dr. Chasen testified that avoiding the risk of hemorrhage is especially important for women with clotting problems caused by metabolic conditions, inherited disorders, cancer and associated chemotherapy, and uterine infection. Further, reducing the woman's exposure to forceps inserted into the uterus reduces the risk of uterine rupture and disrupting the placenta, thereby reducing the risk of hemorrhage. (Ex. 121, Test. Dr. Chasen 1607-08.)

During 20 to 24 weeks of gestation, Dr. Lockwood identified the available abortion options as D&E, medical induction, intact D&E, and hysterotomy. According to Dr. Lockwood, scientific and medical literature establishes that medical induction and D&E by dismemberment are safe methods of abortion from 20 to 24 weeks. Further, the Chasen study, discussed below, "suggests" that the intact D&E method of abortion is "safe" during 20 to 24 weeks of gestation. While intuitive or anecdotal evidence regarding the safety of the intact D&E cannot "firmly establish [the] procedure as an acceptable and preferred alternative clearly," there are "compelling enough arguments as to its safety, that [Dr. Lockwood] certainly would not want to prohibit its use in [his] institution." (Tr. 1704-06, Test. Dr. Lockwood.)

Based on her experience, Dr. Fredericksen believes the intact D&E is always safer than the dismemberment D&E for the following reasons:

* Intact removal of the fetus ensures that fetal tissue is not retained and the placenta can be removed virtually intact. Dr. Frederiksen testified that retained fetal and placental tissue increases the risk of infection. Infection can cause post-abortal uterine hemorrhage. Retained tissue can result in Asherman's syndrome, which is associated with procedures requiring multiple curettage of the endometrial tissue and associated infection. Asherman's Syndrome affects the patient's future reproductive health because it affects or eliminates menstrual periods, and the uterine scar tissue that develops may be so encompassing that embryo implantation is impeded. (Ex. 123, Test. Dr. Frederiksen 1045, 1060, 1062-64; see also Ex. 125, Test. Dr. Paul 72-73 (intact D&E permits doctor to readily know whether all fetal parts have been removed from uterus; retained fetal tissue can cause infection and bleeding, and this risk not eliminated with use of ultrasound).) Ultrasound and a suction curette are used by physicians to determine if the uterus is empty, but even with these procedures, fetal and placental tissue may be retained. (Ex. 123, Test. Dr. Frederiksen 1218-19.)

* The intact D&E procedure is shorter. Dr. Frederiksen stated that as physicians have improved the procedure to remove the fetus more intact, the total time necessary to ensure that the uterus contracts and is empty has become less. The shorter operating time results in less blood loss, less anesthesia time, less pain, and less risk of exposure to infection. (Ex. 123, Test. Dr. Frederiksen 1064-66, 1234; see also Ex. 125, Test. Dr. Paul 68 & 73 (dismemberment D&E takes, on average, 10 to 15 minutes, whereas intact D&E can be completed in less than 2 minutes; quick evacuation of uterus limits bleeding and shortens woman's discomfort; until uterus is fully evacuated, it cannot contract to stop the bleeding from the detached placenta); Ex. 126, Test. Dr. Westhoff 826-27 & 836 (intact D&E has shorter operating time than dismemberment

D&E, with shorter exposure to anesthesia and lower risk of hemorrhage).)

* There are less passes of instruments into the uterus. With less instrument passes, there is less risk of perforating the uterine wall and delivering maternal tissue. Dr. Frederiksen explained that due to irregularities in the thickness of uterine walls, including those created by scar tissue, a doctor may believe the forceps has grabbed fetal tissue, but the tissue may actually be uterine or uterine scar tissue. While uterine perforation is a low-risk complication, it presents an emergency situation mandating exploration of the maternal abdomen to repair any damage to the bowel or other maternal tissues. Abdominal surgery increases the risk of wound infections, and depending on the extent of the damage caused by the perforation, there may be bowel spillage, damage to the ovaries and fallopian tubes, and internal hemorrhage. Dr. Frederiksen has perforated the uterus while performing a dismemberment D&E.[75] (Ex. 123, Test. Dr. Frederiksen 1045, 1053, 1055-60; see also Ex. 125, Test. Dr. Paul 68-70 (goal is to use as few instrument passes as possible because every instrument pass presents a small risk of lacerating the cervix or perforating or lacerating the uterine wall; risk exists even when ultrasound used); Ex. 126, Test. Dr. Westhoff 824-25 (intact D&E safer than dismemberment D&E because of less instrument passes into the uterus which reduces or possibly eliminates risk of uterine perforation and cervical laceration; dismemberment results in bony fragments which may cause perforation and laceration; in dismemberment D&E, fetal and placental tissue may be retained and cause infection or hemorrhage).) Dr.

[75]Dr. Frederiksen was sued for alleged malpractice in perforating a patient's uterus during a dismemberment D&E. The case was tried to a defense verdict. (Ex. 123, Test. Dr. Frederiksen 1056.)

Frederiksen does not know of any studies comparing the extent of blood loss in intact and dismemberment D&Es. (Ex. 123, Test. Dr. Frederiksen 1216-17.)

* The intact D&E creates less bony parts or fragments that can lacerate the cervix when delivered. According to Dr. Frederiksen, a cervical laceration can nick an internal branch of the cervical artery as well as lacerate the endocervical canal and cause bleeding. The leading cause of cervical laceration and hemorrhage is delivery through the cervix of sharp, bony pieces created during the dismemberment D&E. A laceration of the cervical artery of the internal os characteristically causes an episodic hemorrhage or one that cannot be identified during a patient examination. A cervical laceration may also necessitate abdominal surgery. The risk of cervical laceration is present but lower with intact D&E procedures. (Ex. 123, Test. Dr. Frederiksen 1053, 1058-61, 1213, 1215; see also Ex. 126, Test. Dr. Westhoff 834 (for patients with serious underlying medical conditions such as heart disease, sickle cell anemia, or organ transplant, medical complications may have more catastrophic outcomes and should be avoided; such patients have the most to gain from intact D&E which reduces likelihood of complications that would be unusually risky to women with serious medical problems).) Dr. Frederiksen does not know of any studies comparing the risk of injury from bony parts arising from intact and dismemberment D&Es. (Ex. 123, Test. Dr. Frederiksen 1214-15.) The cause of cervical laceration is not always known. (Ex. 123, Test. Dr. Frederiksen 1214-15.)

In Dr. Frederiksen's opinion, there is never a clinical reason to choose a dismemberment D&E procedure over removing the fetus as intact as possible. (Ex. 123, Test. Dr. Frederiksen 1139.) Moreover, an intact D&E may be safer for women with certain medical conditions because there is less risk of a prolonged procedure,

lacerating the cervix, hemorrhage, retained tissue, and infection. Dr. Frederiksen identified specific examples of medical conditions warranting an intact rather than a dismemberment D&E and the reasons for her opinion:

* Women with sepsis. A patient who is septic, either with chorioamnionitis or infection of the uterus, may be hemodynamically unstable; that is, in shock with a very low blood pressure and a very high pulse. The lack of cardiac output decreases blood to the kidneys, lungs, and other organs causing metabolic acidosis (a change in the acid/base balance [pH] of the maternal bloodstream). This arises because, without adequate blood profusion through the tissues, the acid and waste products created by living maternal tissues cannot be removed from the body. Metabolic acidosis can lead to disseminated intravascular coagulation, a disease process which interferes with clotting because the clotting factors and platelets in the maternal body, the raw materials for clot formation, have been used up. These patients have an increased risk of maternal hemorrhage. In this circumstance, the intact D&E is the optimal way to empty the uterus because it decreases the risk of cervical laceration and hemorrhage and shortens the procedure time for a patient facing potential multiorgan failure. (Ex. 123, Test. Dr. Frederiksen 1141-45; see also Ex. 124, Test. Dr. Hammond 588-90 (in patients with chorioamnionitis, the pregnancy must be delivered; patients with infected uterus have higher risk of uterine perforation because uterine wall is not healthy and does not have its usual rigidity; more importantly, manipulating interior of infected uterus with multiple instrument passes may seed infection from uterine lining into bloodstream causing sepsis).)

* Women with acute fatty liver of pregnancy. When an inborn error of metabolism exists that prevents the fetus and placenta from metabolizing long-chain fatty acids, these fatty acids accumulate and are then

transferred to the maternal cardiovascular system for excretion. The fatty acids deposit in the mother's liver, resulting in acute liver failure, which in turn may cause renal failure or kidney failure. Liver failure may also cause a low platelet count, low concentrations of clotting factors, and disseminated intravascular coagulation. Once the woman presents with acute fatty liver disease, there is no available treatment other than delivering the fetus. If acute fatty liver disease occurs during the second trimester, labor induction is a poor option because the mother is very ill and the prolonged procedure increases the risk of renal failure. (Ex. 123, Test. Dr. Frederiksen 1145-47.) Either an intact or a dismemberment D&E can be performed on women with acute fatty liver disease. (Ex. 123, Test. Dr. Frederiksen 1226.)

Dr. Hammond explained why he believes the intact D&E is a safer abortion procedure for women with bleeding disorders and heart problems:

* Bleeding disorders. Avoiding the risk of uterine perforation and cervical laceration is important in women with inherited, acquired, or pregnancy-related clotting problems due to insufficient clotting factors or platelets. Thrombocytopenia (low platelets) may arise as a result of pregnancy, and low platelets may be associated with HELLP syndrome, preeclampsia, and toxemia. (Ex. 124, Test. Dr. Hammond 586-88 & 594-95.) Unlike the unpredictability of induction abortion, the time period when evacuation of uterine contents is to occur is scheduled in a D&E procedure. The patient can be given platelets or medications to assist with clotting, both of which will help for only the short time after they are administered. (Ex. 124, Test. Dr. Hammond 593-94.)

* Heart problems. In patients with underlying valvular heart disease or cardiomyopathies,[76] hemorrhage presents a heightened risk of death. These patients do not tolerate fluid shifts, and what may be a minor problem in a healthy patient is a major problem in these patients. Any risk of hemorrhage from cervical laceration and uterine perforation should be avoided, and a predictable 20-minute surgical procedure with scheduled anesthesiologist and cardiologist assistance is preferred. (Ex. 124, Test. Dr. Hammond 590-93.)

### *(b) TESTIMONY ESTABLISHING THAT INTACT D&E IS NOT MEDICALLY NECESSARY, IS NOT THE SAFEST, AND IS NOT THE ONLY ABORTION OPTION*

Dr. Shadigian can identify no circumstances "in which the D&X procedure would be the only option to save the life or preserve the health of the woman." (Tr. 1597-98, Test. Dr. Shadigian.) Similarly, Dr. Bowes has never "seen any situation where [he] perceived the need to use an intact D&E" or where he "perceived any advantage to using an intact D&E over other methods of abortion." (Tr. 920, Test. Dr. Bowes.)

Dr. Sprang has never "seen a situation where a D&X would be the safest, the best, or the only procedure to use to protect the health of the mother." In fact, he cannot identify "any indications . . . where a D&X would be the thing to do." Dr. Sprang believes it is never necessary to perform an intact D&E, or D&X, on a living fetus during the second trimester because "there is both induction and D&E." According to Dr. Sprang, even if one could fathom a situation in which the intact D&E would be preferable, the operator could "cut the cord" at the beginning of the

[76]Cardiomyopathy is the "[p]rimary disease process of heart muscle in absence of a known underlying etiology." Stedman's Medical Dictionary 290 (27th ed. 2000) (quoting World Health Organization).

procedure "[a]nd, obviously, the baby would exsanguinate,"[77] or use "intrafetal Digoxin or potassium chloride." Such injections are "becoming more and more common in the medical community" and Dr. Sprang's institution has a policy that every patient who undergoes a D&E gets a intrafetal injection that causes "immediate death" of the fetus. Dr. Sprang testified that studies have shown such injections to be safe for the mother, and physicians at his institution have already successfully used the technique for selective reduction procedures—that is, when one or more fetuses in a multiple pregnancy are injected so the mother can carry the remaining fetuses to term. "[F]rom ethical points of view, . . . if you kill the fetus in the uterus, none of these issues are there." (Tr. 1162-70 & 1171-72, Test. Dr. Sprang.)

Despite never having performed an intact D&E, Dr. Sprang believes from his general OB/GYN experience and training, and his review of medical literature, that the intact D&E procedure presents a "significant risk to the woman." Specifically, Dr. Sprang believes that the two-day dilation period presents a risk of infection because "[b]acteria have a better chance [of] moving along the laminaria and getting inside the endocervical os and running a risk of infection, because they are in contact with the vagina, and up against the amniotic sack." Dr. Sprang also testified that if mechanical dilation is used along with laminaria, the patient risks an incompetent cervix later—that is, a cervix that cannot hold a subsequent pregnancy to term. Further, performing an internal podalic version as part of an intact D&E creates a greater risk of uterine rupture. Finally, using sharp instruments on the fetal skull "blindly in a very vascular area" creates a risk of cervical laceration. (Tr. 1148-55, 1161-62, 1164, Test. Dr. Sprang; Tr. 1358, Test. Dr. Cook (multiple insertions of laminaria increase risk for infection).) Dr. Sprang admitted that he uses mechanical dilators and laminaria to perform D&Cs and second-trimester inductions; the risks of infection and trauma to

[77]To exsanguinate is to "remove or withdraw the circulating blood; to make bloodless." Stedman's Medical Dictionary 633 (27th ed. 2000).

the cervix are present with just one insertion of laminaria; and the causes of cervical incompetence are not well understood. (Tr. 1179-84, Test. Dr. Sprang.)

Dr. Sprang noted that the intact D&E "process is clearly continually changing." For instance, using Cytotec may reduce trauma to the cervix in the dilation process, and using ultrasound during the procedure makes the procedure safer with respect to trauma caused by "grasping" and determining whether the physician has left "any fetal parts in there." (Tr.1153-57, Test. Dr. Sprang.)

Dr. Cook believes that the intact D&E, or D&X, procedure "is never medically necessary, in order to safely evacuate a uterus, and . . . it is not even necessarily the preferred method." Dr. Cook defines "medically necessary" as necessary "to preserve the life of the mother or to improve upon her medical condition over and above any other readily-available and commonly-used alternatives." According to Dr. Cook, the intact D&E procedure "doesn't add anything to existing medical options that are already safely and readily available for the mother for ending her pregnancy or evacuating her uterus"; the procedure does not "facilitate[] our ability to empty a uterus in that it is still a multiple-day procedure, in less than an optimally-monitored situation"; and "it's an inhumane way to deliver a fetus." (Tr. 1299-1300 & 1390-91, Test. Dr. Cook.)

Dr. Clark testified that regardless of gestational age, the intact D&E is never necessary to preserve the life or health of the mother. "Under no circumstance would the abolition of this procedure in any way jeopardize the life or health of any mother regardless of what medical condition she may have." (Ex. 891, Test. Dr. Clark 2311 & 2313.) Dr. Clark further testified that:

* There is no medical literature to support a claim that the intact D&E would be necessary to preserve the life or health of the mother. "There

are always equally if not more safe alternatives that do not involve D&X." (Ex. 891, Test. Dr. Clark 2377-78.)

* There are no publications analyzing the long-term safety of the intact D&E. The Chasen article (discussed below), when analyzed, confirms what doctors have suspected—an "incredibly disturbing" rate (a three-fold increase) of preterm birth in women who have previously had an intact D&E. (Ex. 891, Test. Dr. Clark 2311, 2388-89, 2394.) Premature birth accounts for more morbidity and mortality than any other single condition in all of obstetrics and pediatrics, and a woman who has previously experienced a preterm delivery is at a higher risk of preterm delivery in later pregnancies. (Ex. 891, Test. Dr. Clark 2393 & 2412.)

* The risks associated with the intact D&E are absolutely unknown. However, the Chasen article may indicate that the extent of dilation in the intact D&E increases the risk of premature birth. (Ex. 891, Test. Dr. Clark 2386.)

Dr. Cook maintains that the intact D&E "may entail unforeseen and unnecessary risk both immediately and in the future . . . whether we are dealing with a healthy mother and a healthy fetus, or a sick mother and/or a sick fetus." He believes that various elements of the intact D&E procedure "have an unacceptable either immediate or potential later risk associated with them," including "over distension" of the cervix that may compromise the patient's later ability to maintain a pregnancy and conversion of the fetus within the uterus which increases the risk of maternal injury and is a technique "generally . . . abandoned in the practice of modern obstetrics."[78] (Tr. 1299

[78]The intact D&E procedure also concerns Dr. Cook because of patient discomfort and lack of patient monitoring during two days of dilation and "the method in which a baby's life is taken, when it's virtually completely delivered, then has its . . . brains sucked out of its head." (Tr. 1342, Test. Dr. Cook.)

& 1341-42, Test Dr. Cook.) Dr. Cook characterizes the risks of performing an internal podalic version of the fetus to the breech position as perforation of the uterus, trauma to the uterus, bleeding, and infection. (Tr. 1364-65, Test. Dr. Cook.)

Many of the witnesses appearing before the court in this case testified regarding specific maternal physical health conditions and whether the intact D&E procedure is medically necessary, the safest, or the only abortion option available for women with these health conditions.

Dr. Cook knows of no maternal physical health conditions that could create a medical need to perform the intact D&E procedure to terminate a pregnancy prior to fetal viability. "I have been involved in this process and these discussions for a number of years, and . . . I have considered many scenarios, and I have yet to come across a single case where I see it's necessary, medically or otherwise, to do a partial-birth abortion." (Tr. 1307 & 1327, Test. Dr. Cook.) Specifically, Dr. Cook testified that the intact D&E procedure is not medically necessary in the following circumstances:

* Preeclampsia: According to Dr. Cook, intact D&E is not necessary to terminate the pregnancy in this situation because "there are other better options available that . . . are readily accessible to most practitioners that would allow a safer completion of the delivery process, while still maintaining the option for the best outcome for the fetus." Between 20 and 23 weeks, Dr. Cook would administer medications to get the fetus to viability, then deliver the fetus vaginally or by cesarean. If the situation is not being controlled, Dr. Cook would proceed with medical induction of labor with careful monitoring of the mother's health status. Surgical termination of pregnancy for preeclampsia between 20 and 23 weeks is not indicated because preeclampsia is an abnormality of the vascular

system which predisposes one to low platelets, clotting difficulties, and increased bleeding. (Tr. 1307-10, Test. Dr. Cook.)

* Renal Disease: In Dr. Cook's view, intact D&E would never be necessary to terminate a pregnancy for renal disease because "there are other safer and readily available options that are present. In addition, a woman that has an underlying severe renal condition is also not a woman who can tolerate significant blood loss, loss of fluid, need for fluid replacement, and other situations that would be I think just too high a risk to proceed with a surgical evacuation in the later second trimester." (Tr. 1310-11, Test. Dr. Cook; Tr. 1688-89; see also Test. Dr. Lockwood (cannot see reason why intact D&E would be necessary to terminate previable pregnancy for renal disease); Ex. 891, Test. Dr. Clark 2368-71 (except in the case of toxemia of pregnancy,[79] pregnancy does not negatively affect kidney function and does not necessitate aborting fetus; toxemia can require termination of pregnancy to save mother's life; unless available platelets or clotting factors are very low, either labor induction or dismemberment D&E are appropriate second-trimester abortion techniques for women with underlying kidney disorders).)

* Cardiac Disease: Dr. Cook testified that conditions that might necessitate early termination of pregnancy include pulmonary hypertension; shunting of blood in the opposite direction of its usual course, causing problems delivering adequate oxygen to the patient's tissues; and dilation of the aorta as part of a condition known as Marfan's Syndrome. The intact D&E procedure would never be medically necessary for patients having

[79]Toxemia is a term used to describe preeclampsia and eclampsia. Eclampsia is similar to preeclampsia, but the disease has advanced to include seizures. (Ex. 891, Test. Dr. Clark 2370-71.)

any of these cardiac conditions, nor would it be "the preferable way to go or even an[] equivalent option." It is "unacceptable" to use a surgical abortion procedure late in the second trimester under circumstances where possible perforation, bleeding, infection, and other complications would not be well-tolerated by the mother. In addition, the use of epidural anesthesia in induction procedures allows the woman to remain awake, alert, and able to report chest pain, shortness of breath, or other symptoms. The need to carefully monitor the mother's pain sensation and her hormonal stress responses, both of which can further complicate her underlying cardiac condition, requires proceeding with an abortion method "that is as physiologic as normal, as controlled and as gentle a process as possible." While the induction method can impose physiological stress on the mother, use of epidural anesthesia, cardiovascular monitoring, and evaluation of fluid input and output makes the induction method more "normal," "physiologic," and "gentle." (Tr. 1311-16, Test. Dr. Cook (also testifying that he would use medical induction to terminate pregnancy in patient with preexisting cardiomyopathy); see also Tr. 1697-98 & 1700, Test. Dr. Lockwood (intact D&E, D&E, and medical induction all "acceptable" and "reasonable" methods to safely terminate pregnancy prior to viability for peripartum cardiomyopathy and pulmonary hypertension).)

* HELLP Syndrome: Dr. Cook stated that HELLP syndrome, a variant of severe preeclampsia, may be an indication for termination of pregnancy prior to viability. The intact D&E procedure would never be necessary to terminate a pregnancy involving this condition because there are "safer readily available options." This condition involves low platelet counts and a high risk for bleeding complications. "So anything that we think would potentially increase the risk for a bleeding complication, perforation, hemorrhage . . . would be something we would want to avoid

at all costs." (Tr. 1316-18, Test. Dr. Cook; see also Tr. 1694-95, Test. Dr. Lockwood (better approach for HELLP syndrome is medical termination because patient has low platelet count and physician should avoid risk of uterine perforation and cervical laceration); Tr. 106-08, Test. Dr. Doe (neither D&E nor intact D&E would be indicated for a woman suffering from HELLP syndrome; in his or her former obstetrics practice, Dr. Doe would induce labor, if appropriate, in cases of preeclampsia, and if the labor did not progress satisfactorily or could not be expected to work in time, he or she would perform a cesarean section); Ex. 891, Test. Dr. Clark 2339-45 & 2349-50 (surgical abortion procedure should not be performed on woman with very low platelet count or severe lack of clotting factors, including women with HELLP syndrome, inherited clotting disorders, or acute fatty liver of pregnancy; any possibility of bleeding caused by surgery must be avoided, and labor induction should be performed; however, if platelets or clotting factors are not significantly low and risk of uncontrolled bleeding is not significant, either labor induction or dismemberment D&E could be performed).)

* Leukemia: In the rare cases in which leukemia is an indication for early termination of pregnancy, Dr. Cook believes the intact D&E procedure is never medically necessary to terminate the pregnancy because there are other safer alternatives. Further, this condition involves low platelets and depressed blood counts if the patient is receiving chemotherapy, so Dr. Cook would want to avoid anything that would increase the risk for hemorrhage, bleeding, and perforation, as would a surgical termination. (Tr. 1318-19, Test. Dr. Cook; see also Tr. 1698-99, Test. Dr. Lockwood (medical induction would be preferable to surgical termination of previable fetus if patient had low platelet count).)

* Infection: The intact D&E procedure would never be medically necessary to terminate a pregnancy in a woman who had a severely infected uterus because a surgical termination "would potentially increase the risk for seeding or allowing extension of infection into the general maternal vascular system because of the instrumentation involved, and the risk . . . for bleeding and perforation. So we would not like that contained infection to have access either to her intraabdominal area, peritoneal cavity or to her vascular system." (Tr. 1321, Test. Dr. Cook; see also Tr. 1695-96,Test. Dr. Lockwood (woman with infected uterus would generally already be in labor because infection triggers labor; because cervix is already dilated, physician could continue medical termination or do D&E; may be theoretical advantage to doing intact D&E if uterine wall was damaged and thinned, but there is "no data to drive that"); Ex. 891, Test. Dr. Clark 2346-48 (in cases of uterine infection or chorioamnionitis, either labor induction or dismemberment D&E are generally appropriate methods for second-trimester abortions; if infection has substantially reduced available platelets and clotting factors, labor induction preferred; labor induction usually performed when uterus infected because infection itself often induces labor).)

* Breast Cancer: Dr. Cook opined that it would never be necessary to use the intact D&E procedure to terminate the pregnancy of a woman with breast cancer who has opted to end her pregnancy and begin cancer therapy. Women with malignancies "as part of their disease process, commonly [have] severe anemia and . . . very low platelets and other conditions that . . . would not allow a woman to tolerate a surgical procedure, particularly a riskier surgical procedure, meaning that done at later gestational ages." (Tr. 1322-23, Test. Dr. Cook; see also Ex. 891, Test. Dr. Clark 2372-73 (cancer itself does not require termination of pregnancy, but termination may be medically indicated to surgically or

chemically treat mother's cancer; either labor induction or dismemberment D&E are appropriate second-trimester abortion techniques for mother with cancer).)

* Emergencies: In an emergency situation in which a pregnancy must be ended as quickly as possible, Dr. Cook believes that an intact D&E procedure would not be appropriate because "other available options, both medical and surgical, that have been available for a long period of time, can be done safely. Patients have ready access to those procedures." Further, if a physician is in an emergency situation, the intact D&E would not be possible because of the two-day cervical-dilation process involved. (Tr. 1327-28, Test. Dr. Cook.) However, Dr. Cook admitted that "there could be a scenario that would arise in the early or mid second trimester where we feel the [mother's] condition had deteriorated to the point we can no longer treat the mother effectively. And if she is in danger, then I would not have an objection . . . to proceed[ing] in any manner I felt was necessary in order to deliver her baby and allow her to recover. And if that included D&E on a baby that was still living at that time, then that would be what we would have to do." (Tr. 1329, Test. Dr. Cook.)

Dr. Clark agrees that there are no cases where an intact D&E is preferable to a dismemberment D&E or medical induction. (Ex. 891, Test. Dr. Clark 2313-14.) He also agrees with Dr. Cook that maternal cardiac conditions do not justify the intact D&E procedure. Dr. Clark has published many articles and written textbook chapters on the issue of cardiac complications in pregnancy. Either labor induction with adequate pain relief by epidural or a dismemberment D&E can be used to terminate a second-trimester pregnancy when the mother has cardiac problems. Although some doctors have argued that the intact D&E is appropriate because of the cardiac risk posed by the fluid shift experienced by women in labor, this fluid shift occurs when

the woman retains fluid in the lower extremities when carrying a term pregnancy. Fluid shift concerns do not arise with second-trimester abortions, and any cardiac concerns raised by the pain of labor are ameliorated by administering an epidural. (Ex. 891, Test. Dr. Clark 2319-25 & 2328-29.)

According to Dr. Clark, the intact D&E offers no benefit over a dismemberment D&E in the context of a mother's cardiac health. (Ex. 891, Test. Dr. Clark 2328-29.)[80] Noting that there are no sufficient studies concerning the relative risk of the intact D&E, Dr. Clark opined that using an unstudied procedure is irresponsible, especially in the context of women with cardiac conditions who are more susceptible to complications. (Ex. 891, Test. Dr. Clark 2329-30.)

Dr. Clark testified that a woman suffering from cardiomyopathy in her second trimester may be treated in a manner that permits her to carry and vaginally deliver the fetus at term, although the pregnancy is difficult. However, some cardiomyopathies are severe or do not respond to treatment, and an abortion is necessary to save the mother's life. In such cases, Dr. Clark testified that either a dismemberment D&E or medical induction are appropriate abortion methods. (Ex. 891, Test. Dr. Clark 2332-34.) The risk of blood loss from, for example, perforating the uterus may be life-threatening to the mother. In cardiac patients, Dr. Clark prefers vaginal rather than cesarean delivery of the term infant. (Ex. 891, Test. Dr. Clark 2325-26.)

Dr. Doe cannot identify a specific maternal physical health indication for which an intact D&E would be necessary because of that physical health condition. (Tr. 103-

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[80]The actual question was, "Can you think of any circumstances in which D&X would be necessary to preserve the health of a cardiac patient?" The response was that the mother's hormone levels and blood supply would be similarly affected by the dismemberment and intact D&E. The doctor's answer did not address the risk of maternal complications involving any organ (including the cervix or uterus) other than the heart.

04, Test. Dr. Doe; see also Tr. 1514, Test. Dr. Shadigian (necessity to terminate previable pregnancy for maternal health reasons is "uncommon"); Tr. 1687-88, Test. Dr. Lockwood ("generally not" necessary to perform an intact D&E on a previable fetus to protect maternal health; "safe and effective ways exist to terminate a pregnancy for a maternal health reason prior to viability without the need to resort to the D&X procedure on a living fetus"; pregnancy termination for severe preeclampsia, renal disease, placenta previa, and HELLP syndrome does not necessitate performance of a D&X).)

According to Dr. Lockwood, an intact D&E is not medically "necessary" postviability to preserve the health of the mother because "[b]y definition, any procedure that . . . requires the intentional killing of the fetus isn't going to improve the mother's condition." (Tr. 1681, Test. Dr. Lockwood.)

Dr. Shadigian cannot "think of a situation" constituting a "medical need to use the D&X procedure to terminate a pregnancy . . . because of a particular type of health condition that the mother is facing in the pregnancy." In her opinion, there are safe and effective ways to terminate a pregnancy for maternal health reasons without using the intact D&E, or D&X, procedure—the disarticulation D&E procedure and medical induction "with many different kinds of medicines that have both been well studied." (Tr. 1517-18, Test. Dr. Shadigian.) Further, the intact D&E would not be an appropriate procedure when maternal health is rapidly deteriorating because "it takes so many days to treat the cervix ahead of time and get the body prepared for the actual procedure itself." (Tr. 1518, Test. Dr. Shadigian.)

As with maternal medical conditions, Dr. Cook has "not found a single fetal condition" that would medically necessitate use of the intact D&E to terminate a pregnancy. Dr. Cook believes it is not necessary to destroy a fetus that has an abnormality because such anomalies rarely affect maternal physical health interests. If a fetal anomaly did create high blood pressure in the mother, for example, "[y]ou

just need to separate the fetus and the placenta from the mother," not destroy the fetus. (Tr. 1330-31 & 1334, Test. Dr. Cook.) Dr. Cook described a much-discussed fetal condition that would not necessitate, in his opinion, use of the D&X procedure to terminate the pregnancy:

* Hydrocephaly: Dr. Cook explained that hydrocephaly is distention of the ventricular system in a baby's brain, which is the fluid-filled canal system within a fetus's central nervous system. If the canal system becomes overly distended due to a blockage or overproduction of cerebral spinal fluid, hydrocephaly occurs which, in its most extreme form, can lead to macrocephaly, a large fetal head. In the rare instances involving macrocephaly, Dr. Cook performs an intrauterine procedure to decompress the ventricular system. A needle is surgically placed into the distended ventricular system in order to aspirate some of the fluid to make the head small enough to allow for vaginal delivery. If a patient declines this procedure, Dr. Cook would proceed with a cesarean delivery. (Tr. 1334-35, Test. Dr. Cook; Tr. 1700-01, Test. Dr. Lockwood (not necessary to use intact D&E to terminate pregnancy with fetal anomaly; for hydrocephaly, pregnancy could be terminated by medical induction, D&E, or intact D&E, which are all "acceptable" in this circumstance; fluid in fetal brain should be aspirated by cephalocentesis before any termination procedure to ensure fetus is delivered without complications).)

Dr. Shadigian believes the intact D&E procedure is never necessary to terminate a pregnancy involving a fetal anomaly because "we have such other well studied techniques that work very effectively; both the D&E, and the medical induction are very well studied, and we know where the lines are that there are increased risks with one or the other." (Tr. 1521, Test. Dr. Shadigian.) For example, if the fetus's head is "very big with hydrocephaly, there is actually a procedure we can do to draw off the

fluid around the baby's head, for the head to get a little bit smaller and make it easier to have the baby come out." (Tr. 1522, Test. Dr. Shadigan; see also Ex. 891, Test. Dr. Clark 2380 (in cases of hydrocephalis, labor induction or dismemberment D&E are available methods of second-trimester abortion; if head is very large, fluid can be suctioned out of fetal brain by cephalocentesis to allow delivery of fetal head).)

Further, Dr. Clark testified that the intact D&E is not necessary for diagnostic pathology of fetal anomalies. If the fetus is dismembered, data important to the diagnosis may be lost. The intact D&E removes the possibility of doing an autopsy on the fetal brain. Dr. Clark believes that medical induction is the best method of securing a fetal specimen for pathological diagnosis because the fetus remains entirely intact. (Ex. 891, Test. Dr. Clark 2394-95.) If labor induction cannot be safely performed due to the mother's physical circumstances, the intact D&E is an available option. Under these circumstances, Dr. Clark believes the Act would not ban the intact D&E, provided potassium chloride or digoxin were used to kill the fetus prior to removal. Provided the amniocentesis is skillfully done, there are no risks associated with performing an intrauterine injection to carry out an abortion. In Dr. Clark's view, the risk to the mother is the same irrespective of whether the doctor induced fetal demise. (Ex. 891, Test. Dr. Clark 2395-97 & 2415.)

Dr. Shadigian used medical induction for a set of conjoined twins who were past 20 weeks and who were connected from the chest to the abdomen. "[T]he babies didn't have to be destroyed in any way. They just naturally died in the labor process."[81] (Tr. 1522, Test. Dr. Shadigian; see also Ex. 891, Test. Dr. Clark 2383 (depending on how they are attached, either labor induction or dismemberment D&E could be used to abort conjoined twins; in most cases, dismemberment is preferred).)

[81]The mother of the conjoined twins later had a term birth under Dr. Shadigian's care. (Tr. 1522, Test. Dr. Shadigian.)

Dr. Cook believes that the safety of the intact D&E procedure cannot be proven by the plaintiffs' assertions that the procedure appears to be safe because it involves fewer instrument passes and does not require removing sharp fetal fragments from the uterus. When actually studied, medical techniques or drugs that appear to offer benefits may prove to be harmful, as evidenced by this country's experience with DES,[82] a drug used nationwide after noncontrolled study to prevent miscarriages, but later found to cause many complications, including vaginal cancer and genital tract abnormalities. (Tr. 1354-55, Test. Dr. Cook.) However, "an intact D&E or D&X procedure may be a preferable procedure at the same gestational age than a D&E, if you are able to have less need for instrumentation inside the uterus." (Tr. 1425, Test. Dr. Cook.)

If a physician is attempting to abort a 17-week fetus via D&E and the fetus delivers in one pass, except for the fetal head which becomes stuck in the internal cervical os, Dr. Cook believes it would be medically reasonable to administer nitroglycerin[83] in an attempt to loosen the cervix and "do what [he] can to manipulate the head out of the cervix which could include a single small incision on the cervix." If this procedure did not work, the physician could perform a crushing or aspiration procedure on the fetal head without violating the Act because the fetus would no longer be alive because "it's now been hanging out for some number of minutes with complete occlusion of the cord. . . . You can't completely occlude a cord for more than a few minutes and still have a live fetus." (Tr. 1462-65, Test. Dr. Cook; see also Tr. 1598-1602, Test. Dr. Shadigian (in same situation, physician could try to change

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[82]DES is the abbreviation for diethylstilbestrol. Stedman's Medical Dictionary 483 & 499 (27th ed. 2000).

[83]Dr. Lockwood testified that nitroglycerin—which directly relaxes smooth muscle tissue—is used in obstetrics to effect rapid uterine relaxation. The uterus is made of smooth muscle tissue. Because the cervix is comprised of only 30 to 40% smooth muscle tissue, with some exceptions, in utero nitroglycerin is generally not effective for dilating the cervix. (Tr. 1760, Test. Dr. Lockwood.)

angle of baby's head, use maneuvers similar to those used in breech deliveries, administer medicine to increase uterine contractions, and apply nitroglycerin to relax the cervix).)

In the above scenario, if the woman was bleeding such that a quick delivery was necessary, Dr. Shadigian stated that the physician could use forceps to grasp a part of the baby, "pull harder" to cause dismemberment, and try to change the angle of the fetus to pull it out. If the mother is "hemorrhaging and you need to get the baby out, [it] could be possible to collapse the skull" without violating the standard of care. (Tr. 1601, Test. Dr. Shadigian.)

Dr. Cook criticized as "extreme and absurd" the examples given in Dr. Philip Darney's March 12, 2003, letter to Senator Feinstein[84] of cases in which the intact D&E procedure was purportedly critical to the safety of Dr. Darney's surgery.

> When they first presented this to me, I honestly thought it was laughable and didn't believe these were real cases because I could not imagine somebody managing these pregnancies in this way. . . . [I]n the first case . . . you have a placenta previa, meaning you have a placenta that is presenting ahead of the baby, and you're having so much bleeding that you're replacing blood products, and you have a patient who is coagularpathic . . . the last thing I know of any maternal fetal medicine person would do or obstetrician would be to attempt further vaginal procedures on that patient. That patient needs a definitive procedure like yesterday, so we would have proceeded with hysterotomy, removal of the placenta, removal of the fetus, and the reason for that is that you want to be able to correct the situation rapidly. Also, there is at least 5% risk of a placenta accreta which is the next situation. . . . [w]hich would be an even further complication where you require hysterectomy to control bleeding, so to me, it was a very poorly made decision . . . .

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[84]Dr. Darney's letter is reproduced in my summary of the congressional record in this case, supra.

. . . .

> [Y]ou could pretty much consult any basic obstetrics text, and they would say that having the situation of placenta previa would be a contraindication to vaginal delivery. . . . [T]hey had a patient who had this history of this placenta previa, and she was already known to have risk factors with a clotting disorder, and they went ahead, despite that, and tried to deliver her vaginally by intentionally causing contractions and cervical change which is why you have bleeding with the placenta previa . . . because the cervix starts to dilate or the lower end segment thins out, so they intentionally caused a situation that [they] knew was going to complicate bleeding in a patient with underlying risk factors . . . and then when they decided the heavy bleeding was so great they couldn't keep up, then they did this intact D&X procedure. . . . They would never have had to have gone down that road at all nor put that patient in jeopardy had they proceeded with what I think any reasonable maternal fetal medicine person would have done which was a hysterotomy.

(Tr. 1470-72 & 1476-77, Test. Dr. Cook; Ct.'s Ex. 3.)

Dr. Lockwood also addressed Dr. Darney's example of the 25-year-old with two previous vaginal deliveries, bleeding placenta previa, and a clotting disorder at 20 weeks who was referred for termination of pregnancy. Noting the lack of information regarding the patient's blood condition, Dr. Lockwood stated that if the physician had to "move very quickly in doing the termination" because of a bleeding situation, "the time to do a D&E and D&X, at least according to Chasen's study, was the same." Dr. Lockwood opined that "if the law were in force, they could have injected KCl. They are very skilled at doing that at UCSF. They could have injected lidocaine. They could have injected Digoxin. A variety of ways to induce fetal death, then have done an intact D&X." (Tr. 1690-92, Test. Dr. Lockwood.)

Dr. Lockwood expressed "shock" about Dr. Darney's example of a 38-year-old patient with three previous cesarean deliveries, evidence of placenta accreta, and a

75% risk of massive hemorrhage and hysterectomy at the time of delivery who was referred for pregnancy termination at 23 weeks.

> The placenta accreta is where the placenta invades the wall of the uterus. I see many of these patients in New York. . . . [T]hese patients . . . generally are not symptomatic to 36 weeks. I have no idea why they would want to do a termination at 22 weeks, unless the woman was interested in a termination. The management of placenta accreta is cesarean hysterectomy. Anyone that attempts to do anything short of that is playing an incredible game with this patient's life. Now, this may have been a patient that deeply wanted to retain her fertility. Well, in which case, why was she terminating a pregnancy? That makes no sense to me. It's very clear from the literature . . . [and] from our experience that the critical event, in the management of placenta accreta, is definitive surgery at the time. Conservative management has failed time and time again. It's placed the patient's life in great jeopardy. The only conceivable reason you might do it is in a woman who['s] never had children, desperately desires children. If the accreta were small, I have no idea why anyone would try to do this, to be honest with you. So should they have done this? No. Did they get incredibly lucky? Yes. If there had been a bad event, would they have been sued by many, many lawyers? Yes, absolutely.

(Tr. 1693-94, Test. Dr. Lockwood.)

Dr. Shadigian finds no basis on which to conclude that the intact D&E procedure is safer than other methods of abortion because her international and domestic literature search revealed no studies stating "what the correct indication should be for a D&X. We don't know what the short-term complications are. We don't know the long-term complications. And because it hasn't been studied at all, we can't really even compare it to a D&E or to a medical induction of labor." (Tr. 1522-23, Test. Dr. Shadigian.)

> [This lack of formal study of the intact D&E procedure] tells me, I don't know if it's safe or not. I don't know if it's going to cause women even more problems in the end or less problems. And when something is so unstudied . . . I'm just not willing to . . . put my patients' own reproductive health on the line for something [when] I know we already have good data on D&E procedures and medical induction procedures.

(Tr. 1523, Test. Dr. Shadigian.) "[M]edicine is based on evidence. It's based on doing studies. It's based on compar[ing] what we know to what we don't know. And in the absence of that, [practitioners' assertions that the intact D&E is safe] are just anecdotal thoughts or feelings that a physician may have." (Tr. 1524, Test. Dr. Shadigian.)

According to Dr. Shadigian, while the intact D&E procedure involves less instrument passes than the traditional D&E, which "should" reduce the risk of laceration and perforation, the "whole picture as to the safety of the procedure" also includes short-term and long-term complications, which are impossible to gauge if women do not return to their abortion provider for follow-up care. (Tr. 1526-27, Test. Dr. Shadigian (citing the 1999 "Picker study" which showed that only 29% of women follow up with their abortion provider).)

While the risks of the intact D&E procedure have not been established in medical and scientific literature, Dr. Lockwood believes that the "risks of D&E and D&X could be comparable." However, beyond the "intuitive or theoretical advantages" of performing an intact D&E, Dr. Lockwood does not see any evidence that the intact D&E is a "safer procedure." (Tr. 1712, Test. Dr. Lockwood.)

The intact D&E procedure "might be reasonable in some circumstances," but Dr. Lockwood cannot "envision a circumstance in which the D&X procedure would be required as opposed to a D&E or a medical induction." In Dr. Lockwood's opinion, the short-term risks of the intact D&E procedure would be identical to those

of a D&E. "[T]he theoretical benefit of an intact D&X is fewer manipulations, which might reduce the risks of perforation. Risk of perforation is not insubstantial. . . . [I]t's the most feared complication. So that, I think, is the great appeal of the procedure. . . . [and] a theoretical advantage." Although reports from Europe are "conflicting" regarding the relationship between abortion and subsequent preterm birth, the "primary" and "most serious" "long-term concern" with the intact D&E procedure is subsequent preterm birth.

> [W]e don't know what the risk would be. Some have argued that the further along you go, the greater the risk because the laminaria are not the most physiologic way to dilate the cervix. Others have argued that earlier D&Es might even be more dangerous, because you're mechanically dilating the cervix. I think, since this is, in fact in the focus of my professional existence, it's a topic I'm very, very interested in. And I am concerned, in general, about the association of abortions and prematurity. And I don't know the answer, to be honest with you. But I'm certainly suspicious and would certainly like more data.

(Tr. 1712-15, Test. Dr. Lockwood.)

### *v. INDUCTION*

Dr. Frederiksen testified that in the early portion of the second trimester, before 15 to 16 weeks, labor induction is less successful and difficult to perform. (Ex. 123, Test. Dr. Frederiksen 1171.) Dr. Shadigian told the court that medical-induction pregnancy terminations after 18 or 20 weeks are "safe and effective" procedures. (Tr. 1534, Test. Dr. Shadigian.) At about 20 weeks, several physicians testified that induction and D&E terminations are comparable for safety purposes. (Tr. 1555-56, Test. Dr. Shadigian ("the medical induction and D&E are safe procedures, especially in the 16- to 20-week range"); Tr. 1765, Test. Dr. Lockwood (after 20 weeks, the rates of safety of D&E and induction are "comparable"; safety rate of intact D&E not yet known); Ex. 123, Test. Dr. Frederiksen 1174 (between 20 and 24 weeks of gestation,

the risks of D&E and medical induction may be similar).) Dr. Creinin knows of no medical data supporting the claim that induction is safer than a D&E for aborting a fetus after 18 or 20 weeks of gestation. (Ex. 122, Test. Dr. Creinin 721-22.)

Although induction abortion is a safe method, based on his experience, CDC statistics, and published medical literature, Dr. Chasen believes the D&E is the safest (and most common) method of abortion after 20 weeks of gestation. (Ex. 121, Test. Dr. Chasen 1578 & 1682-83; Ex. 124, Test. Dr. Hammond 541-43 (D&E safer and more common after 20 weeks of gestation).) Based on her experience and medical literature, Dr. Frederiksen believes labor induction is safe, but the intact D&E is the safest method of performing a second-trimester abortion. The D&E has evolved and become safer over time. (Ex. 123, Test. Dr. Frederiksen 1051 & 1066.)

Dr. Broekhuizen believes that D&E and labor induction are both safe abortion procedures and that the complications of cervical and uterine damage, hemorrhage, and infection are common to both medical-induction and D&E abortion. However, he also believes that, as compared with the D&E procedure, labor induction poses less risk of injury by instrumentation and less risk of trauma. (Ex. 120, Test. Dr. Broekhuizen 504 & 579-80.) Dr. Frederiksen testified that labor-induction abortion poses a lower risk of uterine perforation than the D&E method. (Ex. 123, Test. Dr. Frederiksen 1213.)

Dr. Clark believes that labor induction is a safe and recognized abortion procedure. (Ex. 891, Test. Dr. Clark 2306.) However, barring medical complications, he views the D&E as the preferable second-trimester abortion option before 18 weeks of gestation. It is the procedure Dr. Clark would recommend to his patients at that gestational age because labor induction is much more difficult for the mother prior to 18 weeks of gestation; is uncomfortable until the mother is given an epidural; and can be psychologically draining on the mother. Moreover, a D&E takes less than an hour, while labor induction can take up to 48 hours. (Ex. 891, Test. Dr. Clark 2405-07.)

According to Dr. Cook, since D&Es are performed at an earlier gestational age, it is more accurate to compare the intact D&E, which is performed later in pregnancy, to contemporary induction techniques using prostaglandins administered orally, vaginally, or intramuscularly. (Tr. 1355 & 1367-68, Test. Dr. Cook.) Despite the lack of randomized controlled trials comparing contemporary induction techniques to the D&E, Dr. Cook believes that modern induction procedures are safer than the D&E after 20 weeks of gestation. (Tr. 1423, Test. Dr. Cook.) After 20 weeks, the D&E becomes more complicated due to "[a] larger, more distended uterus, a larger fetus, greater calcification of the fetus. More difficulty disarticulating the fetus . . . . more cervical dilation than is necessary." (Tr. 1424, Test. Dr. Cook.)

Dr. Sprang's experience and review of medical literature and textbooks lead him to the opinion that the "safety of induction as a termination method . . .[is] at least, comparable to D&E after 20 weeks." (Tr. 1129, Test. Dr. Sprang.) In his expert report, Dr. Sprang concluded that "induction is, in general, the safest method of abortion for the pregnant woman beyond approximately 20 to 22 weeks given the chemical agents used for induction to prepare the cervix and the uterus for delivery and that induction, unlike other methods, does not necessarily involve introduction of instruments into the uterus." (Tr. 1207, Test. Dr. Sprang.) Dr. Sprang's preference is to use induction because he "like[s] natural things," induction is a "more natural process," and "it's just more physiologic. You're basically doing what the body was going to do anyway." (Tr. 1132 & 1200, Test. Dr. Sprang.) Because Dr. Sprang believes that induction is the safest abortion option at 20 weeks of gestation, he "probably wouldn't even bring . . . up" the D&E option to his patients because "in my belief, induction is [a] safer process for the patient at 20 weeks." (Tr. 1213-14, Test. Dr. Sprang.)

Dr. Hammond believes that labor induction is a very safe second-trimester abortion method, and that from 20 to 24 weeks, D&E and labor induction are about equal in terms of safety. (Ex. 124, Test. Dr. Hammond 541-42.)

According to Dr. Lockwood, after 21 weeks, most women and physicians choose surgical abortions over induction abortions. (Tr. 1749-50, Test. Dr. Lockwood.) However, Dr. Broekhuizen testified that the majority of patients who want an intact fetus choose labor induction. (Ex. 120, Test. Dr. Broekhuizen 580.)

Dr. Cook believes that for many maternal-complication cases, as with women having major cardiovascular or central nervous system conditions, monitored medical induction is more appropriate to terminate pregnancies after 16 weeks than the "less physiologic, more invasive and potentially more complicated" surgical options available so that sophisticated monitoring can be used to demonstrate that the patient is "doing well during the process." (Tr. 1279, Test. Dr. Cook.)

For fetal anomalies after 20 weeks of gestation, Dr. Shadigian would "generally" recommend medical induction because:

> [T]he safety data is so much better on medical inductions, especially with the newer Prostaglandins. It used to take much longer to induce labors and it was more distasteful for women and even more difficult to manage people over three days. But now, we have Misoprostol and we can actually deliver babies within four to 24 hours with the new medication, so it's safer. And, also, the older studies show that there is a lot less maternal mortality for medical inductions for 21 weeks and later.

(Tr. 1520, Test. Dr. Shadigian.) However, Dr. Westhoff explained that induction may be contraindicated when fetal anomalies exist, including fetal anomalies that involve the presence of large body parts, such as hydrocephalus. Labor induction will not likely be successful in these circumstances, and a D&E will ultimately be required. (Ex. 126, Test. Dr. Westhoff 821-22.)

Although Dr. Fitzhugh believes that second-trimester D&Es and induction abortions are both "relatively safe," inductions involve a "much higher" discomfort

level for the patient, "much greater" hospitalization time, and a "much greater" amount of care. (Tr. 259-60, Test. Dr. Fitzhugh; see also Ex. 121, Test. Dr. Chasen 1580 & 1588 (medical induction requires hospitalization for several hours or days, but the D&E is an outpatient procedure allowing the woman to go home or to work during the process; with medical induction, the woman receives an epidural with no sedation; in contrast, Dr. Chasen performs D&Es with general anesthesia or local anesthesia and substantial degrees of sedation); Ex. 123, Test. Dr. Frederiksen 1067-68 (labor induction riskier than D&E because second-trimester uterus is not ready for labor and cervix is not ready to dilate; process of inducing uterine contraction and causing the cervix to change from long and closed to short and dilated can take from 9 to 48 hours; medical induction abortion is labor and delivery—a painful process); Ex. 125, Test. Dr. Paul 91-92 (labor induction can be difficult and women tend to prefer shorter D&E procedure); Ex. 126, Test. Dr. Westhoff 812-13 (uterine contractions of induced labor abortion similar to contractions women experience during childbirth where labor is induced using similar medications; induced labor contractions more painful than spontaneous labor contractions).)

Dr. Lockwood identified the primary risks of medical-induction abortions between 20 and 24 weeks as retained placenta,[85] infection, and rarely, tearing of the cervix. (Tr. 1708-09, Test. Dr. Lockwood; see also Ex. 123, Test. Dr. Frederiksen 1148 & 1078-81 (blood loss is possible complication of induction abortion; generally more blood is lost during induction abortion than with D&E; risk of infection exists with any second-trimester termination, but process of labor exposes uterus to vaginal

[85]Dr. Lockwood testified that retained placenta means the fetus delivers, but the placenta does not. Physicians typically wait a period of time for the placenta to deliver on its own. If it fails to do so, the placenta can be removed by suction curettage or manually with risks equivalent to a 10- to 12-week suction curettage procedure. Retained placenta in medical inductions may be viewed either as a side effect since it occurs 20% of the time, or as a complication. (Tr. 1710-11, Test. Dr. Lockwood.)

organisms resulting in higher risk of infection with induction than with D&E; sepsis may arise during labor induction, necessitating a D&E to preserve life and health of mother).) According to Dr. Lockwood, the occurrence of these complications decreases with gestational age because "the uterus is . . . more biologically ready for labor as is the cervix. And it's already stretched out . . . and enlarged. And so those things . . . help contribute to the avoidance of lacerations or asymptomatic tears." (Tr. 1709, Test. Dr. Lockwood.)

Many of the physicians appearing before the court testified that one possible "complication" of induction procedures that does not occur with D&E procedures is retained placenta. In a normal induction procedure, the fetus passes first, the placenta follows shortly thereafter, the uterus contracts, and significant bleeding stops. If the fetus passes, but the placenta remains inside or is partially, but not completely, separated, the bleeding continues. If the bleeding becomes excessive and the placenta is not expelled, the patient must undergo immediate removal of the placenta by emergency operation. Emergency removal of the placenta does not occur in the D&E procedure because the fetus and placenta are removed at the same time during the procedure. (Tr. 142-43, Test. Dr. Doe; Ex. 123, Test. Dr. Frederiksen 1076-79 (separation of placenta can be long process associated with increased blood loss; retained placenta prevents uterus from fully contracting to stop bleeding; often necessary to surgically remove retained placenta in second-trimester induction procedures); Ex. 122, Test. Dr. Creinin 715-16 (labor induction may not empty the uterus of fetal and placental tissue, necessitating follow-up surgery); Ex. 125, Test. Dr. Paul 86-87 (retained placenta is common complication of induction abortion; standard is to wait about two hours after delivery of fetus for delivery of placenta; if placenta not delivered, suction curettage is done, sometimes under general anesthesia, to remove placenta; if placenta is retained more than two hours after fetus is delivered, literature reflects increased risk of bleeding and fever).)

Dr. Knorr believes D&Es are safer than induction abortions. Placentas "come out complete" in induction abortions only 80% of the time because immature placentas are more firmly attached than more mature placentas and because the cord, which is gently pulled to deliver the placenta, tends to break. "While you're waiting for that placenta to come out over that half hour, generally that woman is bleeding, and there have been several times where I have been involved in that kind of procedure and have had to take the woman to the [operating room] hemorrhaging to remove that placenta and stop the blood flow." (Tr. 520-21, Test. Dr. Knorr; see also Tr. 975-76, Test. Dr. Bowes (overall, D&E is safer than induction; contraindications exist for inductions in the second trimester; retained placenta is complication of induction abortion); Tr. 1749, Test. Dr. Lockwood (there is 10 to 30% chance of retained placenta in medical-induction abortions; considers retained placenta to be a complication of induction method); Tr. 1137-39 & 1210-12, Test. Dr. Sprang (retained placenta not "complication" of induction; rather, it is "just a part of the process" in 10 to 20% of induction patients; "Everything we do," including inductions, creates standard risks of "hemorrhage, infection and trauma to the tissue"; it is "a known part of medical abortions [inductions] that 5 to 10% of the time, the placenta won't follow immediately afterwards" and the patient will require D&C to remove retained products of conception); Ex. 121, Test. Dr. Chasen 1587 & 1608 (retained placenta and infection are common complications of medical induction that increase the risk of hemorrhage).)

Dr. Hammond stated that depending on the inducing agent used, in 15 to 30% of labor-induction cases, the placenta is retained and follow-up surgery is required. While waiting is an option, at some point the doctor must intervene to avoid the risk of infection and bleeding. The standard practice is to wait no more than two hours. Based on medical studies, waiting beyond two hours doubles the risk of hemorrhage, infection, and other major complications. Another more recent (late 1980s) study indicates the risk tends to rise after 30 minutes. Therefore, Dr. Hammond and his colleagues at Northwestern begin to consider surgical delivery of the placenta if it has

not been delivered within 30 minutes after the fetus is delivered. The woman continues to be under epidural anesthesia at that time. (Ex. 124, Test. Dr. Hammond 580-86.)

Dr. Vibhakar believes induction abortions to be safe, but has experienced more cases of significant blood loss and infection with induction abortions than with D&E abortions. Several of Dr. Vibhakar's patients who had retained placenta after an induction have required emergency care to control hemorrhage. Dr. Vibhakar has seen a lower rate of retained placenta through use of misoprostol. (Tr. 321-23 & 392, Test. Dr. Vibhakar.) However, Dr. Creinin's research, and his discussions with the co-author of his chapter on induction in an obstetrics and gynecology textbook, have led him to conclude that the medications used today, including misoprostol, have not significantly improved the overall rate of complications related to induction abortions. (Ex. 122, Test. Dr. Creinin 717-18.)

Dr. Creinin noted other complications that are possible in induction-abortion procedures:

* Bleeding, perhaps enough to require a transfusion, may arise from abruption, infection, cervical injury, and uterine injury. (Ex. 122, Test. Dr. Creinin 715.)

* Labor induction requires administering high doses of medications, enough to override the body's internal mechanism for retaining the fetus and to cause the uterus to contract and expel the fetus at a time when it is not physiologically prepared to do so. The uterus can contract so strongly that "it can just break apart, to put it in simplistic terms." (Ex. 122, Test. Dr. Creinin 715.)

* There is a risk (albeit incredibly low) of disseminated intravascular coagulation arising from prolonged bleeding and the liver's inability to manufacture clotting factors as quickly as the body is consuming them. (Ex. 122, Test. Dr. Creinin 716-17.)

According to Drs. Chasen and Hammond, in women with medical complications who need a pregnancy terminated on an urgent basis, the intact or dismemberment D&E procedures are safer than induction because a woman who is already having medical problems is even more susceptible to the complications encountered with medical induction, medical induction can take considerably longer than 24 hours, and its success is not as predictable. (Ex. 121, Test. Dr. Chasen 1610-11; Ex. 124, Test. Dr. Hammond 542-43 & 548 (labor-induction abortion, before 20 weeks in particular, is unpredictable in that it may take only six hours, but could take three days; the longer induction takes, the higher risk of complications such as infection and hemorrhage).)

Dr. Chasen explained that as the uterus contracts forcefully during an induction procedure, the placenta may be expressed or the membranes may rupture and the umbilical cord can get compressed or fall out of the cervix. These conditions deprive the fetus of oxygen, resulting in fetal asphyxiation that can last many minutes. (Ex. 121, Test. Dr. Chasen 1587-88.)

Several physician witnesses testified that in some cases, medical induction is unsuccessful despite prolonged labor. In such cases, a D&E may be required and if the D&E is not an available technique, the woman may need a hysterotomy. (Ex. 121, Test. Dr. Chasen 1587; Ex. 123, Test. Dr. Frederiksen 1077; see also Ex. 126, Test. Dr. Westhoff 823-24 (inductions can fail to expel fetus, requiring D&E to complete the abortion; in 10 to 25% of cases, induction fails to expel placenta and follow-up D&C is required); Ex. 891, Test. Dr. Clark 2409-10 (labor induction does not always succeed in emptying the uterus; as with D&E, instruments may need to be used to remove the placenta, and using instruments poses risk of infections and perforation of

the uterus); Ex. 124, Test. Dr. Hammond 548-49 & 580 (inducing labor does not always work because some patients do not respond to medication or their response is so slow that the mother's health will be harmed unless pregnancy is promptly terminated by D&E; failed induction less common when fetus has died; some patients arrive from outside areas where induction was attempted over period of days, and by the time Dr. Hammond sees them, they have infections and their underlying medical condition has worsened).)

Some physicians believe that induction abortions are "absolutely" contraindicated for patients who have placenta previa—a condition in which the placenta overlies the opening of the cervix, preventing the fetus from passing without causing heavy bleeding—or placenta accreta—a condition in which the placenta grows into the uterine wall and is difficult to separate without causing serious bleeding. (Tr. 26-28, Test. Dr. Doe; Ex. 120, Test. Dr. Broekhuizen 506 (in cases of placenta previa, after 24 weeks a cesarean section would be performed, and after 22 weeks, D&E causes less bleeding); Ex. 123, Test. Dr. Frederiksen 1081 (labor can cause profound maternal hemorrhage in women with placenta previa); Ex. 126, Test. Dr. Westhoff 818 (if cervix dilates in woman with placenta previa, maternal hemorrhage can occur); Ex. 891, Test. Dr. Clark 2350-54 (for patients with placenta previa, carrying pregnancy to term poses less risk than second-trimester abortion; if woman with placenta previa elects to abort second-trimester fetus, labor induction contraindicated due to risk of excessive bleeding, and dismemberment D&E is preferred second-trimester abortion method); Ex. 124, Test. Dr. Hammond 553-54 (labor induction absolutely contraindicated for women with complete placenta previa; if labor is induced, fetus would have to be delivered through the placenta, which cannot occur and, even if it did, would result in severe maternal hemorrhage; in such circumstances, there are only two logical options—hysterotomy or D&E, the latter of which is the better choice because at this stage of gestation, the uterus is a more vascular organ and

cutting through it during a hysterotomy would result in severe bleeding and would make the uterus more prone to rupture in later pregnancies).)[86]

Others believe that induction abortions are contraindicated for women with chorioamnionitis who need evacuation of the uterus as soon as possible to control sepsis. (Tr. 326-27, Test. Dr. Vibhakar; Ex. 126, Test. Dr. Westhoff 814 (cervix is soft and easy to dilate due to infection, but uterus does not respond well to medication; prompt removal of pregnancy by D&E safer and quicker); Ex. 124, Test. Dr. Hammond 555-60 (uterus must be evacuated for chorioamnionitis; can evacuate uterus by labor induction, but D&E is better choice because (1) it is predictable; (2) the longer the mother stays pregnant, the sicker she will become and as the uterus contracts, bacteria within the uterus may inoculate the woman's bloodstream which, with prolonged labor, may cause life-threatening sepsis, particularly if infection is caused by gram negative bacteria; (3) the infected uterus does not contract well and may not be able to sufficiently contract to stop bleeding after the fetus is delivered; and (4) a D&E can be performed on an emergency basis, such as when premature rupture of the membranes occurs and vaginal flora gain access to the uterus and cause infection).)

Still others believe that medical induction may be contraindicated for some women because medications that induce labor, like misoprostol and other prostaglandins, may have adverse effects on patients with certain maternal conditions such as severe asthma. (Ex. 120, Test. Dr. Broekhuizen 506-07.) Further, the use of prostaglandins, such as misoprostol, has been associated with cardiac arrythmia and sudden death. (Ex. 123, Test. Dr. Frederiksen 1076.)

[86]Except for the underlying clotting disorder, this scenario and Dr. Hammond's response to it parallels that of Dr. Darney as discussed in his letter to Congress.

Some physicians believe that medical induction is contraindicated for a woman whose uterus is scarred by a prior cesarean section (particularly with a vertical incision) or myomectomey (removal of a benign tumor from the uterine muscle) because the uterus is prone to rupture at the site of the scar during medically induced labor. In contrast, a D&E does not stimulate strong contractions in the uterine muscle and does not present the risk of uterine rupture. (Ex. 121, Test. Dr. Chasen 1582-85; Ex. 120, Test. Dr. Broekhuizen 505-07 (medical induction contraindicated for woman whose uterus is scarred by a prior cesarean section or who has undergone prior uterine surgery; uterus is prone to rupture at the site of the scar during medically induced labor); Tr. 1749, Test. Dr. Lockwood ("there might be an advantage to vaginal abortion over medical [induction] abortion after 20 weeks, before viability, in a setting where there was a previous C section or other uterine surgery that had been performed"); Ex. 123, Test. Dr. Frederiksen 1079-80 & 1138 (when uterus is scarred, higher risk of uterine rupture with labor induction than with D&E because scars can open during induction process; D&E usually safer method of terminating second-trimester pregnancy in women who have undergone prior cesarean section, hysterotomy, or myomyectomy); Ex. 122, Test. Dr. Creinin 712-14 (when upper portion of uterus is scarred, where contractions are the strongest, induction abortion is contraindicated; D&E is wiser and safer method of terminating second-trimester pregnancy in women who have undergone prior cesarean section or myomyectomy if incision was made in upper portion of uterus); Ex. 126, Test. Dr. Westhoff 815-17 (scarred uterus can rupture during induction abortion; hemorrhage can occur, and if uterus cannot be repaired, woman may have to undergo hysterectomy which eliminates her ability to have children in the future); Ex. 891, Test. Dr. Clark 2358-61 & 2407-08 (although there is no published data on the issue, it is reasonable to believe that dismemberment D&E is safer second-trimester abortion method for women with scarred uterus; no reason to believe D&E would present higher risk of uterine rupture in patients with prior uterine scar, but based on risk presented by uterine contractions at term, it is reasonable to believe contractions of labor induction may rupture uterus).)

Dr. Creinin believes that medical induction may also be contraindicated for a woman:

* With liver failure and associated clotting disorders. Induction is a very prolonged process, and bleeding occurs when the fetus passes through the birth canal and when the placenta separates. When the woman's ability to clot is compromised, an expeditious surgical procedure in a controlled environment is the medically appropriate abortion method. (Ex. 122, Test. Dr. Creinin 689-90; see also Ex. 126, Test. Dr. Westhoff 820 (prefers D&E over induction for women with bleeding disorders affecting clotting factors and platelets because missing clotting factors can be replaced during short duration of D&E procedure, as compared with prolonged induction process).)

* With significant underlying heart or respiratory diseases. Labor induction prompts a fluid shift in the woman's body, medications must be administered, the induction process occurs over a prolonged period of time, and it may not be successful. When underlying heart and lung conditions exist, D&E is the preferred treatment for the health of the mother. (Ex. 122, Test. Dr. Creinin 714-15.) In Dr. Westhoff's practice, a patient's cardiologist may refer them to Dr. Westhoff for a D&E because prolonged labor is considered dangerous to their patients due to the change in dynamics of the blood supply. (Ex. 126, Test. Dr. Westhoff 819.) Anesthesia care during the D&E can protect the body's systems, including the lungs, while prostaglandins used to induce labor may cause bronchiospasm which interferes with the patient's breathing and oxygenation. (Ex. 126, Test. Dr. Westhoff 819.)

Dr. Vibhakar has had two cases where induction terminations were not the best medical option for the patient:

> I remember one case where the patient had atypical severe pre-eclampsia at about 19 weeks, and she had pulmonary edema and her respiratory status was worsening. She was already undergoing an induction termination procedure, but it was taking time, and it did not appear that she would deliver in the near future, so I was asked to perform a D&E. I did and she . . . clinically improved rapidly after that.
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> . . . .
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> There was another patient who was approximately 20 weeks pregnant when she developed headache and loss of vision and was diagnosed with five to six centimeter intracranial hemorrhage due to a ruptured AVM, arterial venus malformation, and she wanted to terminate the pregnancy. She was counseled that she would be at risk of the AVM rebleeding should she carry the pregnancy to term and labor. She was also rather, the neuro surgeons at the University of Iowa did not want to treat the AVM. They did not want to ligate it or embolize it until after pregnancy. And my maternal fetal medicine colleague and the neurosurgeons in consultation with each other decided the best method for termination would be a D&E as opposed to an induction because it could be a more controlled procedure.

(Tr. 327-28, Test. Dr. Vibhakar.)

In cases where Dr. Cook performs an induction and the fetal head becomes trapped in the woman's cervix, he does not perform a "crushing procedure on the baby's head or some sort of suctioning or evacuation of the fetal brain contents." Instead, he waits several minutes to see if the woman passes the fetus on her own; administers medical agents like nitroglycerin to the mother that help relax the uterus; uses forceps on the head; or makes one or more Dührssen incisions[87] in the cervix to

[87]Dührssen incisions are "three surgical [incisions] of an incompletely dilated cervix, corresponding roughly to 2, 6, and 10 o'clock, used as a means of effecting immediate delivery of the fetus when there is an entrapped head during a breech delivery." Stedman's Medical Dictionary 887 (27th ed. 2000).

allow the head to pass. If incisions are used, Dr. Cook sutures the incisions if they are bleeding, but if no bleeding is present, he does not suture the incisions in order to reduce the risk of adhesion formation. Dr. Cook views these cervical incisions as "more gentle" than dilation with osmotic dilators because "[i]t's a single incision that's done in a portion of the cervix with immediate repair"; cervical lacerations or tears are "observed frequently as part of the natural physiologic process of labor"; and damage caused by osmotic dilators that are placed into the "entire length of the cervical canal" creates a "zone of injury [that] goes to the entire cervix, not just to the area we are making an incision." (Tr. 1418-22 & 1462-63, Test. Dr. Cook.)

Dr. Broekhuizen opined that if bleeding is significant or the membranes have ruptured easily and early such that infection may result if the labor-induction process is prolonged, labor induction may be converted to a D&E for the safety of the mother. According to Dr. Broekhuizen, once bleeding and infection occur during a labor induction, antibiotic administration alone is not sufficient because the body cannot respond quickly enough to this treatment. Waiting for more dilation, administering antibiotics, or making Dührssen incisions are also not appropriate medical responses. Dührssen incisions inflict trauma to the cervix which can be repaired, but may present problems in future pregnancies. (Ex. 120, Test. Dr. Broekhuizen 531-34.) Labor induction may progress to the point that the fetus is living and partially delivered with the fetal head lodged at the internal cervical os. Under these circumstances, compressing the fetal skull to complete the abortion may be the best option. (Ex. 120, Test. Dr. Broekhuizen 532-34, 551-52.) This situation may also arise from a spontaneous midtrimester miscarriage. (Ex. 120, Test. Dr. Broekhuizen 555-56.)

The fetus may be delivered intact and alive in an induction abortion. In Dr. Hammond's practice, if the fetus has even a remote chance of viability, the 24-hour neonatologist on site is called to provide assistance. However, in all cases, an abortion is not performed absent very good data indicating that the fetus is not viable. When

it is born alive, it is kept warm or, if the mother wants to hold it, given to the mother until it dies. (Ex. 124, Test. Dr. Hammond 616-17.)

Dr. Shadigian's article analyzing available peer-reviewed abortion literature examined seven potential complications of abortion, which was defined as elective termination of pregnancy, including surgical methods and medical induction—subsequent spontaneous miscarriage, subsequent infertility, subsequent ectopic or tubal pregnancy, breast cancer, placenta previa, preterm birth, and psychological effects. (Ex. 631 & Tr. 1562.) The study concluded that induced abortions were not associated "in the aggregate" with ectopic pregnancy, subfertility (i.e., the ability to get pregnant after the abortion), or subsequent spontaneous miscarriages. The study also found that based on a review of population-based studies, induced abortion increases the risk of preterm birth in subsequent pregnancies by up to two times, and the more abortions a woman has, the higher the risk for subsequent preterm births. The article found notable the increased risk of preterm deliveries at 20 to 30 weeks of gestation after induced abortion "which is especially relevant because these are the infants with the most risk of morbidity and mortality upon which society expends so many resources." (Tr. 1537 & 1542-50, Test. Dr. Shadigian; see also Ex. 126, Test. Dr. Westhoff 1790 (greater cervical dilation must be achieved for second-trimester induction abortion to accommodate delivery of the fetal head).) Dr. Shadigian is concerned that because her study focused primarily on first-trimester abortion procedures, showing a doubling effect of preterm birth in later pregnancies, "in the D&X procedure, we are talking a much greater size of the baby, and this baby being pulled through a partially-open cervix such that . . . the potential for damage to the cervix is much greater in a D&X procedure than it would be in a simple first[-]trimester procedure" and there could be "even more pre-term birth with second[-]trimester abortions or later gestational age ones." (Tr. 1549-50 & 1578, Test. Dr. Shadigian.)

According to Dr. Frederiksen, the history of abortion in this country proves that labor-induction techniques are riskier than D&Es. While the percentage of second-trimester terminations performed by labor induction has been decreasing, the proportion of those abortions performed by D&E has increased and with that change, the overall safety record of second-trimester abortions has improved. (Ex. 123, Test. Dr. Frederiksen 1066-67.)

### *vi. HYSTEROTOMY AND HYSTERECTOMY*

Hysterotomy[88] and hysterectomy[89] are available abortion options that account for 0.01% of all abortions and 0.07% of second-trimester abortions performed in the United States. (Ex. 125, Test. Dr. Paul 46-47.) Dr. Broekhuizen explained that hysterotomy is a major surgery, and although it can be performed when induction and D&E procedures fail, it is a last option before 24 weeks. (Ex. 120, Test. Dr. Broekhuizen 508.) In Dr. Paul's opinion, the death rates associated with abortions performed by hysterotomy or hysterectomy are prohibitively high. (Ex. 125, Test. Dr. Paul 46-47.)

Dr. Frederiksen explained that, for midtrimester pregnancies, the hysterotomy incision must be made vertically, similar to a classical cesarean section, because the lower segment of the uterus is not yet present and, therefore, a horizontal lower segment transverse incision is not an option. As a result, as with classical cesarean

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[88]A hysterotomy is an abdominal incision through the abdominal wall and uterus performed for the purpose of emptying the uterus. (Ex. 123, Test. Dr. Frederiksen 1077-78.) See also Stedman's Medical Dictionary 869 (27th ed. 2000) (a hysterotomy is an incision of the uterus). If performed before the fetus is at 23 to 24 weeks of gestation, the surgical method used for performing a cesarean section is called a hysterotomy. (Ex. 891, Test. Dr. Clark 2379-80.)

[89]A hysterectomy is removal of the uterus. Stedman's Medical Dictionary 867 (27th ed. 2000).

sections, women who have undergone a hysterotomy should not go through labor to deliver future pregnancies. All subsequent pregnancies should be delivered by cesarean section. Labor induction for termination of any future second-trimester pregnancy also presents a 2.3% higher risk of uterine rupture and hemorrhage. (Ex. 123, Test. Dr. Frederiksen 1077-78.)

### *b. TYPES OF STUDIES*

Joel D. Howell, M.D., Ph.D., received his medical degree from the University of Chicago in 1979 and his Ph.D. in history and sociology of science from the University of Pennsylvania in 1987. He completed his internship and residency in internal medicine at the University of Chicago hospitals, is licensed to practice in Michigan, and is board-certified in internal medicine. Dr. Howell is a professor at the University of Michigan in the Department of Internal Medicine, the Department of History in the College of Literature Science and the Arts, and the Department of Health Management and Policy in the School of Public Health. Dr. Howell directs the Clinical Scholars' Program, which is a two-year fellowship program for physicians in a variety of clinical specialties that teaches physicians how to conduct research benefitting the health of all Americans. He has lectured and published papers in peer-reviewed journals about the development of surgical techniques, and he serves as a manuscript reviewer and member of the editorial board for numerous medical journals. Dr. Howell has never performed an abortion, nor has he seen one being performed. (Ex. 97; Tr. 414-29 & 472, Test. Dr. Howell.)

Dr. George Mazariegos is a board-certified surgeon who received his medical degree from Northwestern University in Chicago in 1986. In 1991, he completed his internship and residency in general surgery at Michigan State University, after which he entered fellowships in critical care and organ transplantation at the University of Pittsburgh. Following his fellowships in 1994, Dr. Mazariegos became a faculty member at the University of Pittsburgh School of Medicine Department of Surgery,

where he is now an associate professor of surgery and anesthesiology and critical care medicine and co-director of pediatric transplantation. He performs several transplant-related surgeries per week. Dr. Mazariegos is a fellow in the American College of Surgeons and serves as a reviewer of manuscripts dealing with pediatric transplantation for various journals. Dr. Mazariegos has never performed an abortion and observed less than five first-trimester abortions during medical school. (Ex. 890; Tr. 793-804, 839-40, Test. Dr. Mazariegos.)

Several physicians testified that clinical studies used to conduct medical research are prospective or retrospective and experimental or observational. Observational studies include case reports, case controlled studies, and retrospective cohort studies. "Case reports" are presentations or medical journal articles that describe one case or a series of cases over time. "Retrospective" studies look at something that has happened in the past. "Case controlled studies" are used to identify the cause of relatively uncommon events by comparing actual cases with controls having characteristics that might be responsible for causing the event. "Retrospective cohort studies" describe findings as to a particular group of people—like people living in a particular community or people who have undergone a particular surgical or medical procedure. (Tr. 433-36, Test. Dr. Howell; Tr. 907-10, Test. Dr. Bowes; Ex. 121, Test. Dr. Chasen 1622 (retrospective cohort studies are most common way to evaluate and compare surgical techniques).)

One type of experimental study is a "prospective randomized clinical trial" that looks at something from the present into the future where the "allocation of interest is assigned randomly" so that biases in the selection process are removed. (Tr. 436-37, Test. Dr. Howell; Tr. 908, Test. Dr. Bowes.) Such a study uses two or more groups and randomly assigns (often by computer) the groups to a specific treatment or intervention. The study participants have no choice on the treatment or intervention they receive. The participants are followed from the time of intervention forward. (Ex. 122, Test. Dr. Creinin 702-03.)

Randomized clinical trials eliminate bias by randomization and, because they are prospective, the person conducting the study can decide in advance what data needs to be collected and what outcome is of interest. This type of study is a "much more powerful statistical technique than simply looking for differences." The disadvantage of this type of study is that the benefits of doing the study must be worth the considerable costs involved. Drug studies are often conducted in this manner. (Tr. 440-44, Test. Dr. Howell; Tr. 828-29, Test. Dr. Mazariegos (discussing controlled prospective trials); Ex. 121, Test. Dr. Chasen 1667 (randomized trial would ideally allow for a better understanding of complications attributable to a procedure).)

Drs. Howell and Mazariegos explained that while the case series, retrospective cohort studies, and retrospective case control studies are simpler to perform because they do not require randomizing patients and they allow one to proceed as usual, they are limited in terms of range of patients and providers, they may reflect one's particular expertise or lack thereof, they suffer from potential bias in identification of confounders,[90] and relevant information may not have been recorded on the subjects' medical charts. (Tr. 437-38, Test. Dr. Howell; Tr. 825-26, Test. Dr. Mazariegos (describing flaws of case series).)

Dr. Howell noted that unlike retrospective studies, prospective studies may involve alteration of the physician-patient relationship. A patient trusts a doctor to do what is best for the patient, while a study comparing two different treatment choices may conclude that one of the choices is dangerous. "And that's going to mean that some patients won't want to enroll and some physicians won't want to do the study." (Tr. 439-40, Test. Dr. Howell.)

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[90]For example, if you do not believe that smoking is related to lung cancer and you do not control for smoking in your study, you have "missed a potential confounder . . . and you would come up potentially with a result that was erroneous." (Tr. 438, Test. Dr. Howell.)

Dr. Howell believes that surgical techniques are difficult to standardize for study purposes. Unlike a drug that is being studied that remains the same with each dose, surgical techniques vary because different operators have different skill levels, the same operator has different skill levels over time, and patient/surgeon interaction during surgery may cause the procedure to change or be done slightly differently in any given case. While the FDA monitors and manages the introduction of new drugs, there is no equivalent for the introduction of new surgical procedures. (Tr. 443-44, Test. Dr. Howell; contra Tr. 830, Test. Dr. Mazariegos (controlled trials in surgery not difficult to standardize because of varying skill levels of surgeons because all surgeons are expected to uphold certain standard, and it is the standard that is being tested, not the skill of the surgeon; including other institutions and surgeons can eliminate any possible bias).)

> [A]sking patients to randomize themselves to surgical procedure[s] is asking them to have a very different sort of interaction with the surgeon than is the case for a drug study. . . . [T]he surgeon is asking the patient to agree to the surgeon being constrained in terms of what she or he might want to do, when they actually are in the course of performing that particular operation. And some patients . . . would be less likely to want to agree to that.

(Tr. 445-46, Test. Dr. Howell.)

Drs. Howell and Mazariegos identified "having power" as a challenge associated with conducting a study comparing two procedures that both appear, from initial study, to have very low complication rates; that is, the likelihood that the study will establish a clinically significant difference between the two procedures. When one expects to see major differences between two procedures, a smaller study would suffice, but when the differences between two procedures will be smaller, "you're going to need a huge number of patients, because otherwise, you're simply not going to be able to make that differentiation." It may also be difficult to justify continued

investment of physician and patient time and money when both procedures have very low complication rates. (Tr. 448-52 & 460, Test. Dr. Howell; Tr. 834-36, 858, 864, Test. Dr. Mazariegos.)

According to Drs. Howell and Bowes, in order to "randomly allocate" patients to study "two treatment arms, be they drugs, surgery," clinical equipoise must exist—that is, the physician conducting the study cannot know that drug A or surgery A is better than drug B or surgery B or that either are better than a placebo. A physician cannot ethically enter patients into a study comparing two treatments when the physician does not believe that equipoise exists. (Tr. 453-54, Test. Dr. Howell; Tr. 938, Test. Dr. Bowes (describing equipoise).)

Dr. Mazariegos testified that studies may be published in peer-reviewed journals, which are journals that require outside evaluation and critique of submitted data in an effort to assure that there are uniform standards for data presentation. He explained that data published in a peer-reviewed journal generally has "greater worth to clinicians" compared to medical literature that has not been subject to any sort of review process. The latter type of literature may suffer from a lack of accountability on the part of investigators who have failed to uphold certain standards of informed consent, as well as bias resulting from a lack of objective review of the process used to answer the question at issue, statistical methods, and use of control groups. (Tr. 821-23, Test. Dr. Mazariegos.)

Surgeons disagree about what is an acceptable variation of an existing surgical technique and what is a new or innovative surgical technique that warrants study by an institutional review board.[91] Whether a new surgical procedure is a "major

[91]Dr. Mazariegos explained that an institutional review board ("IRB") is a body that functions within a hospital setting to review investigations of procedures, devices, medicines, or new therapies. The board contains physicians from the relevant specialty and from other specialties. Physicians not affiliated with a hospital

modification" of an existing surgical technique is a "perceptual question on the part of the surgeon." (Tr. 852 & 881-82, Test. Dr. Mazariegos.)

Drs. Howell and Mazariegos stated that if a case series or several case series have demonstrated the safety of a modification of a surgical technique, whether the modification would receive additional study depends on the extent of the modification and whether the modification produces significant outcomes as compared with the original surgical technique. Problems in studying surgical technique modifications include standardization, patient recruitment, and study design (i.e., defining an important question, finding an answer that will be useful to patients, and designing a study to accomplish those goals). (Tr. 447-49, Test. Dr. Howell; Tr. 831, Test. Dr. Mazariegos (only major surgical modifications should be subject to further study and peer review; major surgical modifications are those that "alter the risk to a patient in a perceptible . . . manner").) According to Dr. Howell, randomized clinical trials can be suitable for evaluating variations in surgical techniques if standardization, patient recruitment, and study design problems are solved. "It is often held up as a goal. It is rarely achieved." (Tr. 453, Test. Dr. Howell.)

Dr. Howell testified that in situations where a physician wishes to study a surgical procedure, but still wants to offer the procedure to his or her patients, observational studies like publishing the results of a case series and presenting the results at professional meetings are appropriate. (Tr. 458, Test. Dr. Howell.) Peer review and observational studies in retrospective reviews provide objective, reliable information about the risks and benefits of surgical procedures to guide surgeons as to the safety and efficacies of new procedures. Many studies in the surgical arena are retrospective in design and many retrospective reports regarding surgery involve procedures performed at a single institution. (Tr. 866-67, Test. Dr. Mazariegos.)

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may submit potential protocols to the hospital's IRB for study and analysis. (Tr. 819-20 & 875-76, Test. Dr. Mazariegos.)

Dr. Howell noted that the coronary artery bypass grafting procedure was studied only after the technique had been used on many patients.

> [The coronary artery bypass grafting procedure] was studied in the sense that when people first tried the different approaches, they took note of what happened. They took note of whether they saw an improvement in the patient or not. The technique rapidly expanded, and within . . . a decade of its being introduced, it was being performed on probably hundreds of thousands of patients. It was only after that point that systematic standardized trials began to be done. And when they were performed, there was a considerable amount of controversy about whether or not those trials needed to be done.

(Tr. 432-33 & 458, Test. Dr. Howell.)

Dr. Howell also testified that there are clinical procedures, such as removing fluid from a lung ("thoracentesis"), that are performed in varying ways, yet such variations have not been subject to clinical trials. Thoracentesis—a procedure performed daily in hospitals across the nation with a low, but not insignificant, rate of complications—can be done from the side or from the back, with ultrasound guidance, or with physical examination.

> [Thoracentesis] is learned by craft, by doing it side-by-side. And to the best of my knowledge, nobody has ever done a systematic study to say is it better to do it one way or the other way. Typically, you learn how to do it one way, as I did, and then you teach others how to do it that way, and maybe somebody does it slightly differently at another institution. And we see this all the time, particularly in people who are trained in different institutions work together. We see minor variations in the way that a procedure is done. It's very common.

(Tr. 460-61, Test. Dr. Howell.)

Dr. Howell characterized new surgical techniques that warrant further study as techniques that "represent[] a distinct shift from the way things were being done in the past; perhaps a different approach, perhaps a different intent of the operation and, again, the outcome would also differ." (Tr. 462, Test. Dr. Howell.) Assessing the safety of a new surgical technique requires passing a "much higher standard" than evaluating the safety of a variation of an established surgical technique when the technique and variation have initially been found to have a "similar safety record." (Tr. 462-63, Test. Dr. Howell.)

Defendant's witness Dr. George Mazariegos agreed that innovative surgical procedures that fall within a "gray zone" between a variation of a standard procedure and a unique departure from accepted standards should be reviewed in a "more flexible manner" than the formal IRB process, and that statistically significant results from a retrospective study of a surgical technique may not be available until the technique has been used in an appropriately large number of cases over a time period that could be years. (Tr. 869-70, Test. Dr. Mazariegos; Tr. 970-71, Test. Dr. Bowes (new procedure cannot be studied until it has been performed enough).)

Drs. Mazariegos and Bowes testified that once a physician obtains new data establishing the safety or effectiveness of a new surgical procedure, the data typically is disseminated in a peer-review setting, such as to colleagues at meetings, followed by a report in medical literature. If initial information suggests a possible role for a new therapy or procedure, "that would typically spur on the development of comparative trial." Some surgeons expect to see peer-reviewed studies of new procedures within one to two years, although there are exceptions to this standard, such as large studies that require follow-up and studies focusing on long-term benefits or risks. (Tr. 836-38, Test. Dr. Mazariegos; Tr. 912 & 966, Test. Dr. Bowes (once a procedure is introduced, "there comes a point at which you really need to confirm with some good evidence that it is a better procedure"; before a new procedure is used in

medicine, it must be subjected to a randomized or case-controlled study before it becomes widely used).)

Dr. Howell believes the intact D&E "came about as a logical consequence of physicians doing the D&E procedure"; the intact D&E has developed "well within the bounds of currently-accepted medical practice" and consistent with the "very typical pattern" of surgical developments; and the intact D&E is not a new surgical technique, but a variation thereof. (Tr. 465-66, Test. Dr. Howell.)

Drs. Howell and Bowes opined that structuring a study comparing the intact D&E with other D&E variations would be "difficult." Conducting a retrospective study would be "useful," but would involve locating enough case files that contain the necessary information. Prospective studies would involve standardizing the procedures being compared; locating surgeons and women willing to perform only the assigned procedure "even if, in the course of performing the procedure, [the surgeon] might wish to do it the other way"; and locating enough participants in order to find any meaningful difference in the risk of the two procedures. (Tr. 467-68 & 470, Test. Dr. Howell; Tr. 939, Test. Dr. Bowes (retrospective study comparing intact D&E to D&E or other abortion method difficult, but possible).)

In Dr. Howell's opinion, it would be "extraordinarily difficult" and undesirable to design a randomized prospective study comparing the intact D&E and the D&E because the knowledge gained from such a study would be minimal when "the risks [of the two procedures] are already low enough. . . . on both sides, and we know the problems of doing this sort of a study would be considerable." (Tr. 468-69, Test. Dr. Howell; Tr. 861, Test. Dr. Mazariegos (may be difficult to get sufficient number of patients who would agree to be randomized between two treatment options or surgical procedures); Tr. 933-34 & 964-65, Test. Dr. Bowes (although difficult, a prospective or retrospective study could be designed comparing the intact D&E with the traditional

D&E; a randomized prospective study comparing inductions to D&Es would be difficult to do in the United States where induction is not the norm).)

Dr. Creinin has been the principal investigator in 8 prospective randomized trials, and has been involved in more than 20 others. He believes a prospective randomized trial comparing second-trimester abortion techniques would be unfeasible, unreasonable, and impossible to accomplish (Ex. 122, Test. Dr. Creinin 703-05) because:

* His experiences with similar first-trimester studies have been unsuccessful.

    1) Dr. Creinin began a prospective randomized trial comparing medical and surgical abortions in women with fetuses of up to seven weeks of gestation. To be included in the study, and after receiving counseling, the women had to state they had no preference as to which method was performed. Dr. Creinin's goal was to have 100 study participants. After two years, the study was stopped; 1,000 women had been interviewed for the study but only 50 agreed to participate. With further follow up, only 15 of the 50 really had no preference as to the method of abortion performed. (Ex. 122, Test. Dr. Creinin 703-05.)

    2) Dr. Creinin was involved in an NIH study of treatment of early miscarriage. Four respected medical centers were awarded a contract to study medical versus surgical treatment of miscarriage with a goal of soliciting 800 participants over 1 ½ years. After 2 years, only about 600 women had agreed to have their treatment randomized. (Ex. 122, Test. Dr. Creinin 707.)

* Dr. Grimes did a study to determine if a randomized controlled trial of labor induction versus D&E was feasible and, based on the lack of willing participants, concluded such a study was not feasible. Dr. Creinin believes Dr. Grimes is "an incredibly well-respected mentor, researcher, teacher. And I can think of nobody who would be a greater example of how to construct such a study. And if they couldn't find it feasible there . . . I can't see this as being feasible anywhere." (Ex. 122, Test. Dr. Creinin 707-09.)

* A very large number of participants would be required in a randomized study of induction versus D&E because both induction and D&E are safe second-trimester abortion methods. With a 1% risk factor, there would need to be 5,000 participants in both groups to reach a statistically significant conclusion; for a 2% risk factor, 2,500 participants would be needed in both groups. (Ex. 122, Test. Dr. Creinin 705-07.)

* The available pool of first-trimester abortions is far greater than second-trimester abortions, yet Dr. Creinin's similar first-trimester study failed for lack of participation. (Ex. 122, Test. Dr. Creinin 705.)

There are no randomized clinical studies comparing the safety of intact and dismemberment D&Es. In Dr. Paul's opinion, such a study would not be feasible or warranted because: (a) the intact D&E is a variant of the D&E and probably does not merit a separate study; (b) the occurrence of an intact D&E is hard to predict at the outset; (c) a very large number of study participants in each group would be required because the complication rates are so low; and (d) the percent of second-trimester abortions, and therefore the available pool to draw from for a study, is small. (Ex. 125, Test. Dr. Paul 89-90 & 107.)

Dr. Lockwood believes that the safety of the intact D&E procedure could be studied by randomized trial to identify possible complications caused by the procedure:

> I think that patients would have to be fully informed that they were going to be part of a study. I think that strict guidelines that led to differing degrees of cervical dilation would have to be employed, and that patents would have to be randomized at the intent[-]to[-]treat point. So that even if the procedure turned out to be . . . a D&E, they are part of the intact D&X group, and vice-versa. And having done all that, then appropriate comparisons could be made of blood loss, procedure time, complication rate, and so forth.

(Test. Dr. Lockwood 1707.)

Dr. Creinin pointed out that prospective randomized trials have been successfully performed comparing elective versus routine episiotomies and comparing cesarean section versus vaginal birth for breech-presentation term deliveries with a study group exceeding 2,000 women. (Ex. 122, Test. Dr. Creinin 775-76.) However, these were not abortion-procedure studies. Dr. Creinin testified that the breech-delivery study was government-funded, the data indicates that women seeking abortions do not want to be randomized, and it is difficult to standardize intact versus dismemberment D&E procedures when, irrespective of the doctor's intent at the outset, the procedure actually performed depends on the unpredictable factor of cervical dilation. (Ex. 122, Test. Dr. Creinin 778-80.)

"[N]o one has ever done a study to show what the optimum dilation is of the cervix to reduce trauma," and these types of safety issues could be studied by a prospective randomized blinded trial or a retrospective case-controlled study comparing types of abortion procedures, according to Dr. Shadigian. From her experience in doing a prospective "term breech trial," Dr. Shadigian believes women would agree to be randomized to various comparison groups because "women

undergoing the D&E or D&X or medical induction would, with good informed consent, be able to say, . . . Doctor, if you don't know what's safer, I want my care to be part of something bigger than myself so I can help other women." (Tr. 1531-34, Test. Dr. Shadigian.)

Dr. Broekhuizen testified that if one wanted to study whether cervical dilation increases the risk of cervical incompetence, a group of women would have to be monitored long-term to assess their subsequent pregnancies. The larger the group of women followed, the more reliable the study. However, it is probably impossible to conduct such a study in Dr. Broekhuizen's view. A retrospective study would require review of records from several institutions and physicians, and would therefore incorporate the inconsistencies and variations of the different physicians. It could be set up only with the cooperation of multiple institutions operating under a very tight protocol so that data collection and reporting was internally consistent. Dr. Broekhuizen is not aware that this type of study has been done. Dr. Broekhuizen thinks that a randomized clinical trial comparing induction abortions and the D&E would be impossible because patients have very strong feelings about the abortion procedure performed and would not want to be randomized for scientific study. (Ex. 120, Test. Dr. Broekhuizen 615-17.)

To establish the safety of the intact D&E method of abortion, Dr. Lockwood would like to see "retrospective studies of those centers that have large experience, preferably comparing it to D&Es and doing [statistical analysis] to control for variables such as parity, cervical dilation, gestational age." He would like to "get some sense as to whether or not there is a lower incidence of . . . hemorrhage, perforation, the occurrence of lower hematocrits, decreased procedure time. The various end points that theoretically appeal to those who do it." (Test. Dr. Lockwood 1707.)

Dr. Lockwood also believes that retrospective chart reviews would be helpful in analyzing the safety of the intact D&E procedure. (Tr. 1706-08, Test. Dr. Lockwood.) A retrospective cohort study may be used to compare intact and dismemberment D&Es, but only if the doctor recorded which variation of the D&E was actually accomplished. Currently this specificity in charting is not usually done in the medical community. (Ex. 125, Test. Dr. Paul 108.) Descriptive case studies by physicians who have utilized the intact D&E procedure have "some value," but such studies are generally used "as the basis for then pursuing additional studies; whether they are retrospective . . . cohort studies or case controlled studies, or actual randomized clinical trial." (Tr. 1708, Test. Dr. Lockwood.)

The defendant's witness, Dr. George Mazariegos, agrees that "stifling innovation would be bad for medicine" and there are some cases in which a clinician may believe there is enough data to support the introduction of a surgical process without conducting a randomized controlled trial. (Tr. 867-69, Test. Dr. Mazariegos.) However, Dr. Mazariegos cautions that when a small universe of physicians believes there is no appreciable risk in performing a certain surgical procedure, like the intact D&E, compared with an existing surgical procedure, like the D&E, "until there is either an outside body of review or until there is a demonstration of the safety efficacy of a procedure . . . there exists such a high likelihood of bias that it's impossible to draw a conclusion to support that without some type of peer review literature to support that or some type of outside review that would be more objective." (Tr. 882-83, Test. Dr. Mazariegos; see also Tr. 1528-29, Test. Dr. Shadigian (case reviews like Dr. Haskell's 1992 paper not sufficient basis for evaluating safety of new procedure because designers of procedures have a vested interest in their technique and are biased toward safety; case reviews and presentations/discussions at national meetings are "initial steps" which should be followed by a "series of evidence-based studies" in order to make conclusions regarding general safety of a procedure).)

Dr. Westhoff believes that intuition is not an accepted method of clinical analysis. (Ex. 126, Test. Dr. Westhoff 975.)

### *c. STUDIES*[92]

### *I. MCMAHON*

A paper prepared by Dr. McMahon and presented on April 2, 1995, to the National Abortion Federation was received into evidence as Plaintiffs' Exhibit 64. The paper, entitled "Intact D&E, The First Decade," explains in great detail Dr. McMahon's experience in performing the procedure he called "intact D&E" from June of 1983 through February of 1995. The paper indicates that he would sometimes convert the fetus to a footling breech and sometimes take the fetus as he found it, depending upon whether there was a "[l]ongitudinal lie, calvarium presentation" (head-first), "[l]ongitudinal lie, breech presentation" (feet-first), or "[t]ransverse/oblique lie, various presentations" (sideways or at an angle). (Ex. 64, at CH0000501-02.)

Dr. McMahon's paper gives a clear explanation of why he performed the intact D&E procedure:

> **Intact vs. Disruptive D&E**
>
> Why intact? Why should a surgeon decide to embark upon a plan that is tedious, time consuming and logistically difficult?

[92]The various studies discussed below were received, along with other evidence, "[n]ot to prove that these articles are true or not true, but one, to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the Congressional effort to ascertain the true facts." (Tr. 1626.)

Certainly, if the pregnancy involves an unusual fetal flaw, the dysmorphologist, geneticist and perinatologist would much prefer a specimen in which the *in situ* relationships of the organs are preserved. This allows, with the exception of the central nervous system, for getting complete and accurate information from the post-mortem examination.

It is often the patient[']s preference, in that it's less offensive to their sensibilities. Also, if they want to hold or, just spend some time with their child, they can.

Staff turnover drops when the usual result is that the fetus comes out whole rather than disrupted.

All fine reasons, but insufficient to make such significant and burdensome changes in one[']s surgical approach. However, the evidence, although inconclusive, is beginning to suggest that this may be a safer approach, especially in the last half of pregnancy. Also, it is an approach that may be easier to teach. It may be less dependent upon requiring the attendance of a physician with inordinate talent in the blind handling of a large grasping forcep inside a very vascular uterus.

IDE is different in that it forces the surgeon to analyze the situation and arrive at a plan based upon the analysis. Standards of dilatation must be set. The intact D&E is not done by protocol that is derivative of the characteristics of the average cervix. The extraction isn't done because it is Wednesday and that is the day when the D&E surgeon is scheduled to work. Something better guides our actions. It is the <u>cervix</u> that is finally sovereign.

DIC is much less of a problem using this technique because this new human genome is not being morsalized and shedding its foreign proteins into the mother's vascular system. Tissue thromboplastins in the fetal dermis probably escape during extraction, but perhaps what is the main culprit—the central nervous system—is gone before the calvarium begins its exit.

In reviewing charts for doctors who have had complications and then subsequent legal problems, I have seen several recurring themes. But, one stands out. The surgical summary lists the fetal parts as they are removed. The calvarium is the last to be extracted. In pursuing this part, the doctor describes sensing it being within the jaws of the forcep only to have it escape as he/she attempts to grasp it. Trying and trying and failing each time causes the bleeding, inexorably, to increase. The doctor feels the frustration gradually giving over to desperation. Finally, the instrument leaves the confines of the uterine cavity. The catastrophe commences.

This scenario never occurs with intact D&E. The surgeon knows the spacial relationship of the part coming out of the external os because it is anatomic. The calvarium never slips out of one[']s grasp, because it is always attached. Control is maintained throughout the surgery.

(Ex. 64, at CH0000506-08.)

Dr. McMahon stated his conclusion in this way:

The bottom line . . .

The trauma of D&E derives from force of two types:

1. Cervical expansion

2. Traction of removal

Since it is through force that we cause harm, we must seek to balance these two forces to minimize trauma.

Begin by setting standards for cervical dilatation for each length of gestation. Oversee the implementation of these standards by methodically measuring and recording cervical dilatation at each surgical encounter, but most especially prior to extraction.

So what is the message of this survey?

- Is it a tedious approach to D&E? Yes, two dilatations per day are difficult to schedule.

- Does it take too long? No, the average is 48 hours to complete the largest cases. In fact, beyond 30 weeks it trends downwards towards 40 hours.

- What about mechanical dilatation? Many surgeons "augment" the diameter that the passive dilatation has produced just prior to performing the extraction. Does this compromise future cervical competence? We have no good evidence that it does.

Certainly this survey tells us that if one perseveres with the cervix and waits until the ideal diameter is reached, the extraction is much less sanguineous, and it is easier.

When I describe this technique to other D&E surgeons, the greatest appeal is that it avoids the excruciating experience of chasing the calvarium. To repeatedly sense it between the jaws of your forcep only to feel it slip away as you attempt to grasp it, is not something that one wants to re-visit.

Is intact D&E better than the classical disruptive D&E? It depends upon the circumstances. Late in pregnancy, it may be the preferred method. Additional data is necessary. Although it is not the panacea that we all seek, it is yet another tool for us to help our patients.

(Ex. 64, at CH0000511-12.)

### *ii. CHASEN*

Plaintiffs' Exhibits 27 and 28 are a peer-reviewed article by Stephen T. Chasen, et al., entitled Dilation and evacuation at >20 weeks: Comparison of Operative

techniques, 190 Am. J. Obstet. & Gynecol. 1180 (2004), and a chart representing underlying data. This article describes a retrospective cohort study[93] comparing patients who underwent the intact D&E and patients who had the traditional D&E. The objective of the study was to describe a large series of patients who had a D&E at 20 weeks or beyond, look at the characteristics of these patients, and compare the outcomes based on which variation of D&E was used. (Ex. 121, Test. Dr. Chasen 1613.)

The study began in March 2003 and was completed in July or August of 2003.[94] It was a retrospective cohort study based on medical records of the New York Weill Cornell Medical Center from 1996 through June 2003. Records from 1996 through

[93]The study was approved by the hospital's institutional review board, a panel of physicians and lay persons that ensures that any research undertaken is ethical and protects the patients' interests. (Ex. 121, Test. Dr. Chasen 1614 & Sub-Ex. 30.)

[94]The manuscript was complete in late August or early September 2003 and was sent to the Journal of Obstetrics and Gynecology, an ACOG publication. It was rejected in October 2003. One reviewer deemed the manuscript vitally important and another stated it warranted publication with major revisions. One reviewer believed the terminology "dilation and extraction with disarticulation" was not an appropriate way to describe the non-intact D&E. The terminology was changed. Another reviewer believed Dr. Chasen was too conclusive when the article stated "Dilation and evacuation with intact extraction is as safe as dilation and extraction with disarticulation after 20 weeks' gestation," and claimed the study did not prove the intact D&E was safe, but only that there were no obvious differences in safety between the intact D&E and the dismemberment D&E. The conclusion was changed, but not in response to the reviewer. The conclusion was reworded to note that the outcomes of the two procedures were similar, thereby including not only safety issues, but issues related to subsequent pregnancies. The manuscript was re-submitted and tentatively accepted for publication in December 2003. (Ex. 121, Test. Dr. Chasen 1658-60, 1665, 1668, 1697.) Dr. Chasen did not mention to the Journal of Obstetrics and Gynecology that he was a plaintiff in a pending suit challenging the Partial-Birth Abortion Ban Act. (Ex. 121, Test. Dr. Chasen 1668.)

May 2000 had previously been compiled for a different study, and the additional available data from May 2000 through June 2003 was added to the database. The study compared 383 cases where a D&E was performed at or beyond 20 weeks of gestation and placed these cases in two groups: 263 cases involved dismemberment D&E and 120 cases involved the intact D&E procedure. If a forceps was used, the procedure was defined as a dismemberment D&E. The complications identified included the requirement of a blood transfusion, the requirement of suturing a laceration, an unplanned hospital admission, readmission to the hospital, perforation of the uterus, and admission to intensive care. The individual patient characteristics noted included age, obstetric history, whether the patient had a prior cesarean section, gestational age, and the indication for the D&E. (Ex. 121, Test. Dr. Chasen 1615-25 & 1652-53.)

Dr. Chasen's study compared outcomes of these two groups of patients with regard to surgical complications, amount of bleeding, cervical lacerations, and infections. A certain number of the patients who had subsequent pregnancies were then evaluated regarding premature birth. The study found no difference in the complication rate between the two groups (5%) and no statistically significant difference in the incidents of premature birth. (Exs. 27 & 28.)

Comparing D&E and "intact dilation and extraction," the authors found:

> Outcomes appear similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation. Subsequent obstetric outcomes are similar between the two groups. The technique for surgical abortion should be determined by the physician based on intraoperative factors.

(Ex. 27, at SC0034.)

The authors of the Chasen study added:

> Our approach of performing intact dilation and extraction when possible is intended to minimize the use of forceps in extracting the fetus. We believe that use of forceps to grasp the fetus can cause inadvertent trauma to the uterine wall. At these gestational ages, evacuation of a fetus can require multiple insertions of forceps, and intact dilation and extraction avoids this. Though we believe our low complication rate validates our approach, we acknowledge that the retrospective nature of this study precludes us from concluding with certainty that intact dilation and extraction prevent adverse outcomes.

(Ex. 27, at SC0040-41.)

The data from physicians who performed only dismemberment D&Es and not intact D&Es was not included in the Chasen study. The D&Es of two physicians were included in the study. One-third of those were performed by Dr. Chasen. (Ex. 121, Test. Dr. Chasen 1653.)

The complication rates for the two groups were identical, but the serious complications (uterine perforation, amniotic fluid embolus, sepsis, and pulmonary embolus) all occurred with dismemberment D&E. These complications could not have been avoided by performing an intact D&E because that procedure was not feasible on those patients. There is generally a higher rate of complications associated with abortions performed at later gestational ages. However, in the Chasen study, the rate of complications was the same for the intact D&E procedure (average gestational age of 23 to 24[95] weeks) compared to the dismemberment D&E procedure (average gestational age of 20 to 21 weeks). Although not proved with certainty by the study data, Dr. Chasen believes that since each serious complication occurred in the dismemberment D&E group, and the intact D&E group did not have a higher complication rate despite the higher risk of complications due to greater gestational

[95]The study population at 24 weeks included several anencephalic fetuses. (Ex. 121, Test. Dr. Chasen 1647.)

age,[96] the intact D&E has safety advantages over the dismemberment D&E. (Ex. 121, Test. Dr. Chasen 1627-30, 1632-34, 1661, 1665-66.)

Sixty-two of the 383 women had subsequent pregnancies that were documented in the hospital's medical records. Four of these women delivered prematurely in a subsequent pregnancy. Two had previously had a dismemberment D&E (2 of 45, or 4% to 5%), and 2 had an intact D&E (2 of 17, or 11 to 12%). The 2 women with a history of a prior intact D&E aborted their fetuses because the woman's membranes had ruptured or there was considerable premature cervical dilation. Based on this history, both women were at a high risk of premature delivery in a later pregnancy irrespective of having a D&E. Though both delivered prematurely in a subsequent pregnancy (32 weeks and 35 weeks), these pregnancies were considered highly successful in light of the women's underlying risk factors for premature birth. The remaining 15 women who previously had an intact D&E procedure did not have underlying obstetric risk factors for premature delivery, and all 15 delivered at term. Dr. Chasen believes that although the statistical sampling is small, the data from his study indicates women who were not considered at high risk for premature delivery in a later pregnancy did not have a preterm birth following an intact D&E procedure. (Ex. 121, Test. Dr. Chasen 1630-32.)

Dr. Bowes found the Chasen study limited because the number of patients participating in the study was too small to conclude to a statistically valid degree that there was no difference in outcomes; the authors did not clearly describe their patient follow-up procedures or how they decided which patients would receive which procedure; and the patients in each group varied in age, gestation at the time the abortion was performed, and indications for which the abortions were performed, and

[96]According to Dr. Chasen, between 21 and 23 weeks, the fetus grows 50% larger. This growth increases the risk of complications during abortion. (Ex. 121, Test. Dr. Chasen 1694.)

these factors were not adjusted for using regression analysis because the sample size was too small. Dr. Bowes believes the Chasen study "does not prove the superiority of one of these procedures over the other." (Tr. 926-31, Test. Dr. Bowes.) However, the Chasen study establishes the general level of complications in two groups of patients, which is "important information to have" in designing a prospective randomized controlled trial. Dr. Bowes testified that a retrospective study like Chasen's is "often the first step in the process towards a randomized controlled trial." (Tr. 979, Test. Dr. Bowes.)

Dr. Sprang opined that the Chasen study involved such small numbers in terms of number of patients, complications, and subsequent pregnancies that, although indicating trends, the numbers "didn't have any power. . . . The study [had] so few cases that you can't say anything is statistically significant." (Tr. 1157-60 & 1225-26, Test. Dr. Sprang.) Further, "the conclusions they came to didn't seem consistent . . . with the data." (Tr. 1222, Test. Dr. Sprang.)

Dr. Lockwood testified that the Chasen study "suggests [the intact D&E method of abortion is] safe." (Tr. 1705, Test. Dr. Lockwood.) However, the study is not "adequate to demonstrate that the D&X procedure has safety advantages over the procedure of D&E by dismemberment" because "the study essentially shows that [the two procedures] are remarkably similar in their outcomes. The procedure times were literally identical, and the blood loss was literally identical, and the occurrence of complications was virtually identical." (Tr. 1719, Test. Dr. Lockwood.)

According to Dr. Lockwood, the size of the patient groups used in the Chasen study (120 and 263) are "not trivial," but "[t]he study is obviously underpowered, doesn't have adequate numbers to rule out differences in grave complications; death, perforation, which would require many, many more patients than this. But it gives us a good sense that the overall rate of standard complications, immediate short-term

complications were very similar in the two groups." (Tr. 1720-21, Test. Dr. Lockwood.)

In contrast, the study does not tell us "much" about potentially significant long-term complications. Dr. Lockwood stated that the Chasen study found a disparity regarding the long-term complication of preterm birth for the intact D&E (11.8%) and the traditional D&E (4.4%). However, this disparity is "not statistically significant" and there were additional risk factors in the intact D&E group for subsequent premature delivery.

> [F]ormally as a clinician researcher, I wouldn't draw any conclusions from it. Would this provoke me to want to do additional studies? Absolutely. Does it sort of already fit into my bias about the procedure as an expert on prematurity? Yes, it does. Would it make me prohibit [the procedure's] use . . . [n]o, but it certainly would prompt me to want additional studies [regarding the potential preterm birth complication].

(Tr. 1722, Test. Dr. Lockwood.)

Dr. Lockwood pointed out that the risks of morbidity from abortion, while very low, increase each week of gestation. In the Chasen study, the median gestational age of women receiving intact D&Es was 23 weeks, while the median gestational age of women receiving a traditional D&E was 21 weeks. While one would expect that the complication rates of the intact D&E group would be higher, they were not. (Tr. 1761-62, Test. Dr. Lockwood.)

The Chasen study (published May 2004) confirms Dr. Westhoff's impression and conforms to her clinical experience that intact D&E is safer than dismemberment D&E. (Ex. 126, Test. Dr. Westhoff 840.) In fact, Dr. Westhoff believes Chasen's conclusion, that dismemberment and intact D&E have similar complication rates, is too conservative. She notes that, in the Chasen study, intact D&Es were performed on

patients whose fetuses were at a greater gestational age than the dismemberment D&E group. A higher rate of complication was expected in this later gestational group, yet with intact D&E, that group's complications were kept at a lower gestational age rate of risk. She believes this indicates intact D&E is actually safer than dismemberment D&E. (Ex. 126, Test. Dr. Westhoff 855.)

However, Dr. Westhoff acknowledges that the Chasen study is an observational study and not a random clinical trial. The study sample size was small, the study groups for intact and dismemberment D&E were not equal in size, and the study groups involved procedures done at different mean gestational ages. Dr. Westhoff opined that these factors reduce the value of the Chasen study's statistical comparisons and conclusions. (Ex. 126, Test. Dr. Westhoff 975-79.)

Dr. Clark believes that the Chasen study proves the intact D&E is not safer than the dismemberment D&E. He believes the study shows a threefold increase in preterm birth in women who have had an intact D&E (Ex. 891, Test. Dr. Clark 2388-89 & 2394), and may indicate that the extent of dilation in the intact D&E increases the risk of premature birth. (Ex. 891, Test. Dr. Clark 2311 & 2386.) He states that the increase in preterm birth described in the Chasen article and related to intact D&E is "dynamite waiting to go," and believes that once published, this information ethically obligates doctors to warn women of the long-term complication of preterm birth before the woman consents to an intact D&E. (Ex. 891, Test. Dr. Clark 2390-92.)

Dr. Clark acknowledges, however, that a woman who has previously experienced a preterm delivery is at a higher risk of preterm delivery in later pregnancies. (Ex. 891, Test. Dr. Clark 2412.) Based on their underlying history discussed in the Chasen article, the two women in the intact D&E group who experienced subsequent preterm delivery were at a higher risk of preterm delivery irrespective of whether they had an intact D&E—that is, both women already had a risk of preterm delivery before undergoing any abortion procedure. (Ex. 891, Test. Dr. Clark 2412, 2427-29 & 2430.)

He further acknowledges that, based on the statistical analysis set forth in the Chasen article, there is no statistical difference in the rate of preterm birth associated with intact versus dismemberment D&E. There is a 30% chance the differences seen were based on chance alone. (Ex. 891, Test. Dr. Clark 2425.)

### *iii. GRIMES*

Plaintiffs' Exhibit 44 is a report authored by David A. Grimes and others entitled Mifespristone and misoprostol *versus* dilation and evacuation for midtrimester abortion: a pilot randomised controlled trial, III Brit. J. Obstet. & Gynecol. 148 (Feb. 2004). The report describes the feasibility of mounting a randomized controlled trial comparing midtrimester abortion using two drugs, mifepristone and misoprostol, and midtrimester abortion using dilation and evacuation (D&E) with laminaria.

This study was discontinued at one year because the individuals conducting the study had difficulty recruiting people into the medical abortion group. "Of 47 women eligible for the trial, 29 (62%) declined participation, primarily because of a preference for D&E abortion." (Ex. 44, at 148.) The authors concluded that "most women are unwilling to participate if D&E is available outside the trial." (Ex. 44, at 153.)

Of the 18 women remaining in the trial, 9 received the mifepristone-misoprostol method and 9 underwent a D&E. The authors found that "[c]ompared with D&E, mifepristone-misoprostol abortion caused more pain and adverse events, although none was serious." (Ex. 44, at 148.) The study described its results only as "hypothesis-generating" and potentially useful in planning a larger randomized controlled trial. The authors noted that such a trial would be difficult to mount in the United States, and recommended that further study be conducted in a setting where labor-induction abortion is the norm, such as Europe or Asia. (Ex. 44, at 152-53.)

### *iv. AUTRY*

Plaintiffs' Exhibit 19 is an article by Autry, et al., A comparison of medical induction and dilation and evacuation for second-trimester abortion, 187 Am. J. Obstet. & Gynecol. 393 (2002). This peer-reviewed article describes a retrospective study of 297 women who underwent either D&E or medical abortion. The study concludes that D&E is the safest method of second-trimester abortion. Specifically, the overall complication rate was significantly lower in patients who underwent dilation and evacuation than in patients who underwent medical abortion (4% vs. 29%). The article concludes that misoprostol is safer than other methods of medical abortion and that maximal use of laminaria will decrease complication rates in surgical abortion.

Some witnesses criticized the Autry study because many of the patients in the study lacked follow-up analysis and one of the defined complications that accounted for 77% of the study's complications was retained products of conception that required a D&C, which is not a complication in Dr. Sprang's view, but an inherent part of the procedure. (Tr. 1136-37, Test. Dr. Sprang; see also Tr. 1371-74, Test. Dr. Cook (disagreeing with Autry study results because retained placenta is not complication, but normal result of medical induction; other complications were similar between the two procedures); Tr. 1557-61, Test. Dr. Shadigian (discrediting study due to retained placenta as complication; study not randomized and unclear if authors were blinded; gestational age for induction and D&E groups differed by two weeks).)

### *v. PAUL*

Plaintiffs' Exhibit 70 is A Clinician's Guide to Medical and Surgical Abortions, Chapters 4-16 (1999), by Maureen Paul, et al. This is a guide for abortionists edited by Maureen Paul, M.D., who was then an associate professor of obstetrics and gynecology at the University of Massachusetts, and Medical Director, Planned Parenthood League of Massachusetts, and four other doctors, including E. Steve

Lichtenberg, Lynn Borgatta, David A. Grimes, and Phillip G. Stubblefield. At the time, Lichtenberg was the Medical Director at the Albany Medical-Surgical Center. Borgatta was an associate professor, Department of Obstetrics and Gynecology, Boston University School of Medicine. Grimes was a clinical professor in the Department of Obstetrics and Gynecology at the University of North Carolina School of Medicine. Stubblefield was a professor and Chair of the Department of Obstetrics and Gynecology at Boston University School of Medicine.

Chapter 10 of the guide, entitled "Surgical Abortion After the First Trimester," is authored by W. Martin Haskell, Thomas R. Easterling, and E. Steve Lichtenberg. In that chapter, the authors extensively discuss the banned procedure.

The authors first state:

> When possible, intact delivery in pregnancies over 18 weeks reduces the number of instrument passes necessary for extraction. During the second trimester vertex, breech, and transverse/compound presentations occur with roughly equal frequency. Below are some suggestions for operative strategies for each of these presentations.
>
> **Vertex Presentation.** The key to delivery of a vertex presentation is achieving collapse of the calvarium. A variety of methods are used for this purpose, depending on the calvarium's firmness and accessibility. They include breaching and compressing the calvarium with the forceps' jaws, inserting a finger through a fontanel or along a suture line, or piercing the calvarium with a sharp instrument, such as a tenaculum or a large-bore needle. Decompression using attached suction is sometimes necessary. When cervical dilation is adequate but not generous, numerous instrument passes may be necessary to collapse and control the calvarium. Rotating the grasped calvarium as it passed through the cervix facilitates safe removal. When the fetus is compressed tightly against the cervix, freeing upper extremities affords extra space. Once the thorax is grasped, rotating the torso often frees the remainder of the corpus.

**Breech Presentation.** The signal maneuver for facilitating breech delivery is obtaining control of a lower extremity. With frank breech presentation, the surgeon's fingers or an instrument can be used to disentangle a lower extremity. Rotation of this extremity usually frees the second lower extremity. An intact extraction may be possible using a Mauriceau-Smellie-Veit maneuver, as follows: Grasp the iliac crests, draw the torso downward until the scapulae emerge, then rotate the thorax to disentangle each upper extremity. If the cervix is compliant, the provider can deliver the uncollapsed calvarium by lifting the torso upward. Because this maneuver carries a small risk of cervical laceration, collapsing the calvarium is usually preferable.

**Transverse/Compound Presentation.** The advantage of ample dilation is nowhere more evident than in the case of transverse and compound presentations. Extraction is greatly facilitated if the provider can reposition the fetus into breech or vertex presentation digitally or instrumentally. Uterine palpation, digital examination, or ultrasonography may help assess fetal lie. Failing conversion, often the only option is disarticulation of an upper extremity and sequential deconstruction. Deconstruction is the usual recourse when a back-down transverse lie cannot be converted. With a back-up transverse lie, control of a lower extremity can convert the presentation to breech.

(Ex. 70, at 135 (footnotes omitted).)

Later, the authors extend their discussion on the banned procedure, giving reasons for its use, thoroughly discussing Dr. McMahon's experience as set forth in his paper, "Intact D&E, The First Decade," and also discussing Haskell's experience. They write:

**Intact Dilation and Evacuation**

The intact D&E procedure combines long-standing obstetrical practices for delivery of advanced, compromised pregnancies with modern techniques of cervical dilation. The aim of intact D&E is to minimize instrumentation within the uterine cavity and achieve vaginal delivery of

an intact fetus. Intact D&E is used as a method of second trimester abortion and, in the case of compromised pregnancies, as a technique for third trimester terminations. Intactness allows unhampered evaluation of structural abnormalities and can be an aid to patients grieving a wanted pregnancy by providing the opportunity for a final act of bonding.

Generally, cervical dilation is accomplished with multiple, serial osmotic dilators over 2 days or more. The goal is to achieve sufficient dilation to extract the largest part of the fetus, the bitrochanteric diameter of the pelvis, which is approximately 75% of the biparietal diameter. Combinations of different types of osmotic dilator are typically used.

In 1995 McMahon presented a 13-year personal series of 1362 intact D&E cases. Ninety-eight percent of these cases were performed at a licensed ambulatory surgical center. Only cases with serious fetal ($n$ = 451) or maternal ($n$ = 173) indications were done after 24-26 weeks' gestation. McMahon devised and refined exacting protocols for vertex and breech delivery to minimize the danger of cervical and uterine injury.

McMahon effected delivery only after achieving ample cervical dilation, and he used a minimum of instrument passes. For example, in vertex position, once the central nervous system (CNS) contents were evacuated using an auger-tipped trocar, he grasped the calvarium with forceps in a controlled manner and extracted the fetus. In breech presentation, he converted the lie to footling and delivered the fetus using a Mauriceau-Smellie-Veit maneuver as described above. Dilation was sufficient to enable most complex presentations to be converted digitally or with a version forceps to vertex or breech presentation. McMahon devised special instruments for the procedure, and he recorded case-by-case measurements of fetal and cervical dimensions to improve delivery intervals, odds of intact delivery, and safety.

Using CDC criteria, four patients in McMahon's series experienced major complications, for a rate of 2.94 per 1000 cases. Three patients required transfusion, two for DIC and one for hemorrhage during dilation. The fourth patient required hospitalization for subacute bacterial endocarditis diagnosed 2 weeks after abortion. This major complication

> rate is virtually identical to that of an earlier series of nonintact D&Es reported by Hern (3.0/1000 cases) despite the fact that nearly one-fourth of the cases in McMahon's series exceeded Hern's 25-week gestation limit. In addition, Haskell has performed more than 1500 intact D&Es at 20-26 weeks' gestation without a serious event. No patient in his series experienced hemorrhage requiring transfusion, cervical laceration, uterine perforation, or retained tissue; and no hospitalizations or laparotomies were required.

(Ex. 70, at 136-37 (footnotes omitted).)

### *vi. ELCHLAL*

Plaintiffs' Exhibit 110 is a peer-reviewed article authored by Uriel Elchlal, Inbar Ben Shachar, Dan Peleg, and Joseph G. Schenker entitled Maternal Mortality following Diagnostic 2nd-Trimester Amniocentesis, 19 Fetal Diagnosis & Therapy 195 (2004). The article recounted the death of two women, one 19 weeks pregnant and the other 21 weeks pregnant, after undergoing transabdominal amniocentesis for prenatal diagnosis of genetic disorders.

While acknowledging that amniocentesis is generally safe, after a review of the literature, the authors report "several cases of serious maternal complications, especially chorioamnionitis and septic shock." (Ex. 110, at 195 (footnote omitted).) The authors then present two new cases where women died undergoing this procedure in the second trimester. Among other things, the authors conclude that: "A full explanation prior to patient's consent is of importance, since maternal mortality, although rare, is a real danger even if the proper precautions are taken." (Ex. 110, at 198.)

According to Dr. Vibhakar, "the risk of an amniocentesis to remove fluid would be similar to performing [intraamniotic or intrafetal] . . . injections" of digoxin or KCl. (Tr. 348-50, Test. Dr. Vibhakar.)

### *vii. DREY*

Defendant's Exhibit 560 is an article authored by Eleanor A. Drey, Lisa J. Thomas, Neal L. Benowitz, Nora Goldschlager, and Phillip D. Darney entitled Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation, 182 Am. J. Obstet. & Gynecol. 1063 (2000). This article describes the use of digoxin to cause fetal death in abortions between 18 and 23 weeks when the termination was accomplished by D&E.

The authors describe their study this way:

> More than 140,000 second-trimester abortions are performed annually in the United States, 94% of which are by dilation and evacuation. Second-trimester abortions account for a disproportionate burden of the morbidity and mortality related to abortion, with the risks of complications rising with each subsequent week of pregnancy. For example, the mortality risk associated with abortions performed at $\leq 8$ weeks' gestation is 0.4 per 100,000 procedures, compared with a risk of 10.4 per 100,000 procedures associated with abortions performed at $\geq 21$ week's gestation.
>
> Clinicians have been using digoxin to facilitate second-trimester pregnancy termination for several years. Digoxin injection causes fetal death and is believed to make the dilation and evacuation procedure easier and safer because the fetal tissue is softened. Another advantage is that both the patient and the clinician may prefer to abort a dead fetus. Digoxin has been administered by the intracardiac, intrathoracic, intrafetal, and intra-amniotic routes, with doses varying from 0.25 to 2

mg. Most clinicians who use digoxin usually inject it 1 to 2 days before the dilation and evacuation procedure, at the time of laminaria placement.

Although there are no reports of maternal side effects or complications as a result of this use of digoxin, neither are there any evaluations of digoxin's safety or efficacy before dilation and evacuation. The purpose of this study was to assess the safety of intra-amniotic administration of digoxin before late second-trimester dilation and evacuation by evaluating its systemic absorption and its effects on cardiac rhythm and conduction and on coagulation measurements.

(Ex. 560, at 1063 (footnotes omitted).)

The authors acknowledge that certain women were not considered appropriate subjects for use of injections. Those women were excluded

because of significant medical illness or cardiovascular disease, current use of cardiac or antihypertensive medications, a known digoxin allergy, pregnancy complications (oligohydramnios, polyhydramnios, multiple gestation, or congenital anomalies), maternal weight ≥30% above ideal, difficult maternal venous access, or abnormal serum potassium levels (<3.5 mmol/1. or >5 mmol/1.).

(Ex. 560, at 1064.)

The authors conclude:

We conclude that intra-amniotic administration of 1 mg digoxin before termination of pregnancy during the late second trimester does not result in clinically significant elevation of maternal serum digoxin levels, is not associated with evidence of digoxin toxicity, does not alter maternal cardiac rate or rhythm, and does not change clotting parameters. Although digoxin injection appears safe, determination of its clinical efficacy requires a randomized trial.

(Ex. 560, at 1066.)

### *viii. SHULMAN*

Defendant's Exhibit 624 is an article written by Lee P. Shulman and Sherman Elias entitled Second-Trimester Pregnancy Termination by Dilation and Evacuation After Detection of Fetal Abnormalities, 1 J. Women's Health 255 (1992). The article concludes that since D&E is superior to labor induction "with respect to morbidity, mortality" and other factors, the procedure should be used between 14 and 22 weeks of gestation to terminate pregnancy in the case of fetal abnormality. (Ex. 624, at 255.)

In 99% of the cases where the D&E was used, "[c]ytogenetic analysis" was successful. (Ex. 624, at 257.) In other words, the fetal parts dismembered during a D&E could be tested to determine the nature and extent of the abnormality. However, the authors acknowledge that "[p]athological examination of an intact fetus may be required in rare instances." (Ex. 624, at 257.) The authors conclude that "D and E by experienced obstetrician-gynecologists is the procedure of choice for most patients who elect to terminate pregnancies because of fetal abnormalities at or before the 22nd gestational week." (Ex. 624, at 257.)

### *ix. ABORTION SURVEILLANCE STATISTICS*

Plaintiffs' Exhibit 32 contains United States Abortion Surveillance statistics for 2000 issued by the Department of Health and Human Services Centers for Disease Control and Prevention. Centers for Disease Control & Prevention, Morbidity and Mortality Weekly Report: Abortion Surveillance—United States, 2000, Vol. 52, No. SS-12 (Nov. 28, 2003). The statistics show that "[a]bortion ratios were highest for the youngest women (708 abortions per 1,000 live births for women aged <15 years)" and "[a]bortion trends by age indicate that since 1973, abortion ratios for women aged <15 years have been higher than for any other age group." (Ex. 32, at 4.) Further, the

percentage of women who obtained "late" abortions—defined as at or after 16 weeks of gestation—was greatest in women under 15 years of age. (Ex. 32, at 13 (Figure 4).)

The data also provide information on types of abortion procedure used:

> The percentage of abortions known to be performed by curettage (which includes dilatation and evacuation [D&E]) increased from 88% in 1973 to 98% in 2000, while the percentage of abortions performed by intrauterine instillation declined sharply, from 10% to 0.4%. The increase in use of D&E is likely due to the lower risk for complications associated with the procedure . . . . The percentage of abortions performed by D&E (curettage) at ≥13 weeks' gestation increased from 31% in 1974 (the first year for which these data were available) to 96% in 2000; the percentage of abortions performed by intrauterine instillation at ≥13 weeks' gestation decreased from 57% to 1.7%.

(Ex. 32, at 7 (internal references to tables omitted).)

### *x. STUDIES REFERENCED BY DR. FREDERIKSEN*

Dr. Frederiksen identified several pieces of medical literature which she believes suggest that the D&E is safer than the second-trimester medical-induction abortion:

* A March 2004 Obstetrics and Gynecology publication entitled "Risk Factors for Legal Induced Abortion Related Mortality in the United States" was a descriptive epidemiological study of women dying of complications of abortion performed at all gestational ages. The article stated that D&E was two and one-half times safer than second-trimester instillation-induction terminations. (Ex. 123, Test. Dr. Frederiksen 1051 & 1172-73.) Dr. Frederiksen testified that the study states the risk factor most strongly associated with mortality from legal abortion is gestational age. (Ex. 123, Test. Dr. Frederiksen 1173.) She acknowledges, however,

that the study includes inductions performed with saline and prostaglandin instillations, a procedure which has declined in use since the 1970s due to its higher risk. (Ex. 123, Test. Dr. Frederiksen 1173-74.)

* The series of publications by David Grimes supports the safety of D&E procedures to about 20 weeks. Thereafter, the safety of the D&E depends on the physician performing the procedure. (Ex. 123, Test. Dr. Frederiksen 1052.)

* Chapman published a paper in the American Journal of Obstetrics and Gynecology that showed a 2.3 times higher risk of uterine rupture and hemorrhage in second-trimester induction abortions for patients who had a prior cesarean section. (Ex. 123, Test. Dr. Frederiksen 1052.) The Chapman article was based on a retrospective review of patient records from the University of Alabama hospital from 1980 through 1995. (Ex. 123, Test. Dr. Frederiksen 1171-72.)

* As a follow-up to the Chapman paper, Northwestern University performed a five-year study under IRB guidance to review the relative risks of D&E (including intact D&E) and medical-induction abortion procedures. The study did not reflect that medical inductions were associated with an increased risk of uterine rupture and bleeding for patients with a history of prior cesarean section. According to Dr. Frederiksen, the study did show that "the induction method was significantly more risky for a patient and that D&E was significantly . . . safer." (Ex. 123, Test. Dr. Frederiksen 1052-53.) However, while an abstract of this study was published, the submitted paper was returned for revision. It has never been revised or published. The study was based on a D&E group with 561 patients compared to 85 induction-abortion patients, and the

inductions were performed with medications that are not used today. (Ex. 123, Test. Dr. Frederiksen 1168-69 & 1171.)

* Phillip G. Stubblefield, First and Second Trimester Abortion 1046, in Gynecologic, Obstetric, and Related Surgery (David H. Nichols & Daniel L. Clarke-Pearson eds., 2000), states, "Early in [mid]trimester D&E is the safest method. Labor induction methods and D&E are comparable in the later midtrimester and both are much safer than hysterotomy or hysterectomy for abortion." (Ex. 123, Test. Dr. Frederiksen 1175-76; see also Exs. 65 & 628, at 1046.)

Dr. Frederiksen testified that although no specific study exists comparing intact D&Es and classical D&Es, the D&E data over the last 10 to 15 years indicates that physicians have moved from doing strictly dismemberment procedures to intact D&Es and the D&E has become safer over this time period. (Ex. 123, Test. Dr. Frederiksen 1054 & 1208.)

### *xi. STUDIES REFERENCED BY DR. CREININ*

Dr. Creinin cited several studies regarding cervical incompetence following abortion procedures:

* The Kalish article (Exs. 55 & 596) entitled "Impact of Mid-trimester Dilation and Evacuation on Subsequent Pregnancy Outcome" is a retrospective chart review of D&E procedures performed at 14 to 24 weeks of gestation on 600 women. Ninety-six of these women had subsequent pregnancies. Ten of the women with subsequent pregnancies had deliveries before 37 weeks of gestation, with 5 having maternal and obstetrical reasons for early delivery. Of the remaining 5, 4 had cervical incompetence that pre-dated their prior D&E, and 1 had DES exposure

which prompted her doctor to perform a cervical cerclage. None of the patients who delivered early had cervical incompetence related to the osmotic dilation involved in D&E surgery. The study is small but consistent with the theoretical understanding of what is physiologically expected. (Ex. 122, Test. Dr. Creinin 693-94.) The study did not include information on women who delivered babies at different institutions or who experienced first-trimester miscarriages. (Ex. 122, Test. Dr. Creinin 753-54.)

* The Schneider article (Exs. 73 & 621) entitled "Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation" was a case series of 171 women who had D&Es at 18 to 22 weeks of gestation. At the time of the report, 61 of the women had become pregnant after the D&E. None experienced cervical incompetence. (Ex. 122, Test. Dr. Creinin 701-02.) The article states: "Dilation and evacuation for late second trimester termination seems to be safe. Intra- and postoperative complications are negligible." The study did not evaluate the intact D&E procedure and the average dilation was 2.9 centimeters +/- .9 centimeters. (Ex. 122, Test. Dr. Creinin 759-60.)

* The Henriet article (Exs. 49 & 585) entitled "Impact of induced abortions on subsequent pregnancy outcome: the 1996 French national perinatal survey" was a study of all births in France over a series of days with a study population of 12,432 women. The study concluded that induced abortion results in cervical incompetence. Dr. Creinin believes this "is an awful study" that cannot be relied on for any real conclusions related to second-trimester abortions because it is a retrospective study (with recall bias—the likelihood of receiving affirmative responses to leading questions about past events to explain a current bad outcome), and only

four percent of the participants had a prior second-trimester abortion. (Ex. 122, Test. Dr. Creinin 754-56 & 780-83.)

* The Zhou article (Exs. 78 & 639) states: "[w]e have previously studied long-term consequences of an induced abortion in a subsequent pregnancy and found a slightly increased risk of low birth weight and pre-term birth, as well as placenta complications." (Ex. 122, Test. Dr. Creinin 757-58.) However, preterm birth is not the same as cervical incompetence. The majority of preterm births are caused by preterm labor and not cervical incompetence. (Ex. 122, Test. Dr. Creinin 783-84.)

* The Autry article (Exs. 19 & 545) entitled "A comparison of medical induction and dilation and evacuation for second trimester abortion," published in 2002, compared labor induction and D&E procedures done between 14 and 24 weeks of gestation. Approximately 75% of the women had misoprostol inductions. According to Dr. Creinin, the study reflects that D&E is safer than labor induction, but it is a retrospective study and cannot be interpreted as a conclusive determination that D&E is safer. (Ex. 122, Test. Dr. Creinin 721-24.) The most common complication reported for labor induction was retained products of conception, but the article does not indicate how long the operators waited before performing a D&C. Moreover, a D&E virtually always requires surgical removal of the placenta by suction curettage. (Ex. 122, Test. Dr. Creinin 776-77.)

Dr. Creinin knows of no data indicating that the osmotic dilation of the D&E leads to cervical incompetence. (Ex. 122, Test. Dr. Creinin 702.) Further, Dr. Creinin knows of no studies which consider whether the intact D&E procedure leads to a higher rate of cervical incompetence or preterm labor. (Ex. 122, Test. Dr. Creinin 758.)

### *xii. STUDIES REFERENCED BY DR. PAUL*

Dr. Paul testified that from 1971 through 1979, a Joint Program for the Study of Abortion ("JPSA") was conducted by the Centers for Disease Control ("CDC"). JPSA was a prospective study that involved numerous hospitals and clinics throughout the United States. Reports to the CDC were made by people trained to follow up on women who had abortions to determine if complications arose. The study included approximately a quarter of a million reports. Dr. Willard Cate and Dr. David Grimes were the co-directors of the JPSA study. (Ex. 125, Test. Dr. Paul 25-26.)

The Binkin article (Ex. 20)[97] entitled "Trends in Induced Legal Abortion Morbidity and Mortality" summarizes the conclusions of the 1971 through 1979 JPSA study conducted by the CDC under the direction of Dr. Cates and Dr. Grimes. The JPSA monitored 15 types of major complications, but most of the reported complications fell into the categories of sustained fever for three or more days, hemorrhage requiring transfusion, and unintended major surgery (e.g., abdominal or hysterectomy). Retained placenta was reported as a complication, but not a major complication. Based on the JPSA data, for first-trimester D&Cs, the rate of major complications was 0.2 to 0.6%; for saline and prostaglandin instillation inductions from 13 to 17 weeks of gestation, the rate of complications ranged from 1.7 to 3.0%; and for D&Es performed from 13 to 17 weeks of gestation, the rate of complications ranged from 0.6 to 0.9%. (Ex. 125, Test. Dr. Paul 26-30; see also Ex. 20, at 92, tbl. 7.) Although the medications and methods of induction abortion and of cervical dilation in D&Es have both changed since the 1970s, Dr. Paul believes the JPSA remains relevant in assessing the current safety of abortion procedures because it established the foundation for abortion safety and is the largest data set collected on the issue. The

[97]This article was not received into evidence in total, but certain portions were projected on a screen and testified about at trial.

JPSA no longer exists because its purpose, determining if abortion is safe, has been served. (Ex. 125, Test. Dr. Paul 30-32.)

In the Binkin article, D&Es were compared to inductions that did not involve the use of prostaglandins or oxytocin to induce labor. (Ex. 125, Test. Dr. Paul 112-13.) The Binkin article reflects higher morbidity and mortality rates for second-trimester induction abortion than for D&E. (Ex. 125, Test. Dr. Paul 82-83.)

The Lawson article (Ex. 58)[98] entitled "Abortion mortality, United States, 1972 through 1987" is based on mortality data from 10 different sources, including vital records, death certificates, medical examiner reports, health care providers, and media reports. According to Dr. Paul, the article and its data reflect: (a) the rate of abortion-related death is very low; (b) the rate of abortion-related death increases with gestational age; (c) with legalization of abortion, the risk of death from abortion decreased 90% from 1972 until 1987; and (d) there is no association between the age of the woman and her risk of abortion-related death. (Ex. 125, Test. Dr. Paul 34-37.)

Dr. Paul testified that for second-trimester abortions performed before 16 weeks of gestation, the Lawson article reflects higher mortality rates for induction abortion than for D&E. After 16 weeks of gestation, the rate is approximately equal. The mortality rates for hysterotomy and hysterectomy are much higher than the rate of abortion-related death by D&E or induction. (Ex. 125, Test. Dr. Paul 84-85.)

Dr. Paul described the Autry article (Exs. 19 & 545) entitled "A comparison of medical induction and dilation and evacuation for second trimester abortion," published in 2002, as a retrospective cohort study that compared labor induction and D&E procedures. There was a higher rate of complications with labor induction than with

[98]This article was written by CDC investigators interpreting CDC data. It was received into evidence over the government's hearsay objection.

D&E, mostly due to retained placenta in the induction procedures. (Ex. 125, Test. Dr. Paul 85-86.) Dr. Paul opined that selection bias exists in the Autry study due to the lack of randomization and a difference in gestational age between the induction and D&E groups. However, the study includes a multiple regression analysis in an attempt to account for that bias. (Ex. 125, Test. Dr. Paul 114-15.)

Dr. Paul also pointed out that there are single-institution reports confirming that induction and D&E are both safe procedures, but that retained placenta occurs with inductions. (Ex. 125, Test. Dr. Paul 88-89.)

### *xiii. STUDIES REFERENCED BY DR. HAMMOND*

Dr. Hammond testified that there are no medical studies supporting a finding that cervical dilation to perform a D&E, including an intact D&E, increases the risk of cervical incompetence. The Schneider and Caspi article (Ex. 73 and 621) entitled "Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation" found no evidence of subsequent obstetrical problems related to the cervical dilation performed for D&E surgery. (Ex. 124, Test. Dr. Hammond 596-97 & 684-86.) According to Dr. Hammond, for abortions between 20 and 24 weeks of gestation, there is some medical literature indicating that the D&E is safer and other medical literature indicating that labor induction is safer. (Ex. 124, Test. Dr. Hammond 690.) Dr. Hammond noted that most of the medical literature discussing retained placenta following medical induction is from the 1980s and before the use of misoprostol. (Ex. 124, Test. Dr. Hammond 689-90.)

### *e. EXISTENCE OF MEDICAL DEBATE REGARDING SAFETY AND NECESSITY OF ABORTION PROCEDURES*

#### *I. GENERALLY*

This case involves "an extraordinarily complex and delicate matter. I don't think that there really is any other topic in obstetrics, certainly, that is as controversial or as polarizing, as I have detected from my colleagues over the last month, than this particular topic." (Tr. 1646, Test. Dr. Lockwood (responding to why witness agreed to be an expert for the government in this case).)

Dr. Shadigian co-authored an article that systematically[99] studied available peer-reviewed abortion literature and attempted to assess potential long-term complications of abortion procedures. (Ex. 631 & Tr. 1562.[100]) The article stated that the long-term health consequences of elective abortion have become "highly politicized"—that is, people on "both sides" fear that their personal opinions about abortion will influence what their research shows. "[I]nstead of people on both sides of this argument saying women's health is really important and we are both for healthy women and we need to . . . make some kind of collaborative effort to study long-term effects, it has been polarized instead." (Tr. 1535-39, Test. Dr. Shadigian.) As stated in Dr. Shadigian's article:

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[99]Dr. Shadigian's study used inclusion and exclusion criteria to look only at bigger studies, not anecdotal case reports; studies having at least 100 subjects; and studies requiring its subjects to have a follow-up of two months or longer after an elective abortion. (Tr. 1536, Test. Dr. Shadigian.)

[100]This exhibit was received "[n]ot to prove that these articles are true or not true, but one, to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the Congressional effort to ascertain the true facts." (Tr. 1626.) However, there was no objection to the portions of the article which were read into the record by Dr. Shadigian.

> Those who would grant a moral status to an embryo or fetus, and thus limit elective abortion, often use adverse health consequence claims as a tool to further their moral agenda while those who support no restriction on abortion access are, at times, unwilling to consider that pregnancy interruption could affect future and mental and physical health.

(Tr. 1540, Test. Dr. Shadigian.)

Appendix IV to this Memorandum and Order lists a myriad of journal articles, papers, CDC data, statements, press releases, letters, and newspaper editorials which were received by this court during the course of trial. As stated previously, these items were received not to prove that the assertions stated therein are true or not true, but to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the congressional effort to ascertain the true facts. (Tr. 1626.)

### *ii. MEDICAL ETHICS*

The AMA committee on partial-birth abortion on which Dr. Sprang served did not reach a consensus regarding the medical ethics of the intact D&E procedure. (Tr. 1241-43, Test. Dr. Sprang; Ex. 13.)

### *iii. MEDICAL NECESSITY*

Defense witness Dr. Bowes testified that there is "no consensus in the medical community that an intact D&X is never medically necessary." (Tr. 963, Test. Dr. Bowes.)

### *iv. SAFETY*

Dr. Shadigan testified that it is possible that use of ripening agents such as laminaria and misoprostol may help reduce trauma to the cervix during abortion and reduce potential long-term risks of preterm birth in subsequent pregnancies. However, in her opinion, the issue needs to be studied because "there are no head-to-head studies looking just at how the cervix is dilated in a serial dilation [with laminaria] over several days versus how it's dilated over four hours [with misoprostol]." (Tr. 1553 & 1576-77, Test. Dr. Shadigian.)

Dr. Shadigian agrees that "cervical incompetence and compromised subsequent pregnancies are important but unresolved concerns related to second or third trimester abortions. Little research exists on whether those complications are more likely to result from D&E (or intact D&X) or from labor induction methods." (Tr. 1587, Test. Dr. Shadigian.)

Dr. Lockwood is "not an advocate" of the Partial-Birth Abortion Ban Act of 2003, but he believes there "is no established scientific evidence demonstrating the D&X procedure is a safer procedure." He believes the intact D&E warrants further study in order to determine its long-term complications. (Tr. 1732, Test. Dr. Lockwood; see also Ex. 126, Test. Dr. Westhoff 902 (there is no peer-reviewed publication finding that intact D&E is less safe than dismemberment D&E).)

While defense witness Dr. Bowes is aware that Drs. Haskell and McMahon in 1992 and 1995, respectively, have compiled case series describing their personal experience with the intact D&E or D&X, Dr. Bowes is not aware of any published peer-reviewed studies in the medical literature evaluating the safety of an intact D&E as compared with a disarticulation or dismemberment D&E or as compared with induction abortions. In Dr. Bowes's opinion, the only conclusion that can be drawn from the results of Dr. Haskell and Dr. McMahon is that "two physicians were able to

accomplish a substantial number of these procedures with, at least, their assertion that there were very few complications." (Tr. 922-25 & 939-40, Test. Dr. Bowes.)

Dr. Cook is not aware of any published comparison studies looking at short-term and long-term safety issues involved with the intact D&E procedure. Dr. Cook believes the papers presented by Drs. Haskell and McMahon presenting short-term complication rates associated with the procedure do not contain a "historically concurrent" comparison or control group with which to compare outcomes and do not include long-term follow-up on the patients. Dr. Cook testified that while the Haskell and McMahon reports may be an initial step to gathering medical evidence, investigation by an independent body or investigation with the oversight of a supervisory committee or peer review is necessary in order to draw any significant inferences regarding safety of a new proposed medical procedure. Such investigation could then be followed by a clinical trial. (Tr. 1342-46, Test. Dr. Cook.) In Dr. Cook's opinion, one introducing a new medical procedure with a purported low complication rate has the "onus . . . to show that those complications, even if low, are lower than other existing techniques, or offer some real benefit over other existing techniques." (Tr. 1346, Test. Dr. Cook.)

Dr. Lockwood is not aware of any medical literature that provides evidence that the intact D&E offers any safety advantage over the traditional D&E or medical induction. (Tr. 1700, Test. Dr. Lockwood.) Dr. Paul knows of no data indicating whether the intact D&E might lead to higher rates of cervical incompetence, preterm birth, or any other long-term adverse consequence. (Ex. 125, Test. Dr. Paul 105-07.)

Defense witness Dr. Bowes is not aware of any study or other valid scientific evidence that establishes that the intact D&E is less safe than the traditional D&E or than an induction abortion, or that establishes that the intact D&E is more dangerous to a woman than any other abortion method. Because of inadequate study in this regard, Dr. Bowes disagrees with the Act's second Congressional Finding which states

that "partial-birth abortion remains a disfavored procedure that is not only unnecessary to preserve the health of the mother but, in fact, poses serious risks to the long-term health of women and in some circumstances their lives." Dr. Bowes believes there is no valid scientific evidence that supports Congress's Finding that "[a] ban on the partial-birth abortion procedure will therefore advance the health interests of pregnant women seeking to terminate a pregnancy." In short, Dr. Bowes believes it has not been "proven" that the intact D&E would be dangerous to women. (Tr. 953-57 & 994, Test. Dr. Bowes; Partial-Birth Abortion Ban Act of 2003, 18 U.S.C.A. § 1531, Cong. Findings (2) & (14(F)).) Dr. Bowes did not communicate his views with regard to these Congressional Findings to House or Senate members prior to enactment of the Partial-Birth Abortion Ban Act of 2003. (Tr. 993, Test. Dr. Bowes.)

Dr. Lockwood agrees with "very little" of Congressional Finding (14)(A) of the Partial-Birth Abortion Ban Act of 2003, which describes purported "serious risks to the health of a woman" who has a "partial-birth abortion." For example, amniotic fluid embolism, categorized by Congress as a risk of the banned procedure, occurs in 1 of 5,000 deliveries and has an approximate 40% mortality rate. While surgical abortions might be more likely than nonsurgical abortions to uncover maternal blood vessels in the uterus that would allow amniotic fluid to enter into the uterine cavity, Dr. Lockwood "would be a little more suspicious about D&Es where there might be an increased risk of trauma than intact D&Xs where there might be a slightly reduced risk." Another risk mentioned in paragraph (14)(A) of the Congressional Findings, conversion of the fetus to a footling breech, could create a serious risk to the mother's health if it caused uterine perforation, but "there is some risk to all medical and surgical abortions."[101] (Tr. 1724-26, Test. Dr. Lockwood.)

[101]Dr. Lockwood admits that the documented and published risks of internal podalic version relate to periods of time closer to term when the uterine wall is thinner. (Tr. 1751, Test. Dr. Lockwood.)

According to Dr. Broekhuizen, although Congress concluded that converting a fetus to a breech position increases the risk of uterine rupture, abruption, amniotic fluid embolus, and trauma to the uterus, this finding is incorrect. Obstetrical literature may support this statement in the context of postviability fetuses, but it has no application to second-trimester pregnancy terminations or inductions up to 24 weeks. Dr. Broekhuizen testified that there are no known complications associated with breech conversion of the fetus during the second trimester. (Ex. 120, Test. Dr. Broekhuizen 517-18, 628-31.)

Dr. Creinin testified that Congress was incorrect in finding that converting the fetus to a breech presentation increases the risk of uterine rupture, abruption, and amniotic fluid embolus. (Ex. 122, Test. Dr. Creinin 669-70.) Specifically, Dr. Creinin made the following observations:

* Abruption is premature separation of the placenta from the uterus. Where a live birth is the goal, this is a severe complication because separating the placenta from the uterus eliminates the supply of oxygen to the fetus. Abruption is not, however, a risk or complication of a D&E because a live birth is not contemplated, and removing the placenta is an innate part and goal of the D&E procedure. (Ex. 122, Test. Dr. Creinin 670-71.)

* Amniotic fluid embolus occurs when amniotic fluid enters the woman's circulation, usually through a sinus (a large opening in the uterine lining which provides access for blood to reach the placenta). The embolus travels to the heart and lungs, causing respiratory and cardiac arrest. This complication of pregnancy or delivery is extremely rare and it would be very hard to show any increased risk at second-trimester gestational ages. More importantly, in a D&E, the amniotic fluid is removed at the outset of the procedure. (Ex. 122, Test. Dr. Creinin 673-75.)

* The act of abortion, whether done by labor induction or D&E, increases the risk of uterine rupture, but grasping a lower limb of the fetus and converting it to a breech presentation does not increase that risk. (Ex. 122, Test. Dr. Creinin 676-77.)

* Congress relied on a textbook statement that breech conversion is inappropriate, but this statement is inapplicable to the D&E procedure. The text cited was discussing delivery at term. (Ex. 122, Test. Dr. Creinin 677-78.)

Further, Dr. Creinin believes that Congress was incorrect in finding that dilating the cervix to perform an intact D&E increases the risk of cervical incompetence. Dr. Creinin maintains that there is no physiological basis for this conclusion and no medical studies that support that finding. (Ex. 122, Test. Dr. Creinin 691-92.)

Dr. Sprang is not aware of any published studies comparing the safety and risk of the intact D&E with the traditional D&E involving dismemberment of the fetus. He is also unaware of studies analyzing whether four-hour induction abortions, second-trimester laminaria dilation, or combined use of laminaria with misoprostol cause cervical incompetence. (Tr. 1157 & 1184, Test. Dr. Sprang.)

Dr. Cook admits that data "comparing contemporary induction methods versus other methods" between 16 and 20 weeks of gestation is "lacking" and there is not a "significant body of medical opinion that holds that induction abortion is sometimes the safest for a particular woman between 16 and 20 weeks of pregnancy." (Tr. 1398-99, Test. Dr. Cook.)

Dr. Shadigian believes "there is no basis to say the D&X is safer than any other procedure" because "the D&X has never been studied in a formal way in peer review literature." Specifically, "there is no sound basis on which to conclude the D&X is

safer than medical induction." (Tr. 1513, Test. Dr. Shadigian.) However, Dr. Shadigian believes that medical induction is a safer abortion procedure than the intact D&E, even though there are no published peer-reviewed medical studies evaluating the intact D&E procedure. (Tr. 1570, Test. Dr. Shadigian.) Dr. Shadigian admits that her opinion that induction is safer than intact D&E for abortions at 20 weeks and later is "a hypothesis [she has] developed from looking at studies that don't look at D&X but look at other aspects of abortion procedure." (Tr. 1589, Test. Dr. Shadigian.)

Dr. Shadigan testified that because the D&E and intact D&E are separate procedures involving different gestational ages and amounts of dilation, safety data regarding the D&E cannot be used to demonstrate the safety of the intact D&E procedure. While the procedures share similarities, each procedure "has a different set of ways of going about delivering the infant." Similarly, safety data comparing the traditional D&E to old methods of induction cannot be applied to analyze the safety of the intact D&E as compared to modern medical induction. (Tr. 1554-55, Test. Dr. Shadigian.)

Dr. Shadigian believes there "is a substantial body of medical opinion that induction is safer than D&E after 20 weeks," but some physicians believe that the D&E is safer than induction after 20 weeks. (Tr. 1562, Test. Dr. Shadigian.)

Based on her review of relevant medical literature, Dr. Shadigian does not believe there "is a substantial body of medical opinion that D&X may be the safest and most appropriate procedure for some women in some circumstances." However, there may be "a substantial body of personal opinion [personal medical anecdotal evidence] that D&X may be the safest procedure for some women in some circumstances." (Tr. 1582, Test. Dr. Shadigian.)

Dr. Shadigian agrees that:

> Abortion-related morbidity is lower for D&E procedures than for labor-induction methods used in second-trimester abortions. However, the rates are similar for procedures performed at 20 weeks gestation and beyond. More research on complications and complication rates associated with various procedures and by gestational age is needed before firm conclusions about the relative safety of procedures can be drawn.

(Tr. 1593, Test. Dr. Shadigian (quoting from Ex. 41, Janet E. Gans Epner, et al., Late-term Abortion 280 JAMA 724, 727-28 (1998)).)

An ACOG Statement of Policy provides in part:

> A select panel convened by ACOG could identify no circumstances under which [the intact D&X], as defined above, would be the only option to save the life or preserve the health of the woman. An intact D&X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor, in consultation with the patient, based upon the woman's particular circumstances can make this decision. The potential exists that legislation prohibiting specific medical practices, such as intact D&X, may outlaw techniques that are critical to the lives and health of American women. The intervention of legislative bodies into medical decision making is inappropriate, ill advised, and dangerous.

(Ex. 5, at 3.)

Dr. Lockwood believes there is "a significant body of medical opinion that in some circumstances for some women, an intact D&E may be safer than the available abortion options." (Tr. 1752, Test. Dr. Lockwood.) However, if the intact D&E is the "preferred route" in any given case, "there are ways in which the practitioner can avoid violating the Act and still carry out the procedure." For example, "potassium chloride or Digoxin can be administered prior to the procedures." (Tr. 1769-71, Test. Dr. Lockwood.)

Based on the medical literature, Dr. Creinin believes that labor induction and D&E are equally safe, but the literature reflects a trend showing D&E as the safer procedure. The sample sizes of the studies are too low at this time to statistically confirm that perception. The relative safety of the procedures is primarily determined by considering the individual patient and whether, based on that patient's personal and medical circumstances, D&E is the preferred procedure. (Ex. 122, Test. Dr. Creinin 718-19.)

### *3. DEVELOPMENT OF SURGICAL TECHNIQUES*

#### *a. SURGICAL PROCEDURES GENERALLY*

Dr. Mazariegas explained that when implementing a new surgical procedure, "there is a wide body of care and standard of care that we apply to our patients that may include the clearly evidence-based therapies that are well[-]documented but may also include a large experience with alternative therapies that may be supported by other strong data or by therapies that are well[-] known but have not yet been subject to a formalized testing." (Tr. 807, Test. Dr. Mazariegos.)

According to Dr. Paul, evidence-based medicine means that if scientific information exists indicating that a particular method or procedure should be used, the doctor has a responsibility to use that method. Evidence-based medicine has, over the last two decades, become accepted in the medical community. (Ex. 125, Test. Dr. Paul 98-99.) Intuition per se is not used in the field of epidemiology. However, in the absence of scientific studies, doctors must use their best clinical judgment to render the safest care possible. (Ex. 125, Test. Dr. Paul 91 & 95-96.)

Dr. Mazariegos stated that surgeons and physicians are "beholden to the patient to provide the best therapy that is available," which means "to uphold the standard of care to apply to our particular patient in a particular medical condition as judged by the

community in which we practice." Because this duty applies to the development of new procedures, "any development of a procedure that is outside the standard of care should then be expected to meet the minimal criteria of providing a safe approach, an effective approach, and one that has been . . . evaluated in some manner." Without prospective, comparative data, "it's impossible to objectively state that a procedure is better or safer" and "you would be likely to introduce [a] procedure that may not have a strong foundation or may be subject to bias." (Tr. 807-08 & 811, Test. Dr. Mazariegos.)

Different doctors develop different protocols, and a physician's skill and experience influence the safety of the procedure done. (Ex. 123, Test. Dr. Frederiksen 1233.)

Dr. Paul testified that randomized clinical trials are not required before medical techniques are used. (Ex. 125, Test. Dr. Paul 90.) For example, most of what is done in abortion practice has never been subjected to random clinical trials. (Ex. 125, Test. Dr. Paul 90-91.)

According to Dr. Clark, medical intuition or theory is not reliable in choosing safe medical treatment. For example, the rate of cesarean section dramatically increased when doctors believed that fetuses exhibiting certain heart rate patterns should be delivered rapidly to avoid cerebral palsy. However, though more cesarean sections were performed, the rate of cerebral palsy did not correspondingly decrease and the theory has now been proven wrong. Similarly, based on medical theory, DES, a synthetic estrogen, was once used to treat miscarriage, but it is now known to cause vaginal cancer and reproductive problems. (Ex. 891, Test. Dr. Clark 2389-90.)

Dr. Paul stated that ideally, surgical techniques should be subjected to comparison studies. Dr. Haskell's presentation regarding the intact D&E procedure occurred over 11 years ago, but no clinical trial of the procedure has occurred to date,

and there are no "published" peer-reviewed studies considering the safety of the intact D&E.[102] (Ex. 125, Test. Dr. Paul 99 & 101-02.)

There are historical instances when the medical community's judgment on the safety of a procedure or method was proven wrong by subsequent randomized clinical studies. (Ex. 125, Test. Dr. Paul 103-05 (electronic fetal monitoring) & 108-09 (episiotomy).)

### *b. TEACHING OF SURGICAL PROCEDURES*

Surgeons learn to perform surgical techniques in medical school and during their residency, and they update and expand their skills by reading relevant medical literature, consulting with colleagues on a day-to-day basis and at professional meetings, attending specific courses to learn how to perform various procedures, and arranging to work alongside a physician who performs a particular procedure. (Tr. 429-30, Test. Dr. Howell.) "[A] lot of education goes on informally. A lot of it [is] people . . . talking to each other. I talk to my colleagues all the time." (Tr. 434, Test. Dr. Howell.)

According to Dr. Howell, surgical procedures change and develop over time.

> The craft of surgery can change in a variety of different ways. Sometimes a brand new idea will come along and it will be adopted and picked up. That happens rather infrequently. Much more often, people, in the course of doing a procedure, will find that it is easier, safer, better in some way, to do it slightly differently than the way they had been doing it before. They'll adopt that method. If it seems to work, they'll talk to

[102]The wording "published" was added, presumably because of a motion in limine precluding the doctor from testifying about the then-unpublished Chasen study.

> their . . . colleagues about it. They'll present it and, eventually, it may become accepted or it may not.

(Tr. 430-31, Test. Dr. Howell.) The physician shares his or her knowledge of the surgical procedure both informally—"in the hallway and the conference rooms"—and formally at meetings. The information is then "eventually published in a peer review journal for people to read it and study." (Tr. 446, Test. Dr. Howell.)

For example, Dr. Howell noted that coronary artery bypass grafting, now an "absolutely standard" procedure, developed over many years of experimentation and accidental discoveries. For a century, it has been recognized that coronary disease or heart attacks are caused by the interruption of blood flow to some part of the heart, and that it would be helpful to improve blood flow to areas of the heart that do not get enough. "Whether you want to implant an artery or sew an artery in, or interpose a vein between the artery and the blocked area, or whether you want to stick a device up inside the artery and expand it to increase the blood flow, these are all different ways of accomplishing the same goal, which is to improve the blood flow." (Tr. 431-32, Test. Dr. Howell.)

Dr. Howell explained that one aspect of this bypass procedure came about in a "purely serendipitous fashion." While physicians attempted to inject dye into a patient's aorta, the catheter accidentally slipped into the coronary artery, something previously believed to be dangerous and probably fatal. While the doctors predicted that their mistake would kill the patient, it did not. "Instead, they saw that there was an obstruction there from the dye that had been injected. . . . [and then] came the knowledge that if we see the blockage, we can relieve it." Further development of the coronary artery bypass grafting procedure also resulted from physicians experimenting with interposing four different kinds of blood vessels and using different methods to sew the blood vessels together. (Tr. 432, Test. Dr. Howell.)

During his surgical residency, Dr. Carhart was taught to formulate surgical techniques that work for him, as long as the results are as good as, or better than, what is expected of other surgeons. "I have worked in thoracic surgery with many heart surgeons, and I have yet to see any two that do something the same way." (Tr. 625, Test. Dr. Carhart; see also Tr. 850, Test. Dr. Mazariegos (noting "[s]mall differences" in how surgeons perform liver-transplant surgery).)

According to Dr. Frederiksen, institutional review board approval is not required for changes in patient care or variations in a surgical technique used by an individual physician unless the change or technique is part of a medical study. (Ex. 123, Test. Dr. Frederiksen 1158-59.)

Dr. Broekhuizen does not classify the intact D&E as a new procedure. Rather, it is conceptually the same abortion method Dr. Broekhuizen has used since the 1970s in Africa and for his treatment of fetal anomalies in the 1980s, but now he has access to different instruments and medications. (Ex. 120, Test. Dr. Broekhuizen 584-88.)

According to Dr. Frederiksen, the D&E procedure has evolved since the 1970s in a manner consistent with how surgical techniques generally evolve. With the availability of laminaria and misoprostol, the use of serial laminaria, and changes in available instrumentation, more cervical dilation can be obtained and D&Es can be performed later in gestation with fetuses delivered more intact. The D&E performed by Dr. Frederiksen today is an extension of the D&E procedure she learned during her residency. Her method of performing D&Es is derived from discussions with other physicians and incorporates their suggestions when, in light of her personal experience and skill, she believes a change in protocol may be beneficial. Studies can then be published to report a procedural variation and the safety and efficacy of that variation. (Ex. 123, Test. Dr. Frederiksen 1155-58 & 1230-31.)

Dr. Frederiksen believes that the Congressional Finding that intact D&E has "never been subject to even a minimal amount of normal medical practice development" is incorrect. Moreover, a ban on the intact D&E would affect the advancement of abortion practice by stopping the ability to explore the advantages of the intact D&E procedure. (Ex. 123, Test. Dr. Frederiksen 1159-60.)

### *c. INSTITUTIONAL D&X INSTRUCTION*

Dr. Frederiksen opined that the Congressional Finding that there are no medical schools that teach the intact D&E procedure is incorrect. For approximately 10 years, Dr. Frederiksen has been teaching students to perform the D&E by removing the fetus as intact as possible. In her opinion, the Act would prohibit educating physicians on how to perform the safest second-trimester abortion procedure. (Ex. 123, Test. Dr. Frederiksen 1160-61.)

During Dr. Vibhakar's residency, a physician at a women's clinic taught her a procedure similar to that described by ACOG as the intact D&X, but the procedure was called a D&E. The physician taught her to do a "breech extraction up until the level of the calvarium, and then a puncture at the base of the skull, and then suction the cranial contents, and then extract the calvarium attached to the body." Dr. Vibhakar was taught during her residency that more dilation is preferable because it was safer—that is, it required "less manipulation within the uterus, so less risk of perforation, less chance of retained tissue, less chance of small fetal parts causing injuries such as cervical lacerations." (Tr. 343-44, Test. Dr. Vibhakar.)

Dr. Frederiksen's residency included rotating through the abortion service at Boston Hospital for Women where she received training in second-trimester D&Es and induction abortions. She has not had formal training since, but her procedures and methods have evolved based on communications with physicians and advances in equipment and medications. (Ex. 123, Test. Dr. Frederiksen 1044.)

Dr. Doe learned to perform what he or she calls the D&X procedure by reading articles authored by Dr. McMahon and Dr. Haskell, by talking with physicians from North America, by visiting clinics, and by applying personal experience. Dr. Doe currently teaches his or her D&X technique to medical students and OB/GYN residents at a university. (Tr. 65-66, Test. Dr. Doe.)

Dr. Hammond was formally trained to perform abortions to 20 weeks of gestation during his residency at the University of Rochester. With additional training from Dr. Frederiksen at Northwestern University, he gradually advanced the gestational age of his abortion practice to 24 weeks in approximately 2001. (Ex. 124, Test. Dr. Hammond 528-29.)

Dr. Chasen teaches medical residents how to perform D&C, dismemberment D&E, and intact D&E procedures at the New York Weill/Cornell Medical Center. (Ex. 121, Test. Dr. Chasen 1556-57.)

Dr. Lockwood is not aware that the D&X procedure is currently being performed at Yale University, but if the court proceedings challenging the Partial-Birth Abortion Ban Act of 2003 are successful and the Act is struck down, Dr. Lockwood would allow the procedure to be taught at Yale University. (Tr. 1667 & 1745-46, Test. Dr. Lockwood.)

Northwestern University teaches students how to perform second-trimester abortions by medical induction, D&E, and intact D&E. (Ex. 123, Test. Dr. Frederiksen 1046.) Specifically, Dr. Hammond teaches fourth-year residents and first- and second-year fellows to perform first- and second-trimester medical and surgical abortions, including D&E. To the extent that every D&E involves an attempt to remove the fetus as intact as possible, intact D&E is also taught. (Ex. 124, Test. Dr. Hammond 534-35.)

Dr. Paul teaches second-trimester D&E methods to students and physicians at Planned Parenthood Golden Gate. (Ex. 125, Test. Dr. Paul 10-16.)

Dr. Westhoff supervises and trains University of Columbia medical students in performing first-trimester D&Cs and second-trimester D&Es, including the intact D&E. The intact D&E method has been taught for the last five or six years as part of the fellowship program in family planning. (Ex. 126, Test. Dr. Westhoff 748-50 & 752-53.)

Dr. Westhoff is aware that the intact D&E is taught at the Albert Einstein College of Medicine, NYU, Cornell, Northwestern, and the University of California at San Francisco. (Ex. 126, Test. Dr. Westhoff 897-98.)

The intact D&E procedure is identified as an available method of second-trimester abortion in the medical text, Williams Obstetrics, which is regarded as an authoritative text on obstetrics. (Ex. 121, Test. Dr. Chasen 1589.)

### *4. THE ACT'S EFFECT ON THE MEDICAL COMMUNITY*

Dr. Carhart reads the Partial-Birth Abortion Ban Act of 2003 to encompass "every D&E" he does where fetal demise is not first induced because every abortion procedure involves "deliberately and intentionally vaginally" delivering a fetus and "performing . . . overt act[s]" that will cause the abortion. Specifically, the Act would affect Dr. Carhart's D&E procedures before 18 weeks, the point at which Dr. Carhart believes he can safely induce fetal demise before aborting the fetus. (Tr. 640-42, Test. Dr. Carhart.)

Dr. Fitzhugh reads the Act to apply to any gestational age and to the second-trimester procedures he performs, especially since he does not induce fetal demise prior to performing abortions. Dr. Fitzhugh questions the Act's terms "deliberately and

intentionally" because those terms could describe any action he takes; the term "living fetus" because "living" can be measured by signs of life, existence of a heartbeat, cell reactions, or EEG activity; and the phrase "necessary to save the life of a mother" because while patient conditions like toxemia, unconsciousness, severe cardiac failure, and coma are clearly life-or-death situations, heavy bleeding, high fever, and infection are conditions that could be considered life-endangering to some, but only health-endangering to others. (Tr. 264-68 & 297, Test. Dr. Fitzhugh; Tr. 525-26, Test. Dr. Knorr (exception to save life of mother is vague because he would consider poorly controlled diabetes life-endangering, but others may not view it as life-threatening).)

Enforcement of the Act would limit Dr. Fitzhugh's ability to care for women, particularly when he performs 80% of the second-trimester abortions in central Virginia and finding a physician in that area to perform an induction procedure not prohibited by the Act would be difficult. (Tr. 269, Test. Dr. Fitzhugh.)

Dr. Knorr does not recognize the term "partial-birth abortion," as used in the Act, as a medical term. Dr. Knorr believes the Act may cover situations in which a portion of a breech fetus is outside the body of the mother and Dr. Knorr takes the "overt act" of removing a fetal limb, like an arm, that is above the umbilicus and is at the level of the vaginal opening. (Tr. 523-24, Test. Dr. Knorr.) He also believes the Act would cover "a majority" or a "large number" of D&Es he performs, including delivering the fetus intact to the head and reducing the size of the fetal skull; bringing out a part of a fetus in one pass and bringing out the remainder of the fetus in a second pass up to the fetal head; and treating miscarriages. (Tr. 524-25, Test. Dr. Knorr.)

Dr. Knorr is not willing to adjust his dilation procedure in order to avoid violating the Act because he believes that his dilation process is "safe and effective" and he believes that the fewer passes made inside the uterus, and the larger the parts removed, the safer the procedure for the patient. (Tr. 527, Test. Dr. Knorr.) Dr. Knorr does not view second-trimester induction abortions to be a reasonable alternative

because it would be "taking a step backwards," and induction abortions are not readily available to women. (Tr. 527-28, Test. Dr. Knorr.)

In Dr. Vibhakar's opinion, the Act would cover the occasional D&Es she has performed where the fetus delivered to the level of the umbilicus, after which she continued to perform the D&E and "commit overt acts that . . . could result in fetal death." The Act could also cover induction abortions Dr. Vibhakar supervises because:

> Sometimes in the case of an induction, a part of the fetus will deliver and part of the fetus will still be inside the uterus. And in trying to facilitate delivery of the rest of the fetus, the umbilical cord could become compressed, and that could cause fetal death or the fetus could become disarticulated, and that could cause fetal death.

Dr. Vibhakar characterizes the Act as "vague" because it does not specify whether the fetus must be intact up to the level of the umbilicus to be covered by the Act; whether the Act would apply when a portion of the fetus's trunk is removed from the patient early in the procedure, followed by actions that can result in fetal death; and what an "overt act" is. (Tr. 351-53, Test. Dr. Vibhakar.)

If the Act eventually goes into effect, Dr. Vibhakar may discontinue performing second-trimester terminations. (Tr. 353, Test. Dr. Vibhakar.)

Dr. Doe believes the Act would apply to cases like one he or she recently handled. A 16-week patient who had previously had several vaginal deliveries presented herself to Dr. Doe on an urgent basis. After only one day of administering four to five Dilapan and misoprostol on the morning of the procedure, the patient began contracting and was uncomfortable. When Dr. Doe examined the patient with a speculum, he or she observed bulging membranes. After Dr. Doe ruptured the membranes, the fetus prolapsed down and the head got stuck. Dr. Doe then grasped the fetal head with forceps, compressed it, and removed the fetus. Because the fetus was

only 16 weeks, Dr. Doe had not induced fetal demise prior to the procedure. Further, Dr. Doe "had no particular plan" as to whether he or she would remove the fetus intact or dismembered when he or she began the procedure, and he or she paid no particular attention to when fetal death actually occurred. "I have . . . seen fetal life even after the fetal head has been compressed." (Tr. 74-77, Test. Dr. Doe.)

Dr. Doe also believes the Act would cover those cases in which Dr. Doe achieves very generous, yet unpredicted, dilation and the fetus "just pops out when [he or she] rupture[s] the membrane," as well as to his or her D&X procedures in which he or she deliberately attempts to remove the fetus as intact as possible.

> I would never know if I was going to be breaching the [A]ct using the techniques that I currently use, because I don't know when the fetus dies. So I don't know when I can do something. And if the fetus was still to be showing some evidence of life when I performed an overt act, whatever that may be, then I would be in breach of the [A]ct. . . . I would be spending my time trying to determine if there was any evidence of fetal life before removing the fetus for no important medical reason.

(Tr. 77-78, Test. Dr. Doe.) Dr. Doe cannot recall a case in which he or she performed an abortion when the head of a living fetus protruded outside the woman's body at the outset of the procedure. (Tr. 124-25, Test. Dr. Doe.)

When the fetus is alive and passes through the cervix intact or substantially intact past the level of the fetal umbilicus and to the level of the calvarium, Dr. Creinin collapses the fetal head to complete the D&E. He cannot predict at the outset that the fetus will pass through the cervix in this manner, but if it occurs and he responds by collapsing the fetal skull to complete the abortion, he believes the Act has been violated. (Ex. 122, Test. Dr. Creinin 678-81, 744-47, 786.)

Dr. Broekhuizen believes that the Partial-Birth Abortion Ban Act could ban some second-trimester abortions, techniques used to treat women undergoing a second-trimester miscarriage, and procedures that, based on medical judgment, are needed to respond to specific maternal health and fetal conditions or to obtain information for planning future pregnancies. (Ex. 120, Test. Dr. Broekhuizen 494-95.)

According to Dr. Broekhuizen, the Act could impact scenarios where dilation is sufficient in a typical D&E such that the fetus comes out intact, where serial laminaria are used for medical reasons to promote delivery of an intact fetus, and where labor induction is used. (Ex. 120, Test. Dr. Broekhuizen 551.) For example, misoprostol may, within four hours, lead to rapid labor and delivery of the fetus either completely or partially. This response cannot be reliably predicted, according to Dr. Broekhuizen. When partial delivery occurs, the fetus may be alive and outside the woman's body past the fetal umbilicus with the fetal head compressed against the internal cervical os. This circumstance necessitates compression or decompression of the fetal head, which results in fetal demise, to effect complete delivery of the fetus. (Ex. 120, Test. Dr. Broekhuizen 512-13.)

Dr. Broekhuizen described several examples of instances that may have been covered by the Act if it were effective at the time:

* Dr. Broekhuizen had a patient whose fetus was diagnosed with a lethal skeletal dysplasia.[103] The patient had previously had a cesarean section and very traumatic birthing process and was not willing to endure labor induction but wanted a pathological examination of the skeletal structure of the fetus. Serial laminaria were used to cause substantial dilation of

[103]Skeletal dysplasia refers to over 120 types of disorders, "each of which results in numerous disturbances of the skeletal system and most of which include dwarfism." Stedman's Medical Dictionary 556 (27th ed. 2000).

the cervix. While the patient was able to deliver the fetus without necessitating crushing or suctioning of the fetal skull, an intact D&E may have been necessary. (Ex. 120, Test. Dr. Broekhuizen 539-40 & 599-601.)

* An abortion was performed on a fetus diagnosed with a lethal chromosomal anomaly and macrocephaly. The woman could not deliver the large fetal head. She could have undergone a cesarean section with a very large incision. Instead, labor was induced, the fetus was breech delivered and alive when the fetal head lodged in the cervical os. A trocar was used to collapse the skull to complete the delivery. (Ex. 120, Test. Dr. Broekhuizen 540-42 & 602-06.)

* An abortion was performed on a fetus with nonimmune hydrops or fetal ascites (fluid in the abdominal cavity). The fetal head delivered first, but the abdomen was too large to deliver, so a trocar or spinal needle was used to decompress the fetal chest and abdomen to deliver the baby. (Ex. 120, Test. Dr. Broekhuizen 552-53.)

Athough Dr. Broekhuizen's practice is limited to abortions to preserve maternal health, the Act poses a risk to his practice. He questions the meaning of "life endangerment"; who decides a mother's life is being endangered; and what level of mortality risk is sufficient to be considered necessary to save the life of the mother. Dr. Broekhuizen stated that some women will accept a 30% risk of personal death to save the fetus, while others deem a 2% risk too high. He testified that this is a personal and family choice to be made with the doctor's assistance. The Act permits others to second-guess that patient's decision even though the abortion decision made was very necessary for that specific patient under those particular circumstances. (Ex. 120, Test. Dr. Broekhuizen 557-58.)

The Act's language providing for state medical board review provides little comfort to Dr. Broekhuizen. He believes the process starts with an indictment and proceeds to a determination made by those with no expertise in his area of practice re-evaluating decisions made in a specific situation encountered by a specific patient. Further, even if the doctor's decision is upheld, Dr. Broekhuizen believes that the medical review board process would significantly impact his practice and his ability to provide similar services to other patients. (Ex. 120, Test. Dr. Broekhuizen 560-61.)

Dr. Broekhuizen testified that if enforced, the Act will make it significantly more difficult for him to provide medically appropriate services to patients. One alternative would be to increase the use of lethal injection so the fetus is not alive at the time of the abortion, but this solution would in some circumstances undermine the best interests and personal choices of his patients. (Ex. 120, Test. Dr. Broekhuizen 563.)

Dr. Creinin opposes the Act primarily because he believes Congress should not legislate the abortion procedures physicians perform on previable fetuses and because the Act does not serve the best interests of women or their health care providers. (Ex. 122, Test. Dr. Creinin 732-33.)

Dr. Paul believes that first-trimester, hysterotomy, and hysterectomy abortion procedures are not affected by the Act, but the Act does affect D&E abortions and could affect labor-induction abortions. (Ex. 125, Test. Dr. Paul 49-50.) Dr. Paul testified that the Act's language describing delivery of "any part of the fetal trunk past the navel" and outside the woman's body could mean the fetal trunk past the navel is outside the cervix, or that the fetal trunk past the navel is outside the woman's body, or that a disarticulated fetal part above the navel is removed through the cervix. In each of these cases, the fetus may be living. (Ex. 125, Test. Dr. Paul 77-78.)

Dr. Paul stated that the Act does not leave the determination of when a partial-birth abortion is necessary to save the life of the mother to the treating physician and

instead allows the physician to be second-guessed by others as to whether an intact D&E was sufficiently necessary. Moreover, Dr. Paul is unclear whether this language means an intact D&E is not necessary if the abortion can be completed by hysterotomy or hysterectomy, even though these procedures have a much higher morbidity and mortality rate. (Ex. 125, Test. Dr. Paul 81-82.)

Dr. Paul stated, "I don't feel like I can practice medicine well being second-guessed by a third party about what my purpose is in completing and in doing a certain act during an abortion when that person also has the power to put me in prison." (Ex. 125, Test. Dr. Paul 80.) She believes the Act would require her to decide whether to continue practicing medicine in the safest manner possible for women despite the risk of imprisonment, and whether to teach all methods of abortion practice, including the intact D&E, or at least to inform her students that they may risk imprisonment if they perform an intact D&E. (Ex. 125, Test. Dr. Paul 92-93.) She believes the Act will affect her relationship with patients who trust her to provide the best care possible, while permitting spouses and parents of minors to file a civil action against her for allegedly violating the Act when neither has the authority to stop the patient from obtaining an abortion. (Ex. 125, Test. Dr. Paul 93-94.)

According to Dr. Westhoff, the language of what is banned by the Act is written broader than Congress's Findings and could include D&Es that involve dismemberment. It is therefore very difficult in her opinion to determine precisely what medical procedures are banned. (Ex. 126, Test. Dr. Westhoff 845-46.) Dr. Westhoff believes the language of the Act bans her method of performing the D&E. She fears prosecution under the Act because when she performs D&Es, many of the fetuses present in a breech position; they are alive, vaginally delivered intact to the level of the umbilicus, and are killed in the procedure; and each step of the abortion is deliberately performed. (Ex. 126, Test. Dr. Westhoff 842-51.)

Dr. Westhoff testified that the same steps are used to perform a dismemberment D&E as an intact D&E with various outcomes that potentially violate the Act. (Ex. 126, Test. Dr. Westhoff 856-57.) For example:

* A D&E may begin as a dismemberment D&E, with one leg dismembered, but the fetus remains alive and is delivered intact and outside the woman's body to the level of the fetal umbilicus. (Ex. 126, Test. Dr. Westhoff 855.)

* The fetal trunk may be the first part grabbed, and while the fetus remains alive, that part may be pulled into the vaginal area and outside the woman's body. (Ex. 126, Test. Dr. Westhoff 855-56.)

Dr. Westhoff pointed out that one step of all dismemberment D&Es is delivering the fetus for the purpose of committing a lethal act. (Ex. 126, Test. Dr. Westhoff 856.) Further, labor induction involves vaginal delivery of a living fetus outside the woman's body, and cutting the umbilical cord is a lethal act. (Ex. 126, Test. Dr. Westhoff 857-59.)

Dr. Westhoff testified that of the 800,000 miscarriages (spontaneous abortions) that occur in the United States every year, 75% require medical intervention to complete emptying the uterus, a process that is necessary to preserve the woman's health and safety. This process may require the overt act of cutting the umbilical cord or collapsing the fetal skull after the fetus is delivered outside the woman's body to the level of the umbilicus. (Ex. 126, Test. Dr. Westhoff 859-62.)

In Dr. Westhoff's opinion, determining when a woman's life is in danger is a matter of judgment which may be subject to a different interpretation by other physicians or prosecutors. (Ex. 126, Test. Dr. Westhoff 884.)

Dr. Westhoff offered several opinions regarding the Congressional Findings that are attached to the Partial-Birth Abortion Ban Act of 2003:

* Congress was incorrect in finding that dilating the cervix to perform an intact D&E increases the risk of cervical incompetence. There are no medical studies supporting that finding, and physiologically, dilation with osmotic dilators is substantially slower and less than what occurs during delivery at term. Cervical dilation with osmotic dilators does not cause cervical incompetence. (Ex. 126, Test. Dr. Westhoff 789-90 & 889.)

* Congress was incorrect in finding that the intact D&E increases the risk of uterine rupture, abruption, and amniotic fluid embolus. There is no published medical literature to support any of these findings. (Ex. 126, Test. Dr. Westhoff 889-90.)

* Congress was incorrect in finding that the conversion to a footling breech increases the risk of uterine injury. This statement is inconsistent with her practice and the practice of her group, and Dr. Westhoff knows of no medical literature to support this finding. The procedure is more difficult when the fetus is at term because the fetus is larger. (Ex. 126, Test. Dr. Westhoff 890-91.)

* Congress was incorrect in finding that blindly forcing a sharp instrument into the base of the fetal skull poses a risk to the mother of lacerations and secondary hemorrhaging. The procedure is not a blind procedure and neither she nor the colleagues in her group have ever had a complication related to collapsing the fetal skull. (Ex. 126, Test. Dr. Westhoff 891-92.)

* Assuming Congress's Findings regarding risk were valid, inducing fetal demise before beginning surgical removal does not reduce those risks. (Ex. 126, Test. Dr. Westhoff 892-93.)

* Congress was incorrect in finding that the intact D&E poses serious risks to the long-term health of women and a danger to their lives. There is no biological plausibility to this statement. (Ex. 126, Test. Dr. Westhoff 893-94.)

* Congress was incorrect in finding that the intact D&E is never necessary to preserve the health of the woman, poses a serious risk to the woman's health, and violates the medical standard of care. (Ex. 126, Test. Dr. Westhoff 894-96.)

* Congress was incorrect in finding that the intact D&E is not taught at medical teaching institutions. At the time the Act was written, Dr. Westhoff was teaching the procedure, and it was also being taught at the Albert Einstein College of Medicine, NYU, Cornell, Northwestern, and the University of California at San Francisco. (Ex. 126, Test. Dr. Westhoff 897-98.)

* Congress was incorrect in finding that banning the intact D&E advances women's health. The procedure reduces the risk of complications which advances women's health interests. (Ex. 126, Test. Dr. Westhoff 898.)

* Congress was incorrect in finding that the intact D&E confuses the medical, legal, and ethical duties of physicians to preserve and promote life because the physician acts directly against the physical life of the child when it delivers the fetus intact to the head and then kills it. The goal of abortion is to terminate the pregnancy and the fetus will not be

alive at the end of the procedure. As with all abortions, the procedure is done at the patient's consent after the medical, legal, and ethical issues have been discussed. (Ex. 126, Test. Dr. Westhoff 899-900.)

* Congress was incorrect in finding that the intact D&E is not an accepted medical practice, and was incorrect in finding that it has never been subject to even a minimal amount of normal medical practice development. (Ex. 126, Test. Dr. Westhoff 901.)

Dr. Clark disagrees with most of Congress's Findings as set forth in section (14)(A) of the Act. With the exception of the risk of preterm birth now raised by the Chasen article, there is no medical evidence to support the risks identified by Congress. Aside from the risk of preterm birth, saying the intact D&E is less safe than the dismemberment D&E is pure speculation and has no place in scientific discussion. (Ex. 891, Test. Dr. Clark 2418-21.)

Within the context of safe medical procedures, Dr. Clark believes that doctors need some flexibility to perform procedures in a manner that accounts for their particular skills, experience, and the unanticipated events that occur in the course of a procedure. (Ex. 891, Test. Dr. Clark 2422-23.)

Dr. Hammond offered several observations about the Partial-Birth Abortion Ban Act of 2003 and its Congressional Findings:

* The language of what is banned by the Act is written more broadly than Congress's Findings in support of the Act. The language of the ban could include dismemberment D&Es and medical-induction abortions. It is therefore very difficult to determine precisely what medical procedures are banned. (Ex. 124, Test. Dr. Hammond 618, 621-22, 630-34.)

* The overt and lethal act of the ban itself is not limited to what is discussed in the Congressional Findings. Although Congress's Findings discuss a fetus with the head lodged in the uterus and the use of a scissors to decompress and suction the fetal head, the ban is not limited to such circumstances. For example, Dr. Hammond does not clearly understand if the Act would be violated if the fetus is delivered to the level of the navel, and the umbilical cord is cut, which is an overt lethal act, even if the skull has not been decompressed. (Ex. 124, Test. Dr. Hammond 624.) Further, in a breech presentation, the fetus may be delivered intact to the fetal navel, but the contents of the fetal abdomen have been pushed upward and are now distending the abdomen above the internal cervical os which precludes the fetus from passing through the cervix intact. In such cases, Dr. Hammond puts an incision in the fetal abdomen to cause decompression. This is a lethal act and although not discussed in Congress's Findings, may be banned by the Act. (Ex. 124, Test. Dr. Hammond 631-32.)

* Dr. Hammond testified that for every D&E, the doctor is deliberately and intentionally dilating the cervix to vaginally deliver a fetus. (Ex. 124, Test. Dr. Hammond 630.) Dr. Hammond questions whether many circumstances that arise during a dismemberment D&E, described below, violate the Act. For example, if the fetal abdomen is the first part grasped and pulled, a living fetus may be delivered outside the body of the woman past the fetal navel. The dismemberment thereafter will kill the fetus and may be a lethal act that is banned by the Act. (Ex. 124, Test. Dr. Hammond 630-31.) Also, if the doctor is able to grasp one lower extremity and remove the fetus past the level of the fetal navel, a dismemberment D&E will occur. The dismemberment itself is a lethal act that may violate the Act. (Ex. 124, Test. Dr. Hammond 632-33.)

* Dr. Hammond testified that for every labor-induction abortion, the doctor is deliberately and intentionally dilating the cervix to vaginally deliver a fetus. The labor induction may not be fully successful and the fetus may deliver until the head is lodged in the cervical os. This circumstance can occur and is not uncommon with hydrocephalic fetuses. According to Dr. Hammond, the doctor can either: (1) collapse the fetal head, which violates the Act, or (2) continue to pull the fetus, causing it to tear at the neck. This is also a lethal act, but now the doctor must reach into the uterus with a forceps and try to grasp the fetal head to remove it. (Ex. 124, Test. Dr. Hammond 641-43.)

* Regarding the "living" fetus language in the Act, every D&E is an intentional and deliberate vaginal delivery of a living fetus, which to Dr. Hammond means a fetus with a heartbeat. (Ex. 124, Test. Dr. Hammond 626-27.)

* Dr. Hammond believes "outside the body of the mother" is ambiguous in the context of medicine. In the reality of an operating room, it is hard to tell when the fetus is outside the woman's body. It is unclear whether "outside the women's body" means outside the uterus, or beyond the vaginal opening. Even if it means beyond the vaginal opening, for some women, the relaxation caused by anesthesia or the use of the tenaculum causes the cervix to lower to the level of the vaginal opening, and sometimes this condition evolves during the course of the surgery. (Ex. 124, Test. Dr. Hammond 627-29.)

Dr. Hammond identified several of the Act's Congressional Findings that, in his opinion, are erroneous:

* Congress was incorrect in finding that dilating the cervix to perform an intact D&E increases the risk of cervical incompetence. There are no medical studies supporting that finding, and the Schneider and Caspi article (Exs. 73 & 621) entitled "Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation" found no evidence of subsequent obstetrical problems related to the cervical dilation performed in preparation for D&E surgery. (Ex. 124, Test. Dr. Hammond 597 & 684-86.)

* Congress was incorrect in finding that the intact D&E increases the risk of uterine rupture, abruption, and amniotic fluid embolus. Dr. Hammond knows of no published medical literature to support any of these findings. The risk of uterine rupture is less with intact D&E, there is no difference in the rate of abruption, and since the amniotic fluid is absent at the outset of the D&E, amniotic fluid embolus is not a risk. (Ex. 124, Test. Dr. Hammond 598-99.)

* Congress was incorrect in finding that conversion of a fetus to a footling breech increases the risk of uterine injury. Dr. Hammond knows of no medical literature to support this finding in the context of second-trimester abortion. The uterus at that stage is much different than at term, with much more room for fetal movement. D&Es, whether dismemberment or intact, all require manipulation and movement of the fetus within the uterus, and have been done safely for 30 years. While the internal podalic version is more dangerous when the fetus is at term because the fetus is larger, that fact has nothing to do with a second-trimester abortion. (Ex. 124, Test. Dr. Hammond 600-03.)

* Congress was incorrect in finding that blindly forcing a sharp instrument into the base of the fetal skull poses a risk to the mother of lacerations and secondary hemorrhaging. The procedure for decompressing the skull in

an intact D&E is not a blind procedure; on the other hand, trapping and grasping the dismembered skull in a dismemberment D&E is a blind procedure. In an intact D&E, the fetal head is at the level of the cervical os and the doctor can see the placement of the scissors in nearly every case, and can in all cases feel where the scissors are with his or her finger to confirm that they are not in a position to injure the cervix or uterus. In contrast, if the fetal skull is dismembered, instruments must be used to feel the inside of the uterus while attempting to grasp the bobbing skull at the end of the forceps. (Ex. 124, Test. Dr. Hammond 604-06.)

* Congress was incorrect in finding that the intact D&E poses serious risks to the long-term health of women and a danger to their lives. There is a lower risk of medical complications associated with intact D&E. (Ex. 124, Test. Dr. Hammond 607-08.)

* Congress was incorrect in finding that the intact D&E is never necessary to preserve the health of the woman, poses a serious risk to the woman's health, and violates the medical standard of care. Since Dr. Hammond has been doing the procedure, or for the last 15 years, the standard of care has been to remove the fetus as intact as possible. (Ex. 124, Test. Dr. Hammond 608-09.)

* Congress was incorrect in finding that the intact D&E is not taught at medical teaching institutions. Northwestern has been teaching it since Dr. Hammond arrived there in 2001, and it is described in the Clinician's Guide to Medical and Surgical Abortion,[104] which is the textbook his residents and fellows use for training. (Ex. 124, Test. Dr. Hammond 610.)

[104]Edited by Dr. Paul, the textbook was "developed" by the National Abortion Federation. (Ex. 124, Test. Dr. Hammond 656.)

* Congress was incorrect in finding that banning intact D&E advances women's health. A ban on intact D&E will place patients at risk by removing the safest abortion choice as an option. (Ex. 124, Test. Dr. Hammond 612.)

* Congress was incorrect in finding that the intact D&E confuses the medical, legal, and ethical duties of physicians to preserve and promote life because the doctor's patient is the woman, and the doctor is acting on the woman's behalf to perform the safest procedure under the circumstances. (Ex. 124, Test. Dr. Hammond 613.)

Dr. Howell noted that if the Act becomes effective, physicians could not study the intact D&E procedure and variations thereof. (Tr. 470, Test. Dr. Howell.)

### *5. GROUP STATEMENTS REGARDING ACT*

#### *a. ACOG*

Dr. Joanna M. Cain was a member of the ACOG task force created in 1996 specifically to review late-term abortion procedures. She was designated as the 30(b)(6) ACOG representative for these legal proceedings. (See Ex. 39 (30(b)(6) deposition notice) & Ex. 115, Test. Dr. Cain 216.)

Dr. Cain graduated from Creighton University Medical School and completed a residency in obstetrics and gynecology at the University of Washington. Her residency program included training on second-trimester abortion methods. She also completed a fellowship at the Memorial Sloan-Kettering Cancer Center in New York City where she was trained in the care of pregnant women with malignancies, including performing first- and second-trimester abortions related to those underlying health issues. Dr. Cain now chairs the department of obstetrics and gynecology at a university

and serves as director of a women's health center. Dr. Cain does not currently personally perform abortions, but supervises physicians who perform D&E, induction, intact D&X (as defined by ACOG), hysterectomy, and hysterotomy abortion procedures. Dr. Cain has special certifications in biomedical ethics, obstetrics and gynecology, and gynecologic oncology. She specializes in gynecologic cancer treatment and biomedical ethics consulting. (Ex. 115, Test. Dr. Cain 13-18 & 22-30.)

Dr. Cain has never performed an elective abortion or an intact D&E. She has performed less than 25 D&Es over the course of her career, less than 5 induction abortions, 1 hysterotomy, and less than 10 hysterectomies. (Ex. 115, Test. Dr. Cain 19-22.)

## *I. ACOG GENERALLY*

ACOG is a nonprofit organization dedicated to the ongoing education of its members, research, and advocacy on the topic of health care for women. It has 44,000 members from the United States, Canada, and Mexico. ACOG is organized into 12 regional districts that report to the national organization. Each state is a subsection within an assigned district. The executive board consists of officers and representatives from each of the ACOG districts. Members of the executive board are elected by vote of the district membership. (Ex. 115, Test. Dr. Cain 222-26.)

The members of ACOG committees and task forces are ACOG fellows. To become an ACOG fellow, the doctor must first be certified by the American Board of Obstetrics and Gynecology and then must apply for and be accepted as an ACOG fellow. Over 90% of the physicians who are board-certified in obstetrics and gynecology are members of ACOG. (Ex. 115, Test. Dr. Cain 44-45 & 223-24.)

### *ii. THE INTACT D&X TASK FORCE*

In 1996 and 1997, ACOG policy statements were developed through committees or task forces of experts in a particular area of medicine. These policy statements were then proposed to the ACOG executive board. Members of the board reviewed the proposed policy statements, made any appropriate editorial changes, and adopted the policy statements if they were deemed worthy. The ACOG executive board had the ability to change both the wording and substance of a proposed policy statement. A policy or guideline under consideration by an ACOG task force is not formally discussed with non-committee fellows of ACOG until it is accepted by the ACOG executive board. (Ex. 115, Test. Dr. Cain 40-41 & 45-46.)

Consistent with its standard business practice, AGOC created a task force in 1996 specifically to review late-term abortion procedures.[105] Dr. Cain was a member of the task force. (Ex. 115, Test. Dr. Cain 216.) Other than the task force and the ACOG executive board, there were no other ACOG committees or groups involved in developing the 1997 ACOG policy statement on intact D&E. (Ex. 115, Test. Dr. Cain 43-44 & 226-27.)

The process for developing the ACOG Statement on Intact Dilation and Extraction (Ex. 6) was consistent with the method used by ACOG in formulating other policy statements. The process began by carefully selecting task force members based on their expertise and viewpoint. These members were sent background materials for review. The members reviewed materials they were provided, reviewed other relevant sources of expertise in the area, and wrote and edited the policy as a committee. The proposed ACOG Statement on Intact Dilation and Extraction (Ex. 655) was then

[105]ACOG has standing practice-related committees, but does not have such a committee to deal specifically with the issue of abortion. (Ex. 115, Test. Dr. Cain 41-42.)

presented to the ACOG executive board by Dr. Fred Frigoletto, the president of ACOG at the time, and was discussed with the board members at that meeting.[106] The board members had access to the materials reviewed by the task force and, as leaders within ACOG, had a broad range of expertise. Editorial concerns were discussed, and the final document was produced with the agreement of the board members. (Ex. 115, Test. Dr. Cain 46-52.)

Dr. Frigoletto chose task force members from diverse backgrounds. Factors considered in choosing the members included geography, gender, race, viewpoint, and expertise. Dr. Cain's area of expertise for this project was medical ethics. (Ex. 115, Test. Dr. Cain 55-58.)

In addition to Dr. Cain, the task force members included:

* A practicing OB/GYN who is Catholic and not strongly affiliated with a university or academic practice. This physician opposed abortion and would not have overseen or performed the intact D&X, as defined by ACOG. (Ex. 115, Test. Dr. Cain 61-62, 70, 198.) This physician was present at the meeting and chaired the task force meeting. As the chairperson, he or she assured that everyone's opinions were heard and each aspect was fully discussed. (Ex. 115, Test. Dr. Cain 158-59.)

* An African-American OB/GYN who is affiliated with a university and treats primarily an uninsured and immigrant population. The physician had performed abortions and had overseen or performed the intact D&X, as defined by ACOG. This physician was unable to attend the task force meeting. (Ex. 115, Test. Dr. Cain 62-63 & 199.)

[106]Dr. Frigoletto was recovering from heart transplant surgery at the time of the ACOG 30(b)(6) deposition. (Ex. 115, Test. Dr. Cain 229.)

* An OB/GYN practicing at a university in the area of maternal-fetal medicine and ultrasound who has performed abortions. This physician may have overseen or performed the intact D&X, as defined by ACOG. (Ex. 115, Test. Dr. Cain 64-65 & 198.) This physician was present at the meeting. (Ex. 115, Test. Dr. Cain 158.)

* The chief of a university medical facility who approached the task force from the viewpoint of maternal health and had experience in performing abortions. This physician had overseen and performed the intact D&X, as defined by ACOG, and was present at the meeting. (Ex. 115, Test. Dr. Cain 67, 158, 198-99.)

* A practicing OB/GYN with experience in treating maternal complications during pregnancy. This physician opposes abortion and would not have overseen or performed the intact D&X, as defined by ACOG. This physician was not present at the meeting. (Ex. 115, Test. Dr. Cain 67-68, 70, 158, 198.)

* The chair of a university department of obstetrics and gynecology who has abortion experience and has written textbooks on maternal-fetal medicine. This physician had overseen performance of the intact D&X, as defined by ACOG. This physician was not present at the meeting. (Ex. 115, Test. Dr. Cain 68-69, 158, 198-99.)

* A practicing OB/GYN with expertise in providing abortions who had overseen and performed the intact D&X, as defined by ACOG. This physician was present at the meeting. (Ex. 115, Test. Dr. Cain 69, 158, 198-99.)

The meeting of the task force was held on October 5-6, 1996. The members met at a working dinner and documents were reviewed. The members were then required to review the materials over the evening to prepare for their discussion at the meeting. (Ex. 115, Test. Dr. Cain 79-80.)

At the task force meeting, the members reviewed the intact D&X procedure in detail and together crafted language they believed represented expert opinion on the issues of concern to the fellowship. A staff member typed the draft language and it was then edited by the committee. (Ex. 115, Test. Dr. Cain 80.) As different topics were discussed, a member would volunteer to try to put the discussion into written words for editing by the committee. Separate paragraphs were circulated for comment, as was the entire document. (Ex. 115, Test. Dr. Cain 84-87.)

### *iii. INTACT D&X TASK FORCE DELIBERATION*

Exhibit 8 is the agenda for the October 1996 task force meeting. (Ex. 115, Test. Dr. Cain 158.) The documents provided to task force members by ACOG for consideration included:

* Exhibit 656: A letter written by President Clinton concerning the reason he vetoed H.R. 1833, proposed legislation banning "partial-birth abortion." This letter was used to identify the public's questions and concerns for consideration in formulating the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 88-90 & Ex. 656.)

* Exhibit 657: A letter sent by Dr. David Grimes to Senator Robert C. Byrd regarding the partial-birth abortion ban. This letter was used to identify medical and ethical issues to be considered in formulating the ACOG Statement on Intact Dilation and Extraction. Although Dr. Grimes is a well-regarded expert and leading authority in the area of abortion, his

letter to the senator was not used to provide a medical basis for the ACOG Statement on Intact Dilation and Extraction. The task force did not receive or review letters from other doctors in the field of obstetrics. (Ex. 115, Test. Dr. Cain 94-99, 148 & Ex. 657.)

* Exhibit 658: A National Abortion Federation question and answer sheet entitled "Later Abortions: Questions and Answers." This document was used to identify common questions to be considered in formulating the ACOG Statement on Intact Dilation and Extraction, and examples of medical situations discussed in Exhibit 658 were considered by the task force. Exhibit 658 was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 100-03 & Ex. 658.)

* Exhibit 659: The statement of the National Abortion Rights Action League entitled "Third-trimester Abortion: The Myth of 'Abortion on Demand.'" This document was used to identify specific medical circumstances a woman and physician may face. The task force members reviewed the specific examples referenced in Exhibit 659, along with others raised by the task force members, and considered whether, in the context of their own practice and expertise, the intact D&X procedure was the most appropriate abortion method to be used under the circumstances. The medical records of the patients discussed in Exhibit 659 were not available to the task force. (Ex. 115, Test. Dr. Cain 103-06 & Ex. 659.)

* Exhibit 660: A National Abortion Federation document entitled "Fact Sheet. Abortion after Twelve Weeks." This document was used to identify areas for task force consideration. The document was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 106-09 & Ex. 660.)

* Exhibit 661: A National Abortion Federation document entitled "Second trimester Abortion: From Every Angle, Fall Risk Management Seminar, September 13-14, 1992, Dallas, Texas." The document included a paper by Martin Haskell. Exhibit 661 was used to provide background concerning the intact dilation and extraction procedure from the viewpoint of a provider who performs the procedure, and it explained the various methods used to describe the procedure. The Haskell paper was used solely to define the procedure for the policy statement. Other than that, it was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 109-12 & 176:3-22, Ex. 661.)

* Exhibit 662: A brochure published by the Wisconsin Right to Life Education Fund entitled, "The D&X Abortion Procedure: Scientific Advancement or Human Rights Abuse?" This document was used to identify areas for task force consideration and contains graphic images of the intact D&X procedure. These images were discussed, and the document was used as an example of how disseminated literature defines the dilation and extraction procedure. It was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 115-17 & Ex. 662.)

* Exhibit 663: An article written by Dr. Allen Rosenfield and published by the New York Times. Dr. Rosenfield is an obstetrician-gynecologist and was the dean of the Columbia School of Public Health, a preeminent school of public health in the United States. This document was used to provide general background concerning the use of the dilation and extraction abortion procedure. The Rosenfield article commented on ACOG's concern with Congress superseding medical judgment. Since the document did not contain statistical information deemed appropriate for

reaching a medical conclusion, it was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 118-20 & Ex. 663.)

* Exhibit 664: A New York Times editorial entitled "Abortion Politics." This document was used to provide general background concerning the use of the dilation and extraction abortion procedure. It also stated that the terminology used by Congress is not recognized in the medical community. It was not relied on as a source of medical expertise or information. (Ex. 115, Test. Dr. Cain 120-21 & Ex. 664.)

* Exhibit 665: "The Partial-Birth Abortion Act of 1995," with a subtitle "Medical Assertions Made in the Debate on HR 1833." The document contains quotes from the congressional debate on the 1995 version of the Act. These quotes were compiled by ACOG staff for the task force's deliberation. The task force did not review the congressional record itself. Exhibit 665 also contained data from Dr. McMahon which was included in the congressional record. The examples of maternal fetal indications discussed in Exhibit 665 were used by task force members to expand their discussion and consider the intact D&X procedure in the context of the members' own practice and expertise. It raised questions concerning possible medical complications, but it was not relied on to answer those questions. (Ex. 115, Test. Dr. Cain 121-22, 125-28, 147-48, Ex. 665.)

* Exhibit 666: A memorandum to the task force on third-trimester abortion written by Kathy Bryant, who is a lawyer and the Associate Director of ACOG's Department of Government Relations. An ACOG document entitled, "Medical Questions and Answers on Third Trimester Termination Procedures," was attached to the memorandum. Exhibit 666 noted that many terms were being used to describe the intact D&E or D&X procedure. The task force believed that much of the confusion

regarding partial-birth abortion arose from the fact that there was no clearly delineated description of the procedure. The task force, and ultimately ACOG, defined the procedure and gave it a name. (Ex. 115, Test. Dr. Cain 129-32, 161-62, Ex. 666.)

* Exhibit 667: An exhibit compiling the ACOG document entitled "Medical Questions and Answers on Third Trimester Abortion Procedures," Dr. Frigoletto's letter in response to that document, and Dr. Murray Nusbaum's letter to Dr. Penny Murphy in response to Dr. Frigoletto's letter. (Ex. 115, Test. Dr. Cain 135-36 & Ex. 667.)

* Exhibit 668: An October 3, 1996, memorandum on third-trimester abortion from Elsa P. Brown which provided the "additional background material requested by Dr. Frigoletto." This document was used to provide general background information and statistical information from the Centers for Disease Control and the Alan Guttmacher Institute. (Ex. 115, Test. Dr. Cain 137-38 & Ex. 668.)

* Exhibit 671: Letters sent by Dr. Robert Hale, as the executive director of ACOG, to President Clinton and Senator Dole. (Ex. 115, Test. Dr. Cain 156-57.)

* Exhibit 9: A 1987 ACOG technical bulletin. At the time it was written, labor was induced with hypertonic saline and urea. The document was likely available to the task force, and may have been discussed in terms of the relative safety of induction and D&E based on gestational age. It would have been discussed along with other information that may have superseded this 1987 bulletin. (Ex. 115, Test. Dr. Cain 183-86 & Ex. 9.)

In forming the task force's proposed ACOG Statement on Intact Dilation and Extraction, the members relied on their own education and expertise, obstetrics and gynecology textbooks, CDC information, published information on the safety of D&E and the D&X subset of D&E, and information about the safety of available alternatives. The textbooks were referenced for information about specific abortion procedures. The task force did not rely on information received from the public, did not interview or receive testimony from doctors, and did not draft and circulate individual position papers or statements for review and comment by other task force members. (Ex. 115, Test. Dr. Cain 143-47, 149-50, 171-73.) Before and during the task force meeting, neither ACOG nor the task force members conversed with other individuals or organizations, including congressmen and doctors who provided congressional testimony, concerning the topics addressed in the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 151-55.)

Dr. Cain does not specifically recall any document reviewed by the task force comparing the relative safety of induction versus D&E. The task force discussed the findings of Haskell and McMahon regarding the relative safety of the intact D&X procedure, but it did not rely on these articles in reaching its conclusions on the relative safety of the intact D&X. (Ex. 115, Test. Dr. Cain 186-88.)

To the extent they were part of the textbook literature available to the task force, the articles published by Dr. Grimes in the 1980s were likely considered by the task force in drafting the proposed ACOG Statement on Intact Dilation and Extraction. The task force did not discuss Dr. Grimes's 1983 conclusion with respect to the relative state of D&E and induction after 16 weeks of gestation. (Ex. 115, Test. Dr. Cain 179-81.) The task force did not request additional information from ACOG. (Ex. 115, Test. Dr. Cain 148.)

In considering the relative safety of abortion procedures, the committee discussed patient factors such as the woman's general state of health, the nature of the

disease process, other options available and their particular risks in light of that patient's specific medical circumstances, and the patient's autonomous choice among the options presented. (Ex. 115, Test. Dr. Cain 231-32.) The task force considered the cases discussed by its members as examples of when an intact D&X may be the safest procedure, but these were not published case reports. There are no randomized prospective studies demonstrating that the intact D&X may be the best or most appropriate procedure in certain circumstances. (Ex. 115, Test. Dr. Cain 195-97 & 203-04.)

The task force relied on CDC data regarding the overall safety of D&E for second-trimester abortions. It recognized that the procedure it defined as intact D&X was primarily performed in the second trimester starting at 18 weeks of gestation; however, the data concerning the safety of the intact D&X was not separately documented from D&E data and was therefore not well-defined. (Ex. 115, Test. Dr. Cain 174-79 .) Task force members were, however, able to think of individual patient circumstances where the intact D&X was a better choice for the individual patient. These circumstances were discussed during the deliberation on the proposed ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 210 & 229.) For example, with a form of cancer of the placenta most often diagnosed in the second trimester and associated with severe preeclampsia, instrumentation on the uterine wall should be avoided as much as possible. In such a case, it is much safer for the woman to have an intact D&X procedure to remove the molar pregnancy. (Ex. 115, Test. Dr. Cain 177.) At least 25 to 30 different types of cases were discussed among the task force members. (Ex. 115, Test. Dr. Cain 201.)

Ethical issues were considered as part of the task force deliberation process. The sentence of the policy which states "[t]he physician, in consultation with the patient, must choose the most appropriate method based upon the patient's individual circumstances" factors in the three key elements of medical ethics decision-making in the United States and worldwide. (Ex. 115, Test. Dr. Cain 230 & 236-37.)

### *iv. EXHIBIT 655: TASK FORCE'S PROPOSED ACOG STATEMENT ON INTACT DILATION & EXTRACTION*

Exhibit 655 is the proposed ACOG Statement on Intact Dilation and Extraction that was sent to the board from the task force. (Ex. 115, Test. Dr. Cain 80-81, 159; Ex. 655.)

The first paragraph of the proposed ACOG Statement on Intact Dilation and Extraction discusses the general background of "partial-birth abortion" and acknowledges the existence of broad and inconsistent definitions for the term. The second and third paragraphs present a clear medical definition of the procedure within the practice of obstetrics. The paragraph relating to the general safety of second-trimester abortion was based on the materials provided to the task force.[107] The final paragraph stated ACOG's concern with legislation that may prohibit specific medical techniques that are critical to the lives and health of American women. (Ex. 115, Test. Dr. Cain 82-84.)

#### *(a) THE DEFINITION OF INTACT D&X*

The task force's definition of "intact D&X" included the four elements listed in the ACOG Statement on Intact Dilation and Extraction. Based on this definition, an intact D&X requires instrumental conversion of the fetus to a footling breech. ACOG's definition of the intact D&X has not changed since 1997. (Ex. 115, Test. Dr. Cain 164-66.) Removal of intracranial contents as described in ACOG's intact D&X definition

[107]Exhibit 668, the October 3, 1996, memorandum on third-trimester abortion drafted by Elsa P. Brown and providing the "additional background material requested by Dr. Frigoletto" was not the basis for the CDC statistical information contained in the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 138-39.)

includes more than removal of the fetus's cerebral spinal fluid. (Ex. 115, Test. Dr. Cain 169-70.)

### *(b) THE CONCLUSION*

The proposed ACOG Statement on Intact Dilation and Extraction submitted by the task force (Ex. 655) concluded that it could identify no circumstances where the intact D&X was the only available option to save the life of the woman or preserve her health. The task force had discussed numerous circumstances where it may be the best procedure for the woman's life and health, and therefore stated that the decision should be left to the woman and her doctor. Exhibit 655 did not, however, specifically state that the intact D&X was sometimes the safest and best available procedure. (Ex. 115, Test. Dr. Cain 189-91, 194-95, 208.)

As reflected in Exhibit 655, ACOG and the task force are strongly opposed to the intervention by legislative bodies in medical decision making between the patient and doctor. ACOG believes legislative intervention may have the unintended side effect of outlawing medical procedures that may be best for the woman's health and well-being, and in doing so, may cause harm to women. (Ex. 115, Test. Dr. Cain 211-14.)

The proposed ACOG Statement on Intact Dilation and Extraction did not identify any studies concerning the relative safety of the intact D&X (Ex. 115, Test. Dr. Cain 178 & Ex. 655), and the task force reached no conclusions regarding how frequently the intact D&X is performed. (Ex. 115, Test. Dr. Cain 188-89.)

### *v. EXHIBIT 6: ACOG STATEMENT ON INTACT DILATION & EXTRACTION*

Exhibit 11 is the report provided to the ACOG executive board by Dr. Frigoletto regarding the task force's proposed ACOG Statement on Intact Dilation and Extraction (Ex. 655; Ex. 115, Test. Dr. Cain 142-43; Ex. 11.) The executive board edited the task force's proposed policy by adding, "[a]n intact D&X, however, may be the best or most appropriate procedure to save the life or preserve the health of a woman." The additional phrasing was consistent with the task force's discussion. (Ex. 115, Test. Dr. Cain 191-94.)

Exhibit 6 is the January 1997 statement of policy regarding the intact D&E which was adopted by ACOG pursuant to its general policy-drafting and adoption processes. (Ex. 115, Test. Dr. Cain 38- 39 & 219-20.) As with any other ACOG policy statements, the ACOG Statement on Intact Dilation and Extraction was not submitted for vote of approval by the membership of the College. (Ex. 115, Test. Dr. Cain 76-77.) Once approved by the executive board, the ACOG Statement on Intact Dilation and Extraction was disseminated to the membership (fellows) of ACOG. Although forums can be held at the ACOG annual meetings to discuss policy statements, and annual meetings were held after the 1997 ACOG Statement on Intact Dilation and Extraction was approved and after it was re-affirmed in 2000, Dr. Cain is not aware of any forums conducted regarding the ACOG Statement on Intact Dilation and Extraction. (Ex. 115, Test. Dr. Cain 53-55 & 233.)

### *vi. EXHIBIT 5: ACOG STATEMENT—ABORTION POLICY*

Exhibit 5 is ACOG's September 2000 statement on abortion policy. The ACOG Statement on Intact Dilation and Extraction (Ex. 6) was inserted verbatim into ACOG's overall statement of abortion policy. Exhibit 5, the ACOG statement of abortion policy, was prepared in the course of ACOG's business pursuant to ACOG's general

procedures for drafting, adopting, and issuing policy statements on behalf of the College. (Ex. 115, Test. Dr. Cain 29, 210-11, 220-22; Ex. 5.)

### *vii. EXHIBIT 7: ACOG FACT SHEET*

Exhibit 7 is the fact sheet prepared by ACOG staff concerning the January 1997 ACOG policy statement regarding intact D&X. The document was prepared in the normal course of ACOG's business to further explain to ACOG fellows the issues regarding intact D&X. Fact sheets such as Exhibit 7 are not adopted by the executive board. (Ex. 115, Test. Dr. Cain 39 & 227-29.) The fact sheet was written by ACOG staff and sent to task force members for comment. (Ex. 115, Test. Dr. Cain 78-79.)

### *b. APHA*

Mr. Alan Baker is the Chief of Staff for the American Public Health Association ("APHA"). He was the designated 30(b)(6) witness for the APHA. (Ex. 117, Test. Baker 7-8 & 45.)

APHA is a membership association comprised of people interested or working in public health from a multitude of backgrounds, including doctors, medical researchers, epidemiologists, nurses, health educators, social workers, and statisticians. APHA has approximately 50,000 direct and charter members. Its members are predominantly from the United States, but there are also members from Canada, Mexico, and Europe. (Ex. 117, Test. Baker 30, 33, 45-48.)

APHA policies are member-initiated. On a yearly cycle, APHA posts publications on its website so members can act to initiate proposals for policies on issues not addressed by current APHA policy. APHA is divided into sections for public health nursing, health administration, and epidemiology. Members belong to the section of their choice. A section committee or an individual member may choose

to initiate a new APHA policy by preparing a draft policy. A member or committee initiating a proposed policy has chosen to work on it and has a sincere interest and often significant expertise on the topic. The drafting individual or committee will sometimes cite to scientific and peer-reviewed literature in support of a policy proposal. The proposed policy is then submitted to the APHA action board. Members of the action board serve at the appointment of the APHA executive board. The action board reviews and/or revises the policy and distributes it to other APHA sections and member groupings. At the APHA annual meeting, the policy review committee discusses, reviews, and possibly revises the policy proposal. It may then be advanced to the APHA governing council. (Ex. 117, Test. Baker 30-32 & 33.)

The APHA governing council is comprised of representatives from each state and the past presidents of the association. There are approximately 200 APHA governing council members. Proposed policies are presented to the governing council, which may discuss the policy at length, amend the policy, or change its wording. Policies are voted on by the governing council. (Ex. 117, Test. Baker 32-33.)

Exhibit 18, pages 00003-00006, are copies of 1981 and 1989 APHA policy statements adopted in accordance with APHA procedure. These policies set forth APHA's position on constitutional amendments or statutes which prohibit abortion (the 1981 policy) and the duties of members to safeguard the right to abortion as a reproductive choice (the 1989 policy). (Ex. 117, Test. Baker 34; Ex. 18.)

Exhibit 17 is a letter from the APHA executive director to the House of Representatives. Exhibit 17 was primarily prepared by APHA's director of federal and congressional relations. No particular members of APHA were contacted regarding the preparation of Exhibit 17. While the letter reflects the application of APHA's long-standing policies on abortion to the proposed partial-birth abortion legislation, the letter itself is not a policy adopted though the APHA policy-review process. The content of the letter was discussed with APHA's assistant director for policy and the association's

executive director. The letter was part of a "mail drop," a collection of letters from organizations of like mind which were submitted as a packet of material to Congress. Pro-Choice America organized and coordinated the mail drop. (Ex. 117, Test. Baker 9-14, 18-19, 24, 34-35; Ex. 17.)

The Exhibit 17 letter is an APHA statement to Congress opposing the Partial-Birth Abortion Ban Act because the Act fails to include an adequate health exception allowing the physician to determine the best or most appropriate procedure to preserve the health of the woman. This opposition statement was based on the professional knowledge of the APHA officers involved in creating the letter, APHA's 1981 long-standing and officially adopted policy supporting the woman's right to choose, and APHA's 1989 policy stating that public health workers have a duty to challenge congressional actions or proposed constitutional amendments which would impact the woman's right to choose. The letter was signed by Georges C. Benjamin, M.D., the APHA executive director. (Ex. 117, Test. Baker 21-23, 25-29, 55; Ex. 17.)

### *c. AMWA*

Ms. Meghan Kissell, the director of communications and advocacy for the American Medical Women's Association ("AMWA"), was the designated 30(b)(6) witness for the AMWA. (Ex. 116, Test. Kissell 8 & 84-86.) The AMWA is an association of 10,000 female medical professionals dedicated to advancing women in medicine and improving women's health. Some of the members are obstetricians and gynecologists that perform abortions. (Ex. 116, Test. Kissell 10 & 86.)

Exhibit 16 is the set of records provided by AMWA to the Department of Justice in response to the government's subpoena. Exhibit 16, pages 00003-00006, are the AMWA position statements on abortion and access to comprehensive reproductive health services. Position statements of the AMWA are reviewed and approved by the organization's members and its board of directors. (Ex. 116, Test. Kissell 11-13.)

Ms. Kissell testified that the AMWA has not issued a formal position statement on the Partial-Birth Abortion Ban Act of 2003 or any of the Act's underlying bills. (Ex. 116, Test. Kissell 13-14.) However, Ms. Kissell also testified that Exhibit 14 is a March 25, 2003, letter opposing HR 760, the "Partial-Birth Abortion Ban Act of 2003," and Exhibit 15 is a July 18, 2002, letter opposing HR 4965, the "Partial-Birth Abortion Act of 2002." Kissell testified that these letters are the current position statements of the AMWA and were subjected to the AMWA's position-statement-approval process. (Ex. 116, Test. Kissell 91-92.)

The blackened box in the middle of page AMWA 00012 of Exhibit 16 references the process for proposing and responding to resolutions. An AMWA member may propose that the association take a position on an issue. A member proposal is called a resolution. The resolution is considered through a formal process which culminates with a meeting of the members. No resolutions have been proposed to the AMWA regarding the Partial-Birth Abortion Ban Act of 2003 or 2002. (Ex. 116, Test. Kissell 26-28.)

The AMWA may also act on behalf of the association by advancing positions in amicus briefs, court cases, and correspondence to members of Congress. (Ex. 116, Test. Kissell 29-30.) Exhibit 14 is a letter from the president of AMWA to Congressman Jerrold Nadler regarding the Partial-Birth Abortion Ban Act of 2003. It is very similar to the letter AMWA sent regarding the Partial-Birth Abortion Act of 2002. The letter was based on the position papers of the AMWA and was consistent with its amicus brief in Carhart v. Stenberg. As the AMWA Director of Communications and Advocacy, Ms. Kissell generated the 2003 letter as a near duplicate of the letter previously submitted by the association on the 2002 proposed Act, the president signed it, and the executive director was notified that the letter was sent. The board of directors did not direct her to prepare the 2003 letter, and the membership was not asked to and did not respond to its content. The position of

AMWA has not changed since the 2002 letter (Ex. 15) was sent. (Ex. 116, Test. Kissell 31-35; Ex. 14.)

The second sentence of Exhibit 14 states that the proposed Partial-Birth Abortion Ban Act would ban a procedure that in some circumstances is the safest and most appropriate alternative for the life and health of the woman. The letter was directed at late-term abortion procedures. AMWA believes doctors should retain the option of choosing the most appropriate procedure for a woman at the time she chooses to terminate a pregnancy. (Ex. 116, Test. Kissell 39-41; Ex. 14.)

The organizational position related in Exhibit 14 is that the Act is imprecise, does not include correct medical terminology, and that choosing the appropriate abortion procedure in a specific case should be left to the doctor and not the government. The question of whether the letter was directed at a particular abortion procedure must be answered by the AMWA's expert members. (Ex. 116, Test. Kissell 43-45.)

Exhibit 15 is a letter from the president of AMWA to Congressman Steve Chabot regarding the Partial-Birth Abortion Act of 2002. The AMWA had opposed similar bans in the past, and the documents opposing previous bans were reviewed by past government affairs chairmen, executive directors, women's health committees, and chairmen of the advocacy committee. The letter also references AMWA's involvement in the amicus brief in Carhart v. Stenberg. Ms. Kissell prepared the Exhibit 15 letter for the president's signature. No other AMWA staff saw or assisted in preparing the letter. (Ex. 116, Test. Kissell 54-57; Ex. 15.)

AMWA is in coalition with organizations that have legal counsel, including the Pro-Choice Lobby Group. The AMWA's position that the bill was imprecise, included non-medical terminology, and could ultimately undermine the legality of other

techniques used in obstetrics and gynecology was based on discussions with organizations other than AMWA that had legal counsel. (Ex. 116, Test. Kissell 75-77.)

Exhibits 14 and 15 are the current position statements of the AMWA and were subjected to the AMWA's position-statement-approval process. The AMWA presidents who signed the 2003 letter (Ex. 14) and the 2002 letter (Ex. 15) were physicians. (Ex. 116, Test. Kissell 91-92, 94-95; Exs. 14 & 15.)

### *6. ENFORCEMENT OF THE ACT*

Mr. Wan J. Kim, a graduate of the University of Chicago law school and a deputy assistant attorney general with the United States Department of Justice, was identified by the government as the person within the Department of Justice who has knowledge concerning how the Partial-Birth Abortion Ban Act of 2003 will be enforced. Pursuant to a 2003 political appointment, Mr. Kim is assigned to the Civil Rights Division which enforces statutes, mainly in discrimination matters. Assuming enforcement of the Act is not permanently enjoined, the Civil Rights Division will be charged with the responsibility of enforcing the Partial-Birth Abortion Ban Act of 2003. (Ex. 118, Test. Kim 14-18 & 24.)

To Mr. Kim's knowledge, the Department of Justice has not adopted a policy or position regarding how the Act will be enforced if it is not enjoined. (Ex. 118, Test. Kim 38-42.) Exhibit 42 is the department's directive to the FBI field offices from its Criminal Investigation Division concerning the Partial-Birth Abortion Ban Act of 2003. (Ex. 118, Test. Kim 102-103.) Under this directive, the Federal Bureau of Investigation is not to investigate any complaint concerning an alleged violation of the Act without first forwarding the complaint to the Civil Rights Division for an initial determination. Enforcement of the Act is to be coordinated by a task force within the criminal enforcement section of the Civil Rights Division, but this task force has not been formed. (Ex. 118, Test. Kim 24, 32-34, 79.)

### *a. THE FIELD GUIDANCE DOCUMENT*

Mr. Kim was the principal author of the document entitled "Field Guidance on New Criminal Authority Enacted in The Partial-Birth Abortion Ban Act of 2003," which was an attachment to the Department of Justice's November 5, 2003, memorandum on implementation of the Partial-Birth Abortion Ban Act of 2003 (Ex. 40). The field guidance document was intended to explain the law to United States Attorneys, Assistant United States Attorneys, and FBI agents. Field guidance documents are often, but not always, generated by the Department of Justice when new statutes are enacted. The field guidance document Mr. Kim wrote concerning the Partial-Birth Abortion Ban Act of 2003 is the only statement of policy by the Department of Justice regarding interpretation and enforcement of the Act. (Ex. 118, Test. Kim 68-73, 75-76, 120; Ex. 40, at ENF 00011-00012.)

The field guidance document identifies two essential elements for finding a violation of the Act: (1) a physician must knowingly perform a partial-birth abortion, thereby killing a human fetus, and (2) the violation must be in or affecting interstate or foreign commerce. These elements were gleaned from the plain language of the Act. (Ex. 118, Test. Kim 84-85; Ex. 40, at ENF 00011.) Under the terms of the field guidance document, partial-birth abortion is defined to incorporate "two separate and sequential acts: (1) the partial delivery of a living fetus and (2) an overt act that kills a partially delivered living fetus." This definition arises from the plain language of the Act as interpreted by the Attorney General. (Ex. 118, Test. Kim 85-86; Ex. 40, at ENF 00011.) The Department of Justice has not, however, made a formal and final decision or created a policy defining "partial delivery," "living fetus," or "overt act," and these terms are not defined in the field guidance document. (Ex. 118, Test. Kim 87; Ex. 40, at ENF 00011-00012.)

### *b. PROSPECTIVE ENFORCEMENT*

In the context of criminal enforcement, Mr. Kim is required to interpret statutory language to decide whether the government will prosecute under the specific facts raised in a case. (Ex. 118, Test. Kim 20-21.) He is not aware of any policies or guidance within the Department of Justice concerning what specific procedures are covered by the Partial-Birth Abortion Ban Act. To his knowledge, those decisions have not been made. (Ex. 118, Test. Kim 42-44 & 68.)

Assuming the injunction barring enforcement of the Act were lifted tomorrow, if the Department of Justice receives a complaint alleging a violation of the Act, the allegation will be investigated. After the facts are collected, the department will determine what procedures fall within the scope of the Act's prohibition and whether the facts justify prosecution. Decisions as to prospective application of the Act will probably be made by attorneys within the Department of Justice in the context of specific cases. (Ex. 118, Test. Kim 92-94 & 98-99.) When asked how a physician would know what conduct fell within the scope of the Act's prohibitions, Mr. Kim responded:

> You're asking me to speculate. I would speculate . . . the NAF would probably issue guidance. Physicians may look up—I don't know. I really don't know. I mean, I assume they would read the act, but I don't know the physician you're talking about.

(Ex. 118, Test. Kim 90-91.)

To date, the Department of Justice has not made a final policy decision as to whether, for the purposes of the Act, a physician commits a lethal overt act for the purposes of the Act by cutting the fetus's umbilical cord, collapsing the fetal skull or suctioning out its contents, crushing the fetal trunk, or dismembering the fetus. (Ex. 118, Test. Kim 89 & 124-26.) The Department of Justice has made no final policy

decision as to whether a physician violates the Act by performing a partial-birth abortion when a hysterectomy or hysterotomy were available options to save the patient's life. (Ex. 118, Test. Kim 101-02 (Mr. Kim acknowledges that he does not know what some of these medical terms mean).) It has formulated no final policy concerning whether the Act bans only late-term abortion procedures, how early in pregnancy the Act will apply, or whether it will be enforced before the fetus is viable (Ex. 118, Test. Kim 115 & 122-23); whether the Act bans abortions involving suctioning the uterus, dismemberment D&Es, or labor-induction abortions (Ex. 118, Test. Kim 119-20 & attached errata sheet); or whether the Act will be enforced when procedures are performed on nonviable fetuses. (Ex. 118, Test. Kim 65-66.)

Dr. Broekhuizen testified that physicians are not certain whether particular situations would be covered by the Act such that the Department of Justice would pursue enforcement. For example, a woman was referred to Dr. Broekhuizen for a medically necessary abortion at 23 weeks and one day. She had scleroderma with pulmonary hypertension and significant vascular disease. The doctors believed she faced serious and potentially life-threatening complications if she underwent the stress of labor or was given anesthesia, and the use of prostaglandins (including misoprostol) was contraindicated. Dr. Broekhuizen treated her with three sets of serial laminaria for approximately 24 to 30 hours. Although the dilation was sufficient to permit the fetus to deliver intact without compressing the fetal head, at the outset of the procedure he intended to perform an intact D&E. (Ex. 120, Test. Dr. Broekhuizen 537-38, 592, 594-95.) It is not clear whether those who would enforce the Act would consider this situation sufficiently life-threatening to be covered by the Act's exception.[108] (Ex. 120, Test. Dr. Broekhuizen 558-59.)

[108]His concern may not be unwarranted given the level of second-guessing by the government and its extensive cross-examination regarding Dr. Broekhuizen's decision. (Ex. 120, Test. Dr. Broekhuizen 591-99.)

## *II. LAW*

Condensed, the plaintiffs assert four arguments. First, they argue that the ban is unconstitutional because it lacks an exception for the health of women. Second, they argue that the ban is unconstitutional because it threatens to reach other needed abortion procedures or medical techniques, specifically, second-trimester previability D&E and induction abortions and treatment methods used for spontaneous abortions (miscarriages). Thus, they claim, the ban is an undue burden on women. Third, they argue that the ban is unconstitutional because it is vague; that is, the statute fails to clearly define the banned procedure and, more generally, the statute uses vague words. Finally, they argue that the ban's "life" exception is unconstitutional because it permits use of the banned procedure only when "necessary" as opposed to when "necessary in appropriate medical judgment."

With some important qualifications, I agree that the ban is unconstitutional for the first three reasons asserted by the plaintiffs. Specifically, the law is unconstitutional because: (1) it lacks a health exception; (2) accepting Mr. Ashcroft's proposed "specific intent" limiting construction, the law nevertheless bans D&E abortions of the type performed by Dr. Carhart when he does not first induce fetal death by injection prior to 18 weeks;[109] and (3) if Mr. Ashcroft's proposed "specific intent" limiting construction is improper, the law is too vague regarding the behavior the law seeks to criminalize.

I do not agree that the law, properly limited, bans certain D&E abortions where the physician lacks the requisite specific intent. Similarly, when a physician conducts induction abortions or when a physician treats spontaneous abortions, he or she lacks

[109]Whether because the law does not contain a health exception or because it bans certain D&E abortions, the effect of the law is an undue burden as it places a substantial obstacle in the path of women seeking an abortion of a nonviable fetus. I decline to decide whether that was its purpose.

the requisite specific intent and therefore the law does not ban those activities. Moreover, I do not believe the law is too vague because of the use of certain words.

In addition, I do not agree that the ban's "life" exception is unconstitutional, although, again, only a limiting construction by this court saves it from Congress' deficient drafting. I must read into the ban's "life" exception the important clarification urged by Mr. Ashcroft; that is, "The Act's life exception is subject to a . . . construction that permits a physician to perform a partial-birth abortion if 'necessary,' in his or her own professional judgment, 'to save the life of the mother[.]'" (Filing 161, Def.'s Br. at 98) (citing Doe v. Vuitch, 402 U.S. 62, 72 (1971).)

Moreover, I do not agree with the plaintiffs that I should declare this law unconstitutional with respect to abortions where the fetus is undisputably viable. There was little or no evidence presented to me on what really happens during this gestational stage. Moreover, none of the plaintiff-doctors perform abortions on fetuses that are obviously viable in order to preserve the health, as opposed to the life, of women. Therefore, I decline to determine whether the law is constitutional or unconstitutional when the fetus is undisputably viable. In other words, my ruling is limited to deciding that the law is unconstitutional in all circumstances where the fetus is either not viable or where there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion.

Finally, and out of deference to the other federal courts that have simultaneously heard similar challenges, I will limit the reach of the injunction that I issue to these plaintiffs and their associates. That is, I decline to issue a "nationwide" injunction.

## *A. BECAUSE IT CONTAINS NO HEALTH EXCEPTION, THE BAN IS UNCONSTITUTIONAL.*

### *1. A STATUTE RESTRICTING A PARTICULAR ABORTION METHOD MUST PROVIDE AN EXCEPTION FOR THE HEALTH OF THE WOMAN WHERE SUBSTANTIAL MEDICAL AUTHORITY ESTABLISHES THAT BANNING THAT PROCEDURE COULD SIGNIFICANTLY ENDANGER THE WOMAN'S HEALTH.*

In Stenberg v. Carhart, 530 U.S. 914 (2000) (hereinafter Stenberg), the Supreme Court upheld this court's determination that a Nebraska law banning "partial-birth abortion" was unconstitutional because, among other reasons, the law failed to include an exception for the health of women. Obviously, that case is very similar to this one. Dr. Carhart was the plaintiff in Stenberg, and he is a plaintiff in this case. The law in Stenberg sought to ban "partial-birth abortion" and the law here seeks to ban "partial-birth abortion." Still further, the federal law challenged here explicitly attacked the factual findings of this court in Stenberg. Because of the close legal and factual similarity between Stenberg and this case, I must be guided primarily by the principles laid down by the Supreme Court in Stenberg.[110]

The core legal principle of Stenberg is this: While the government is not required to "grant physicians 'unfettered discretion' in their selection of abortion methods[,] . . . where substantial medical authority supports the proposition that

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[110]Of course, I recognize that the law dealt with by Stenberg was a state law and the law at issue here is a federal law, but I do not believe that such a difference makes a relevant distinction in terms of the right to an abortion. Whatever the constitutional source of abortion rights, those rights have always been understood to apply equally to the federal and state governments and Mr. Ashcroft does not contend otherwise. Indeed, when questioned on this point, Mr. Ashcroft's able counsel affirmatively stated that he was not urging the court to make such a distinction. (Tr. 1866.) Based upon that representation, I pursue this matter no further.

banning a particular abortion procedure could endanger women's health," the Constitution "requires the statute to include a health exception when the procedure is '"necessary, in appropriate medical judgment, for the preservation of the . . . health of the mother."'" Id. at 938 (quoting Casey, 505 U.S. at 879, in turn quoting Roe v. Wade, 410 U.S. at 164-65). That primary rule is premised upon the following precepts:

* "[T]he Constitution offers basic protection to the woman's right to choose." Id. at 921.

* "[B]efore 'viability . . .[,] the woman has a right to choose to terminate her pregnancy.'" Id. (quoting Casey, 505 U.S. at 870 (omission in original)).

* A "'law designed to further [the government's] interest in fetal life which imposes an undue burden on the woman's decision before fetal viability' is unconstitutional." Id. (quoting Casey, 505 U.S. at 877).

* The phrase "'undue burden'" is "'shorthand for the conclusion that a [governmental] regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus.'" Id. (quoting Casey, 505 U.S. at 877).

* After "'"viability, the [government] in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."'" Id. (quoting Casey, 505 U.S. at 879, in turn quoting Roe v. Wade, 410 U.S. at 164-65).

* "The word 'necessary' in Casey's phrase 'necessary, in appropriate medical judgment, for the preservation of the life or health of the mother,' cannot refer to an absolute necessity or to absolute proof." Id. at 937 (citation omitted). Nor does "'necessary, in appropriate medical judgment' . . . require unanimity of medical opinion." Id. These words "tolerate responsible differences of medical opinion . . . ." Id.

* The government's "interest in regulating abortion previability is considerably weaker than postviability." Id. at 930. Therefore, "[s]ince the law requires a health exception in order to validate even a postviability abortion regulation, it at a minimum requires the same in respect to previability regulation." Id.

* The government "cannot subject women's health to significant risks" and that principle applies "where [governmental] regulations force women to use riskier methods of abortion." Id. at 931. That is, the Court's "cases have repeatedly invalidated statutes that in the process of regulating the methods of abortion, imposed significant health risks." Id. (emphasis in original).

### *2. WHEN BANNING "PARTIAL-BIRTH ABORTION," CONGRESSIONAL FINDINGS THAT A HEALTH EXCEPTION IS UNNECESSARY ARE NOT ENTITLED TO DEFERENCE WHEN THOSE FINDINGS ARE UNREASONABLE AND NOT SUPPORTED BY SUBSTANTIAL EVIDENCE.*

Mr. Ashcroft asserts that I must give binding "deference" to the legislative Findings made by Congress in the law banning "partial-birth abortion."[111] In particular, he asserts that I must give the type of deference the Supreme Court gave to Congress in two cases dealing with the cable industry. See Turner Broadcasting Sys. Inc. v. FCC, 512 U.S. 622, 667 (1994) (plurality opinion) (regarding a First Amendment challenge to a law that required cable stations to carry the shows of local commercial and public broadcast stations, and despite congressional findings set forth in the law and three years of congressional hearings upon which those findings were based, the Court remanded the case to the district court for an evidentiary hearing because of the "paucity of evidence" and other "deficienc[ies] in [the] record") ("Turner I"); Turner Broadcasting Sys. Inc. v. FCC, 520 U.S. 180 (1997) (based upon the congressional record, as supplemented by the findings of the district court on remand, the entire record supported Congress' predictive judgment that the "must-carry" provisions of the law furthered important governmental interests and therefore the law did not violate the First Amendment) ("Turner II").

In those cases, the Court stated that when "reviewing the constitutionality of a [federal] statute, 'courts must accord substantial deference to the predictive judgments of Congress.'" Turner II, 520 U.S. at 195 (quoting Turner I, 512 U.S. at 665) (emphasis added). The Court went on to state that deference was due if the "legislative conclusion was reasonable and supported by substantial evidence . . . ." Id. at 211.

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[111]In its Findings, Congress also states the deference it believes it is due. Not surprisingly, Mr. Ashcroft's argument tracks the position urged by Congress.

The Supreme Court's language about "substantial deference" in the Turner cases is explicitly related to "predictive judgments of Congress." Id. at 195. That is, when Congress is predicting events, such as the impact of a particular cable regulation on the economy of a still-developing industry as compared to the impact of that same regulation on a related but better-developed industry, those estimates are entitled to unusual latitude "lest we infringe on traditional legislative authority" to make "predictive judgments when enacting nationwide regulatory policy." Turner II, 520 U.S. at 196. Stated in simple terms: When the answer to the relevant question can only be a guess because the answer will turn on accurately predicting future facts, Congress, being an elected body, is most often the place to make that guess. Here, in contrast, the answers to the relevant questions require no prophesy.

Still further, sometimes, as is the obvious case here, Congress' fact-finding authority has the potential to redefine the meaning of the Constitution as articulated by the Court in prior cases, and thus effectively take from the Supreme Court the ability to say what the Constitution means. In such a situation, judicial deference to facts found by Congress is much reduced and sometimes eliminated entirely. See, e.g., United States v. Morrison, 529 U.S. 598, 614 (2000) (explicitly disregarding "numerous findings regarding the serious impact that gender-motivated violence has on victims and their families" when determining whether a particular activity substantially affected interstate commerce). See also City of Boerne v. Flores, 521 U.S. 507, 536 (1997) (striking down the Religious Freedom Restoration Act, a law enacted pursuant to the enforcement powers of Congress under section 5 of the Fourteenth Amendment, that attempted to "overrule" a prior decision of the Supreme Court; stating "[w]hen the political branches of the Government act against the background of judicial interpretation of the Constitution already issued, it must be understood that in later cases and controversies the Court will treat its precedents with the respect due them under settled principles, including stare decisis, and contrary expectations must be disappointed.") (emphasis in original).

For these two reasons—because the fact-finding process engaged in by Congress in this case requires no "predictive" judgment and because the fact-finding process engaged in by Congress in this case is explicitly intended to undercut Stenberg—I conclude that the Findings of Congress are not due "substantial" deference when deciding whether the ban is constitutional. But this conclusion does not mean that I can ignore Congress.

As previously noted, the Supreme Court made it clear in Stenberg that the government was not required to "grant physicians 'unfettered discretion' in their selection of abortion methods." Stenberg, 530 U.S. at 938. Since that is true, it must also be true that Congress has the power, subject to judicial review, to determine whether a health exception is necessary regarding the performance of a particular abortion procedure. And, if that premise is also correct, then Congress' factual judgments about "the selection of abortion methods" must, under certain circumstances, be entitled to binding deference. Otherwise, the power possessed by Congress to limit a physician's exercise of unprincipled discretion in the selection of abortion methods becomes illusory.

Therefore, and shorn of the adjective "substantial," I believe the Findings of Congress are entitled to binding deference if the test (as opposed to the gloss) announced by the Turner line of cases is satisfied. Specifically, I conclude that the factual judgments of Congress when banning an abortion procedure are entitled to binding deference if "the legislative conclusion was reasonable and supported by substantial evidence . . . ." Turner II, 520 U.S. at 211. In this regard, I am not "at liberty to substitute [my] judgment for the reasonable conclusion of a legislative body." Id. at 212.

Nevertheless, simply because Congress has spoken does not mean that the court becomes a rubber stamp. As Justice Thomas has made clear when discussing the deference due congressional findings in another context, if Congress "could make a

statute constitutional simply by 'finding' that black is white or freedom, slavery, judicial review would be an elaborate farce." Lamprecht v. FCC, 958 F.2d 382, 392 n.2 (D.C. Cir. 1992) (the Court of Appeals, with Justice Thomas sitting as Circuit Justice, held that a governmental preference for female radio station owners violated equal protection principles). Thus, a deferential standard of review must never be allowed to convert judicial review of congressional fact-finding into an "elaborate farce."

Indeed, the Turner cases require that I closely examine the congressional record to determine its adequacy to support the factual findings reached by Congress. Turner I, 512 U.S. at 664, 667 (despite three years of congressional hearings and resultant congressional findings, there was a "paucity of evidence" and "deficienc[ies] in" that record requiring the government to prove at an evidentiary hearing before the district court that the "recited harms are real" and the law "will in fact alleviate these harms in a direct and material way"). For afficionados of "levels of scrutiny," Justice Breyer has described the Turner standard as "heightened, not 'strict' scrutiny," United States v. American Library Ass'n, Inc., 539 U.S. 194, 217 (2003) (Breyer, J., concurring) and Justice Souter has described the standard as involving "intermediate scrutiny." City of Erie v. Pap's A.M., 529 U.S. 277, 311 (2000) (Souter, J., concurring and dissenting).[112]

I may also take additional evidence to decide the reasonableness of the congressional fact finding. Turner II, 520 U.S. at 196 (to ascertain whether a "substantial basis" exists to "support Congress' conclusion[,]" the Supreme Court would consider "first the evidence before Congress and then the further evidence presented to the district court on remand to supplement the congressional determination"). In fact, the weakness of the congressional record in Turner I caused

[112]According to Justice Souter, the Supreme Court's "cases do not identify with any specificity a particular quantum of evidence" that must exist in order to sustain a legislative enactment subject to Turner-like review. City of Erie, 529 U.S. at 311.

the Supreme Court to remand and require an evidentiary hearing where the government had the burden of persuasion. Turner I, 512 U.S. at 667-68.

Most importantly, stating this abstract approach to deference is only the beginning and not the end of the inquiry. Generalized standards of review are never meaningful until they are applied to the substantive law. Here the substantive law is set forth in Stenberg, and the primary holding of that decision states: "[W]here substantial medical authority supports the proposition that banning a particular abortion procedure could endanger women's health," the Constitution "requires the statute to include a health exception when the procedure is '"necessary, in appropriate medical judgment, for the preservation of the . . . health of the mother."'" Stenberg, 530 U.S. at 938 (quoting Casey, 505 U.S. at 879, in turn quoting Roe v. Wade, 410 U.S. at 164-65).

In other words, where a plaintiff-doctor presents some evidence showing a need for a particular surgical procedure, the burden of persuasion rests upon the government (Congress) to "convince[] us that a health exception is never necessary to preserve the health of women."[113] Id. at 937-38 (internal quotation marks omitted). Colloquially, if the evidence is no more than evenly balanced, a "tie" goes to the health of women and not to the fetus. This is the substantive law to which the Turner standard of review applies.

Therefore, applying the Turner standard of review to the Stenberg substantive legal principle, the case-deciding question may be properly stated as follows: Is there substantial evidence in the relevant record from which a reasonable person could conclude that there is no substantial medical authority supporting the proposition that

[113]However, and as discussed more fully later, if the plaintiff-doctor's evidence relates only to previability abortions, then the court should limit its decision accordingly.

banning "partial-birth abortions" could endanger women's health? One might also phrase that question this way: Is there substantial evidence in the relevant record from which a reasonable person could conclude that the banned procedure is never necessary, in appropriate medical judgment, for the preservation of the health of the woman? Remembering always the legal obligation of Congress and the courts to "tolerate responsible differences of medical opinion," Stenberg, 530 U.S. at 937, I respectfully answer these questions in the negative.

### *3. THE CONGRESSIONAL RECORD PROVES THAT THERE IS A SUBSTANTIAL BODY OF MEDICAL OPINION SUPPORTING USE OF THE BANNED PROCEDURE TO PRESERVE THE HEALTH OF WOMEN AND THERE IS NO CONTRARY "CONSENSUS."*

The first Congressional Finding states that a "medical . . . consensus exists that the practice of performing a partial-birth abortion . . . is never medically necessary and should be prohibited." Congressional Finding (1), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003) (emphasis added). In the same vein, Congress also found that the banned procedure was "outside the standard of medical care." Id. at Finding (13). However, this conclusion is contradicted by the record that Congress gathered. In fact, there was no evident consensus in the record that Congress compiled. There was, however, a substantial body of medical opinion presented to Congress in opposition. If anything, and assuming reliance upon physicians with experience in surgical abortions is appropriate, the congressional record establishes that there was a "consensus" in favor of the banned procedure.

For example,

* Opposition to the ban and support for the banned procedure in certain circumstances came from nearly half (22 out of 46) of all individual physicians who expressed non-conclusory opinions to

Congress. (See Appendix II to this opinion.[114]) If one only counts doctors who claimed to practice obstetrics and gynecology, including the performance of abortions, more than half (19 out of 37) of those physicians opposed the ban and supported the banned procedure in certain circumstances. (See Appendix II to this opinion.[115])

* Opposition to the ban and support for the banned procedure in certain circumstances came from board-certified obstetricians and gynecologists.

* Opposition to the ban and support for the banned procedure in certain circumstances came from professors of obstetrics and gynecology (including two chairs of departments) at such medical schools as Johns Hopkins; Washington University; the University of Illinois; Cornell University; Albert Einstein; University of California; New Jersey; and Columbia University.

* Opposition to the ban and support for the banned procedure in certain circumstances came from physicians practicing in the obstetrics and gynecology departments at major metropolitan hospitals in New York, Chicago, and San Francisco.

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[114]Of the 47 physicians listed in Appendix II, one physician, testifying about anesthesiology, remained neutral.

[115]Drs. Haskell, Robinson, McMahon, Campbell, Hern, Schrieber, Cromer, Burd, Scommegna, Sherline, Edwin, Rashbaum, Jones, Grimes, Roche, Weiss, Darney, Cullins, and Davis.

* Opposition to the ban and support for the banned procedure in certain circumstances came from ACOG, the nation's leading medical association concerned with obstetrics and gynecology.

Based upon its own record, it was unreasonable to find, as Congress did, that there was "consensus" of medical opinion supporting the ban. Indeed, a properly respectful review of that record shows that a substantial body of contrary, responsible medical opinion was presented to Congress. A reasonable person could not conclude otherwise.

### *4. THE CONGRESSIONAL RECORD CONTRADICTS THE MAIN CONGRESSIONAL FINDINGS[116] REGARDING THE NEED FOR AND SAFETY OF THE BANNED PROCEDURE AND ESTABLISHES THAT USE OF THE BANNED PROCEDURE IS NECESSARY TO PRESERVE THE HEALTH OF WOMEN UNDER CERTAIN CIRCUMSTANCES. IN PARTICULAR, "PARTIAL-BIRTH ABORTIONS" PROVIDE WOMEN WITH SIGNIFICANT HEALTH BENEFITS IN CERTAIN CIRCUMSTANCES.*

The critical Findings by Congress—such as that the banned procedure "poses serious risks to the . . . health of a woman" undergoing the procedure,[117] that there is "no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures,"[118] and that the banned procedure "is never necessary to

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[116]Many of the subsidiary Findings of Congress are incorrect as well. However, no good purpose would be served by pointing them out.

[117]Congressional Findings (2) & (14)(A), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003).

[118]Id. at Finding (14)(B).

preserve the health of a woman"[119]—are unreasonable and not supported by substantial evidence in the congressional record. Again, the congressional record disproves the Congressional Findings.

For example,

* Of the 11 doctors who presented information to Congress and who clearly appeared to have recent surgical abortion experience, 10[120] of them opposed the ban. Even the one dissenter[121] acknowledged that he had used, and would use, the banned procedure to save the life of a woman. Thus, 91% of the doctors with relevant experience in performing abortions opposed the ban.

* Of the eight doctors who presented information to Congress and who had actually used the banned procedure, or some variant of it, seven of them opposed the ban, finding the procedure to be either the best and safest in certain circumstances or possibly so.[122] (As noted, the dissenter[123] used the procedure in life-threatening emergencies.) Of these seven doctors, at least two are board-certified in obstetrics and gynecology,[124] one has been routinely

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[119]Id. at Finding (13).

[120]Drs. Haskell, Robinson, McMahon, Campbell, Hern, Rashbaum, Jones, Grimes, Darney, and Cullins.

[121]Dr. Calvin.

[122]Drs. Haskell, McMahon, Hern, Rashbaum, Jones, Grimes, and Darney.

[123]Dr. Calvin.

[124]Drs. Jones and Grimes.

performing and teaching the procedure as a professor of obstetrics and gynecology at Cornell University since 1979,[125] one is the author of a leading textbook on abortion,[126] and another[127] is the chief of obstetrics and gynecology at a major metropolitan hospital where a large number of abortions are performed. The other two[128] performed the procedure thousands of times with very low complication rates and they reported the results of their surgeries in detailed papers presented to peers who performed abortions. Thus, 100% of the doctors who used the banned procedure or some variant believed that it was necessary and safe in some circumstances, and 88% of those same doctors opposed the ban's lack of a health exception.

* When challenged by one Senator to provide specific examples of the need for the banned procedure to preserve the physical health of a woman, another Senator presented the statement of Dr. Philip Darney. Darney provided two very specific and detailed examples. He said: "These two patients provide examples from my memory of situations in which the 'intact D&E' technique was critical to providing optimal care. I am certain that a review of our hospital records would identify cases of sever [sic] pre-eclampsia, for example, in which 'intact D&E' was the safest technique of pregnancy termination." (Court's Ex. 9, at 101.) Mindful that one

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[125]Dr. Rashbaum.

[126]Dr. Hern.

[127]Dr. Darney.

[128]Drs. Haskell and McMahon.

of the ban's supporters[129] praised Dr. Darney's "broad experience with surgical abortion" (id. at 109), Congress did not seriously pursue Dr. Darney's specific explanation. Indeed, only one doctor who claimed to have any experience performing abortions (Dr. Calvin, who "rarely" did so and who used the banned procedure himself to save the life of a woman) disagreed with Dr. Darney, and that doctor disagreed with Dr. Darney only after acknowledging that the cases described by Dr. Darney "are certainly complicated." (Id. at 105.) The remainder of the doctors who disagreed with Dr. Darney claimed to have no experience performing surgical abortions. Thus, when Congress asked for, and was provided with, detailed and specific examples of the need for, and safety of, the banned procedure to preserve the physical health of women from a highly qualified and very experienced doctor who performed abortions to protect the health of women, it failed to make a diligent inquiry and instead elected to accept the contrary views of the inexperienced.

* While Congress relied upon part of the statements from the AMA, Congress ignored a critical qualification in the AMA's scientific report on this subject. That is, when the AMA's scientific panel recommended against use of the procedure, it qualified that proviso with this caveat: "unless alternative procedures pose materially greater risk to the woman." (Ct.'s Ex. 8, at 203.) Then the AMA emphasized that a "physician, must, however, retain the discretion to make that judgment, acting within standards of good medical practice and in the best interest of the patient." (Id.)

[129]Dr. Goodwin.

* ACOG, the nation's leading medical organization in the field of obstetrics and gynecology, told Congress several times that the procedure should not be banned. In part this was because "[w]hen abortion is performed after 16 weeks, intact D&X is one method of terminating a pregnancy" and that procedure "may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman . . . ." (Ct.'s Ex. 8, at 231-32.) In fact, Stanley Zinberg, M.D., Vice President of Clinical Practice Activities of ACOG, told the Senate that "there are rare occasions when Intact D&X is the most appropriate procedure" and "[i]n these instances, it is medically necessary." (Def.'s Ex. 897, at S12982.)

The long and short of it is that Congress arbitrarily relied upon the opinions of doctors who claimed to have no (or very little) recent and relevant experience with surgical abortions, and disregarded the views of doctors who had significant and relevant experience with those procedures. It is unreasonable to ignore the voices of the most experienced doctors and pretend that they do not exist.

A fetal and maternal specialist (like Dr. Cook) who has never, or very infrequently, performed a surgical abortion of a live fetus, can only speculate about the real health risks of surgical abortion. The views of such inexperienced doctors have little value when compared to the opinions of surgeons who are experienced abortionists.[130] Relying upon experienced surgeons, with specific clinical experience

[130]I do not use the term "abortionist" pejoratively. So long as abortion is legal, doctors who perform abortions and who properly concentrate on the health of their female patients will be treated in this court with the same high degree of respect as fetal and maternal specialists who do not perform abortions and who properly divide their loyalties between the health of the fetus and the health of its mother.

in the technique under discussion, is the reasonable and customary practice for those in the medical profession.

For example, in a non-political setting, Mr. Frist, the Senate Majority leader, and a highly regarded heart surgeon, has indicated that reliance upon "very experienced surgeons" with "vast clinical experience" in the specific "technique" is appropriate. See William H. Frist, M.D. & D. Craig Miller, M.D., Repair of Ascending Aortic Aneurysms and Dissections, J. Cardiac Surg. 33, 45-46 (March 1986) (discussing "composite operative techniques" and stating, "For these reasons, certain very experienced surgeons and authorities in this field have abandoned the 'graft inclusion' or (Bentall) wrapping technique. On the basis of his vast clinical experience, Crawford now prefers to perform the coronary anastomosis[131] and distal aortic anastomosis using full-thickness end-to-side suture lines (similar to the methods illustrated herein) and not to wrap the completed repair with the residual aneurysm sac."[132]) (citations omitted).

In summary, the congressional record proves that the key Congressional Findings are unreasonable. The inferences that Congress drew from its record are not supported by substantial evidence contained within that record. In fact, the congressional record proves the opposite of the Congressional Findings. According to responsible medical opinion, there are times when the banned procedure is medically necessary to preserve the health of a woman and a respectful reading of the congressional record proves that point. No reasonable and unbiased person could come to a different conclusion.

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[131]In this sense, "anastomosis" means "[a]n operative union of two structures (e.g., vessels . . .)." Stedman's Medical Dictionary 70 (27th ed. 2000).

[132]Incidentally, Dr. Frist cites no peer-reviewed studies when lauding Crawford's technique. Apparently, Crawford's "vast clinical experience" was sufficient.

### *5. THE TRIAL RECORD CONFIRMS THAT THERE IS A SUBSTANTIAL BODY OF MEDICAL OPINION SUPPORTING USE OF THE BANNED PROCEDURE TO PRESERVE THE HEALTH OF WOMEN AND THERE IS NO CONTRARY "CONSENSUS."*

Aware that the Supreme Court's abortion jurisprudence, as it regards the need for specific types of abortion procedures, "tolerate[s] responsible differences of medical opinion[,]" Stenberg, 530 U.S. at 937, Congress found that partial-birth abortions were never medically necessary and that such a conclusion was accepted by the medical community.[133] As I have earlier indicated, the record Congress itself compiled disproves this assertion. As I shall next describe, the trial record also flatly contradicts that Finding.

Ignoring the plaintiffs' presentation for a moment, the evidence presented at trial by Mr. Ashcroft disproves Congress's Finding that a medical consensus agrees that partial-birth abortions are never necessary. Three examples illustrate the point:

* Dr. Watson Bowes, a supporter of the ban, who was described in the congressional record as "an internationally recognized authority" (Ct.'s Ex. 4, at 107), agreed that "there is no consensus in the medical community that an intact D&X is never medically necessary." (Tr. 963.) On the contrary, he testified that there was a "body of medical opinion" consisting of the "position taken by the American College of Obstetrics and Gynecologists" and "a responsible group of physicians practicing at a variety of hospitals and teaching at a variety of medical schools" that "an intact D&E

[133]Congressional Findings (1) & (13), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003) (a "medical . . . consensus exists" that the banned procedure "is never medically necessary and should be prohibited"; the banned procedure "lies outside the standard of medical care").

may be the safest abortion procedure for some women in some circumstances." (Tr. 962-63.)[134]

* Dr. Elizabeth Shadigian, a full-time faculty member at the University of Michigan in obstetrics and gynecology, testified for the government. She admitted that the chair of her department, Dr. Timothy R. B. Johnson, was a "plaintiff in the New York case challenging the partial-birth abortion ban"; that having known Dr. Johnson for 20 years she respected him as a physician; and that Dr. Johnson and Dr. Shadigian disagreed on this issue. (Tr. 1561 & 1591.) Moreover, during the 17th week of gestation, before many physicians are comfortable inducing fetal death by injection, Dr. Shadigian also admitted that it would be consistent with the standard of care at the University of Michigan to crush the skull of a living fetus when the body was delivered intact outside the cervix and into the vaginal cavity if the skull was trapped by the cervix and the woman was hemorrhaging. (Tr. 1598-1602.)

* Dr. Charles Lockwood, the Chair of the Department of Obstetrics and Gynecology at Yale, testified for the government (Tr. 1639-40) to provide "objective . . . data" (Tr. 1647), although he was not an "advocate of the" ban[135] and was "enraged" by certain portions of it. (Tr. 1731-32.) Among many other things, Dr. Lockwood

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[134]Although Dr. Bowes provided Congress with information supportive of the ban, he was not consulted about the specific Findings. Therefore, Dr. Bowes did not believe that Congress was aware that he disagreed with some of the Act's significant Findings at the time the ban was passed. (Tr. 992-94.)

[135]I found Dr. Lockwood extremely credible particularly because he was unusually candid.

testified that: (1) when he was the Chair of the Obstetrics and Gynecology Department at New York University (NYU), he hired a physician who performed intact D&E procedures (Tr. 1744); (2) during his last year at NYU, between 75 to 100 second-trimester intact D&E procedures were performed, and, although he was not specifically aware that those procedures were being conducted, he would have allowed those intact D&E procedures to be performed had he known of them (Tr. 1745 & 1764); and (3) in his opinion there are "compelling enough arguments as to [the banned technique's] safety, that I certainly would not want to prohibit its use in my institution." (Tr. 1706 & 1763 (statement on direct examination, affirmed on cross-examination).)

The plaintiffs' trial evidence also disproves Congress' Finding that a medical consensus exists that partial-birth abortions are never necessary. Once again, several examples from the plaintiffs' evidence prove that, if anything, a medical consensus of physicians experienced in surgical abortions favors the banned procedure, to wit:

* From California, Dr. Maureen Paul, a board-certified physician in obstetrics and gynecology, who holds a master's degree in epidemiology, testified in opposition to the ban. She was the editor-in-chief of the 1999 publication, A Clinician's Guide to Medical and Surgical Abortion,[136] which is one of the standard reference guides on abortion care. (Pls.' Ex. 125, at 11-12.) Dr. Paul has experience with all types of abortion, including the banned procedure; she serves as the Director of Training at the University

[136]In this record the Guide may be found as Pls.' Ex. 70. Chapter 10 of the Guide is entitled "Surgical Abortion After the First Trimester." That chapter is authored by W. Martin Haskell, Thomas R. Easterling, and E. Steve Lichtenburg. In Chapter 10, the authors extensively discuss the banned procedure.

of California San Francisco Center for Reproductive Health Research and Policy; and she teaches abortion techniques to residents and medical care providers. In addition, she hires and supervises physicians at eight medical clinics run by Planned Parenthood where a wide range of medicine is practiced including abortions up to 18 weeks 6 days of pregnancy. (Pls.' Ex. 125, at 6-9; Pls.' Ex. 125A.) Based upon this experience, Dr. Paul believes that, while the standard D&E is safe, the intact D&E is safer. (Pls.' Ex. 125, at 102-03.)

* From New York, Dr. Carolyn Westhoff, who holds a medical degree from the University of Michigan, subsequently studied epidemiology at the London School of Hygiene and Tropical Medicine, and was a post-doctoral fellow at Oxford University in epidemiology, testified against the ban. (Pls.' Ex. 126, at 737-38; Pls.' Ex. 126A.) She is a board-certified obstetrician and gynecologist and holds a joint professorship at Columbia University in obstetrics and gynecology in the College of Physicians and Surgeons and in epidemiology, population, and family health in the School of Public Health. (Pls.' Ex. 126A.) She teaches and supervises medical students and residents and is experienced with all forms of abortions including the intact version. She testified that the intact D&E procedure has been taught for the last five or six years as a part of the fellowship program in family planning at her institution (Pls.' Ex. 126, at 748-51), and is taught at various other medical schools such as Albert Einstein, NYU, Cornell University, Northwestern, and the University of California at San Francisco. (Pls.' Ex. 126, at 897-98.) Dr. Westhoff holds the view that the intact D&E is safer than the dismemberment D&E because there are less instrument passes, fewer bony fragments, and

a reduced likelihood of retaining fetal parts in the uterus. (Pls.' Ex. 126, at 824-25.) In her opinion, Congress was wrong in finding that the intact D&E is not an accepted medical practice. (Pls.' Ex. 126, at 901.)

* From Chicago, Dr. Cassing Hammond, who is board-certified in obstetrics and gynecology, a diplomate of the National Board of Medical Examiners, and an assistant professor at Northwestern University's Department of Obstetrics and Gynecology, testified against the ban. (Pls.' Ex. 124A.) He is very experienced with both medical and surgical methods of abortions from early in gestation through 24 weeks. Understanding that he supervises Northwestern's two-year fellowship program in family planning and contraceptive research, which includes teaching abortion procedures; that he has been performing abortions for 15 years (Pls.' Ex. 124, at 520, 522, 526-27); and that he routinely performs intact D&E abortions (Pls.' Ex. 124, at 533 & 675), including occasional conversions of fetuses to the breech position (Pls.' Ex. 124, at 686), Dr. Hammond testified that: (1) Congress was incorrect in finding that the intact D&E is never necessary to preserve the health of the woman and violates the standard of care; and (2) since Dr. Hammond has been doing D&E abortions, or for the last 15 years, the standard of care has been to remove the fetus as intact as possible. (Pls.' Ex. 124, at 608-09.)

If one looks at the trial evidence in the aggregate, the same thing is true. The purported consensus in favor of the ban does not exist:

* Overall, 19 physicians testified[137] in this case who personally had some post-internship experience (no matter how minimal) with pregnancy terminations.[138] Of those 19 physicians, one of the government's witnesses[139] agreed that there was no medical consensus supporting the ban, another[140] agreed that the safety of the procedure had been sufficiently shown such that he would not want the procedure banned in his institution, and a third government witness[141] admitted that use of the procedure was within the standard of care under certain circumstances. Of the remaining 16 doctors, only 3 thought the ban was appropriate.[142]

* Thus, out of 19 doctors who provided sworn testimony in this case and who personally had some post-internship experience with pregnancy terminations, 16 of them (84%) opposed the ban

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[137]This number includes doctors who testified live in this case, who testified in the New York or California cases, or who testified by deposition. By stipulation, the parties agreed that some of the trial testimony from the New York and California cases would be considered as evidence in this case, and that certain depositions would also be considered as trial evidence here.

[138]See Appendix III. Those physicians were: Dr. Carhart, Dr. Fitzhugh, Dr. Vibhakar, Dr. Knorr, Dr. Bowes, Dr. Sprang, Dr. Cook, Dr. Shadigian, Dr. Lockwood, Dr. Doe, Dr. Chasen, Dr. Broekhuizen, Dr. Frederiksen, Dr. Creinin, Dr. Westhoff, Dr. Paul, Dr. Clark, Dr. Hammond, and Dr. Cain.

[139]Dr. Bowes.

[140]Dr. Lockwood.

[141]Dr. Shadigian.

[142]Those three were Dr. Sprang, Dr. Cook, and Dr. Clark. They had very little experience with surgical abortions generally, and very little experience with D&E abortions specifically. They had no experience with the banned procedure.

> outright, agreed that there was no medical consensus in favor of the ban, agreed that the safety of the procedure had been sufficiently shown such that he would not want the procedure banned in his institution, or conceded that the banned procedure was within the standard of care under certain conditions.

In summary, I find and conclude from the trial evidence that Congress' Finding—that a medical consensus supports the ban because partial-birth abortions are unnecessary—is both unreasonable and not supported by substantial evidence. Congress was plainly mistaken.

### *6. THE TRIAL RECORD CONTRADICTS THE MAIN CONGRESSIONAL FINDINGS REGARDING THE NEED FOR AND SAFETY OF THE BANNED PROCEDURE AND ESTABLISHES THAT USE OF THE BANNED PROCEDURE IS NECESSARY TO PRESERVE THE HEALTH OF WOMEN UNDER CERTAIN CIRCUMSTANCES. IN PARTICULAR, "PARTIAL-BIRTH ABORTIONS" PROVIDE WOMEN WITH SIGNIFICANT HEALTH BENEFITS.*

Emphasizing, again, that the Constitution protects, and Congress has the legal obligation to accept, "responsible differences of medical opinion" regarding the need for specific types of abortion procedures, Stenberg, 530 U.S. at 937, the trial evidence establishes that a large and eminent body of medical opinion believes that partial-birth abortions provide women with significant health benefits in certain circumstances. In particular, the trial evidence shows that Congress was wrong, and unreasonably so, when it found that the banned procedure "poses serious risks to the . . . health of women,"[143] that there is "no credible medical evidence that partial-birth abortions are

[143]Congressional Findings (2) & (14)(A), Pub. L. No. 108-105, § 2, 117 Stat. 1201 (2003).

safe or are safer than other abortion procedures,"[144] and that the banned procedure is "never necessary to preserve the health of a woman."[145]

It is worth remembering that an enormous amount of time has already been spent on this issue by federal trial judges throughout this country. Those judges have heard and carefully considered the need for and safety of the banned procedure. In Stenberg, the Supreme Court observed that this court had found that a "partial-birth abortion" (as defined by Nebraska) "'may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman,'" and, "[w]ith one exception, the [eight other] federal trial courts that have heard expert evidence on the matter have reached similar factual conclusions." 530 U.S. at 932 (quoting ACOG Statement) (citations to cases omitted).

In 2004, two more federal trial courts have specifically found that "partial-birth abortions" are safe and sometimes necessary to preserve the health of women. See Planned Parenthood Fed'n of Am. v. Ashcroft, 320 F. Supp. 2d 957, 1033 (N.D. Cal. 2004) ("[T]he record before this court, like the district court's record in Stenberg, demonstrates that 'significant medical authority supports the proposition that in some circumstances, [intact D&E] is the safest procedure.' Stenberg, 530 U.S. at 932. These include the following considerations, present also in the Stenberg case, that among other maternal and fetal conditions for some women, other abortion procedures present 'a larger than necessary risk' of: ['](1) a longer operating time; (2) greater blood loss and infection; (3) complications from bony fragments; (4) instrument-inflicted damage to the uterus and cervix; (5) exposure to the most common causes of maternal mortality (DIC and amniotic fluid embolus); [and] (6) complications arising from retained fetal parts.[']") (quoting Carhart v. Stenberg, 11 F. Supp. 2d 1099, 1127 (D. Neb. 1998) (also considering Partial-Birth Abortion Ban Act of 2003));

[144]Id. at Finding (14)(B).

[145]Id. at Finding (13).

Richmond Med. Ctr. v. Hicks, 301 F. Supp. 2d 499, 514 (E.D. Va. 2004) (considering Virginia law) ("There is substantial medical authority, including testimony from defendants' experts, that supports the proposition that banning D&E's, and the manner in which Dr. Fitzhugh[146] performs D&E's, including intact D&E's, could endanger women's health. Through testimony and declaration, Dr. Fitzhugh and Dr. deProsse have stated that the manner in which Dr. Fitzhugh performs D&E's that are prohibited by the Act is both the safest and most medically appropriate for some of his patients and have relied on their experience and additional medical authority in forming those opinions.").

While not deciding for himself whether the banned procedure was safe, Judge Casey recently declared the Partial-Birth Abortion Ban Act of 2003 was unconstitutional as it lacked a health exception. National Abortion Federation v. Ashcroft, ___ F. Supp. 2d ___, 2004 WL 1906165 (S.D.N.Y. Aug. 26, 2004). In his view, Congress acted unreasonably in omitting such an exception given the evidence. In particular, he found that both the congressional record and the trial record demonstrated that a significant body of medical opinion "supports the notion that D&X offers some safety advantages." Id. at 86.

In short, the vast majority of federal trial courts to carefully weigh the evidence on this question have found that the procedure is safe and medically necessary. While those opinions are no substitute for my independent judgment of the evidence in this case, they provide a measure against which to test both the validity and objectivity of my decision.

With this important context firmly in mind, I find and conclude that the over-whelming weight of the trial evidence proves that the banned procedure is safe and medically necessary in order to preserve the health of women under certain

[146]Of course, Dr. Fitzhugh is also a plaintiff in this case.

circumstances. In the absence of an exception for the health of a woman, banning the procedure constitutes a significant health hazard to women. Such a ban is therefore an undue burden. In the same vein, I also find and conclude that Mr. Ashcroft, who bears the burden of persuasion, has failed to present substantial evidence to the contrary. Given the tolerance for responsible differences of medical opinion required by the substantive law, no reasonable person could come to different conclusions.

In particular, I decide that:

1. Childbirth is more dangerous to the health of women than abortion.

2. Congress's Finding that the banned procedure is dangerous to the health of women is not supported by competent medical evidence and is based upon speculation.

3. The D&E method is the "gold standard" for previability abortions from early in the second trimester through 24 weeks; it is the most common method of abortion during this time and it is safer than induction abortions through approximately 20 weeks. While induction abortions are roughly comparable in relative safety to D&E abortions after 20 weeks, induction abortions are not available to many women because hospitals refuse to perform them; induction abortions are absolutely or relatively contraindicated for some women; and induction abortions in hospitals typically take more time, involve more expense, and are more painful to women than D&E abortions. Hysterotomies or hysterectomies are much more dangerous both in terms of mortality and morbidity than either D&E or induction abortions during the second trimester.

4. The intact D&E or D&X (the banned procedure) is merely a variant of the standard D&E.

5. In the hands of surgeons with experience using it, the banned procedure is, sometimes, the safest abortion procedure to preserve the health of women. Oversimplified, this is because: (a) the intact procedure reduces the need for placing forceps into the uterus thus reducing the risk of trauma to the uterus and the cervix; (b) the intact procedure reduces the possibility of retaining fetal parts or fluids in the uterus and retention of fetal parts or fluids can cause death or serious illness; (c) removal of the intact fetus reduces the possibility of exposing maternal tissues to sharp bony fragments stemming from the dismemberment of the fetus; and (d) the intact procedure is faster than the standard D&E, thus reducing the time and expense of the operation, the risk of hemorrhage, and the risk of complications from anesthesia.[147] These significant safety advantages are particularly evident when the fetus does not require manual conversion in order to complete the intact procedure. In these general circumstances, the benefits of the procedure to these women are significant.

6. In the hands of surgeons with experience using it, the banned procedure is the safest abortion procedure to preserve the health of women in special cases. For example, the banned procedure is the safest in the case of cancer of the placenta most often diagnosed in

[147]These are the same findings that I made in Dr. Carhart's suit against Nebraska and which the Supreme Court found to have been "highly plausible" and "record-based." Stenberg, 530 U.S. at 936. The evidence presented to me in this case more strongly supports my earlier factual findings about the need for and safety of "partial-birth abortions" to preserve the health of women when the fetus is nonviable.

> the second trimester and associated with severe preeclampsia, where instrumentation of the uterine wall should be avoided as much as possible. Another example is where a woman, who is between 20 and 24 weeks pregnant, suffers from a complete placenta previa and where an induction abortion is always contraindicated. In these special cases, and others, the benefits of the banned procedure to women are significant.

### *a. THE TRIAL EVIDENCE PROVES THAT CONGRESS ERRED WHEN IT FOUND THE BANNED PROCEDURE POSES SERIOUS RISK TO THE HEALTH OF WOMEN.*

Congress tried to turn the Stenberg decision on its head. Contrary to the findings of numerous federal trial courts throughout the nation, Congress asserted that "partial-birth abortions" are dangerous to the health of women. The trial evidence in this case proves that Congress grievously erred when it made that finding.

When objectively trying to assess the danger of abortion procedures, one must start with childbirth. That is, absent an abortion, what are the risks of childbirth? In general, childbirth is more dangerous than abortion, particularly when the fetus is not viable and when the woman is older. As Dr. Maureen Paul—a board-certified obstetrician and gynecologist, an expert in abortion, and an epidemiologist—put it, abortion is "hands down" a safer option than carrying a pregnancy to term. (Pls.' Ex. 125, at 38.) Thus, any assertion that a particular abortion method is risky must be judged against the generally more dangerous alternative of childbirth.

That said, in the gestational age ranges we speak of in this case, there are three broad choices for abortion. They are: (1) the method involving vaginal surgery typified by the D&E abortion; (2) the method, using drugs, which mimics childbirth, commonly referred to as an induction abortion (sometimes called a medical abortion); and (3) the abdominal-surgery method, for example, a hysterotomy. Of these three, virtually

everyone agrees that surgery of the abdomen is far more dangerous to both life and health than the other alternatives. That is why it accounts for only a tiny fraction (0.07%) of second-trimester abortions. (Pls.' Ex. 125, at 46-47 (Dr. Paul).) Consequently, when one tries to determine the risk of abortion during the relevant gestational ages, one must compare the risks of vaginal surgery (D&E abortions) versus the risks of mimicking childbirth (induction abortions).

But, before one directly compares the risks of the two procedures, one must first assess the frequency of use. Frequency of use tends to show the nationwide preferences of physicians, and, indirectly, their assessment of the comparative risks of the two procedures.

Based on data from the Centers for Disease Control, 95% of all second-trimester abortions at 16 to 20 weeks of gestation were performed by D&E, and after 20 weeks of gestation, 85% were performed by D&E. In these statistics, intact D&Es were included in the figures for D&Es more generally. (Pls.' Ex. 125, Test. Dr. Paul 47-49; Pls.' Ex. 32, at 32 (Table 18) (Morbidity and Mortality Weekly Report, prepared by the Centers for Disease Control and Prevention) (November 28, 2003).) Thus, the clear choice of doctors was the D&E as opposed to the induction method.

Aside from the inference of relative safety shown by the national preference for the D&E method, the clear choice of the D&E, as opposed to the induction method, is probably driven in part by the refusal of many hospitals to allow abortions to be performed in their facilities. Moreover, since induction abortions typically involve more time, expense, and pain than D&E abortions, it is quite likely that most women prefer D&E abortions as a result. For example, when doctors recently tried to conduct a randomized trial between D&E abortions and induction abortions, they reportedly dropped the study because not enough women were willing to undergo induction. (Pls.' Ex. 44 (David A. Grimes, et al., Mifespristone and misoprostol versus dilation and evacuation for midtrimester abortion: a pilot randomised controlled study, 111 Brit. J.

Obstet. & Gynecol. 148 (Feb. 2004) ("The trial was stopped at one year because of low enrolment. Of 47 women eligible for the trial, 29 (62%) declined participation, primarily because of a preference for D&E abortion. Among the 18 participants enrolled, nine were randomised to treatment with mifepristone-misoprostol and 9 to D&E. Compared with D&E, mifepristone-misoprostol abortion caused more pain and adverse events, although none was serious.")).)

Turning then to a more direct comparison, according to the literature, D&Es are generally believed to be safer than induction abortions during the entire second trimester. (E.g., Pls.' Ex. 19 (Amy M. Autry, et al., A comparison of medical induction and dilation and evacuation for second-trimester abortion, 187 Am. J. Obstet. & Gynecol. 393 (Aug. 2002) (a retrospective study comparing complication rates of patients undergoing D&E or induction between 14 and 24 weeks of gestation found that the "overall complication rate was significantly lower" for patients undergoing D&E abortions and "[m]ore Laminaria was associated with a decreased risk of complications with surgical abortions.")).) Most of the experienced physicians in this case would not, however, make this generalization for the entire second trimester.

For example, Dr. Lockwood, the Chief of Obstetrics at Yale and a government witness, stated that prior to 20 weeks "there seems reasonable evidence that D&Es are associated with fewer complications than medical [induction] abortions." (Tr. 1746.) Dr. Hammond, a very experienced professor at Northwestern, also indicated that the D&E procedure is likely the safest procedure through approximately 20 weeks. (Pls.' Ex. 124, at 541-42.) However, in the hands of physicians who are very experienced with both types of abortion, the risks of D&E and induction can become roughly comparable after approximately 20 weeks. Thus, Dr. Hammond, who has a great deal of experience with the D&E method, including the intact D&E variation, and who also has a great deal of experience with induction abortions, believes that the risks are roughly comparable after 20 weeks. (Id.) Dr. Lockwood agreed that "after 20 weeks,

D&Es, intact D&Es and medical induction abortions are comparable in terms of safety . . . ." (Tr. 1747 (emphasis added).)

One must keep in mind that the banned procedure, whether one calls it an intact D&E or a D&X or some other name, is only a variant of the D&E. Appearing before me was the very knowledgeable board-certified physician and professor of medicine and the history of science at the University of Michigan, Joel D. Howell, M.D., Ph.D. He has lectured and published papers in peer-reviewed journals about the development of surgical techniques. Dr. Howell opined that: (1) the intact D&E "came about as a logical consequence of physicians doing the D&E procedure"; (2) the intact D&E procedure has developed "well within the bounds of currently accepted medical practice" and consistent with the "very typical pattern" of surgical development; and (3) the intact D&E is not a new surgical technique, but a variation thereof. (Tr. 465-66.)

Therefore, since the standard D&E is safe; since the standard D&E is safer than, or at least as safe as, induction abortions during the relevant gestational ages; and since the banned procedure is merely a variant of the safe D&E, it borders on ludicrous to assert that the banned procedure is dangerous. But there is much more.

In addition to the testimony in this case of the many board-certified physicians who stated that the banned procedure was not dangerous, but was as safe as, and sometimes safer than, standard D&E and induction abortions, the lack of dangerousness is supported by hard data. For example, Chapter 10 of A Clinician's Guide to Medical and Surgical Abortion examined the intact procedure and data on complications regarding the procedure. (Pls.' Ex. 70.)

As noted earlier, Dr. Paul was the editor-in-chief of the Guide. Other editors included Drs. E. Steve Lichtenburg, Lynn Borgatta, David A. Grimes, and Phillip Stubblefield. At the time the Guide was written, Lichtenburg was the Medical Director

at the Albany Medical-Surgical Center. Borgatta was an associate professor in the Department of Obstetrics and Gynecology at the Boston University School of Medicine. Grimes was a clinical professor in the Department of Obstetrics and Gynecology at the University of North Carolina. Stubblefield was professor and Chair of the Department of Obstetrics and Gynecology at the Boston University School of Medicine.[148] Chapter 10 was written by Drs. W. Martin Haskell, Thomas R. Easterling, and E. Steve Lichtenburg.

The authors of Chapter 10 to the Guide wrote that the complication rates for the banned procedure showed that the procedure was very safe:

> The intact D&E procedure combines long-standing obstetrical practices for delivery of advanced, compromised pregnancies with modern techniques of cervical dilation. The aim of intact D&E is to minimize instrumentation within the uterine cavity and achieve vaginal delivery of an intact fetus. Intact D&E is used as a method of second trimester abortion and, in the case of compromised pregnancies, as a technique for third trimester terminations. Intactness allows unhampered evaluation of structural abnormalities and can be an aid to patients grieving a wanted pregnancy by providing the opportunity for a final act of bonding.
>
> Generally, cervical dilation is accomplished with multiple, serial osmotic dilators over 2 days or more. The goal is to achieve sufficient dilation to extract the largest part of the fetus, the bitrochanteric diameter of the pelvis, which is approximately 75% of the bipartietal diameter. Combinations of different types of osmotic dilator are typically used.

[148]Dr. Stubblefield appeared before me in Stenberg. He was very knowledgeable and very credible.

In 1995 McMahon presented a 13-year personal series of 1362 intact D&E cases.[149] Ninety-eight percent of these cases were performed at a licensed ambulatory surgical center. Only cases with serious fetal (n = 451) or maternal (n = 173) indications were done after 24-26 weeks' gestation. McMahon devised and refined exacting protocols for vertex and breech delivery to minimize the danger of cervical and uterine injury.

McMahon effected delivery only after achieving ample cervical dilation, and he used a minimum of instrument passes. For example, in vertex position, once the central nervous system (CNS) contents were evacuated using an auger-tipped trocar, he grasped the calvarium with forceps in a controlled manner and extracted the fetus. In breech presentation, he converted the lie to footling and delivered the fetus using a Mauriceau-Smellie-Veit maneuver as described above. Dilation was sufficient to enable most complex presentations to be converted digitally or with a version forceps to vertex or breech presentation. McMahon devised special instruments for the procedure, and he recorded case-by-case measurements of fetal and cervical dimensions to improve delivery intervals, odds of intact delivery, and safety.

Using CDC criteria, four patients in McMahon's series experienced major complications, for a rate of 2.94 per 1000 cases. Three patients required transfusion, two for DIC and one for hemorrhage during dilation. The fourth patient required hospitalization for subacute bacterial endocarditis diagnosed 2 weeks after abortion. This major complication rate is virtually identical to that of an earlier series of nonintact D&Es reported by Hern (3.0/1000 cases) despite the fact that nearly one-fourth of the cases in McMahon's series exceeded Hern's 25-week gestation limit. In addition, Haskell has performed more than 1500 intact D&Es at 20-26 weeks' gestation without a serious event. No patient in his series experienced hemorrhage requiring transfusion, cervical laceration, uterine perforation, or retained tissue; and no hospitalizations or laparotomies were required.

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[149]That important paper, which Congress appears to have ignored, is found as Pls.' Ex. 64 (J. T. McMahon, Intact D&E: The First Decade, presented at the National Abortion Federation Conference (April 2, 1995)).

(Id. at 136-37.)

Harping on the fact that no "peer-reviewed" paper had examined the technique, past critics have relied upon the false premise that if a surgical variation is not in a journal article, it must be unsafe. Aside from the silliness of requiring every variation of a proven surgical technique to be "peer-reviewed," this argument was lost to Congress and Mr. Ashcroft when Dr. Chasen and his colleagues in the Department of Obstetrics and Gynecology at the Weill Medical College of Cornell University wrote a "peer-reviewed" journal article on the subject. (Pls.' Ex. 27, Stephen T. Chasen, et al., Dilation and evacuation at >20 weeks: Comparison of Operative techniques, 190 Am. J. Obstet. & Gynecol. 1180 (2004).)

In that article, 383 patients were studied who were undergoing surgical abortions after 20 weeks at the New York Weill-Cornell Medical Center from June 1996 to June 2003. The intact procedure was performed in 120 cases, and the standard D&E in 263 cases. All of the procedures were performed by two physicians who were skilled in both techniques. Institutional-review-board approval was obtained for the study.

There was "no difference in procedure time or estimated blood loss in the two groups." (Id. at 3.) Complications occurred in 19 cases and "with similar frequency in the two groups." (Id.) Follow-up indicated that after the procedure, 62 subsequent pregnancies occurred, and there were no second-trimester miscarriages. (Id.) Spontaneous preterm birth in these subsequent pregnancies occurred twice in the intact group and twice in the standard D&E group. While the percentage of preterm births in the intact group (2 of 17 or 11.8%) was greater than the standard D&E group (2 of 45 or 4.4%), the difference was not statistically significant because the numbers of spontaneous preterm births in both groups were so small. (Id.)

The authors came to two conclusions. First, despite the fact that the intact group presented at a greater gestational age thus suggesting an increased likelihood of

complications, the complication rate for the surgeries were "similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation." (Id. at 3 & 9.) Regarding subsequent pregnancies, the "outcomes are similar between the two groups." (Id. at 3.)

Realizing that this article dramatically defeats the argument that without a peer-reviewed journal article one can infer that a variation of a surgical technique is dangerous, Mr. Ashcroft spent an enormous amount of time trying either to disparage or qualify away this study. He was not successful. And this lack of success is best explained by Dr. Lockwood, Mr. Ashcroft's final witness:

> Well, the study essentially shows that they are remarkably similar in their outcomes. The procedure times were literally identical, and the blood loss was literally identical, and the occurrence of complications was virtually identical. I would say that to be fair to—if one can be fair to a procedure, to be fair to the intact D&X procedure, the D&X was generally done at a more advanced gestational age, which I have already testified, increases the risk of surgical abortions for sure at higher parity. That may have actually made it easier potentially, but might have increased the risk of perforation. And so, you know, and the cervix was obviously more dilated. I don't think that affects complications. So from that standpoint, then, I think that one can conclude that it would be extraordinarily unlikely that these two procedures have markedly different occurrences in the rate of complications, short-term complications.

(Tr. 1719-20 (emphasis added).)

When asked by Mr. Ashcroft's counsel whether the size of the study was "sufficient to draw meaningful conclusions," Dr. Lockwood responded this way:

> Well, they are not trivial; 120 patients and 263 patients are certainly a very large study. One that would—I think, prove to be a valid indicator of certain—this gets into some really complicated statistical stuff, but basically, there is something called power analysis to prove the absence

> of a finding is real. And for some procedures where we, you know, where we might be looking for a 50% increase or decrease in a complication or a procedure time or blood loss, you can be pretty comfortable that there is not anything of that magnitude going on here. Could there be a 5% difference, or 10% difference in bleeding, blood loss or procedure time, yes. That's not terribly important clinically. The study is obviously underpowered, doesn't have adequate numbers to rule out differences in grave complications; death, perforation, which would require many, many more patients than this. But it gives us a good sense that the overall rate of standard complications, immediate short-term complications were very similar in the two groups.

(Tr. 1719-21 (emphasis added).)

Still further, Dr. Lockwood, who has a particular interest in studying subsequent preterm births, indicated that the Chasen article would cause him to do further study on that issue. However, the number of preterm births in the Chasen study following use of the intact procedure was "not statistically significant" (Tr. 1721) and would not "make me prohibit [the banned procedure's] use . . . ." (Tr. 1722.) Indeed, and as I have earlier indicated, Dr. Lockwood thought that there are "compelling enough arguments as to [the banned technique's] safety, that I certainly would not want to prohibit its use in my institution." (Tr. 1706.)

With all the foregoing in mind, it is important to stress that other government witnesses besides Dr. Lockwood disagreed with Congress' adverse safety Finding. For example, with the exception of the possibility that intact D&E may cause more preterm births in subsequent pregnancies,[150] Dr. Clark testified that there is no medical evidence

[150]Dr. Clark derived this single concern from reading Dr. Chasen's peer-reviewed journal article. As just noted, Dr. Lockwood testified that any inference in the Chasen article that the intact D&E procedure caused more preterm births was "not statistically significant." (Tr. 1721.) And, although he would certainly study the issue further, Dr. Lockwood would not put "an enormous amount of weight on it" and he would not prohibit the use of the banned procedure out of a concern for

to support the risks identified by Congress. With that one exception, Dr. Clark said that any suggestion that the intact D&E is less safe than a standard D&E is "pure speculation" and has "no place in a scientific discussion." (Def.'s Ex. 891, Test. Dr. Clark 2421.)

Another of Mr. Ashcroft's witnesses, Dr. Bowes, testified in a similar fashion. He was not aware of any study or other scientific evidence which establishes that the intact D&E is less safe than the traditional D&E or an induction abortion or which establishes that the intact D&E is more dangerous to a woman than any other abortion method. In short, Dr. Bowes believes that it has not been "proven" that the intact D&E would be dangerous to women. (Tr. 953-57.)

In all of the medical testimony presented to me through live witnesses, trial transcripts, or depositions, the only witnesses who unequivocally testified that the banned procedure was dangerous to the health of women were Drs. Sprang and Cook. Their views do not constitute substantial evidence.

Although they are certainly good and dedicated physicians, I found that both Dr. Sprang and Dr. Cook were too rigid in their beliefs to be entirely credible. Two examples will illustrate my point. Despite the need for informed consent, Dr. Sprang testified that he would not even tell his patients about the option of doing a standard D&E abortion at 20 weeks. (Tr. 1213.) At 17 weeks and with the woman bleeding and the intact fetus's head trapped in the cervix, and despite the obvious concerns about cervical incompetence, Dr. Cook testified that, as a last resort, he would cut the women's cervix rather than decompress the skull in order to deliver the nonviable fetus.[151] (Tr. 1462-63.)

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prematurity. (Tr. 1721-22.)

[151]Dr. Cook's answer can profitably be compared with the answer to a similar question given by another government witness, Dr. Shadigian. She told me that it

More importantly, Drs. Cook and Sprang had little or no personal experience with the techniques of surgical abortion that were at issue in this case. For example, Dr. Sprang had performed only one abortion on a living fetus during an emergency hysterotomy, and Dr. Cook had never performed a D&E on a living fetus. Thus, their extreme views about the efficacy and danger of surgical techniques that they have seldom, if ever, performed are unconvincing. In this regard, and to be clear, both the law and common courtesy shield Dr. Sprang and Dr. Cook from criticism regarding their personal decisions not to perform abortions. On the other hand, Dr. Sprang and Dr. Cook (and Congress) are not entitled to use those personal choices, and concomitant lack of experience, as a sword.

In summary, there is no factual basis, that is, no "substantial evidence," in the parlance of Turner, for Congress' Finding that the banned procedure is dangerous to the health of women. In fact, the opposite is true.

### *b. THE TRIAL EVIDENCE PROVES THAT CONGRESS ERRED WHEN IT FOUND THAT THERE WAS NO CREDIBLE MEDICAL EVIDENCE THAT PARTIAL-BIRTH ABORTIONS ARE SAFE OR SAFER THAN OTHER ABORTION PROCEDURES AND PARTIAL-BIRTH ABORTION IS NEVER NECESSARY TO PRESERVE THE HEALTH OF WOMEN.*

The trial evidence that I have heretofore discussed also disproves Congress' Findings regarding the banned technique's alleged lack of safety and need. I shall not recount it again in detail. However, for the sake of completeness, I will explain why the trial evidence proves that the procedure is needed and safe, and sometimes safer

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would be consistent with the standard of care at the University of Michigan to collapse the skull in this circumstance. (Tr. 1601-02.) It is also interesting to note that Dr. Shadigian, like Dr. Cook, practices medicine in Michigan.

than other procedures. In doing so, I also explain why the contrary Findings of Congress are unreasonable and not supported by substantial evidence.

In order to find that the banned procedure is not safe or not needed, I would have to find that the numerous and extraordinarily accomplished surgeons who gave testimony in this case and who routinely use the banned technique throughout this country, many at major metropolitan hospitals, do not know what they are doing. For example, despite her stellar background and vast experience, I would have to conclude that Dr. Marilynn Frederiksen is a quack.

Dr. Frederiksen is a 1974 graduate of Boston University Medical School. She completed her pediatric residency at the University of Maryland and her obstetrics and gynecology residency at Harvard University. She also completed fellowship programs at Northwestern University in maternal-fetal medicine and clinical pharmacology. As a full-time faculty member, Dr. Frederiksen previously managed Northwestern's abortion service which included educating residents in abortion practices. Dr. Frederiksen has been a member of Northwestern's institutional review board for the last 12 years.

According to Dr. Frederiksen, who conducts her procedures in a hospital operating room, the intact D&E is safe and that is why she uniformly tries to deliver the fetus intact when she uses vaginal surgery to perform an abortion. Indeed, for mid-second-trimester abortions, Dr. Frederiksen believes the intact procedure is always safer than other abortion methods including induction. (Pls.' Ex. 123, Test. Dr. Frederiksen 1051-53.)

In order to find that the banned procedure is unsafe or unneeded, one would have to dismiss the views of highly trained and very experienced physicians like Dr. Frederiksen (procedure is safe and necessary) who have detailed knowledge of the surgical methods under discussion. Then, one would have to accept the contrary views

of doctors like Sprang (procedure is unsafe and unneeded), Cook (procedure is unsafe and unneeded), and Clark (procedure is unneeded) who have virtually no experience with abortions.

I have previously described the inexperience of Dr. Sprang and Dr. Cook. Dr. Clark is also inexperienced. Dr. Clark has performed less than 20 induction abortions, "at most a dozen" D&E procedures, and he has never performed an intact D&E. (Def.'s Ex. 891, Test. Dr. Clark 2398-99.)

Choosing this nadir of inexperience over the opinions of physicians like Dr. Frederiksen would be plainly unreasonable. Such a decision would be founded upon insubstantial, rather than substantial, evidence.

The question of what procedure is "safer" or "necessary" is also straightforward, although it requires slightly more explanation. That explanation requires a reiteration of what the Supreme Court said in Stenberg.

The Supreme Court made it clear that words like "safety" and "necessity" in this context do not require absolute proof. Accordingly, the Court said that "[m]edical treatments and procedures are often considered appropriate (or inappropriate) in light of estimated comparative health risks (and health benefits) in particular cases." Stenberg, 530 U.S. at 937. This estimation does not require "unanimity of medical opinion." Id. "Where a significant body of medical opinion believes a procedure may bring with it greater safety for some patients and explains the medical reasons supporting that view," that is enough to insulate the procedure from legislative prohibition. Id.

Here, a "significant body of medical opinion" believes that the banned procedure is "safer" and "necessary" in two circumstances. I next address those two postulates, and the "significant body of medical opinion" upon which they are founded.

The banned procedure, and its various permutations, is "safer" and "necessary" generally because well-trained and very experienced doctors believe that (a) the intact procedure reduces the need for placing forceps into the uterus and cervix thus reducing the risk of trauma to the uterus and cervix; (b) the intact procedure reduces the possibility of retaining fetal parts or fluids in the uterus and retention of fetal parts or fluids can cause death or serious illness; (c) removal of the intact fetus reduces the possibility of exposing maternal tissues to sharp bony fragments stemming from the dismemberment of the fetus; (d) the intact procedure is faster than the standard D&E thus reducing the time and expense of the operation, the risk of hemorrhage, and the risk of complications from anesthesia; (e) these safety advantages are particularly evident when the fetus does not require manual conversion in order to complete the intact procedure; and (f) in these general circumstances, the benefits of the procedure to these women are significant.

The "significant body of medical opinion" that has come to these opinions include doctors who have experience practicing at major metropolitan or teaching hospitals, such as: Dr. Doe, an internationally certified obstetrician and gynecologist who has practiced at several big-city hospitals in this and other countries, and who has been performing abortions since 1972; Dr. Vibhakar, a board-certified obstetrician and gynecologist and assistant professor at the University of Iowa; Dr. Broekhuizen, a board-certified obstetrician and gynecologist at the Medical College of Wisconsin; Dr. Creinin, a board-certified obstetrician and gynecologist at the University of Pittsburgh; Dr. Westhoff, a board-certified obstetrician and gynecologist and a professor at Columbia University who has performed abortions since 1978; Dr. Hammond, a board-certified obstetrician and gynecologist and assistant professor at Northwestern University who has performed abortions for 15 years and who supervises Northwestern's two-year fellowship program in family planning and contraceptive research, which includes teaching abortion procedures; Dr. Paul, a board-certified obstetrician and gynecologist, editor-in-chief of one of the standard references on abortion, and an associate professor at the University of California at San Francisco,

where she teaches abortion techniques to residents and health care providers; and Dr. Chasen, a board-certified physician in obstetrics and gynecology and fetal and maternal medicine, who is an associate professor at the Weill Medical College of Cornell University, where he directs the High-Risk Obstetric Clinic and teaches surgical abortion methods, including the D&E and D&X procedures.

That "significant body of medical opinion" also includes practicing physicians like Dr. Carhart, who headed the surgery department at the Offut Air Force Base Hospital; Dr. Knorr, a board-certified obstetrician and gynecologist who has performed as many as 5,000 to 6,000 abortions a year; and Dr. Fitzhugh, a board-certified obstetrician and gynecologist and former assistant chief of the obstetrics and gynecology department at the Malcom Grow Medical Center, Andrews Air Force Base.

A "significant body of medical opinion" also believes the banned procedure is "safer" and "necessary" in special cases. Just as Dr. Darney warned Congress that the banned procedure was particularly safe and needed in two special cases, numerous physicians in this case gave me similar examples.

Dr. Cain, who is specially certified in biomedical ethics, obstetrics and gynecology, and gynecologic oncology, and who has served as the chairperson of a department of obstetrics and gynecology at a university, stated that in the case "of cancer of the placenta often diagnosed in the second trimester with severe preeclampsia[,]" where "the least amount of instrumentation possible of the uterine wall is desirable[,]" it is "much safer for the woman to have an intact D&X to remove the molar pregnancy." (Pls.' Ex. 115, Test. Dr. Cain 177.)

Dr. Hammond, at Northwestern, stated that in the later gestational ages of the second trimester and in the case of a complete placenta previa (where the placenta covers the entire cervical opening), labor induction is always contraindicated and the D&E method (in which Dr. Hammond includes the intact version) is the option of

choice. (Pls.' Ex. 124, Test. Dr. Hammond 553-54.) In this circumstance, induction would force the fetus through the placenta previa, causing severe maternal hemorrhage, and thus it is absolutely contraindicated. Abdominal surgery is not a good option because, at this stage of gestation, the uterus is an especially vascular organ and cutting through it results in severe bleeding and also makes the uterus more prone to rupture in later pregnancies. (Id.)

Other physicians gave specific examples of special cases where the banned procedure is particularly useful. Those physicians included extraordinarily accomplished surgeons like Dr. Chasen at Cornell University (e.g., Pls.' Ex. 121, Test. Dr. Chasen 1582-85 (prior uterine scar contraindicates induction and suggests D&E, including the intact version, as the preferred alternative)) and Dr. Westhoff at Columbia (e.g., Pls. Ex. 126, Test. Dr. Westhoff 819 (cardiologists refer patients to Dr. Westhoff for D&E, including the intact version, because prolonged labor is considered dangerous to their patients due to the change in dynamics of the blood supply)).

Congress, and Mr. Ashcroft, argue that there are other physicians who come to a different conclusion. Setting to one side the fact that those physicians are inexperienced with abortion, the fact that other doctors may disagree is not important. Legally, an abortion procedure is "safe," "safer," and "necessary" when a significant body of medical opinion believes it to be so. Congress and Mr. Ashcroft bore the burden of persuasion to establish that there is no significant body of medical opinion supporting the safety and necessity of the banned procedure. They failed in their effort.

In summary, examined from the perspective of the trial record, substantial evidence is lacking to support Congress' Findings that there is "no credible medical evidence that partial-birth abortions are safe or are safer than other abortion procedures," and that the banned procedure is "never necessary to preserve the health of a woman." On the contrary, the trial record establishes that there is a significant

body of medical opinion that contradicts Congress. No reasonable person could come to a contrary decision.

### *7. IT IS NOT POSSIBLE IN EVERY CASE TO SAFELY KILL THE NONVIABLE FETUS PRIOR TO AN ABORTION WITHOUT SACRIFICING THE HEALTH OF THE WOMAN. IN ANY EVENT, PRIOR TO VIABILITY, THE ISSUE OF FETAL PAIN IS LEGALLY IRRELEVANT.*

During the trial there was some debate, although not much, about whether it was safe to kill a nonviable fetus by injection or by cutting the umbilical cord. This debate was prompted by Mr. Ashcroft, apparently to show that the banned procedure could be used providing the fetus was first killed. Related to this issue was Mr. Ashcroft's assertion that fetuses suffer pain, the banned procedure is very painful to the fetus, and Congress had a substantial interest in selecting abortion methods that are less painful to the fetus. As I shall next briefly discuss, there is not much to either of these related arguments.

First, nearly everyone agrees that it is not always possible to kill the fetus by injection. That is because injections are sometimes both absolutely and relatively contraindicated. (E.g., Tr. 562, Test. Dr. Knorr (not advisable to cause fetal death by injection when the woman has had a prior surgery or pelvic inflammatory disease causing adhesions); Def.'s Ex. 560, Eleanor A. Drey, et al., Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation, 182 Am. J. Obstet. & Gynecol. 1063, 1064 (2000) (certain women were not considered appropriate candidates for killing the fetus by injection "because of significant medical illness or cardiovascular disease, current use of cardiac or antihypertensive medications . . . , maternal weight [significantly] above ideal, difficult maternal venous access, or abnormal serum potassium levels . . . ."); Tr. 1757, Test. Dr. Lockwood ("I would certainly not want to do it in a patient with HIV or hepatitis.").) It is also true that it is not always possible to cut the cord to cause fetal death without

subjecting the woman to unwarranted risk. (E.g., Tr. 731, Test. Dr. Carhart (if he can, Dr. Carhart will cut the cord, "but I don't go fishing" because "that's when we are starting to induce more risk than benefit.").)[152] So, the argument that the banned procedure may be used when necessary provided the fetus is first killed is simply untrue as a factual matter.

Second, a "significant body of medical opinion" believes that inducing fetal death by injection is almost always inappropriate to the preservation of the health of women undergoing abortion because it poses tangible risk and provides no benefit to the woman. Indeed, Dr. Bowes, the government's witness, agreed that "there is no medical reason to subject a woman" to the risk of injection to cause fetal death. (Tr. 974-75, Test. Dr. Bowes.) Many other physicians agree. (E.g., Tr. 347-50, Test. Dr. Vibhakar; Pls.' Ex. 121, Test. Dr. Chasen 1636; Pls.' Ex. 126, Test. Dr. Westhoff 877.)

In fact, while the risk of death or complication is very small, it is not insignificant, and informed consent should first be obtained prior to performing the fetal-killing injection. (Tr. 347-50 (Dr. Vibhakar discussing Pls.' Ex. 110 (Uriel Elchalal, et al., Maternal Mortality following Diagnostic 2nd- Trimester Amniocentesis, 19 Fetal Diagnosis & Therapy 195, 198 (2004) (recounting the death of two women, one 19 weeks pregnant and the other 21 weeks pregnant, after undergoing transabdominal amniocentesis for prenatal diagnosis of genetic disorders; reporting "several [other] cases of serious maternal complications, especially chorioamnionitis and septic shock"; concluding that: "A full explanation prior to patient's consent is of importance, since maternal mortality, although rare, is a real danger even if the proper precautions are taken.")).)

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[152]As later explained, if the cord is cut after the living fetus has been delivered beyond the relevant anatomical landmarks and if that "overt" act kills the fetus, then the ban may apply to the physician's act of cutting the cord even though the skull is not drained until after the fetus is dead.

Given the significant medical authority that counsels against causing fetal demise as a prerequisite to abortion, it is no answer to argue that a physician may use the banned procedure but must first kill the nonviable fetus. Any such compulsion would mean that women are subjected to unnecessary, potentially lethal risks for the sake of a fetus that will die anyway.

Third, an issue may be important, but not legally relevant. Prior to viability, that is the case with "pain."[153] Thus, while I assume that a nonviable fetus is capable of suffering "pain" at some point during its gestation, before the fetus becomes viable, the issue of fetal pain is not legally relevant or, if it is legally relevant, it is only marginally so.[154]

Before viability, any abortion—be it a spontaneous abortion (miscarriage), a surgical abortion, or an induction abortion—will (1) result in the death of the fetus and (2) also presumably cause the fetus "pain." In a miscarriage or induction abortion, and also where the fetus is removed by surgery from the woman's belly, the nonviable fetus ("baby" if you prefer) will die because it cannot breathe. In a standard D&E abortion, the nonviable fetus dies because it is torn apart. With an intact D&E abortion, the nonviable fetus will die by a blow to the skull. If the nonviable fetus is killed by an

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[153]"Pain" is important because everyone—especially including every last doctor, lawyer, and judge in this case—opposes the unnecessary infliction of distress on any living organism, no matter its stage of development, and no matter whether one uses "baby," "infant," "fetus" or some other word to describe the life form.

[154]Prior to trial, when deciding a motion in limine, I ruled that the issue of fetal pain appeared to be relevant after viability, but probably only marginally relevant prior to viability. (Filing 105.) After further considering the matter, I conclude the issue of "fetal pain" prior to viability is either totally irrelevant or so marginally relevant as to be meaningless when it comes to deciding the constitutionality of the statute as it applies prior to viability. Since I do not reach the question of whether the statute is constitutional as applied to abortions where the fetus is undisputably viable, I give no further consideration to the question of fetal pain after viability.

injection to the heart, that beating organ will be pierced by a sharp instrument and stopped as a poison is injected into it. If the nonviable fetus's cord is cut, the infant will die by asphyxiation.

Since the nonviable fetus will die in any event, and presumably suffer "pain" in every event, the unverifiable views of Congress about which procedure is less or more painful can never trump the clear health interests of the woman when it comes to the selection of abortion methods.[155] If a judge reads Stenberg believing that he or she has an obligation to apply it in good faith, it is impossible to argue with a straight face that (1) causing a nonviable fetus to die a gasping, suffocating, and sometimes prolonged, death (induction) inflicts less pain than a single strike to the skull (the banned technique), and (2) therefore the physician's judgment about which procedure is safer for the woman must give way to government officials' aesthetic preferences.[156] Prior to viability, the precedent that I have sworn to follow dictates that the well-founded health interests of the woman are always superior to Congress' otherwise laudable, but ultimately capricious, concern for fetal pain. Stenberg, 530 U.S. at 930-31 (commenting upon Nebraska's desire to prevent "cruelty to partially born children," the Supreme Court emphasized that the government's "interest in regulating abortion previability is considerably weaker than postviability" and holding that the government cannot enact regulations that "force women to use riskier methods of abortion.").

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[155]No question is presented in this case about whether it would be legally permissible to require fetal anesthesia in every type of abortion procedure when it might be safe for the woman to do so. I therefore have no occasion to address this separate and distinct question. However, and despite the vilification of Dr. Carhart, it is worth noting that in conjunction with his use of digoxin, the doctor has personally decided to use lidocaine in an attempt to anesthetize the nonviable fetus when he believes it safe for the woman to cause fetal death by injection. (Tr. 629-30.)

[156]As Mr. Ashcroft's witness Dr. Lockwood readily agreed, there is no medical basis "whatsoever" to distinguish between D&E and intact D&E "from the perspective of fetal pain." (Tr. 1763.)

Fifth, while I am perfectly willing to assume, for the sake of argument, that a nonviable fetus can suffer pain at some point at or after 20 weeks, because nonviable fetal pain is legally irrelevant, it is not necessary, and to be truthful, it is impossible, to decide precisely when, if at all, a nonviable fetus feels pain. The evidence establishes to a virtual certainty that human fetuses lack the anatomy and physiology to perceive pain prior to 20 weeks. After that, the trial evidence convinces me that it is not possible to pinpoint when a fetus develops sufficiently such that it has the physical ability to perceive pain. Following a thorough cross-examination about the different medical opinions on this subject (Tr. 1058-68, Test. Dr. Anand) and the ambiguity of the data, Dr. Anand, the government's credible pain expert who believed a fetus could feel pain at about 20 weeks, admitted that "there is disagreement in the medical community on the issue of whether fetuses, at 20 weeks and later, are able to feel pain." (Tr. 1068, Test. Dr. Anand.)[157] Indeed, the Royal College of Obstetricians and Gynecologists has concluded that fetuses are unable to feel pain the way humans feel pain until 26 weeks. (Ex. 122, Test. Dr. Creinin 722.)

In the same vein, and because of the lack of legal relevancy, I decline to decide whether a nonviable fetus suffers pain as humans suffer pain. Besides, that decision requires a meaningful understanding of "consciousness" and there is no such understanding. (Tr. 1072-73, Test. Dr. Anand (there is no consensus in the medical community about when fetal consciousness occurs, if at all).)

[157]Based upon a literature review, one law student, after first suggesting that it was probably 20 weeks, has stated that a fetus "almost definitely experiences pain by the twenty-eighth week." Note, The Science, Law and Politics of Fetal Pain Legislation, 115 Harv. L. Rev. 2010 (2002).

### *B. BECAUSE THE BAN REACHES THE D&E ABORTION METHOD USED BY PHYSICIANS LIKE DR. CARHART, THE LAW IS AN UNDUE BURDEN AND UNCONSTITUTIONAL.*

The Stenberg decision also dealt with an ambiguity in the Nebraska law that threatened to ban procedures other than "partial-birth abortions." In particular, the Court found that the plain language of Nebraska's ban also covered "the most commonly used method for performing previability second trimester abortions[,]" D&E procedures. Stenberg, 530 U.S. at 945. Because "Nebraska [did] not deny that the statute imposes an 'undue burden' if it applies to the more commonly used D&E procedure[,]" id. at 938 (emphasis in original), the Court struck down the ban as being an undue burden. Id. at 945-46.

Mr. Ashcroft takes a position similar to that taken by Nebraska. In other words, he does not assert that the ban is constitutional even if it applies to D&E abortions. This is probably because, as his counsel frankly admitted, the D&E method has "a fairly remarkable safety record." (Tr. 191.)

Although the safety differences generally even out at or after 20 weeks, D&E abortions are typically safer than medical-induction abortions during all the gestational ages under consideration in this case. D&E procedures certainly involve less pain and expense than inductions. Furthermore, in many states (like Nebraska) it is not possible to receive an elective induction abortion in a hospital because the hospitals refuse to allow those procedures to be performed. Still further, inductions are contraindicated for some patients. Thus, for millions of women abortion in a hospital using the induction method is simply not an option. In addition, the evidence overwhelmingly demonstrates that a hysterectomy and a hysterotomy, which involve major abdominal surgery, are the most dangerous of all abortion procedures. Many competent physicians consider them the options of "last resort."

In any event, I both find and conclude that, during the second trimester, a law banning D&E abortions would be an undue burden because it would ban the most commonly used method of abortion which is also, generally, the safest method. Such a conclusion is even more true if, as Mr. Ashcroft contends, the ban also extends to D&X or intact D&E abortions. As earlier noted, those abortions are a safe, or sometimes safer, variant of the D&E method.

When addressing the D&E question, and in addition to those principles discussed earlier, the Stenberg Court announced the following rules that I must follow in this case:

* Even if a "statute's basic aim is to ban" one procedure, if "its language makes clear that it also covers a much broader category of procedures[,]" the statute will be construed according to its "plain language" and, if that plain language covers other procedures, the statute must be read to cover all those procedures. Id. at 939.

* While the courts have a "'duty to give [the law] a construction . . . that would avoid constitutional doubts[,]'" such an interpretation must not "'twist the words of the law and give them a meaning they cannot reasonably bear.'" Id. at 941 (citation omitted).

* "When a statute includes an explicit definition, we must follow that definition, even if it varies from that term's ordinary meaning." Id. at 942 (citations omitted).

* "'[I]dentical words used in different parts of the same act are intended to have the same meaning[.]'" Id. at 944 (quoting Gustafson v. Alloyd Co., 513 U.S. 561, 570 (1995)).

The Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, provides criminal punishment for "[a]ny physician who, in or affecting interstate or foreign commerce, knowingly performs a partial-birth abortion and thereby kills a human fetus[.]" The term "partial-birth abortion" means an abortion in which the person performing the abortion:

> (A) deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus; and
>
> (B) performs the overt act, other than completion of delivery, that kills the partially delivered living fetus . . . .

Id. § 1531(b)(1).

In part, I agree with the plaintiffs' argument that the ban as drafted, and construed according to the principles stated in Stenberg, reaches certain D&E abortions. Because D&E abortions are the most common form of abortion in the second trimester, and because they are generally the safest method of abortion during the second trimester, a law like this one which prohibits such a procedure is an undue burden.

However, in part, I also disagree with the plaintiffs. I do not agree that the ban could reasonably be read to pertain to medical inductions or spontaneous abortions and to certain other D&E abortions if I adopt Mr. Ashcroft's proposed "specific intent" limiting construction.

### *1. THE "SPECIFIC INTENT" LIMITING CONSTRUCTION MAKES THE LAW INAPPLICABLE TO INDUCTION ABORTIONS, TREATMENT OF SPONTANEOUS ABORTIONS, AND CERTAIN D&E ABORTIONS.*

The evidence made clear, and Mr. Ashcroft tacitly concedes, that the Act could be interpreted to reach far beyond "partial-birth abortions." Indeed, instead of stating what the Act did not cover (such as D&E abortions, induction abortions, and treatments for spontaneous abortions), Congress was silent on the matter. Physician after physician expressed sincere doubt about how far the ban extended. Their problem is made more acute because Congress did not endeavor to define either prohibited or permitted conduct by reference to commonly accepted medical terms.

Essentially, many doctors worry that they could start out intending to perform one procedure not banned by the Act, but end up doing another procedure that might appear to be similar to the procedure described in the ban. Thus, and particularly because the statute does not use commonly accepted medical terms, a whole host of physicians understandably worry that they could be subject to prosecution for a federal felony when they had no intention of performing the banned procedure, but the exigencies of the situation forced upon them the necessity of doing something that looked similar to the banned procedure.

In order to overcome these legitimate concerns, Mr. Ashcroft asserts that: "Unless a physician begins a particular abortion with a pre-meditated and specific intent to perform the abortion in the manner the Act forbids, the physician has not acted in violation of the statute, even if it so happens, as he or she proceeds, that the fetus's head gets stuck, and must be crushed, or its contents removed, to complete the delivery." (Filing 161, Def.'s Br. at 87.) "In other words, a physician cannot violate the Act unless he or she forms a specific intent, before delivering the fetus, to perform an overt act in mid-delivery (at the specified anatomic threshold) that will kill the

partially delivered fetus." (Filing 161, Def.'s Br. at 86.) As a result, Mr. Ashcroft proposes that I limit the statute using this "specific intent" construction.

As Stenberg made clear, I have an obligation to construe the statute to be constitutional so long as I do not "'twist the words of the law and give them a meaning they cannot reasonably bear.'" Stenberg, 530 U.S. at 941 (citing the Eighth Circuit's decision below, Stenberg, 192 F.3d at 1150). The statute challenged here uses a sequential and chronological step-by-step description of the culpable conduct. It describes three discrete and reasonably specific elements, and couples them to reasonably precise states of mind, to wit:

> 1. The doctor must "deliberately and intentionally" (a) vaginally deliver (b) a living fetus until, (c) in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in a breech presentation, any part of the fetal trunk past the navel is outside the body of the mother.
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> 2. The physician must deliver the living fetus for the specific "purpose" of performing an "overt act" that the provider knows will kill the partially delivered fetus.
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> 3. To complete a "partial-birth abortion," the attending physician must perform "the overt act," other than completion of delivery, that kills the partially delivered living fetus, and he or she must do so "knowingly."

Unlike the Nebraska statute in Stenberg which used "substantial portion" and "delivers vaginally" when trying to describe the prohibited procedure, the ban in this case is more specific. It describes the culpable conduct, in sequence, with regard to specific anatomical features of the fetus ("fetal head"or "fetal trunk past the navel") and with regard to a specific anatomical point with regard to the woman ("outside the body"

of the woman). Most importantly, to become liable, the Act requires the physician to "vaginally deliver[] a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in the case of breech presentation, any part of the fetal trunk past the navel is outside the body of the mother, for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus[.]" 18 U.S.C. § 1531(b)(1)(A) (emphasis added).

Given these factors, and particularly because of the "purpose" language, I agree that the statute must be construed to impose upon the government the obligation to prove the specific intent urged by Mr. Ashcroft.[158] See, e.g., United States v. Bailey, 444 U.S. 394, 404-05 (1980) (construing the federal escape statute and discussing the Model Penal Code's approach; explaining the various meanings of the word "intent"; indicating that the word "intent" can be understood as having a "hierarchy . . . in descending order of culpability, as purpose, knowledge, recklessness, and negligence"; stating that "a person who causes a particular result is said to act purposefully if '"he consciously desires that result, whatever the likelihood of that result happening from his conduct"' and "'purpose' corresponds loosely with the common-law concept of specific intent") (quoting United States v. United States Gypsum Co., 438 U.S. 422, 445 (1978) (other citations omitted)).

In short, Mr. Ashcroft's "specific intent" construction neither misconstrues nor rewrites the statute when I examine the ban's words, sequential and chronological structure, and evident purpose. Therefore, unless a physician begins a particular abortion with a pre-meditated and specific intent to perform the abortion in the manner the Act forbids, the physician has not acted in violation of the statute, even if it so happens, as he or she proceeds, that the fetus's head gets stuck and must be crushed, or its contents removed, to complete the delivery.

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[158]Mr. Ashcroft's concession makes proof that the Act has been violated extremely difficult. That, of course, is of no immediate concern to me.

The foregoing construction forecloses application of the statute to medical induction or spontaneous abortion situations. In those situations, the physician never begins his or her treatment with a pre-meditated and specific intent to perform an overt lethal act in mid-delivery when the relevant portion of the fetus (the head or fetal trunk past the navel) has been delivered outside the woman's body. This construction also protects certain doctors who perform D&E abortions, but who always begin that procedure with the sole intent of bringing the fetus out in pieces of undetermined size from the start of the procedure to the end of it, and regardless of the placement of the fetus with respect to the woman's anatomy. Stated differently, physicians who intend only to perform a D&E, as well as physicians performing induction or treating spontaneous abortions lack the specific intent, prior to the beginning of the procedure, to deliver a living fetus past a specific anatomical point on both the fetus and woman, and only then, in mid-delivery, inflicting the killing act.

### *2. DESPITE THE "SPECIFIC INTENT" LIMITING CONSTRUCTION, THE LAW APPLIES TO CERTAIN D&E ABORTIONS.*

This construction does not, however, foreclose application of the Act to doctors who have a dual intention at the beginning of the procedure. This is particularly true for the surgical abortions performed by Dr. Carhart during and after 14 weeks but before 18 weeks when he intends to perform the intact procedure or a standard D&E abortion on a living fetus.

Indeed, and apparently seeking to avoid this problem, some of the most ardent physician-supporters of the ban unsuccessfully tried to convince Congress to limit the ban to 20 weeks and after. A defense witness, Dr. Cook, who had twice appeared before Congress in support of the ban, addressed this problem at trial. In response to a question on redirect examination from government's counsel about why Dr. Cook had offered the 20-week cutoff, Dr. Cook responded that he had "offered a gestational age limit to try to bring some greater narrowness to the definition." (Tr. 1451 (emphasis added).)

Congress, and Dr. Cook, had good reason to be concerned about the lack of statutory "narrowness" in the 12- to 17-week age range (and thereafter). I discuss that matter next.

At 17 weeks, for example, Dr. Carhart, who does not then induce fetal demise by injection, either (1) extracts the fetus intact after puncturing and draining[159] the skull (about 5% of the time) or (2) extracts the fetus in large pieces (about 95% of the time). In other words, Dr. Carhart always has the specific intent to do either a D&E or the banned procedure on a living fetus when he begins the abortion during this age range. But he does not know which procedure he will perform until he has performed it. In both circumstances, the intact fetal body past the navel may be outside the woman's body prior to the time the lethal act (reducing the skull or tearing the body) takes place.[160]

Alternative (1) or (2) above depends upon whether the fetus presents feet-first or in some other configuration. If the fetus presents feet-first, and if the fetal tissue does not tear apart because of its inherent weakness, Carhart will deliver all the fetus save for the skull (which is trapped by the cervix). At that point, he punctures and drains the skull and removes the fetus intact. If the fetus does not present feet-first, or even if it does, and he cannot remove the fetus up to the head, he will bring out as much of the fetal body as he can before he dismembers it.

Carhart's intention at the inception of the procedure is the same; that is, without manually converting the fetus to a footling breech, the doctor, with pre-meditated and

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[159]Sometimes Dr. Carhart can manually compress the skull, and thus reduces it. Even so, the compression of the skull is likely to be lethal.

[160]Keep in mind that the cervix of the woman will frequently be at or very near the vaginal opening and sometimes even protruding outside the woman's body. Hence delivery of the fetal body, including the trunk past the navel, "outside the body" customarily would be anticipated before the surgery begins.

specific intent, desires to extract the fetus in whole or in part using the fewest uterine-cervical passes possible. This always means that the doctor attempts to extract the fewest number of pieces possible and, hopefully, an intact fetus. In other words, if the doctor cannot remove the fetus in one piece, he hopes to remove it in two large pieces, and if that is not possible, in three slightly smaller pieces, and so forth. He always specifically intends to limit the number of passes into the uterus and cervix.

In either circumstance, whether intact or in pieces, the fetus can be "alive" (but clearly not viable) at the time the surgical extraction begins and at the time the killing act is administered. In both circumstances, the hand movements used by Dr. Carhart in pulling the fetal body from the uterus through the cervix into the vagina and then outside the body of the woman are the same. In both circumstances, the amount of dilation used is the same. In both circumstances, either by puncturing and draining only the skull or tearing the fetus into pieces, the living fetus is killed.[161] In both

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[161]Dr. Carhart, like many other physicians, does not believe it safe to induce fetal demise by injection at 17 weeks and earlier. Furthermore, and although he sometimes tries to do so before crushing the skull, it is potentially dangerous and sometimes impossible to cut the fetal cord. Even if he cuts the cord, the fetus may still display signs of life before it dies. Supporters of the ban (like Dr. Cook) acknowledge that cutting the cord, or merely allowing the compression of the skull and cervix against the cord to occlude it, will not immediately kill the fetus, and one might have to wait up to 15 minutes before the fetus dies. (Tr. 1464, Test. Dr. Cook.) Waiting, of course, means that the surgery is artificially interrupted with no benefit to the woman. Interruption of the surgery also entails appreciable risk to the woman by extending the time of the operation and, among other things, increasing the possibility of unnecessary blood loss. Still further, if the physician: (1) cuts the cord after delivering the intact fetus beyond the relevant anatomical landmarks and the head of the living fetus lodges in the cervix, (2) waits for the fetus to die as a result of cutting of the cord, (3) reduces the skull to remove the fetus after the fetus has died as a result of cutting the cord, and (4) has the "dual intent," like Dr. Carhart, to perform an intact D&E or a standard D&E, the physician appears to have violated the Act even though the skull is not reduced until after the fetus is dead. (Pls.' Ex. 124, Test. Dr. Hammond 624-25.)

circumstances the fetus is killed in mid-delivery—either by dividing it into two or more pieces, sometimes after the intact fetal body beyond the navel has been delivered outside the woman, or by reducing the skull and removing the fetus intact, sometimes after the intact fetal body past the navel has been delivered outside the woman.[162]

Dr. Carhart testified that, at 12 through 17 weeks, he "can normally remove" the fetus in "two, three pieces" and "can often get up to the base of the skull, then go back and remove the skull" or "can often get both lower extremities and divide somewhere at the upper part of the spinal cord, removing abdominal organs and some even thoracic organs on the very first removal." (Tr. 627.) Carhart was asked whether, during this gestational age range, he had ever experienced a situation "where the fetus has been not intact, partially dismembered" but "part of the fetal trunk passed . . . [and] the umbilicus has come outside the body of the mother?" (Tr. 618.) He answered "certainly" and then gave examples of separating the fetus into pieces at the level of the elbow, shoulder, scapula, and chest wall. (Tr. 618.) At another point, Carhart testified

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[162]Interestingly, in the case of a breech presentation, the law does not preclude a doctor from performing the banned procedure by reducing the skull of an intact fetus unless the fetal body past the navel is outside the woman's body. Although infrequent, the evidence reveals that in some second-trimester abortions the distance from the external portion of the cervix to the vaginal opening may be such that the fetal trunk past the navel cannot physically be drawn outside the woman's body when the head lodges against the cervix. For example, Dr. Doe stated that the distance between the cervix and vaginal opening for his or her D&E abortions is usually 3 inches and can be more. (Tr. 44-45, Test. Dr. Doe.) Dr. Paul stated that the distance could be "four or five inches." (Pls.' Ex. 125, at 65.) Other evidence indicated that between 16 and 18 weeks, a fetus is only 5 to 6 inches long. (Ct.'s Ex. 2.) Thus, it is perfectly possible and perfectly legal to perform the banned procedure where the distance between the cervix and the vaginal opening is too long to permit the intact fetal body past the navel to be delivered outside the woman's body when the head is trapped by the cervix. One wonders whether Congress intended such an anomaly. In any event, and among other things, this shows the drafting problems that confront Congress when it tries to write a statute that takes into account the varied anatomy of women and fetuses.

that, in this gestational age range, between 25 to 40 times a year he extracts the fetus "up to the shoulders where I have to go in and do something else [separating that portion of the fetal body below the shoulders from that part of the body at the shoulders]." (Tr. 728.)

Thus, the evidence shows that Carhart will sometimes deliver an intact living fetus past the navel outside the woman's body, but, performing a standard D&E, the fetal body is thereafter removed in pieces rather than intact. For example, he is sometimes able to get the entire fetal body up to the chest out of the cervix before performing a destructive act, and, critically, the trunk of the fetus past the navel is outside the woman's body. Then, he performs the dismemberment procedure, the hallmark of all D&E abortions.[163] It is in that and similar circumstances that the ban applies to D&E procedures.[164]

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[163]When the fetal body (or a portion of it) is trapped by the cervix, the trapped object resists being pulled. It is this resistance that causes the fetus to separate into pieces. To be precise, a physician is able to dismember the fetus because of the force caused by his or her instrument pulling on the fetal body and the counter-traction exerted against the fetal body by the cervix. The counter-traction is caused by the internal cervical os trapping the fetal body and retarding the movement of the fetal body as it is pulled by the doctor's instrument. When the force exerted through the instrument exceeds the tensile strength of the trapped fetal body, the fetus separates. This is the mechanism that causes dismemberment in all D&E abortions. In this sense, a D&E performed by Carhart between 12 and 17 weeks is no different than any other D&E performed by Carhart and most other physicians.

[164]To be fair, however, I agree with Mr. Ashcroft that the Act, properly read, does not reach those situations where, for example, a doctor removes a piece of the rib from the fetal body while the rest of the fetal body is in the uterus. (Filing 161, Def.'s Br. at 96-98.) Simply because a body part above the navel is removed does not trigger the Act. On the contrary, the relevant question under the statute is whether the intact fetal body past the navel has been delivered outside the woman's body before the destructive act takes place.

There is nothing in this law, or the construction proposed by Mr. Ashcroft,[165] that suggests that the physician must have the exclusive intent to perform the banned procedures. In many other criminal cases, a "dual intent" (purpose) is enough for a conviction. See, e.g., Anderson v. United States, 417 U.S. 211, 226 (1974) ("A single conspiracy may have several purposes, but if one of them—whether primary or secondary—be the violation of a federal law, the conspiracy is unlawful under federal law."); United States v. Woodward, 149 F.3d 46, 71 (1st Cir. 1998) ("A defendant may be prosecuted for deprivation of honest services if he has a dual intent, i.e, if he is found to have intended both a lawful and an unlawful purpose to some degree.").

In summary, and even accepting the government's "specific intent" construction, it is in this "dual intent" situation where the law reaches standard D&E abortions of the kind performed by doctors like Dr. Carhart. Given his specific intent at the inception of the procedure, if Dr. Carhart separates the living fetus into two or more pieces when the intact fetal body past the navel has been delivered outside the woman's body, he violates the law even though he has not delivered an intact[166] fetus, but, on the contrary, has performed a standard D&E.[167]

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[165]Mr. Ashcroft could have proposed a limiting construction that explicitly stated that the Act never applies to D&E abortions even when the intact fetus was delivered beyond the relevant anatomical landmarks and even where the physician also had the intent to perform the banned procedure at the beginning of the procedure. I do not fault him for failing to propose such a construction. The plain words and sequential structure of the statute, coupled with Congress' rejection of Dr. Cook's 20-week cut-off, would not have fairly supported such a reading.

[166]As Dr. Vibhakar noted, nowhere in the operative definition of the banned procedure is there a reference to removing the fetus "intact." (Tr. 351-52.) Still further, Deputy Assistant Attorney General Kim made clear during his deposition that the Department has not decided whether the fetus must be removed "intact" in order for the Act to be violated. (Pls.' Ex. 118, Dep. of Kim 94 & 126.)

[167]This real-life scenario was a problem for Mr. Ashcroft's accomplished lawyer. During my questioning, both in opening statement (Tr. 196-98 & 202) and

### *C. IF THE GOVERNMENT'S "SPECIFIC INTENT" CONSTRUCTION OF THE STATUTE IS IMPROPER, THEN THE LAW IS UNCONSTITUTIONAL BECAUSE IT IS TOO VAGUE. OTHERWISE, THE STATUTE IS NOT IMPERMISSIBLY VAGUE.*

The plaintiffs contend that the law is unconstitutionally vague because it fails to clearly define the medical procedure to which it applies and because various words used in the statute are vague. If Mr. Ashcroft's proposed "specific intent" limiting construction is improper, I agree that the Act is hopelessly vague regarding the medical procedures to which it applies.

On the other hand, if the limiting construction is proper—and although the ban is unconstitutional because it lacks a health exception and because it reaches D&E abortions of the kind performed by Dr. Carhart and others like him—then the law is not unconstitutionally vague with respect to the definition of the medical procedures to which it applies. Furthermore, I disagree with the plaintiffs' second assertion regarding the vagueness of certain of the words used in the statute.

A law violates the Constitution's "due process of law" guarantee if it is vague. The Constitution requires that Congress "give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly" and "provide explicit standards" for those who enforce the law so that "arbitrary and

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in closing argument (Tr. 1897-1911), counsel struggled to explain the government's position regarding whether the Act covered Dr. Carhart's practice prior to 18 weeks. At one point, counsel candidly admitted: "The question is whether his intent is one of performing the intact procedure or the procedure banned by the Act, and I'm not, you know, I don't know that that's entirely clear with Dr. Carhart prior to 18 weeks." (Tr. 1900.) I make this point not to pick on Mr. Ashcroft's excellent lawyer, but to illustrate why I believe the situation discussed in the text constitutes a real, rather than an imagined, problem with the Act.

discriminatory enforcement [may] be prevented." Grayned v. City of Rockford, 408 U.S. 104, 108 (1972). A statute is unconstitutionally vague if someone "'of common intelligence must necessarily guess at its meaning.'" Coates v. City of Cincinnati, 402 U.S. 611, 614 (1971) (citation omitted). As in this case, a greater degree of specificity is demanded for criminal statutes or laws that impact upon the exercise of constitutionally protected rights. Village of Hoffman Estates v. The Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498-99 (1982).

The foregoing notwithstanding, laws, like life, are almost always uncertain as to their precise meaning. "Condemned to the use of words, we can never expect mathematical certainty from our language." Grayned, 408 U.S. at 110. Therefore, so long as a law "'delineates its reach in words of common understanding,'" id. at 112 (citation omitted), the statute "will not be struck down as vague, even though marginal cases could be put where doubts might arise." United States Civil Serv. Comm'n v. National Ass'n of Letter Carriers, 413 U.S. 548, 578-79 (1973) (internal quotation marks and citation omitted).

### *1. THE " SPECIFIC INTENT" LIMITING CONSTRUCTION SAVES THE STATUTE FROM VAGUENESS.*

Mr. Ashcroft has represented that the statute contains three elements and specific scienter requirements. (Filing 161, Def.'s Br. at 82-83.) In particular, he states that:

> First, the provider must "deliberately and intentionally" (a) vaginally deliver (b) a living fetus until, (c) in the case of a head-first presentation, the entire fetal head is outside the body of the mother, or, in a breech presentation, any part of the fetal trunk past the navel is outside the body of the mother. Second, the provider must deliver the living fetus for the specific purpose of performing an overt act that the provider knows will kill the partially delivered fetus. Third, to constitute a partial-birth abortion, the provider must perform "the overt act," other than completion of delivery, that kills the partially delivered living fetus, and must do so "knowingly" by virtue of the requirement that the provider "knowingly

> perform []" a partial-birth abortion in order to violate the Act. Act, § 3 (codified at 18 U.S.C. § 1531(b)(1)(A), (B)). The failure to meet any of these deliberate, purposeful, and sequential requirements, including their respective elements of scienter, means that the provider has not performed an abortion proscribed by the Act. Only when the physician deliberately and intentionally performs the procedure in the manner, for the specific purpose, and in the sequence proscribed, does the Act's prohibition apply.

(Filing 161, Def.'s Br. at 82-83 (emphasis added).)

I adopt the foregoing statement of the Attorney General as a proper exposition of the elements of the crime and the state of mind required to commit the crime. In my view, Mr. Ashcroft has fairly and objectively construed the statute in a way which does not improperly twist the words, structure, or evident purpose of the statute. In particular, and as earlier discussed regarding the "specific intent" requirement proposed by Mr. Ashcroft, an abortion provider cannot have liability under the Act for an "accidental" "partial-birth abortion," so long as the provider did not begin the procedure specifically intending to perform the banned procedure.[168]

If the foregoing is true, and while the ban is unconstitutional for other reasons, the law is not unconstitutionally vague. See, e.g., Posters 'N' Things, Ltd. v. United States, 511 U.S. 513, 524 & 526 (1994) (construing a federal criminal statute that banned the interstate sale of drug paraphernalia to require the government to prove that the "defendant knew that the items at issue are likely to be used with illegal drugs"; holding that, as so construed, the law was not void for vagueness; stating that "the scienter requirement that we have inferred in [the statute] assists in avoiding any vagueness problem") (citing and quoting Hoffman Estates, 455 U.S. at 499 ("'[T]he

[168]As noted earlier, if a living fetus is first delivered beyond the relevant anatomical landmarks before the killing act is administered, Mr. Ashcroft's construction does not protect doctors who perform the standard D&E technique, but who begin the procedure specifically intending to do either the banned procedure or a standard D&E.

Court has recognized that a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of the notice . . . that [the] conduct is proscribed.'")).

### *2. ALTERNATIVELY, IF THE "SPECIFIC INTENT" LIMITING CONSTRUCTION IS IMPROPER, THE BAN IS VOID FOR VAGUENESS.*

The decision to accept Mr. Ashcroft's "specific intent" limiting construction is not free from doubt. Indeed, the Supreme Court in Stenberg rejected a similar argument proposed by the Nebraska Attorney General.[169] The Court in Stenberg cautioned that a judge should not rewrite the statute and construct limitations that the words of the statute will not fairly support. 530 U.S. at 940-45.

Mr. Ashcroft endeavors to save the statute by suggesting that the specific intent necessary to commit the crime must be formulated before the procedure begins, but the statute does not explicitly say so. Also, and in addition to use of the "specific intent" word "purpose," the statute uses the "general intent" word "knows" ("for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus"). "Knows" has been understood by the Supreme Court to criminalize conduct when the actor appreciates "'that the result is practically certain to follow from his conduct, whatever his desire may be as to that result.'" United States Gypsum Co., 438

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[169]There are two major differences in this case, however. First, and most importantly, Congress addressed my major concern and the major concerns of the Eighth Circuit and Supreme Court with regard to definitions; that is, instead of using "substantial portion" like Nebraska, Congress used more precise language. Compare Stenberg, 530 U.S. at 940 (rejecting the Nebraska Attorney General's construction that the "statutory words 'substantial portion' mean 'the child up to the head'"). Second, unlike the Nebraska Attorney General, Mr. Ashcroft does have complete control over all federal prosecutors and his instructions to them must be followed. Compare id. at 940-41 (noting that the Nebraska Attorney General's interpretations of state law do not "bind elected county attorneys . . . .").

U.S. at 445 (holding that the Sherman Act did not require proof that the actor consciously desired to bring the unlawful act to fruition or to violate the law) (quoting W. LaFave & A. Scott, Criminal Law 196 (1972)). Arguably, use of the word "knows" dilutes the specific intent required by the use of the word "purpose" in the same sentence.

Moreover, Congress did not spell out those procedures which were not covered by the law, a fact that the Stenberg Court found to be significant. 530 U.S. at 939 ("The language does not track the medical differences between D&E and D&X—though it would have been a simple matter, for example, to provide an exception for the performance of D&E and other abortion procedures."). In the same vein, Congress elected not to use commonly accepted medical terms to help doctors, who use such terms in their day-to-day practices, distinguish between that which is criminal and that which is lawful. In addition, Congress rejected attempts by physician-supporters of the ban (like Dr. Cook) to limit the ban to 20 weeks of gestation and thereafter. These doctors fervently supported the ban, but thought it wise to address the very "vagueness argument" raised in this litigation.[170]

Thus, there is a strong argument that the statute cannot be limited as Mr. Ashcroft proposes[171] because Congress stubbornly refused to follow the Supreme Court's suggestions for clarity and the recommendation of doctors who otherwise supported the ban. Although I believe that I have been faithful to the precedents, I would not be surprised if I was reversed on this point. If I have erred by accepting Mr. Ashcroft's construction, and that is a close question, then the statute is obviously far too vague. The record demonstrates numerous circumstances where a doctor begins

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[170]Although he thought the vagueness argument "disingenuous," Dr. Cook told me that he proposed the 20-week limitation to "alleviate a large number of discussions and battles over the vagueness argument . . . ." (Tr. 1466, Test. Dr. Cook.)

[171]Indeed, and in a persuasive and well-reasoned opinion, Judge Hamilton so found. Planned Parenthood Fed. of Am., 320 F. Supp. at 977-78.

an abortion intending to do a particular procedure, such as a standard D&E, and ends up doing a procedure that is factually identical to the crime created by the ban. In such a circumstance, and in the midst of a surgical procedure, a doctor would, in utter good faith, ask: Does the Act apply to me?[172] Absent the "specific intent" limiting construction, no one, save a jury exercising unguided discretion, could ever know the answer to that question. Doctors would be left in the dark, patients put at real risk, and overly zealous prosecutors emboldened to take improper advantage. In that circumstance, the Act is plainly void for vagueness.

### *3. ON THIS RECORD, WORDS LIKE "LIVING," "OVERT ACT," "PAST THE NAVEL," "DELIBERATELY AND INTENTIONALLY," AND "IN OR AFFECTING INTERSTATE COMMERCE" ARE NOT IMPERMISSIBLY VAGUE.*

In addition to their arguably valid concern that the law is unconstitutionally vague because it fails to define clearly the banned medical procedure, and almost in passing, the plaintiffs also raise concerns about specific words or phrases used in the statute. They mention "living," "overt act," "past the navel," "deliberately and intentionally," and "in or affecting interstate commerce." Plaintiffs spend very little time explaining to me why these terms, when read in context, are truly vague. Accordingly, I shall respond to their arguments with similar brevity.

[172]Without Mr. Ashcroft's "specific intent" limitation, Dr. Charles Lockwood, a highly credible government witness, believes the law is "imprecise" and "vague" from the viewpoint of a practicing physician. (Tr. 1739-40.)

While I might be able to conceive of situations where these terms (and others) are vague,[173] it is not my proper role to conjure up marginal cases demonstrating vagueness. Moreover, the evidence reveals that most of the time, doctors have a practical understanding of commonplace words like "living" and "past the navel." In addition, the plaintiffs have failed to cite any cases from the Eighth Circuit Court of Appeals or the Supreme Court holding that standard statutory terms of art (such as "overt act," "deliberately and intentionally," and "in or affecting interstate commerce") are constitutionally vague. Still further, and most importantly, given my adoption of the "specific intent" limiting construction, the reach of the statute, particularly as it regards "accidental" violations, has been substantially narrowed, and the plaintiffs' plainly legitimate vagueness concerns are thereby obviated.

Therefore, until a case comes along that provides a much more developed record and far more detailed briefing for use in deciding whether certain specific words or phrases used in this statute are constitutionally infirm, I decline to declare them to be so.

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[173]The word "living" comes to mind. For example, is a late second-trimester fetus that has a heartbeat, but which has developed without the cranial vault and absent (or possessing only rudimentary) cerebral and cerebellar hemispheres, brainstem and basal ganglia ("anencephaly"), "living"?

### *D. THE BAN'S "LIFE" EXCEPTION MUST BE CONSTRUED TO MEAN THAT A DOCTOR MAY PERFORM A "PARTIAL-BIRTH ABORTION" IF "NECESSARY" IN HIS OR HER OWN PROFESSIONAL JUDGMENT TO SAVE THE LIFE OF THE WOMAN, AND WHEN SO CONSTRUED THE LAW'S "LIFE" EXCEPTION IS CONSTITUTIONAL.*

The Act does not ban a partial-birth abortion that "is necessary to save the life of a mother whose life is endangered by a physical disorder, physical illness, or physical injury, including a life-endangering physical condition caused by or arising from the pregnancy itself." 18 U.S.C. § 1531(a). The plaintiffs argue that this "life" exception is too narrow because it only applies when it "is necessary to save the life of a mother," 18 U.S.C. § 1531(a), but not when the physician, in his or her appropriate medical judgment, believes a partial-birth abortion is necessary to save the life of the woman. They argue that the absence of the "appropriate medical judgment" phrasing within the life exception allows others to substitute their medical judgment for that of the abortionist in determining whether a woman's medical condition was life-threatening and it also makes the law vague.

Under long-standing Supreme Court precedent, whether an abortion is "necessary" to preserve the woman's life or health is determined in the context of the treating physician's professional judgment under the circumstances presented to him or her while caring for the patient. United States v. Vuitch, 402 U.S. 62, 69-72 (1971); Doe v. Bolton, 410 U.S. 179, 191-192 (1973). Construed in this manner, the statutory phrase "necessary for the preservation of the mother's life or health" is not unconstitutionally vague. Vuitch, 402 U.S. at 72; Bolton, 410 U.S. at 191-92.

Citing Vuitch, the Court in Roe v. Wade, 410 U.S. at 165, held that after viability, a state in promoting its interest in human life may choose to regulate and proscribe abortion "except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother." This interpretation of the life

exception was re-affirmed in Casey, 505 U.S. at 879, and expressly extended to previability abortion procedures in Stenberg, 530 U.S. at 937.

As explained in Stenberg, the word "necessary" as used in the phrase "necessary, in appropriate medical judgment, for the preservation of the life or health of the mother" does not refer to an absolute necessity or to absolute proof. Rather, it embodies "the judicial need to tolerate responsible differences of medical opinion" which may arise when doctors' opinions differ concerning the comparative health risks and appropriate treatment options for women seeking or needing an abortion. Stenberg, 530 U.S. at 937.

Whether explaining the constitutional parameters of the right to an abortion or interpreting statutory language regulating that right, the Supreme Court has consistently incorporated the treating physician's professional medical judgment into the meaning of "necessary" for the woman's life and health. When judicial interpretations have settled the meaning of a statutory provision, repeating the same language in a new statute indicates Congress' intent to incorporate the Court's interpretation of that language. Bragdon v. Abbott, 524 U.S. 624, 645 (1998) (citing Lorillard v. Pons, 434 U.S. 575, 580-81 (1978)). That is the case here.

In recognition of the Supreme Court's abortion jurisprudence and established principles of statutory construction, Mr. Ashcroft concedes, as he must, that although the Act does not expressly say it, the life exception should be interpreted to permit a physician to perform a partial-birth abortion if it is "necessary" in his or her own professional judgment to save the life of the mother. (Tr. 1911-13; Filing 161, Def.'s Br. at 98.) Likewise, I conclude that the Act's exception allowing partial-birth abortions when it "is necessary to save the life of a mother," 18 U.S.C. § 1531(a), means a physician is permitted to perform a partial-birth abortion when the physician, in his or her own professional judgment, believes a partial-birth abortion is necessary

to save the woman's life. Construed as such, the life exception is neither unduly narrow in scope nor unconstitutionally vague.

### *E. WHETHER DESCRIBED AS "FACIAL" OR WHETHER DESCRIBED AS "APPLIED," THE INVALIDATION OF THIS ABORTION-REGULATING STATUTE DOES NOT EXTEND TO SITUATIONS WHERE THE FETUS IS INDISPUTABLY VIABLE. THE RULING SHOULD ALSO BE LIMITED IN SCOPE SO AS NOT TO UNNECESSARILY INTERFERE WITH THE DECISIONS OF OTHER COURTS.*

There are two matters that require clarification. The first deals with the reach of my decision. The second deals with the need to avoid potentially conflicting orders in the two other cases that have concurrently been litigated in California and New York.

#### *1. THIS DECISION DOES NOT INVALIDATE THE BAN WHERE THE FETUS IS INDISPUTABLY VIABLE.*

Ostensibly, the plaintiffs bring their challenge to the ban as a "facial" rather than as an "applied" objection. (Tr. 163, Opening Stmt. of Pls.' Atty's. ("This is a facial challenge to the Act.").) As I will explain, while the plaintiffs' able lawyers may understand what these words mean in the abortion context, I do not. Moreover, I do not understand the implications of labeling this case a "facial" challenge as opposed to labeling it an "applied" challenge.

Nevertheless, and no matter how it might be labeled by others, I should be clear about what I intend my decision to mean. Therefore, I next proceed to explain what I intend. In doing so, I also explain what I do not intend.

In Stenberg, I addressed the "facial" and "applied" distinction. I wrote the following:

> A law may be challenged as unconstitutional in two ways. The law may be challenged "as applied" and "facially." See, e.g., Ada v. Guam Soc. of Obstetricians & Gynecologists, 506 U.S. 1011, 1012-13 (1992) (Scalia, J. dissenting); WMPC II, 130 F.3d at 193-94; Michael C. Dorf, Facial Challenges to State and Federal Statutes, 46 Stan. L. Rev. 235 (1994). If the law is judged unconstitutional on facts peculiar to the plaintiff, then the law is unconstitutional "as applied." Ada, 506 U.S. at 1013 (Scalia, J. dissenting). If, on the other hand, the law is found unconstitutional regardless of how it might be applied to a particular plaintiff then the law is said to be facially unconstitutional. Id. The difference between the two challenges is this: if a law is facially invalid it cannot be enforced against anyone, but if a law is unconstitutional "as applied," while it cannot be enforced against the plaintiff (or others like him), the law is otherwise generally enforceable. Id.

Carhart v. Stenberg, 11 F. Supp. 2d 1099, 1119 (D. Neb. 1998). So far as I am able to determine, the foregoing remains a correct, although tautological, statement of the law.

In Stenberg, I decided that the Nebraska law was unconstitutional for three reasons: (1) it lacked a health exception; (2) it banned all D&E abortions; and (3) it was too vague. Id. at 1132. However, I also found that, although the attack in that case was made both "facially" and as "applied," I should declare the Nebraska statute unconstitutional only as applied to Dr. Carhart and physicians like him. Id. at 1120.

I explicitly limited my decision as "applied" to Dr. Carhart (and others like him) in Stenberg, and I did so primarily for prudential reasons; that is, I thought it unwise to speculate "about a wide variety of fact patterns that might occur in various unknown surgical suites involving various unknown doctors and patients with various unknown motives and conditions." Id. In particular, I refused to make my decision applicable to postviability abortions since Dr. Carhart did not perform those procedures. Id. at 1120 & 1132.

On appeal, the Eighth Circuit decided that the ban failed because it extended to D&E abortions, but the Eighth Circuit did not reach the "health exception" or vagueness questions. Carhart v. Stenberg, 192 F.3d 1142, 1146 n.4 (8th Cir. 1999) ("Because we are holding the law unconstitutional on undue-burden grounds, it is not necessary for us to discuss the vagueness issue. Nor is it necessary for us to discuss whether the law creates an undue burden by prohibiting the D&X procedure. The basis for our holding is the undue burden created by the ban of the D&E procedure.").

In so deciding, the Eighth Circuit considered the appeal as if it were "a challenge to the facial validity of an abortion regulation." Id. at 1149. In the Eighth Circuit's decision, the test for facial invalidity was stated this way: "If the regulation operates 'as a substantial obstacle to a woman's choice to undergo an abortion "in a large fraction of the cases in which [it] is relevant, . . . [i]t is an undue burden, and therefore invalid."'" Stenberg, 192 F.3d at 1149 (quoting Planned Parenthood, Sioux Falls Clinic v. Miller, 63 F.3d 1452, 1458 (8th Cir. 1995), in turn quoting Casey, 505 U.S. at 895).

Ultimately, but without clearly stating whether the Court believed the case involved a "facial" or an "applied" challenge, the Supreme Court affirmed the decision of the Eighth Circuit. The Supreme Court decided that the Nebraska statute was unconstitutional because it lacked a health exception, Stenberg, 530 U.S. at 930-38, (a decision I also reached, but the Eighth Circuit refused to reach) and because it also extended to D&E abortions (a decision that both the Eighth Circuit and I reached). Id. at 938-46. Like the Eighth Circuit (but unlike my decision), the Supreme Court did not deal with the vagueness question.

Although the Supreme Court's opinion in Stenberg was not clear on the "facial" versus "applied" question, the Supreme Court has very recently suggested that at least the second part of the Stenberg decision—because the ban applied to D&E abortions it was unconstitutional—involved a "facial" invalidation. See Sabri v. United States, 124 S. Ct. 1941, 1948-49 (2004) (federal statute prohibiting bribery involving federal

funds was not facially unconstitutional on grounds that it did not require a nexus between criminal activity and federal funds; stating "that facial challenges are best when infrequent" because such challenges frequently involve "'premature interpretatio[n] of statutes' on the basis of factually bare-bones records") (quoting United States v. Raines, 362 U.S. 17, 22 (1960)).

As pertinent here, the Sabri Court said:

> Facial challenges of this sort are especially to be discouraged. Not only do they invite judgments on fact-poor records, but they entail a further departure from the norms of adjudication in federal courts: overbreadth challenges call for relaxing familiar requirements of standing, to allow a determination that the law would be unconstitutionally applied to different parties and different circumstances from those at hand. See, e.g., Chicago v. Morales, 527 U.S. 41, 55-56, n.22, 1849, 144 L.Ed.2d 67 (1999) (plurality opinion). Accordingly, we have recognized the validity of facial attacks alleging overbreadth (though not necessarily using that term) in relatively few settings, and, generally, on the strength of specific reasons weighty enough to overcome our well-founded reticence. See, e.g., Broadrick v. Oklahoma, 413 U.S. 601, (1973) (free speech); Aptheker v. Secretary of State, 378 U.S. 500 (1964) (right to travel); Stenberg v. Carhart, 530 U.S. 914, 938-946 (2000) (abortion); City of Boerne v. Flores, 521 U.S. 507, 532-535 (1997) (legislation under § 5 of the Fourteenth Amendment). See generally Fallon, As-Applied and Facial Challenges and Third-Party Standing, 113 Harv. L. Rev. 1321, 1351 (2000) (emphasizing role of various doctrinal tests in determining viability of facial attack); Monaghan, Overbreadth, 1981 S. Ct. Rev. 1, 24 (observing that overbreadth is a function of substantive First Amendment law). Outside these limited settings, and absent a good reason, we do not extend an invitation to bring overbreadth claims.

Sabri, 124 S. Ct. at 1948-49.

From Sabri it appears that the Court believes that at least a portion of its invalidation of Nebraska's ban against partial-birth abortion was "facial" in nature.

The pinpoint citation in Sabri to the Stenberg opinion, that is, the citation to 530 U.S. at 938-946, refers to the question of whether the Nebraska statute also banned D&E abortions. Sabri, 124 S. Ct. at 1948 ("Accordingly, we have recognized the validity of facial attacks alleging overbreadth (though not necessarily using that term) in relatively few settings, and, generally, on the strength of specific reasons weighty enough to overcome our well-founded reticence. See, e.g., . . . Stenberg v. Carhart, 530 U.S. 914, 938-946 (2000) (abortion) . . . .").

With this background in mind, a host of questions arise. Among them are the following:

* Can an abortion statute be declared "facially" unconstitutional for one reason, and unconstitutional only as "applied" for another reason? If so, when is that proper? If so, how does one tailor the relief in each such circumstance and for the case in its entirety?

* Does Sabri's citation to a specific portion of Stenberg that dealt with the Nebraska ban's coverage of all D&E abortions mean that similar decisions must be treated as "facial" invalidations despite the fact that a trial court might find, as I have found here, that the law covers certain D&E procedures but not others? If so, how does the "large-fraction" test fit?

* Because the Sabri opinion did not refer to the "health exception" portion of the Stenberg opinion, did the Court mean to imply that such challenges are not properly viewed as "facial" in nature under any circumstance? Indeed, why would the "large-fraction" test for facial invalidity articulated by the Eighth Circuit in Stenberg and the Supreme Court in Casey ever be appropriate where a law threatens the health of a single woman whether she be among a

"large fraction" of women or not?[174] If an abortion regulation is invalid as to one woman because of the lack of a health exception, has the law been declared "facially" invalid as to all women?

* Since the Court did not address the vagueness question at all either in Stenberg or Sabri, how do I treat a finding of vagueness? In particular, and as is the case here, is a finding of vagueness that flows from a finding that the statute is vague only if the limiting construction proposed by the government is improper a "facial" or an "applied" invalidation?

I simply do not know the answers to these questions. Without answers to these questions, and to avoid confusion, I refuse to place a label on my decision using the words "facial" or "applied."

Most importantly, none of the cases that I have examined or that the parties have brought to my attention deal with the most critical question in this area. Regarding the "facial" and "applied" dichotomy, how does a trial court properly apply the substantive law of abortion regulation, depending, as that law does, upon whether the fetus is viable, when the evidence presented to the trial court concentrates almost exclusively upon situations where the fetus is not viable?

It is important to remember that the Stenberg Court did not decide or address whether my refusal to invalidate the Nebraska law as it applied to postviability abortions was correct or incorrect. The Eighth Circuit did not address that issue either. Thus, while I must follow these appellate opinions, I have no guidance from my judicial superiors in the Stenberg case about how to deal with a suit attacking a statute banning a certain abortion procedure when the evidence before the trial court is

[174]See, e.g., Stenberg, 530 U.S. at 934 ("[T]he State cannot prohibit a person from obtaining treatment simply by pointing out that most people do not need it.").

directed only at previability abortions, but the remedy sought is invalidation of the law as it also pertains to postviability abortions.

At the beginning of the trial, counsel for the plaintiffs admitted, and the evidence later confirmed, that "all the plaintiffs and all the witnesses are going to be testifying about previability procedures." (Tr. 164, Opening Stmt. of Pls.' Atty's.) At the end of the trial, when I asked how I could apply that previability evidence to the postviability situation, counsel told me that I could "extrapolate." (Tr. 1842, Closing Arg. of Pls.' Atty's.)

As I have earlier indicated when discussing the Turner standard of review, since the Stenberg Court made clear that physicians do not have "unfettered" discretion in selecting abortion procedures, that must mean that the absence of a health exception for "unnecessary" procedures does not constitute a per se violation of the Constitution. It must also mean that Congress has the right to regulate specific abortion methods. And, although widely criticized, the viability dividing line in the Supreme Court's abortion jurisprudence remains crucial to a good-faith application of the precedents of the Court. As the Supreme Court has made clear, the government's interest in the potentiality of human life is so strong that after viability it may, with certain important qualifications, ban abortion altogether. Stenberg, 530 U.S. at 921 (following "'"viability, the [government] in promoting its interest in the potentiality of human life may, if it chooses, regulate, and even proscribe, abortion except where it is necessary, in appropriate medical judgment, for the preservation of the life or health of the mother."'" (quoting Casey, 505 U.S. at 879, in turn quoting Roe v. Wade, 410 U.S. at 164-65)).

If Congress has the abstract power to regulate the "unfettered" discretion of physicians regarding abortion methods, and the viability dividing line is so important that Congress has the abstract power to ban abortions entirely after viability, then surely I ought to insist upon concrete evidence tailored to that time frame before I

invalidate an Act of Congress that regulates abortion during that time frame. If that is so, then this case presents an insurmountable obstacle to declaring the law unconstitutional when applied to a fetus that is undisputably viable.

While I have had no doctor testify before me regarding situations where the fetus is undisputably viable, I know from the congressional record that Dr. Warren Hern does postviability abortions using the banned technique, but he kills the fetus prior to beginning the procedure. I know also from the congressional record that postviability abortions, apparently using the banned technique, are conducted in Kansas, but I know very little more than that.

Should I speculate that a health exception is unnecessary in the postviability situation because Dr. Hern is, apparently, always able to destroy the fetus prior to commencing a postviability procedure? On the other hand, can I reasonably conclude that a health exception is really necessary in the postviability situation because in the previability age range that is so? On this record, and as opposed to the previability period, the answers to these questions would be highly speculative.

If the Supreme Court's precedents are to be rigorously applied by me, judicial validation of a surgery as medically necessary, which would effectively authorize the crushing of the skull of an indisputably viable fetus in the name of a woman's health, particularly in the face of a congressional prohibition, requires more than the "extrapolation" proposed by the plaintiffs. It, at least, requires the explanatory testimony of physicians who would perform such procedures. Absent that evidence, I can only guess. I refuse to do so.

Therefore, I will declare the law unconstitutional in all of its applications when the fetus is not viable or when there is a doubt about the viability of the fetus in appropriate medical judgment of the doctor performing the abortion. To be precise, unless the fetus is indisputably viable, my decision protects the physician when he or

she performs a partial-birth abortion in the exercise of appropriate medical judgment.[175]

I do not determine whether or not the law is constitutional when the fetus is indisputably viable. In this court, that legal issue remains an open question. However, the government would be well-advised to seek an answer to that question before it commences a criminal prosecution. Only an over-zealous prosecutor would seek an indictment against a physician who performed a partial-birth abortion on a viable fetus without first seeking some type of judicial declaration that the statute is enforceable in that circumstance.

And, finally, whether I have declared the law "facially" unconstitutional or as "applied," I do not know. I leave that for others to determine.

### *2. MY DECISION MUST BE TAILORED TO AVOID CONFLICTS WITH OTHER COURTS.*

Other cases similar to this one are in the process of being litigated in New York and California and perhaps elsewhere. This, obviously, raises the specter of conflicting injunctions and declarations.

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[175]The time when "viability" is generally thought to occur has decreased as medicine has developed new and better ways of treating premature infants. Even so, the definition of when "viability" is generally thought to occur changes from institution to institution, fetus to fetus, and physician to physician. In addition to the evolving standard of when viability generally occurs, viability in a given instance turns on a wide range of factors. Thus, in the inevitable cases where there is uncertainty about viability, the abortionist's appropriate medical judgment must prevail. Using this standard, physicians will not fear using the banned procedure in situations where viability is questionable. Even if they are wrong about viability, the government is prohibited from enforcing this law against those doctors unless the fetus was indisputably viable.

Injunctions should never be broader than necessary to afford complete relief to the plaintiffs. Califano v. Yamasaki, 442 U.S. 682, 702 (1979) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs."). This is particularly true in cases of nationwide importance because a broad injunction may interfere with or preclude other courts from ruling on the constitutionality of such matters. Virginia Soc. for Human Life, Inc. v. FEC, 263 F.3d 379, 393 (4th Cir. 2001) (a regulation that violated the First Amendment rights of an issue advocacy group did not justify the district court's injunction against enforcement of the regulation against other parties elsewhere in the United States). Such interference is contrary to the limited jurisdiction of a federal district court. Still further, an expansive injunction may "deprive the Supreme Court of the benefit of decisions from several courts of appeals." Id.

These same concerns are present when the court declares a statute to be unconstitutional. In a case like this one, this court has no power to speak for any other federal court, and no other federal court is bound to follow this decision.

Therefore, I will do as I did when I issued the temporary restraining order in this case. See Carhart v. Ashcroft, 287 F. Supp. 2d 1015, 1016 (D. Neb. 2003). Essentially, I will limit the protection of the injunction to the plaintiffs and those with whom they deal in the course of their medical practice. In addition, as noted above, the declaration of unconstitutionality and the resulting injunction will be limited to those situations when the fetus is not viable or when there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion. Finally, in no sense do I intend my ruling to be binding upon other courts.

## *III. CONCLUSION*

Before summarizing my opinion, a word about the lawyers is in order. The lawyers for both sides were magnificent. They are smart, fair-minded, candid, civil, professional, ethical, good writers, excellent speakers, and accomplished trial lawyers. They represent the very best the legal profession has to offer, and I sincerely thank them for their work in this case.

I have decided that the Partial-Birth Abortion Ban Act of 2003 is unconstitutional. In particular, I have decided that the law is unconstitutional because: (1) it lacks a health exception; (2) accepting Mr. Ashcroft's proposed "specific intent" limiting construction, the law nevertheless bans D&E abortions of the type performed by Dr. Carhart when he does not first induce fetal death by injection prior to 18 weeks; and (3) if Mr. Ashcroft's proposed "specific intent" limiting construction is improper, the law is too vague regarding the behavior the law seeks to criminalize.

On the other hand, I do not agree that the law, properly limited, bans certain D&E abortions where the physician lacks the requisite specific intent. Similarly, when a physician conducts induction abortions or when a physician treats spontaneous abortions, he or she lacks the requisite specific intent and therefore the law does not ban those activities. Moreover, I do not believe the law is too vague because of the use of certain words. In addition, I do not agree that the ban's "life" exception is unconstitutional when it is properly construed. In addition, my ruling does not apply where the fetus is indisputably viable. Finally, I decline to issue a "nationwide" injunction.

Accordingly,

IT IS ORDERED that:

1. Judgment shall be entered by separate document for the plaintiffs and against the defendant substantially as provided in paragraphs 2 through 4 below.

2. The Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, is declared to be unconstitutional in all of its applications when the fetus is not viable or when there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion. The court does not determine whether the Partial-Birth Abortion Ban Act of 2003 is constitutional or unconstitutional when the fetus is indisputably viable.

3. In all cases when the fetus is not viable or when there is a doubt about the viability of the fetus in the appropriate medical judgment of the doctor performing the abortion, John Ashcroft, in his official capacity as Attorney General of the United States, and his employees, agents, and successors in office, are permanently enjoined from enforcing the Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, against the plaintiffs and their officers, agents, servants, and employees, including those individuals and entities (both medical and non-medical) with whom the plaintiffs work, teach, supervise, or refer.

4. Costs are taxed to the defendant.

5. Within 20 days, Plaintiffs shall post a bond in the sum of $500.00 pursuant to Fed. R. Civ. P. 65(c) and 65.1.

6. Any application for attorney fees shall be submitted no later than 20 days following the entry of judgment. If such an application is filed, the defendant shall have 20 days thereafter to respond.

DATED this 8th day of September, 2004.

BY THE COURT:
s/ Richard G. Kopf
Chief United States District Judge

# *Appendix I*

| Exhibit Number | Bluebook Citation | Westlaw Citation |
|---|---|---|
| Ct.'s Ex. 4 | Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. (1995). | Document not available in complete form on Westlaw. |
| Ct.'s Ex. 5 | The Partial-Birth Abortion Ban Act of 1995: Hearing on H.R. 1833 Before the Senate Comm. on the Judiciary, 104th Cong. (1995). | Document not available in complete form on Westlaw. |
| Ct.'s Ex. 6 | Effects of Anesthesia During a Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. (1996). | Document not available in complete form on Westlaw. |
| Ct.'s Ex. 7 | Partial-Birth Abortion: The Truth: Joint Hearing on S. 6 and H.R. 929 Before the Senate Comm. on the Judiciary and the House Comm. on the Judiciary, 105th Cong. (1997). | Document not available in complete form on Westlaw. |
| Ct.'s Ex. 8 | Partial-Birth Abortion Ban Act of 2002: Hearing on H.R. 4965 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 107th Cong. (2002). | Document not available in complete form on Westlaw. |
| Ct.'s Ex. 9 | Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 108th Cong. (2003). | Document not available in complete form on Westlaw. |
| Ct.'s Ex. 10 | H.R. REP. NO. 108-58 (2003). | 2003 WL 1789189 (Leg. Hist.) |
| Def.'s Ex. 502 | H.R. REP. NO. 108-58, at 1 (2003). | 2003 WL 1789189 (Leg. Hist.) |
| Def.'s Ex. 503 | Partial-Birth Abortion Ban Act of 2003: Hearing on H.R. 760 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 108th Cong. 1 (2003). | Exhibit is title page; not available on Westlaw. |
| Def.'s Ex. 504 | Partial-Birth Abortion Ban Act of 2002: Hearing on H.R. 4965 Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 107th Cong. 1 (2002). | Exhibit is title page; not available on Westlaw. |
| Def.'s Ex. 505 | Partial-Birth Abortion: The Truth: Joint Hearing on S. 6 and H.R. 929 Before the Senate Comm. on the Judiciary and the House Comm. on the Judiciary, 105th Cong. 1 (1997). | Exhibit is title page; not available on Westlaw. |
| Def.'s Ex. 506 | Effects of Anesthesia During a Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. 1 (1996). | Exhibit is title page; not available on Westlaw. |
| Def.'s Ex. 507 | The Partial-Birth Abortion Ban Act of 1995: Hearing on H.R. 1833 Before the Senate Comm. on the Judiciary, 104th Cong. 1 (1995). | Exhibit is title page; not available on Westlaw. |

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|---|---|---|
| Def.'s Ex. 508 | Partial-Birth Abortion: Hearing Before the Subcomm. on the Constitution of the House Comm. on the Judiciary, 104th Cong. 1 (1995). | Exhibit is title page; not available on Westlaw. |
| Def.'s Ex. 509 | 148 CONG. REC. E1,096-97 (daily ed. June 19, 2002). | 2002 WL 1337996 (Cong. Rec.) |
| Def.'s Ex. 510 | 148 CONG. REC. H5,352-374 (daily ed. July 24, 2002). | 2002 WL 1676699 (Cong. Rec.) |
| Def.'s Ex. 511 | 148 CONG. REC. H5,353-54 (daily ed. July 24, 2002). | 2002 WL 1676699 (Cong. Rec.) |
| Def.'s Ex. 512 | 148 CONG. REC. H5,346-352 (daily ed. July 24, 2002). | 2002 WL 1676684 (Cong. Rec.) |
| Def.'s Ex. 513 | 148 CONG. REC. H5,346 (daily ed. July 24, 2002). | 2002 WL 1676684 (Cong. Rec.) |
| Def.'s Ex. 514 | 149 CONG. REC. E249-250 (daily ed. Feb. 13, 2003). | 2003 WL 330476 (Cong. Rec.) |
| Def.'s Ex. 515 | 149 CONG. REC. S2,522-23 (daily ed. Feb. 14, 2003). | 2003 WL 330308 (Cong. Rec.) |
| Def.'s Ex. 516 | 149 CONG. REC. S3,383-399 (daily ed. Mar. 10, 2003). | 2003 WL 939675 (Cong. Rec.)<br>2003 WL 939679 (Cong. Rec.) |
| Def.'s Ex. 517 | 149 CONG. REC. S3,422-29, S3456-494 (daily ed. Mar. 11, 2003). | 2003 WL 1025142 (Cong. Rec.)<br>2003 WL 1025150 (Cong. Rec.) |
| Def.'s Ex. 518 | 149 CONG. REC. S3,560-3,614 (daily ed. Mar. 12, 2003). | 2003 WL 1088102 (Cong. Rec.)<br>2003 WL 1088103 (Cong. Rec.) |
| Def.'s Ex. 519 | 149 CONG. REC. S3,653-662 (daily ed. Mar. 13, 2003). | 2003 WL 1093732 (Cong. Rec.) |
| Def.'s Ex. 520 | 149 CONG. REC. H4,910-19, H4,922-953 (daily ed. June 4, 2003). | 2003 WL 21282273 (Cong. Rec.)<br>2003 WL 21282279 (Cong. Rec.) |
| Def.'s Ex. 521 | 149 CONG. REC. S11,589-1,601, S11,614-620 (daily ed. Sept. 17, 2003). | 2003 WL 22143050 (Cong. Rec.)<br>2003 WL 22143061 (Cong. Rec.) |
| Def.'s Ex. 522 | 149 CONG. REC. H9,142-155 (daily ed. Oct. 2, 2003). | 2003 WL 22271695 (Cong. Rec.) |
| Def.'s Ex. 523 | 149 CONG. REC. S12,914-948 (daily ed. Oct. 21, 2003). | 2003 WL 22399089 (Cong. Rec.)<br>2003 WL 22399091 (Cong. Rec.) |
| Def.'s Ex. 893 | Partial-Birth Abortion Ban Act: House Committee Reports Index | N/A |
| Def.'s Ex. 894 | Partial-Birth Abortion Act: Floor Debate Index | N/A |
| Def.'s Ex. 895 | Partial-Birth Abortion Act: Index of Documents, Statements, and Letters from Doctors and Medical Organizations Reprinted in the Congressional Record | N/A |
| Def.'s Ex. 896 | Partial-Birth Abortion Ban Act: Index of Speeches and Prepared Remarks of Members of Congress in the Congressional Record | N/A |

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|---|---|---|
| Def.'s Ex. 897 | 145 CONG. REC. S12,863-899, S12,904-920 (daily ed. Oct. 20, 1999).<br>145 CONG. REC. S12,949-970, S12,972-999 (daily ed. Oct. 21, 1999). | 1999 WL 957925 (Cong. Rec.)<br>1999 WL 957927 (Cong. Rec.)<br>1999 WL 960679 (Cong. Rec.)<br>1999 WL 960681 (Cong. Rec.)<br>1999 WL 960683 (Cong. Rec.) |
| Def.'s Ex. 898 | 146 CONG. REC. H1,771-1,801 (daily ed. Apr. 5, 2000). | 2000 WL 349966 (Cong. Rec.) |
| Def.'s Ex. 899[176] | Bound Vol.:<br>143 CONG. REC. 8,209-229, 8,319-382, 8,794-8,817 (1997).<br>144 CONG. REC. 20,665-692, 20,883-896 (1998).<br><br>Daily Ed.:<br>143 CONG. REC. S4,431-451 (daily ed. May 14, 1997).<br>143 CONG. REC. S4,517-575 (daily ed. May 15, 1997).<br>143 CONG. REC. S4,694-4,716 (daily ed. May 20, 1997).<br>144 CONG. REC. S10,474-499 (daily ed. Sept. 17, 1998).<br>144 CONG. REC. S10,551-564 (daily ed. Sept. 18, 1998). | 1997 WL 250191 (Cong. Rec.)<br>1997 WL 252927 (Cong. Rec.)<br>1997 WL 264645 (Cong. Rec.)<br>1997 WL 264647 (Cong. Rec.)<br>1997 WL 264649 (Cong. Rec.)<br>1998 WL 636884 (Cong. Rec.)<br>1998 WL 638990 (Cong. Rec.)<br>1998 WL 638991 (Cong. Rec.) |
| Def.'s Ex. 900 | Bound Vol.:<br>143 CONG. REC. 4,388-4,429, 21,829-852 (1997).<br>144 CONG. REC. 16,975-995 (1998).<br><br>Daily Ed.:<br>143 CONG. REC. H1,192-1,231 (daily ed. Mar. 20, 1997).<br>143 CONG. REC. H8,640-663 (daily ed. Oct. 8, 1997).<br>144 CONG. REC. H6,190-6,213 (daily ed. July 23, 1998). | 1997 WL 125472 (Cong. Rec.)<br>1997 WL 125477 (Cong. Rec.)<br>1997 WL 617992 (Cong. Rec.)<br>1998 WL 412270 (Cong. Rec.)<br>1998 WL 412274 (Cong. Rec.)<br>1998 WL 412284 (Cong. Rec.)<br>1998 WL 412290 (Cong. Rec.)<br>1998 WL 412292 (Cong. Rec.) |

[176] Although bound editions of the congressional record are now available for the dates covered by Exs. 899-902, the exhibits received by this court were taken from daily editions. Because this opinion cites to the page numbers of the daily editions, this appendix provides the Bluebook citation for the daily edition as well as that for the bound volume.

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| Def.'s Ex. 901 | Bound Vol.:<br>141 CONG. REC. 31,539-561, 31-626-667, 31,670-72, 35,182-5,204, 35,309-319, 35,492-5,508, 35,845-892 (1995).<br>142 CONG. REC. 24,975-25,000, 25,005-029 (1996).<br><br>Daily Ed.:<br>141 CONG. REC. S16,730-752 (daily ed. Nov. 7, 1995).<br>141 CONG. REC. S16,761-6,801, S16,804-06 (daily ed. Nov. 8, 1995).<br>141 CONG. REC. S17,881-7,903 (daily ed. Dec. 4, 1995).<br>141 CONG. REC. S18,002-011 (daily ed. Dec. 5, 1995).<br>141 CONG. REC. S18,071-086 (daily ed. Dec. 6, 1995).<br>141 CONG. REC. S18,183-8,228 (daily ed. Dec. 7, 1995).<br>142 CONG. REC. S11,337-361, S11,366-389 (daily ed. Sept. 26, 1996). | 1995 WL 652739 (Cong. Rec.)<br>1995 WL 656011 (Cong. Rec.)<br>1995 WL 656014 (Cong. Rec.)<br>1995 WL 709778 (Cong. Rec.)<br>1995 WL 713546 (Cong. Rec.)<br>1995 WL 715975 (Cong. Rec.)<br>1995 WL 722593 (Cong. Rec.)<br>1996 WL 546653 (Cong. Rec.)<br>1996 WL 546667 (Cong. Rec.) |
| Def.'s Ex. 902 | Bound Vol.:<br>141 CONG. REC. 31,142-169 (1995).<br>142 CONG. REC. 6,617-18, 6,632-673, 23,815-851 (1996).<br><br>Daily Ed.:<br>141 CONG. REC. H11,593-1,618 (daily ed. Nov. 1, 1995).<br>142 CONG. REC. H2,895-2,929 (daily ed. Mar. 27, 1996).<br>142 CONG. REC. H10,608-642 (daily ed. Sept. 19, 1996). | 1995 WL 639915 (Cong. Rec.)<br>1995 WL 639916 (Cong. Rec.)<br>1995 WL 639917 (Cong. Rec.)<br>1996 WL 137032 (Cong. Rec.)<br>1996 WL 531092 (Cong. Rec.)<br>1996 WL 531093 (Cong. Rec.) |

# *Appendix II*

## *Judge's Summary Table of Individual Physicians' Statements to Congress*

| ***Name of Doctor*** | ***Claimed to Perform Abortions***[177] | ***Claimed to Use the Banned Procedure or a Variant*** | ***Position on Ban*** | ***Board-Certified OB/GYN?*** | ***Comments*** |
|---|---|---|---|---|---|
| Dr. Martin Haskell | Yes | Yes (including conversion to footling breech if necessary) | Opposed | No | Following Dr. McMahon, Dr. Haskell was the second to use the procedure. In information provided to a federal court that was placed in the record, Dr. Haskell stated that he had a complication rate of 2 per 1,000 operations for the standard D&E procedure and no complications for the banned procedure in 1,000 operations using that procedure. |
| Dr. Pamela Smith | No | No | Supported | Yes | President-Elect of American Association of Pro-Life Obstetricians and Gynecologists |
| Dr. J. Courtland Robinson | Yes | Unclear | Opposed | Unclear | Full-time OB/GYN faculty at Johns Hopkins School of Medicine. |
| Dr. Robert White | No | No | Probably supported | No | Gave statement regarding fetal pain. |
| Dr. Watson Bowes | No | No | Supported | Yes | OB/GYN Professor at University of North Carolina. |
| Dr. James McMahon | Yes | Yes (including conversion to footling breech if necessary) | Opposed | No | Pioneered procedure. In information provided to Congress, he stated that he had used the procedure 2,000 times with 5 major complications. |

[177] For purposes of this summary, I did not indicate that a physician performed abortions unless that physician specifically claimed to perform abortions when the fetus was living and as part of his or her normal practice when the doctor made his or her statements to Congress. Thus, some physicians are categorized as not performing abortions when, in fact, they do so. For example, in this table Dr. Creinin is listed as not claiming to do abortions. At trial, I learned that Dr. Creinin in fact does perform abortions. Nonetheless, the table accurately describes what Congress was told. I also followed the same protocol for the next category: "*Claimed to Use the Banned Procedure or a Variant*."

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|---|---|---|---|---|---|
| Dr. Mary Campbell | Probably | Unclear | Opposed | Yes | Observed Dr. McMahon perform the banned procedure. Medical Director of Planned Parenthood of Metropolitan Washington. |
| Dr. Norig Ellison | No | No | Neutral | No | Gave testimony on impact of anesthesiology on fetuses. |
| Dr. Dru Elaine Carlson | No | No | Opposed | Unclear | Perinatologist and geneticist who referred patients to Dr. McMahon because of serious fetal anomalies. |
| Dr. Nancy Romer | No | No | Supported | Yes | Chair of OB/GYN Department at Dayton, Ohio, hospital. |
| Dr. Warren Hern | Yes | Yes (but only on dead fetuses) | Opposed | Unclear | Author of leading textbook on abortion. |
| Dr. James Schreiber | No | No | Opposed | Probably | Professor and head of obstetrics and gynecology at Washington University Medical Center. |
| Dr. David Cromer | No | No | Opposed | Unclear | Member of the Department of Obstetrics and Gynecology at Evanston Hospital in Illinois. |
| Dr. Laurence Burd | No | No | Opposed | Unclear | Associate clinical professor of obstetrics and gynecology at the University of Illinois. Refers patients to a physician who performs the banned procedure. Believes the procedure is safe, necessary, and helpful for the determination of fetal abnormalities. |
| Dr. Antonio Scommegna | Unclear | Unclear | Opposed | Unclear | On staff at the University of Illinois at Chicago College of Medicine in the Department of Obstetrics and Gynecology. “[V]ividly recall[s]” a case where the banned procedure was necessary to avoid “spreading infection, affecting her future fertility and perhaps compromising her life.” |

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|---|---|---|---|---|---|
| Dr. Donald Sherline | Unclear | Unclear | Opposed | Unclear | On OB/GYN staff at Cook County Hospital. Holds the opinion that the banned procedure is "the safest method for the mother when carried out by an experienced operator," but also believes, on ethical grounds, that procedure should not be performed "except in the most demanding medically indicated situations." |
| Dr. Samuel Edwin | Unclear | Unclear | Opposed | Unclear | OB/GYN practitioner from Michigan. Holds the opinion that the "D&X procedure is the safest option" in medical emergencies. |
| Dr. L. Laurie Scott | No | No | Supported | Probably | Maternal-fetal medical specialist at University of Texas Southwest. |
| Dr. Margaret Nordel | No | No | Supported | Unclear | Practicing OB/GYN who holds the opinion that the procedure is "unnecessary to protect either the life or the health" of women. |
| Dr. Karen Shinn | No | No | Supported | Unclear | Practicing OB/GYN who holds the opinion that the procedure is "very dangerous and absolutely unnecessary." |
| Dr. William Rashbaum | Yes | Yes | Opposed | Probably | OB/GYN professor at Cornell School of Medicine and Albert Einstein College of Medicine. Has been using banned procedure "routinely" since 1979. |
| Dr. Herbert Jones | Yes | Yes | Opposed | Yes | Practitioner. Has needed to use the procedure two or three times. |
| Dr. David Birnbach | No | No | Probably supported | No | Gave testimony on anesthesiology. |
| Dr. David Chestnut | No | No | Probably supported | No | Gave testimony on anesthesiology. |
| Dr. Jean Wright | No | No | Probably supported | No | Gave testimony on anesthesiology. |
| Dr. Mitchell Creinin | No | No | Opposed | Unclear | Director of Family Planning at Magee-Women's Hospital. |
| Dr. Albert Corcoran | No | No | Supported | Unclear | OB/GYN practitioner. Thinks banned procedure is dangerous. |

| | | | | | |
|---|---|---|---|---|---|
| Dr. Curtis Cook | No | No | Supported | Yes | Founding member of Physicians Ad Hoc Coalition for Truth About Partial-Birth Abortion (PHACT). |
| Dr. Sheila Kuzmic | No | No | Supported | No | Pediatrician. |
| Dr. David Grimes | Yes | Yes | Opposed | Yes | Former Chief of the Department of Obstetrics, Gynecology, and Reproductive Sciences at San Francisco General Hospital; former Chief of Abortion Surveillance Branch of the Centers for Disease Control; gave an example of use of procedure, concluding that in that case "an intact D&E was the fastest and safest option available for me and to the patient." |
| Dr. C. Everett Koop | No | No | Supported | No | Former Surgeon General. Held the opinion that it was "never necessary" to perform an abortion on a viable fetus to preserve the health of the mother. |
| Dr. Kathi Aultman | No (although she did prior to 1983) | No | Supported | Yes | Member of Ethics Commission of Christian Medical and Dental Association. |
| Dr. Natalie Roche | Unclear | Unclear | Opposed | Unclear | OB/GYN professor at New Jersey Medical College. |
| Dr. Felicia Stewart | Unclear | No | Opposed | Unclear | Former Assistant Secretary for Population Affairs at Department of Health and Human Services; adjunct professor in the Department of Obstetrics, Gynecology and Reproductive Health Services and co-director of the Center for Reproductive Health Research and Policy at the University of California, San Francisco; former director of the Reproductive Health Program of the Henry J. Kaiser Family Foundation; opposed ban because she believed it would force women to have more dangerous procedures, most particularly hysterectomies. |

| | | | | | |
|---|---|---|---|---|---|
| Dr. Gerson Weiss | Unclear | Unclear | Opposed | Probably | Chair of Department of Obstetrics and Gynecology and Women's Health at New Jersey Medical College. |
| Dr. Mark Neerhof | No | No | Supported | Probably | On OB/GYN clinical faculty at Northwestern. |
| Dr. Phillip Darney | Yes | Yes | Opposed | Probably | Professor and Chief of Obstetrics, Gynecology, and Reproductive Sciences at San Francisco General Hospital and the University of California, San Francisco. Responsible for department that performs 2,000 abortions a year. Gave two very case-specific examples of the need for and safety of the banned procedure. |
| Dr. Daniel Wechter | No | No | Supported | Yes | Disagreed with Dr. Darney. |
| Dr. Steve Calvin | Yes (although rarely) | Yes (but only to save the life of the woman) | Supported | Probably | Disagreed with Dr. Darney. Co-chair of Program in Human Rights in Medicine and professor at Minnesota. |
| Dr. Nathan Hoeldtke | No | No | Supported | Yes | Disagreed with Dr. Darney. |
| Dr. Byron Calhoun | No | No | Supported | Yes | Disagreed with Dr. Darney. |
| Dr. T. Murphy Goodwin | No | No | Supported | Probably | Chief of Division of Maternal-Fetal Medicine at the University of Southern California. "Mindful of Dr. Darney's broad experience with surgical abortion," disagreed with Dr. Darney. |
| Dr. Susan Rutherford | No | No | Supported | Yes | Disagreed with Dr. Darney. |
| Dr. Camilla Hersh | No | No | Supported | Yes | Member of PHACT. |
| Dr. Lewis Marola | No | No | Supported | Unclear | Practitioner. |
| Dr. Vanessa Cullins | Probably | Unclear | Opposed | Yes | Vice-President of Medical Affairs for Planned Parenthood. |
| Dr. Anne Davis | Unclear | Unclear | Opposed | Yes | Clinical OB/GYN professor at Columbia University. |

# *Appendix III*

## *Judge's Summary Table of Physicians' Trial Testimony*

| ***Physician Performing Procedure*** | ***Types of Procedures Performed*** | ***Number of Procedures Performed*** | ***Gestational Age Procedures Performed*** | ***Induces Fetal Death Before Abortion*** | ***Frequency of Fetus Delivering Intact up to Head*** | ***Where Abortions Performed*** |
|---|---|---|---|---|---|---|
| Dr. Carhart | RU 486; vacuum aspiration; D&E; intentional intact D&E. Has performed abortions since 1988. | 1,400 per year; 180 of those in second trimester; 5 of those for fetal anomalies. | Performs intact D&E as variant of D&E at 14-17 weeks. Elective abortions up to beginning of 23 weeks; up to end of 24 weeks for medical or psychological reasons unless fetus is viable. | Yes; 18 weeks and later. | 4 to 6 times per year in patients between 13 and 18 weeks. 10% of patients over 20 weeks. | Clinic; abortions not allowed at area hospitals. |
| Dr. Fitzhugh | D&C; D&E; unintentional intact D&E. Has performed abortions since 1969. | 70 per week in first trimester; 5-7 per week in second trimester. | Prefers up to 20 weeks; occasionally later if fetus naturally dies prior to procedure. | No | 2-3 times per year. | Second-trimester abortions performed at hospital per state law. |
| Dr. Vibhakar | Medical abortions; suction curettage; D&E; induction. | 264 in second trimester in 2001-2003; 10-20% of those for fetal or maternal indications. | Through 19 weeks at independent nonprofit clinic; up to 23 weeks at University of Iowa; up to 24 weeks to save life or health of mother. | No | 1-2 times. | Independent nonprofit clinic & university hospital. |

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| Dr. Knorr | D&C; RU 486 & methotrexate; D&E; intentional intact D&Es in second trimester in rare instances.<br>Has performed abortions since early 1980s. | 5,000-6,000 in 2003. 12-15% in second trimester. | Up to 24 weeks. | Very rarely; if so, after 22 weeks. | 10 times per year in patients from 20-24 weeks; much less than that for 16-20 weeks. | Private offices |
| Dr. Howell | Has never performed or observed an abortion. | N/A | N/A | N/A | N/A | N/A |
| Dr. Mazariegos | Has never performed an abortion; has observed less than 5 first-trimester abortions in medical school. | N/A | N/A | N/A | N/A | N/A |

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| Dr. Bowes | D&C for incomplete miscarriages; suction curettage; D&E; induction of labor for fetal death; supervised induction abortions on live fetuses. | Supervised "some number" of induction abortions on live fetuses in both the first and second trimesters. Over the course of his career, supervised or assisted in performing D&Es on live fetuses in two or three cases. Performed or supervised 150 total procedures on demised fetuses, with the majority of those being inductions and the remainder supervision of D&Es. | First and second trimesters. | Saline & urea used in induction abortions cause fetal demise prior to induction. Has never injected fetal heart with substance to cause fetal demise. | Unclear | Some at University of Colorado and University of North Carolina. |
| Dr. Anand | Has never performed an abortion procedure. | N/A | N/A | N/A | N/A | N/A |
| Dr. Sprang | D&C; D&E; induction in cases of fetal demise only. Has never performed intact D&E. | 450-500 miscarriages in all trimesters. Aborted one live fetus during hysterotomy to save life of mother. | D&C up to 14 weeks; D&E up to 17 weeks; inductions for fetal demise up to 40 weeks. | N/A | N/A | Hospital |

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|---|---|---|---|---|---|---|
| Dr. Cook | Suction curettage for spontaneous miscarriage; D&Es after fetus demised in "rare instances"; no D&Es on live fetuses; medical induction. No elective abortions. | D&Es on demised fetuses once per year or less (performed 3-5 himself & supervised under 20 in his career). Inductions for fetuses less than 23 weeks 1-2 times per month. Inductions after 23 weeks once per week. | Suction curettage up to 12 weeks; medical induction after 16 weeks. | Has never used digoxin or KCl to induce fetal demise in performing medical inductions. | Unclear | Unclear; presumably hospital. |
| Dr. Shadigian | D&C; D&E; medical induction of labor, primarily on expired fetuses. Has observed D&Cs and D&Es on live fetuses. | "Hundreds" of D&Cs on expired fetuses. Helped with 30-50 D&Es on expired fetuses during residency; performed 10-20 D&Es on expired fetuses since 1994. Has induced labor for live fetuses 20-40 times in career in situations where mother would die if pregnancy not terminated. Medical induction performed weekly prior to term; it is "more rare" to use induction prior to viability. | D&Cs during 5$^{th}$ to 12$^{th}$ week; D&Es during second trimester. Performed 8 to 10 D&Es on 17- to 19-week fetuses at University of Michigan and on 20-week fetuses during residency. Medical induction most common 20 weeks and up. | No | Unknown | University of Michigan |

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|---|---|---|---|---|---|---|
| Dr. Lockwood | Dilation & aspiration or suction curettage; medical inductions. No abortions on live fetuses. | Observed 10 D&Es up to 20 weeks during residency; 3-4 per year during fellowship; 1-2 per year at Mt. Sinai, NYU & Yale. Medical inductions on nonliving fetuses 40 times during residency & continues to do so. | Dilation & aspiration or suction curettage after fetal death up to 12-13 weeks. | N/A | N/A | N/A |
| Dr. Doe | Suction curettage; manual vacuum aspiration; D&E; intentional intact D&E in some cases. | 1,130 abortions in 2003; 958 abortions in 2002; 940 abortions in 2001. | Suction curettage & manual vacuum aspiration in first trimester. D&E in second trimester. | No in fetal-indication cases. Yes in maternal-indication cases at 18 weeks and after. | In 2003, 35 fetuses delivered intact, at least to the head. | Sealed information. |
| Dr. Baergen | Not identified. No experience with D&X. | A "few [abortion] procedures" as intern in 1983 & 1984. None over past 20 years. | N/A | N/A | N/A | N/A |
| Dr. Chasen | D&C; D&E; D&X; induction abortions. | Total of 500: 200-300 D&Cs; 200-300 D&Es; 50-75 D&Xs. Supervised 50 second-trimester abortions over past year. D&E is only method of second-trimester abortion performed over last year. | D&C before 14th week. D&E from 13 to 23 weeks and 6 days (and possibly later in cases of fetal demise). | Sometimes. If yes, injects KCl into fetal heart. | 12 times per year. | Clinic at the New York Weill/Cornell Medical Center. |

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| Dr. Broekhuizen | D&C; second-trimester D&E; second-trimester induction abortions. | D&Es and induction abortions are "regular" part of practice for past 20 years. 400-500 D&Es over career, with 90 to 95% involving dismember-ment. Total number of inductions unknown, but more inductions than D&Es. | D&Es up to 20 weeks. Inductions up to 24 weeks, the legal limit in Wisconsin. Inductions past 24 weeks only in cases of lethal fetal anomalies. | 30-40 total times by injecting digoxin into amniotic fluid in induction abortions. Never with D&Es. | Unclear | D&Es on outpatient basis at hospital. Unless completed within 23 hours, medical-induction abortion is inpatient hospital procedure. |
| Dr. Frederiksen | D&C; D&E; intentional intact D&E; medical induction. | Thousands of D&Es over career; approximately 100-125 per year. | 23 and 5/7 weeks for elective abortions. Has performed induction abortions at 20 to 24 weeks. After 24 weeks, only induction for lethal fetal anomalies. | Yes, for labor induction with misoprostol. Injects digoxin or KCl into fetal heart. No for D&Es, except at woman's specific request. | Unknown | Hospital |
| Dr. Creinin | Medical abortions; D&C; D&E; intact D&E. No induction abortions for past 10 years. | 5,000 over career; 500 per year. Has performed 3 intact D&Es, as defined by ACOG, over career. | Medical abortions through 9 weeks; D&Cs through 14 or 15 weeks; D&Es from 14 to 15 weeks through 23 and 6/7 weeks (limited to 56 millimeters biparietal diameter). | No | 50 times in career. | Planned Parenthood clinic up to 18 weeks. Hospital at 18 weeks and beyond. |

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| Dr. Westhoff | Medical abortions; D&C; labor induction (in the past); D&E, including intact D&E. | Several thousand abortions since 1978. Several hundred labor inductions over career; 400 out of 500 second-trimester abortions were by induction in 1997; since Special GYN Services opened in 2001, refers labor-induction cases. 750 D&Es (including intact D&Es) in 2001-2003. | Medical abortions up to 9 weeks. D&Cs up to 12 or 13 weeks. D&Es 14 weeks through 23 and 6/7 weeks. Intact D&Es more common after 18 to 20 weeks through 23 and 6/7 weeks. | No | Unclear | Hospital and unidentified facility with operating rooms and access to general anesthesia. |
| Dr. Paul | Medical abortions; D&C; D&E, including intact D&E. | Unknown | D&Es up to 18 and 6/7 weeks, although trained in residency to perform D&Es up to 23 weeks. | Unknown | "1 to 10 to 1 to 20" | Planned Parenthood outpatient clinics. |
| Dr. Clark | D&C; labor induction; dismemberment D&E. Never performed intact D&E. Abortions done only when medically necessary. Has "read about" the intact D&E, but has never seen one being performed. | 12 first-trimester abortions on live fetuses; less than 20 labor-induction abortions; 12 D&Es on live fetuses. In cases of spontaneous abortion (miscarriage or demised fetus), hundreds of procedures, with D&C and labor induction the most common. | D&Cs in first trimester; D&Es never beyond 20 weeks; labor induction to term. | No | Never | Unknown |

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|---|---|---|---|---|---|---|
| Dr. Hammond | Medical abortion; D&C; labor induction; D&E, including intact D&E. | Has performed abortions for 15 years; at least 3,000 total performed, with 1,000 of those being D&Es. At 20 to 24 weeks, 95% are D&Es and remainder are labor induction. | 24 weeks is latest gestational age procedures are performed. | No | In half of D&Es at 20-24 weeks, Dr. Hammond is able to remove the fetus intact to the level of the fetal navel or above. Fetus delivers intact to level of calvarium at least 3 times per month. | Hospital |
| Dr. Cain | D&E; labor induction; hysterectomy for cervical carcinoma; hysterotomy. Has never performed intact D&E or other elective abortion. | Less than 25 D&Es over career; less than 5 inductions over career; 1 hysterotomy; less than 10 hysterectomies. | Unknown | Unknown | Unknown | Unknown |

## *Appendix IV*

## *Exhibits Received for Limited Purpose*

Ex. 3, Press Release, American College of Obstetricians and Gynecologists [hereinafter ACOG], Statement on So-Called "Partial Birth Abortion" Law (Oct. 3, 2003) (stating that "intact D&X 'may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman'").

Ex. 4, Statement, ACOG, The American College of Obstetricians and Gynecologists On the Subject of "Partial-Birth Abortion" Bans (July 8, 2002) (opposing the ban "as an inappropriate, ill-advised and dangerous intervention into medical decision making").

Ex. 5, Statement, ACOG Executive Board, Statement of Policy: Abortion Policy (Sept. 2000) (stating that "[t]erminating a pregnancy is performed in some circumstances to save the life or preserve the health of the mother[,]" and "[i]ntact D&X is one of the methods available in some of these situations. . . ACOG could identify no circumstances under which this procedure . . . would be the only option to save the life or preserve the health of the woman. An intact D&X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor. . . can make this decision.").

Ex. 6, Statement, ACOG Executive Board, Statement of Policy: Statement on Intact Dilation and Extraction (Jan. 12, 1997) (same).

Ex. 7, ACOG, Fact Sheet on the January 1997 ACOG Policy Statement Regarding Intact Dilation and Extraction (Apr. 4, 1997) (elaborating on and responding to possible concerns about ACOG's policy position, stating in reference to safety that "ACOG is unaware of any comparative maternal morbidity studies specifically evaluating Intact D&X procedures with other methods of abortion. However, . . . other data have shown that second trimester instrumental abortion is safe.").

Ex. 9, ACOG Technical Bulletin No. 109, Methods of Midtrimester Abortion (Oct. 1987) (concluding that "[d]ata suggest that D&E may be faster, safer, and more acceptable to patients than induction of labor").

Ex. 11, ACOG Executive Board Minutes at 4 & 19 (Jan. 11-13, 1997) (noting internal ACOG board discussions over a "Statement on Intact Dilations and Extraction" and revisions of that statement).

Ex. 13, Letter from Dr. Seward (Vice President, American Medical Association) to Sen. Santorum of 5/19/97 (expressing AMA support for HR 1122 due to its incorporation of an exception to save

the life of the mother, the clear definition of the procedure within the bill, and the right of the accused physician to have his or her conduct reviewed by the State Medical Board prior to a criminal trial), with attached AMA Board of Trustees Report 26-A-97, presented by Dr. Dickey (June 1997) (presenting medical, legal, and ethical perspectives on abortion).

Ex. 14, Letter from Dr. Epstein (President, American Medical Women's Association) to Rep. Nadler of 3/25/03 (opposing ban as "an inappropriate intervention in the decision-making relationship between physician and patient" and as an imprecise bill that "may ultimately undermine the legality of other techniques . . . used in . . . abortion and non-abortion situations").

Ex. 15, Letter from Dr. Silva (American Medical Women's Association) to Rep. Chabot of 7/18/02 (same).

Ex. 16, Memorandum from American Medical Women's Association to John Ashcroft of 12/19/03 (same).

Ex. 17, Letter from Dr. Benjamin (Executive Director, American Public Health Association) to House of Representatives of 3/31/03 (opposing the ban because "restrictions to safe, medically accepted abortion procedures severely jeopardize women's health and well-being[,]" and because "it fails to include adequate health exception language").

Ex. 18, American Public Health Association, Opposition to Constitutional Amendments or Statutes to Prohibit Abortion (1981), available at http://www.apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=976 (opposing any restriction on the provision of safe and legal abortion services).

Ex. 18, American Public Health Association, Safeguarding the Right to Abortion as a Reproductive Choice (1989), available at http://www.apha.org/legislative/policy/policysearch/index.cfm?fuseaction=view&id=1180 (reaffirming APHA commitment to legal right of women to accessible, affordable, and safe abortion services).

Ex. 19, Amy M. Autry, et al., A comparison of medical induction and dilation and evacuation for second-trimester abortion, 187 Am. J. Obstet. & Gynecol. 393 (2002) (concluding that overall complication rate was significantly lower in patients who underwent dilation and evacuation than in patients who underwent medical induction).

Ex. 20, Nancy J. Binkin, Trends in Induced Legal Abortion Morbidity and Mortality, 13 Clinics in Obstet. & Gynaecol. 83 (1986) (attributing declining abortion mortality rates in the United States to

a "downward shift in the gestational ages at which abortions are obtained and the increased use of D&E for abortions at 12 gestational weeks or later").

Ex. 21, Trude A. Bennett, et al., Pregnancy-associated hospitalizations in the United States in 1991 and 1992: A comprehensive view of maternal morbidity, 178 Am. J. Obstet. & Gynecol. 346 (1998) (concluding that because of under-reporting and changes in medical care, recent declines in maternal hospitalization may not represent true reductions in maternal morbidity).

Ex. 22, William M. Callaghan & Cynthia J. Berg, Pregnancy-Related Mortality Among Women Aged 35 Years and Older, United States, 1991-1997, 102 Obstet. & Gynecol. 1015 (2003) (concluding that "[r]ecognition of the risk of death borne by older pregnant women is needed to inform their care").

Ex. 24, Willard Cates, et al., The Public Health Impact of Legal Abortion: 30 Years Later, 35 Persp. on Sexual & Reprod. Health 25 (2003) (finding that since Roe v. Wade there has been a reduction in abortion-related complications and deaths).

Ex. 25-26, Stephen Chasen, et al., Dilation and evacuation at ≥20 weeks: Comparison of Operative techniques (2004) (draft versions one and two; draft one concluding that "[d]ilation and evacuation with intact extraction is as safe as dilation and extraction with disarticulation after 20 weeks' gestation"; draft two concluding that "[o]utcomes appear similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation").

Ex. 27, Stephen Chasen, et al., Dilation and Evacuation at ≥20 Weeks: Comparison of Operative Techniques, 190 Am. J. Obstet. & Gynecol. 1180 (2004) (concluding that "[o]utcomes appear similar between patients undergoing dilation and evacuation and intact dilation and extraction after 20 weeks' gestation").

Ex. 28, Stephen Chasen, et al., Data Chart (representing underlying data for Chasen publication, supra at Ex. 27).

Ex. 30, Letter from Cornell Univ. Med. Coll. Inst'l Review Bd. to Dr. Chasen of 3/20/03 (approving protocol for study in Chasen publication, supra at Ex. 27).

Ex. 34, Centers for Disease Control and Prevention [hereinafter CDCP], Pregnancy-Related Mortality Surveillance–United States, 1991-1999, 52 Morbidity & Mortality Wkly. Rep. 1 (2003) (finding that reported pregnancy mortality rate substantially increased during 1991-1999, probably because of improved ascertainment of pregnancy-related deaths).

Ex. 36, Isabella Danel, et al., Magnitude of Maternal Morbidity During Labor and Delivery: United States, 1993-1997, 93 Am. J. Pub. Health 631 (2003) (finding 43% of women experienced some type of adverse complication during labor and delivery).

Ex. 41, Janet E. Gans Epner, et al., Late-term Abortion, 280 JAMA 724 (1998) (finding that mortality and morbidity rates for D&E are lower than for labor induction, hysterotomy, and hysterectomy, but the rates between D&E and induction become similar after 20 weeks of gestation).

Ex. 44, David A. Grimes, et al., Mifepristone and misoprostol versus dilation and evacuation for midtrimester abortion: a pilot randomised controlled trial, 111 Brit. J. Obstet. & Gynecol. 148 (2004) (study comparing D&E with induction stopped after one year because most women participating chose D&E abortions rather than allowing the method to be randomly selected).

Ex. 45, David A. Grimes, The Continuing Need for Late Abortions, 280 JAMA 747 (1998) (discussing evidence that D&E is safer than induction, and proposing that intact D&E could be "useful in the presence of fetal anomalies, such as hydrocephalus").

Ex. 50, Warren M. Hern, Abortion Practice, ch. 5, at 101-60 (J.B. Lippincott Co. 1990) (describing operative procedures and techniques for first- and second-trimester abortions, no specific mention made of intact D&E).

Ex. 51, Hugh L. Hodge, The Principles and Practice of Obstetrics 231-73 (Henry C. Lea 1866) (textbook with chapter discussing craniotomy, "the most ancient of obstetric operations." "Delivery by this operation implies perforation of the head, diminution of its size, and then its deliverance.").

Ex. 58, Herschel W. Lawson, et al., Abortion mortality, United States, 1972 through 1987, 171 Am. J. Obstet. & Gynecol. 1365 (1994) (finding that before 1977 infection and hemorrhage were the leading causes of abortion-related deaths, but since 1983 anesthesia complications have been the most frequent causes).

Ex. 59, Herschel W. Lawson, et al., Abortion Surveillance, United States, 1984-1985, 38 Morbidity & Mortality Wkly. Rep. 11(1989) (reporting that abortion mortality rates remained stable between 1984 and 1985).

Ex. 64, James T. McMahon, Intact D&E: The First Decade (presented April 2, 1995, to National Abortion Federation Conference) (describing technique of intact D&E and the comparative costs/benefits of intact D&E with those of classical D&E).

Ex. 70, Maureen Paul, et al., A Clinician's Guide to Medical and Surgical Abortion 39-89, 107-167, 197-228 (Churchill Livingstone 1999) (textbook describing technique of intact D&E, along with other abortion techniques).

Ex. 73, D. Schneider, et al., Abortion at 18-22 Weeks by Laminaria Dilation and Evacuation, 88 Obstet. & Gynecol. 412 (1996) (finding that late second-trimester termination by laminaria dilation and evacuation is safe and probably not associated with future adverse pregnancy outcomes).

Ex. 74, Lee P. Shulman, Dilation and Evacuation for Second-Trimester Genetic Pregnancy Termination, 75 Obstet. & Gynecol. 1037 (1990) (stating that D&E carries morbidity and mortality rates significantly lower than labor induction, but labor induction is the most commonly used method for genetic terminations, probably because it produces an intact fetus which may more consistently confirm genetic abnormalities, and arguing that "D&E is reliable in confirming most prenatal diagnoses and should be the procedure of choice when second-trimester pregnancy termination is chosen because of fetal abnormalities.").

Ex. 110, Uriel Elchalal, et al., Maternal Mortality Following Diagnostic 2nd-Trimester Amniocentesis, 19 Fetal Diagnosis & Therapy 195 (2004) (presenting two cases of maternal mortality after transabdominal amniocentesis).

Ex. 536, Kanwaljeet S. Anand & Bonnie Taylor, Consciousness and the Fetus, Bioethics Newsletter 2 (Am. Acad. Pediatrics, Elk Grove Village, Ill., Jan. 1999) (suggesting that the human fetus may perceive pain, which should be alleviated during fetal surgery or late abortion).

Ex. 537, K. J. S. Anand, et al., Consciousness, Behavior, and Clinical Impact of the Definition of Pain, 8 Pain Forum 64 (1999) (arguing that the current definition of pain is flawed in that it relies too much on linguistic evidence of the subjective experience of pain).

Ex. 538, K. J. S. Anand & Mervyn Maze, Fetuses, Fentanyl, and the Stress Response: Signals from the Beginnings of Pain?, 95 Anesthesiology 823 (2001) (suggesting that the human fetus may perceive pain, which should be alleviated during fetal surgery or late abortion).

Ex. 539, K. J. S. Anand & Kenneth D. Craig, Editorial: New perspectives on the definition of pain, 67 Pain 3 (1996) (same).

Ex. 540, K. J. S. Anand, et al., Pain and its Effects in the Human Neonate and Fetus, 317 New Eng. J. Med. 1321 (1987) (concluding that pain pathways and cortical centers necessary for pain

perception are well developed late in gestation of human fetuses, although the data does not prove that fetuses subjectively experience pain as older children and adults do).

Ex. 543, John Aucar, Editorial Forward: Art, science and craftwork: the role of evidence in surgery, 1 Evidence-Based Surgery 1 (1999) (editor's comment introducing a new journal devoted to discussing the ways various types of evidence can inform and advance surgical techniques).

Ex. 544, B. M. Audu, et al., Diagnostic features of cervical incompetence among women in Maiduguri, 23 J. Obstet. & Gynaecol. 130 (2003) (in a review of 146 cases of cervical cerclage, 80% of the women had a history of previous midtrimester (spontaneous or otherwise) abortions, and 5% of the women had a history of induced abortions).

Ex. 548, Adnan T. Bhutta & K. J. S. Anand, Vulnerability of the developing brain neuronal mechanisms, 29 Clinics in Perinatology 357 (2002) (proposing that two primary mechanisms lead to enhanced neuronal cell death in neonatal brains: excitotoxicity resulting from repetitive or prolonged pain, and enhanced neuronal apoptosis due to multiple metabolic stresses or lack of social stimulation).

Ex. 552, Ronald A. Chez, Cervical Ripening and Labor Induction After Previous Cesarean Delivery, 38 Clinical Obstet. & Gynecol. 287 (1995) (finding that the preponderance of published data on pregnant women attempting a vaginal birth after previous cesarean indicates that if there is no contraindication to spontaneous cervical ripening, there is no contraindication to use of prostaglandin gel or tents to achieve ripening and there is no contraindication to use of oxytocin or amniotomy to induce labor if there is no contraindication to the spontaneous onset of labor).

Ex. 555, Volkan Coskun & K. J. S. Anand, Development of supraspinal pain processing, in Pain in Neonates 23-54 (Elsevier Science B.V. 2d ed. 2000) (finding that data support the conclusion that the pain system undergoes a major reorganization during the perinatal period of life, and that the onset of inhibitory supraspinal processing is a critical component required for the emergence of specific pain behaviors).

Ex. 556, A. D. Craig, A new view of pain as a homeostatic emotion, 26 Trends in Neurosciences 303 (2003) ("findings indicate that the human feeling of pain is both a distinct sensation and a motivation—that is, a specific emotion that reflects homeostatic behavioral drive, similar to temperature, itch, hunger and thirst").

Ex. 558, Philip D. Darney & R. S. Sweet, Routing Intraoperative Ultrasonography for Second Trimester Abortion Reduces Incidence of Uterine Perforation, 8 J. Ultrasound in Med. 71 (1989) (study of D&E second-trimester abortions showed "[t]he routine intraoperative use of

ultrasonographic imaging to guide intrauterine forceps during uterine evacuation . . . resulted in a significant reduction in uterine perforation, the rate declining from 1.4% to .2%.").

Ex. 560, Eleanor A. Drey, et al., Safety of intra-amniotic digoxin administration before late second-trimester abortion by dilation and evacuation, 182 Am. J. Obstet. & Gynecol. 1063 (2000) (concluding that intra-amniotically administered digoxin may be considered safe for use before late second-trimester pregnancy terminations for some, but not all, patients).

Ex. 563, Nicholas M. Fisk, et al., Effect of Direct Fetal Opioid Analgesia on Fetal Hormonal and Hemodynamic Stress Response to Intrauterine Needling, 95 Anesthesiology 828 (2001) (concluding that direct administration of fentanyl blunts the fetal stress response to intrauterine needling).

Ex. 564, Maria Fitzgerald, Spontaneous and evoked activity of fetal primary afferents in vivo, 326 Nature 603 (1987) (finding repeated stimulation of fetuses caused "long-lasting increases of both background and evoked activity. Such sensory input is likely to have a considerable influence on fetal movements and on the development of spinal cord connections.").

Ex. 566, Xenophon Giannakoulopoulos, et al., Fetal plasma cortisol and *B*-endorphin response to intrauterine needling, 344 Lancet 77 (1994) (finding data suggesting that the fetus mounts a hormonal stress response to invasive procedures, which raises the possibility that the human fetus feels pain in utero, and may benefit from anesthesia or analgesia for invasive procedures).

Ex. 567, Xenophon Giannakoulopoulos, et al., Human Fetal and Maternal Noradrenaline Responses to Invasive Procedures, 45 Pediatric Res. 494 (1999) (study results indicate that the fetus is capable of mounting an independent noradrenaline stress response to a needle transgressing its trunk from 18 weeks of gestation).

Ex. 570, Rachel Gitau, et al., Fetal Hypothalamic-Pituitary-Adrenal Stress Responses to Invasive Procedures Are Independent of Maternal Responses, 86 J. Clinical Endocrinology & Metabolism 104 (2001) (study results indicate a correlation between fetal and maternal cortisol levels, but not between fetal and maternal *B*-endorphin levels, suggesting cortisol transfer across the placenta, and fetal *B*-endorphin responses were apparent from 18 weeks of gestation and were independent of gestational age, whereas fetal cortisol responses were apparent from 20 weeks of gestation and were dependent on gestational age).

Ex. 574, Patricia S. Goldman-Rakic, Development of Cortical Circuitry and Cognitive Function, 58 Child Development 601 (1987) (finding that anatomical tracing in primate fetuses indicates various classes of cortical connections begin to form by the second trimester of pregnancy).

Ex. 577, David A. Grimes & Kenneth F. Schulz, Morbidity and Mortality from Second-Trimester Abortions, 30 J. Reprod. Med. 505 (1985) (concluding that D&E appears to be the safest method of second-trimester abortion available in the United States).

Ex. 585, Laurence Henriet & Monique Kaminski, Impact of induced abortions on subsequent pregnancy outcome: the 1995 French national perinatal survey, 108 Brit. J. Obstet. & Gynecol. 1036 (2001) (study suggests a history of induced abortion increases the risk of preterm delivery, but more studies are needed to understand the roles of surgical versus medical abortion techniques).

Ex. 586, Peter G. Hepper, The beginnings of mind–evidence from the behavior of the fetus, 12 J. Reprod. & Infant Psychol. 143 (1994) (study of the prenatal ontogenesis of behavior suggests "that the mind will emerge in an immature form and that stimulation received in utero, and the behavior emitted, will play an important role in its development").

Ex. 590, International Association for the Study of Pain, IASP Pain Terminology (Feb. 13, 2004), available at http://www.iasp-pain.org/terms-p.html (providing definitions for terms related to pain).

Ex. 596, Robin B. Kalish, et al., Impact of midtrimester dilation and evacuation on subsequent pregnancy outcome, 187 Am. J. Obstet. & Gynecol. 882 (2002) (finding that second-trimester D&E is not a risk factor for midtrimester pregnancy loss or spontaneous preterm birth, and that preterm delivery in future gestations appears less likely when greater preoperative cervical dilation is achieved with laminaria, possibly because of a decrease in cervical trauma).

Ex. 598, Hannah C. Kinney, et al., Three-Dimensional Distribution of 3H-Naloxone Binding to Opiate Receptors in the Human Fetal and Infant Brainstem, 291 J. Comp. Neurology 55 (1990) (finding that by midgestation the regional distribution of 3H-naloxone binding in human fetuses is similar, but not identical, to that in infants).

Ex. 599, Ernest A. Kopecky, et al., Fetal response to maternally administered morphine, 183 Am. J. Obstet. & Gynecol. 424 (2000) (study provides evidence that morphine transfer across the human placenta significantly affects some components of the fetus's biophysical profile score).

Ex. 607, Martin F. McKneally & Abdallah S. Daar, Introducing New Technologies: Protecting Subjects of Surgical Innovation and Research, 27 World J. Surgery 930 (2003) (noting that most important advances in the history of medicine "were introduced through an informal, unregulated innovation process that has been enormously productive but can lead to ratification of ineffective or harmful treatment" and suggesting a "surgical innovation ethics paradigm that is a more nimble, flexible source of institutional and public oversight").

Ex. 609, Neena Modi & Vivette Glover, Fetal pain and stress, in Pain Research and Clinical Management 217-227 (Elsevier Science B.V. 2d ed. 2000) (stating that "[a]lthough there is not enough evidence to be certain, given the possibility that pain perception might be present in the fetus during the second trimester, it is reasonable to consider analgesia or anesthesia during potentially painful procedures from this time").

Ex. 610, Mark E. Molliver, et al., The development of synapses in cerebral cortex of the human fetus, 50 Brain Res. 403 (1991) (reporting presence of cortical synapses detected in a fetus at 8.5 weeks of gestation).

Ex. 612, Carl-Joachim Partsch, et al., The Steroid Hormonal Milieu of the Undisturbed Human Fetus and Mother at 16-20 Weeks Gestation, 73 J. Clinical Endocrinology & Metabolism 969 (1991) (study shows several important steroid hormones are actively secreted by fetus independently of the mother at 16-20 weeks of gestation).

Ex. 618, Angelique M. Reitsma & Jonathan D. Moreno, Ethical Regulations for Innovative Surgery: The Last Frontier?, 194 J. Am. Coll. Surg. 792 (2002) (suggesting that the current system of definitions, ethical theories, and voluntary professional guidelines may be inadequate to meet the challenge of surgical innovation).

Ex. 624, Lee P. Shulman & Sherman Elias, Second-Trimester Pregnancy Termination by Dilation and Evacuation After Detection of Fetal Abnormalities, 1 J. Women's Health 255 (1992) (concluding that D&E performed by experienced physicians is reliable for confirming most prenatal diagnoses and should be offered to women who elect to terminate pregnancies in the second trimester because of fetal abnormalities).

Ex. 625, Richard P. Smith, et al., Pain and stress in the human fetus, 92 Eur. J. Obstet. & Gynecol. & Reprod. Biology 161 (2000) (noting that it is not known if the fetus feels pain, but from 18-20 weeks the fetus does mount significant stress hormonal and circulatory changes in response to invasive procedures, but finding the optimal drug, dose, and route of administration of fetal anesthesia remains to be determined).

Ex. 627, Steven M. Strasberg & Philip A. Ludbrook, Who Oversees Innovative Practice? Is There a Structure that Meets the Monitoring Needs of New Techniques?, 196 J. Am. Coll. Surg. 938 (2003) (discussing the unexpected harm to patients that can come from seemingly safe surgical innovations, the lack of a formal compulsory regulatory system overseeing some categories of innovative procedures, and proposing solutions).

Ex. 629, Jeronima Teixeira & Roberto Fogliani, Fetal haemodynamic stress response to invasive procedures, 347 Lancet 624 (1996) (letter to the editor claiming to have shown that the fetus mounts a stress-hormone response to invasive procedures that transgress the fetal trunk).

Ex. 630, Jeronima Teixeira, et al., Acute cerebral redistribution in response to invasive procedures in the human fetus, 181 Am. J. Obstet. & Gynecol. 1018 (1999) (study shows that invasive procedures involving transgression of the fetal body are associated with a fetal hemodynamic stress response that is consistent with redistribution of blood supply to the brain).

Ex. 631, John M. Thorp, et al., Long-term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence, 58 Obstet. & Gynecol. Surv. 67 (2002) (finding that induced abortion is a risk factor for placenta previa, subsequent preterm delivery, and mood disorders).

Ex. 633, Sampsa Vanhatalo & Onno van Nieuwenhuizen, Fetal pain?, 22 Brain & Dev. 145 (2000) (concluding that "it is not reasonable to speculate on the possible emotional experiences of pain in fetuses or premature babies. A clinically relevant aim is rather to avoid and/or treat any possibly noxious stimuli, and thereby prevent their potential adverse effects on the subsequent development.").

Ex. 635, M. P. Ward Platt, et al., The ontogeny of the metabolic and endocrine stress response in the human fetus, neonate and child, 15 Intensive Care Med. S44 (1989) (finding evidence of an endocrine and metabolic response to stress from the midtrimester of fetal life).

Ex. 637, F. G. Cunningham, et al., Techniques for breech delivery, in Williams Obstetrics (19th ed., Appleton & Lange) (describing and diagraming various techniques and positions of breech delivery).

Ex. 647, American College of Surgeons, Statement on Emerging Surgical Technologies and the Evaluation of Credentials, reprinted from 79 Bull. Am. Coll. Surgeons 40-41 (1994), available at http://www.facs.org/fellows_info/statements-18.html (outlining guidelines for evaluating the safety, efficacy, and costs of potentially important new surgical procedures, and for evaluating credentials of individuals for the purpose of awarding surgical privileges in new technologies).

Ex. 648, American College of Surgeons, Statement on Issues to Be Considered Before New Surgical Technology is Applied to the Care of Patients, reprinted from 83 Bull. Am. Coll. Surgeons 46-47 (1995), available at http://www.facs.org/fellows_info/statements/st-23.html (stating that evaluation of the value and safety of new biomedical technology to patients should include comparisons with proven technologies, and qualifications of those who propose to use the new technology must be carefully assessed).

Ex. 655, ACOG, Statement on Intact Dilation and Extraction (unpublished, undated draft) (stating that intact D&X is one method available when termination of a pregnancy is indicated to save the life or preserve the health of the mother, but an ACOG panel could identify no circumstance under which it would be the only method).

Ex. 656, Letter from Pres. Clinton to Dr. Hale of 7/3/96, attaching Statement from Pres. Clinton to the House of Rep. of 4/10/96 (stating that he would not approve H.R. 1833 in part because he had heard from women who "were devastated to learn that their babies had fatal conditions . . . who were advised by their doctors that this procedure was their best chance to avert the risk of death or grave harm which, in some cases, would have included an inability to ever bear children again").

Ex. 657, Letter from Dr. Grimes to Sen. Byrd of 11/30/95 (stating in response to specific questions that the proposed banned procedure is "in reality, an old obstetric procedure" used for centuries called "internal podalic version" followed by "total breech extraction," that many fetal genetic defects are difficult to detect prior to 16 weeks of gestation, and that a fetus cannot feel pain as adults perceive it).

Ex. 658, Statement, ACOG, Later Abortions: Questions and Answers (undated) (giving ACOG position on why it opposes the ban).

Ex. 659, Statement, National Abortion Federation, Third-Trimester Abortion: The Myth of "Abortion on Demand" (June 14, 1995) (stating that the "D&X procedure that opponents of choice want to ban is often the safest available for late abortions").

Ex. 660, National Abortion Federation, Fact Sheet: Abortion After Twelve Weeks (Oct. 1992) (stating that early abortions are the safest, but some abortions after 12 weeks are unavoidable).

Ex. 661, Martin Haskell, Dilation and Extraction for Late Second Trimester Abortion, presented at National Abortion Federation Risk Management Seminar (Sept. 13, 1992) (describing the procedure, the range of patients for which it may be appropriate, and some advantages and disadvantages of the technique).

Ex. 662, Wisconsin Right to Life Education Fund, The D&X Abortion Procedure: Scientific Advancement or Human Rights Abuse? (undated) (leaflet showing diagram of procedure).

Ex. 663, Allan Rosenfield, Congress Plays Doctor, N.Y. Times, April 1, 1996 (editorial) (stating that the anguished decision to use dilation and extraction is usually reached when a woman's life or

health would be jeopardized if the pregnancy is continued or if there is a fetal abnormality incompatible with life).

Ex. 664, Abortion Politics, N. Y. Times, Mar. 31, 1996 (editorial) (stating that opponents of the ban argue that an exception to preserve the life of the mother is too narrow).

Ex. 665, ACOG, The Partial-Birth Abortion Ban Act of 1995: Medical Assertions Made in the Debate on H.R. 1833 (undated) (list of quotations, with sources, from the house debate, expressing a variety of views on the ban).

Ex. 666, Memorandum from Bryant to ACOG Task Force on Third-Trimester Abortion of 9/26/96 (with attachments) (reviewing ACOG District II document Medical Question and Answers on Third Trimester Termination Procedures, expressing concern about possible lack of documentation for document's claims that "[the banned procedure] is done in hospitals by medical providers with special training," that "the medications which are used to anesthetize the mother cross the placenta and anesthetize the fetus," and that "this procedure is not done in the third trimester if the fetus is viable").

Ex. 667, Letter from Dr. Nusbaum to Dr. Murphy of 8/1/96 (suggesting specific wording changes to Information Sheet, and concluding that the assertion that "[t]his procedure is not done in the third trimester if the fetus is viable" is accurate in New York state) (attaching ACOG District II Information Sheet, Medical Questions and Answers on Third Trimester Termination Procedures & letter from Dr. Frigoletto to Dr. Murphy of 7/3/96) (suggesting severe interuterine sepsis as a third-trimester complication that might require termination of a pregnancy, questioning whether all intact D&Es are actually performed under general anesthesia, and questioning whether Information Sheet's assertion that "[t]his procedure is not done in the third trimester if the fetus is viable" is absolutely true)).

Ex. 668, Memorandum from Elsa P. Brown to ACOG Task Force on Third-Trimester Abortion of 10/3/96 attaching National Abortion Federation Leaflet, Later Abortions: Questions and Answers (providing statistics on how often late abortions occur); Alan Guttmacher Institute, Abortion Factbook 1992 Edition: Readings, Trends, and State and Local Data to 1988 (Stanley K. Henshaw & Jennifer Van Vort eds. 1992) (same); Kenneth D. Kochanek, Induced Terminations of Pregnancy: Reporting States, 1988, 39 Monthly Vital Statistics Rep. 1, 6-7 (1991) (reporting statistics on frequency of abortion at various gestational ages for various demographic groups).

Ex. 671, Statement, ACOG, Statement on H.R. 1833: The Partial-Birth Abortion Ban Act of 1995 (Nov. 1, 1995) (stating ACOG's opposition to ban and belief that congressional opinion should never be substituted for professional medical judgment).

Ex. 671, Letter from Dr. Hale (ACOG) to Sen. Dole of 11/6/95 (same).

Ex. 671, Letter from Dr. Hale (ACOG) to Pres. Clinton of 4/9/96 (same).