FILED BY CLERK KS. DISTRICT COURT THIRD JUDICIAL DIST. TOPEKA, KS

# IN THE SECOND JUDICIAL DISTRICT DISTRICT COURT, SHAWNEE COUNTY, KANSAS DIVISION 7

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HODES & NAUSE HERBERT C. HOI TRACI LYNN NAU	ES, M.D.; and	) ) ) ) )	
	Plaintiffs,	) Case No	
v.		)	
DEREK SCHMIDT capacity as Attorne	y General	) )	
	as; and STEPHEN M.	)	
Attorney for Johnson	al capacity as District on County,	)	
		)	
		)	
	Defendants.	)	

# MOTION FOR TEMPORARY INJUNCTION AND/OR TEMPORARY RESTRAINING ORDER

Come now the Plaintiffs and pursuant to K.S.A. § 60-903 and § 60-905 hereby apply to this honorable Court for the issuance of a Temporary Injunction and/or a Temporary Restraining Order enjoining Defendants, their agents, and their successors in office from enforcing Kansas Senate Bill 95 (2015) (the "Act"), which is scheduled to take effect on July 1, 2015. The Act will ban the most commonly-used method of abortion in the second trimester. Enforcement of this unprecedented restriction will cause Plaintiffs' patients seeking abortions affected by the Act to either undergo a more complex, lengthy, and risky procedure, with no medical benefit, to ensure

fetal demise, or forgo the abortion altogether. The burdens imposed by the Act violate the privacy and bodily integrity rights of Plaintiffs' patients protected by the Kansas Constitution. In support of this motion, Plaintiffs submit a memorandum of law and the affidavits of Traci Lynn Nauser, M.D. (Exhibit 1), Anne Davis, M.D., M.P.H. (Exhibit 2), and David Orentlicher, M.D., J.D. (Exhibit 3). In addition, Plaintiffs attach the decisions in *Hodes & Nauser, MDs v. Robert Moser, M.D.*, No. 11-C-1298, Dist. Ct. of Shawnee Cnty, Kan., Div. 7, Order Granting Temporary Restraining Order (Nov. 10, 2011) (Exhibit 4) and *Hodes & Nauser, MDs v. Schmidt*, No. 2013-CV-705, Dist. Ct. of Shawnee Cnty, Kan., Div. 1, Memorandum Decision and Order on Temporary Injunction (June 28, 2013) (Exhibit 5).

As set out in the accompanying memorandum of law, Plaintiffs have demonstrated their entitlement to a temporary injunction, which will prevent injury to their patients and maintain the status quo pending final resolution of the significant constitutional claims at issue. See Idbeis v. Wichita Surgical Specialists, P.A., 285 Kan. 485, 491 (2007) (citing Steffes v. City of Lawrence, 284 Kan. 380, 394 (2007)). Plaintiffs have shown: (1) a substantial likelihood of success on the merits of their claims that enforcement of the Act will violate the privacy and bodily integrity rights of their patients under the Kansas Constitution; (2) that there is a reasonable probability that Plaintiffs' patients will suffer irreparable injury if the Act is allowed to take effect through the imposition of an undue burden on their privacy right to abortion and invasion of their right to bodily integrity as a prerequisite to effectuating their decision to have an abortion; (3) that there is no adequate remedy at law for these violations; (4) that neither the Defendants nor the public interest will be harmed where an injunction will maintain the status quo and prevent the threat of serious and irreparable injury to Plaintiffs' patients. See id. at 492; Steffes, 284 Kan. at 394; Adams

v. Baker, 919 F. Supp. 1496, 1505 (D. Kan. 1996) (finding the public interest would best be served by enjoining the defendants from infringing the plaintiff's constitutional right).

Plaintiffs request that the Court rule on the Motion for Temporary Injunction prior to the July 1 effective date of the Act. In the event that the Court is unable to rule on the motion prior to that time, Plaintiffs seek, in the alternative, a Temporary Restraining Order to remain in effect until the Motion for Temporary Injunction is decided.

Plaintiffs further request that if a Temporary Injunction or Temporary Restraining Order is issued, the Court exercise its discretion under K.S.A. § 60-905(b), to enter the Order without requiring the Plaintiffs to post a bond, because Defendants stand to suffer no pecuniary harm as a result of the requested injunctive relief.

Plaintiffs will serve this motion and supporting papers on Defendants without delay. In addition, Plaintiffs intend to telephone each Defendant on the date of this motion to alert them that the motion has been filed, to provide copies of all of the documents via email, and to hand-deliver a copy of the papers to the Attorney General's office.

Plaintiffs respectfully request oral argument on this motion.

WHEREFORE, Plaintiffs ask the Court to grant them the following relief:

- a. a temporary injunction, without bond, that restrains Defendants, their agents, and their successors in office from enforcing Senate Bill 95 in its entirety until the Court enters a final judgment in this case; and
- b. if necessary, a temporary restraining order, without bond, that restrains Defendants, their agents, and their successors in office from enforcing Senate Bill 95 in its entirety until the Court issues a ruling on Plaintiffs' request for a temporary injunction; and
- c. such other and further relief as the Court deems just, proper, and equitable.

Respectfully submitted, this 1<sup>st</sup> day of June, 2015.

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# COUNSEL FOR PLAINTIFFS

# Exhibit 1

# IN THE SECOND JUDICIAL DISTRICT DISTRICT COURT, SHAWNEE COUNTY, KANSAS DIVISION 7

HODES & NAUSE HERBERT C. HO TRACI LYNN NA	DES, M.D.; and	) ) ) )		
	Plaintiffs,	) ) C	ase No.	 
v.		)		
	ey General sas; and STEPHEN M. ial capacity as District	) ) ) ) ) )		
	Defendants.	) )		

# DECLARATION OF TRACI LYNN NAUSER, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION AND/OR TEMPORARY RESTRAINING ORDER

TRACI LYNN NAUSER, M.D., of lawful age and being duly sworn, states as follows:

I am a Plaintiff in the this challenge to S.B. 95. I am a board-certified OBGYN licensed to practice medicine in Kansas and Missouri and a provider of abortion services. I am a fellow of the American College of Obstetricians and Gynecologists ("ACOG"), the leading medical society of OBGYNs in the United States, and a member of the National Abortion Federation ("NAF"), the leading medical society of abortion providers in North America.

I have been licensed to practice medicine in the State of Kansas since 1998 and in the State of Missouri since 1994.

- 2. I obtained my undergraduate degree and medical degree from the University of Missouri Kansas City as part of a six year combined bachelor's degree and medical degree program.
- 3. After I obtained my medical degree, I completed the Obstetrics and Gynecology Residency Program at the University of Missouri-Kansas City School of Medicine in Kansas City, Missouri.
- 4. I currently provide training to medical students who attend the University of Kansas Medical School and the Kansas City University of Medicine and Biosciences.
- My practice is located in Overland Park, Kansas, and advertises under the name "Center for Women's Health." At the Center for Women's Health, we provide a full range of obstetrical and gynecological services, including but not limited to family planning services, pap smears, prenatal care, delivery of babies, gynecological procedures and surgeries, screening for and treatment of sexually transmitted infections, screening for gynecological and breast cancers, treatment of menopausal symptoms, treatment of dysfunctional uterine bleeding and fibroids, and infertility treatments. We also provide previability abortion services up to 21.6 weeks from the last menstrual period.
- 6. The Center for Women's Health is a private practice with two physicians, myself and Dr. Herbert Hodes, and one nurse practitioner. Dr. Hodes is also a board-certified obstetrician-gynecologist. The Center has been providing comprehensive obstetrical and gynecological care to women in Overland Park, Kansas for 38 years.
- 7. We perform a significant number of abortions in situations where the patient has a medical condition that complicates her pregnancy. We also perform a significant number of abortions for patients who seek to end their pregnancy because the fetus has been diagnosed with a severe or lethal anomaly. Many OBGYNs and perinatologists from Kansas and other states primarily or exclusively refer their patients to the Center for Women's Health when the patient seeks an abortion.
- 8. I am aware of only two other locations in Kansas where abortions are available. The other two providers are Planned Parenthood and South Wind Women's Center. Planned Parenthood is located in Overland Park, Kansas. South Wind Women's Center is approximately three hours away in Wichita, Kansas.

- 9. Our practice abides by the Kansas "Office Based Surgery Guidelines" and is routinely inspected as such. Throughout the years, we have complied with mounting regulations including, but not limited to, those requiring patients to receive state-mandated information 24 hours before an abortion procedure, mandatory ultrasound requirements, limitations on insurance coverage for abortion, a prohibition on abortion after 22 weeks, except in very narrow circumstances in which the woman's life or health is at risk, and a ban on the use of intact D & E, an alternative method of second-trimester abortion, unless the procedure is necessary to preserve the woman's life.
- 10. I have 19 years of experience providing first and second trimester abortions in Kansas and Missouri. My patients come from throughout Kansas and neighboring states.
- In the first trimester, we perform abortions by either medical or surgical means. Surgical abortions in the first trimester are done by suction curettage, in which a plastic curette connected to a suction apparatus is used to remove the products of conception.
- 12. At the Center for Women's Health, we typically use suction curettage to perform surgical abortion procedures through 14 weeks, 6 days gestation.
- 13. We perform Dilation and Evacuation ("D & E") procedures, in which we use forceps or similar instruments to remove the fetus, either without using suction or in conjunction with suction, beginning at approximately 15 weeks gestation.
- 14. There is no firm gestational cutoff between a procedure accomplished solely using suction and D & E. When a physician sets out to perform surgical abortion using suction, even early in the second trimester, the physician cannot always rely solely on suction because it may not be effective at removing certain products of conception. In that case, the use of other surgical instruments, such as forceps, may be necessary. Whether the use of additional surgical instruments will be necessary for a given patient cannot be predicted prior to beginning the procedure. It cannot be predicted for every patient what instruments will be needed to safely complete the surgical abortion prior to the beginning of the procedure.
- 15. A D & E abortion is a surgical procedure, which is performed in two steps: dilation of the cervix and surgical removal of the fetus. When performing a D & E, in general, we first examine the patient, then insert a speculum and spray an antiseptic on the cervix and vagina. Following that, we inject a paracervical block to numb the cervix. We then dilate the cervix using dilators and then break the amniotic sac and remove the amniotic fluid. We then typically place laminaria and/or administer misoprostol as indicated for cervical

ripening. When ready for the evacuation procedure, patients are attached to the appropriate monitoring devices to monitor pulse oximetry, respirations, blood pressure, pulse rate, and a 3 lead ECG. They are administered conscious sedation intravenously as well as IV fluids and pitocin, an uterotonic agent. Then using ultrasound guidance, the uterine contents are removed with a combination of suction and forceps. The use of forceps prior to causing fetal demise would violate the Act. Uterine evacuation typically takes between 3–10 minutes.

- 16. I typically provide D & E's as one day procedures up to 20 weeks 6 days gestation. Beginning at 21 weeks gestation, I sometimes provide D & E's as two day procedures if it is medically indicated for the patient.
- 17. My partner, Dr. Herbert Hodes, provides D & E's as one-day procedures unless a two-day procedure is medically indicated.
- 18. I have reviewed S.B. 95, including the prohibition on the use of what is termed "dismemberment abortion" on a living fetus. It is my understanding that this statute will operate to ban the provision of the standard D & E procedure, the most commonly-used and safest method of second trimester abortion, unless fetal demise is induced prior to the procedure.
- 19. It has not been our practice to intentionally induce fetal demise prior to performing a D & E procedure and, prior to the passage of S.B. 95, we never considered incorporating it into our practice.
- 20. Should S.B. 95 go into effect, umbilical cord transection would not a reliable method of inducing fetal demise to comply with the law. Though I am sometimes able to transect the cord when rupturing the amniotic sac and removing the amniotic fluid using suction, or by using suction after removal of amniotic fluid, in some cases, I am unable to transect the umbilical cord. Further, waiting for fetal cardiac activity to cease before continuing the procedure would prolong the procedure and increases the risk of pain, bleeding, and infection. Waiting for fetal cardiac activity to cease could also lead to the need for additional IV sedation as well, which has its own risks associated with it. Umbilical cord transection is largely unstudied. In my medical opinion, it is a more risky and complex procedure than D & E without demise and provides no medical benefit.
- 21. In cases where we are unable to transect the umbilical cord, we will have to cause fetal demise using digoxin. If we choose to attempt to comply with the law using umbilical cord

transection, prior to beginning a D & E procedure, the patient will not know whether digoxin administration will be necessary.

- I have serious concerns about the administration of digoxin to my patients prior to D & E. The evidence I am aware of shows increased risks of infection, extramural deliveries, and hospital admissions. There is a split of opinion in the medical community about the benefits, if any, of inducing demise. Based on my review of the medical evidence on the use of digoxin, although some physicians believe that digoxin softens the fetal tissue and makes the surgery easier, the medical research data and studies demonstrate no medical benefit of causing fetal demise. In my medical judgment, the evidence does not show the requisite statistically significant improvements to justify routine use of digoxin or any method of inducing fetal demise in our practice. In light of the lack of a clear benefit, I do not think it is medically necessary or appropriate to subject my patients to an additional procedure which carries increased risks.
- 23. In order to comply with S.B. 95 should it go into effect, beginning at 15 weeks gestation, we would need to completely alter the way we do our surgical procedure to include a more complex and risky procedure, with no medical benefit, to induce fetal demise prior to performing a D & E, which in some instances will prolong the procedure from one day to two days. Alternatively, we will be forced to refuse patients services altogether. The vast majority of these patients have maternal health risks complicating their pregnancy or severe and or lethal fetal anomalies.
- Further, if S.B. 95 goes into effect, there are certain patients for whom I would have likely been able to provide care but will be unable to due to the requirement that fetal demise be induced prior to every D & E procedure.
- 25. If fetal demise is not induced in the expected time period after the first digoxin injection, a second injection will be necessary. To my knowledge, there is no published information on the cumulative effects of multiple doses of digoxin totaling more than 2 mg. No studies prove the safety of administering multiple doses of digoxin, and I do not think it is appropriate to mandate multiple doses of digoxin on patients where that treatment is largely untested.
- Moreover, prior to 18 weeks gestation, to my knowledge, there is virtually no research on the induction of fetal demise using digoxin prior to a D & E. To my knowledge, there are not any physicians in the United States who induce fetal demise using digoxin prior to a D & E before 18 weeks gestation. Because there is a dearth of information on induction of fetal demise prior to D & E at this gestational age, S.B. 95 would force doctors to provide

procedures to women that are not practiced, effectively forcing doctors to experiment on women.

- If required to induce fetal demise, it will seriously disrupt patient scheduling at my office. It will impact the times patients are scheduled to receive procedures, will increase the time needed for patient counseling, and will limit the number of days patients can receive treatment per week. Because digoxin can take 24 hours or more to be effective, and because of the potential need for more than one dose of digoxin, we will be forced in some instances to begin providing D & E procedures as a 2 or 3 day procedure, forcing patients to make multiple trips to our office. Likewise, the 24 hours or more needed for digoxin to take effect and the possibility that more than one dose will be necessary will in turn require a that 48 hour buffer be allotted for each patient. That will limit the days in which a D & E can be scheduled to begin to Monday-Wednesday and, consequently, the number of patients who can be treated per week.
- As a result, some patients may be forced to delay their procedure until they can arrange to visit the office for 2 to 3 consecutive days, increasing the length of time a patient must be away from home, work, and other obligations. That will increase the gestational age at which the procedure is scheduled and performed. There will also be increased costs for both the clinic and patients.
- 29. Further, this requirement will prevent me from providing optimal care to my patients or force me to risk prosecution. It will put Dr. Hodes and me in the unethical situation of having to choose between being able to evolve with a medical complication and abiding by the law.
- 30. The result would be an extraordinarily negative impact on the doctor-patient relationship and on my ability to provide the care that I deem to be in my patients' best interests.
- Although fetal demise is induced at 15–18 weeks to selectively reduce multiple fetuses, having a multiple gestation pregnancy is a high risk pregnancy to the patient. By reducing to a smaller number of fetuses, the pregnancy is less risky for both the mother and the fetuses. Further, these procedures are never forced on women who do not wish to induce fetal demise.
- 32. Induction abortion, where labor is induced using medication, is largely unavailable to our patients. These procedures must be performed in a hospital, and we cannot perform this procedure in our offices. Moreover, at the hospitals where we have admitting privileges,

each hospital has its own regulations that further restrict when patients are able to access second-trimester abortion.

33. In sum, I do not believe that inducing demise prior to D & E has any health benefits for my patients. Physicians need to be able to care for patients based on their individual needs and circumstances without fear of criminal prosecution dictating how they practice medicine. There is no one method to provide any procedure for every patient. The human body is too complex and complicated. I view S.B. 95 as imposing a needless and risky procedure on all patients, regardless of medical contraindications or the wishes of women patients, which curtails access to the safest and most commonly used method of second trimester abortion, and increases harms to patients.

LITE HOTARY ARE	CINDY M	BROWN
EARWAN	My Appt. Exp.	26-16

Traci Lynn Nauser, M.D.

Sworn to before me this 25th day of May, 2015.

# Exhibit 2

# IN THE SECOND JUDICIAL DISTRICT DISTRICT COURT, SHAWNEE COUNTY, KANSAS DIVISION 7

<b>HODES &amp; NAUSI</b>	ER, MDs, P.A.;	)		
HERBERT C. HO		í		
TRACI LYNN NA	•	í		
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DEREK SCHMID	T, in his official	Ń		
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Attorney for Johns	•	Ó		
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	Defendants.	í		

# AFFIDAVIT OF ANNE DAVIS, M.D., M.P.H., IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION AND/OR TEMPORARY RESTRAINING ORDER

ANNE DAVIS, M.D., M.P.H., of lawful age and being duly sworn, states as follows:

- 1. I submit this affidavit in support of Plaintiffs' Motion for Temporary Injunction and/or Temporary Restraining Order against enforcement of Kansas Senate Bill 95 ("the Act"). I am a physician licensed to practice medicine in the state of New York. I have been Board Certified in obstetrics and gynecology by the American Board of Obstetrics and Gynecology since 2001. I hold a BA in Psychology and Neurobiology from Cornell University, an MD from the Columbia University College of Physicians and Surgeons, and a Masters of Public Health, Epidemiology from the Columbia University Mailman School of Public Health. I am also a member of the Association for Reproductive Health Professionals. I am a Fellow of the American Congress of Obstetrics and Gynecology and a Fellow of the Society of Family Planning.
- 2. I completed my residency in obstetrics and gynecology ("OBGYN") at the University of Washington, and I completed a Fellowship in Family Planning in the Columbia University

Medical Center Department of Obstetrics and Gynecology. As part of the Family Planning Fellowship, I received training in abortion from experts in the field. I also participated in the training of residents and medical students during my fellowship.

- 3. At the Columbia University College of Physicians and Surgeons and at the Columbia University Medical Center Department of Obstetrics and Gynecology in New York, as well as during my medical residency at the University of Washington, I have gained substantial experience with birth and abortion procedures. I have also worked at freestanding clinics, including at Planned Parenthood in New York and as a physician with the Feminist Women's Health Centers in Renton, Washington and Yakima, Washington.
- 4. At present, I am the Wyeth Ayerst Associate Professor of Obstetrics and Gynecology in the Department of Obstetrics and Gynecology at Columbia University Medical Center and the Director of the Kenneth Ryan Fellowship in Family Planning. In that role, I am responsible for numerous aspects of medical care at Columbia University Medical Center, including gynecological care of patients in the first and second trimester of pregnancy and the provision of first and second-trimester miscarriage and abortion care. I also perform research on contraception for women with chronic medical conditions, including epilepsy, in collaboration with a neurologist. I have overseen a study to determine whether narrative medicine helps physicians improve options counseling for women seeking abortion. I have also done research on pain control for women during abortion procedures and on medical abortion.
- 5. My curriculum vitae, which sets forth my experience and credentials more fully, is annexed hereto as Exhibit A.
- 6. The opinions in this declaration are my expert opinions, which are based on my education, training, practical experience as an OBGYN and an abortion provider, my attendance at professional conferences, review of relevant medical literature, and conversations with other medical professionals.
- 7. I have reviewed S.B. 95, including the prohibition on the use of what is termed "dismemberment abortion" on a living fetus. The Act prohibits a procedure known in medical terms as Dilation and Evacuation ("D & E"). It is my understanding that to avoid the Act's criminal sanctions, physicians will be forced to stop providing D & E altogether, or induce fetal demise prior to the procedure.
- 8. The Act's ban on D & E departs from decades of accepted medical practice. No studies of which I am aware conclude that fetal demise prior to D & E will improve the safety of abortion procedures or promote women's health. Instead, it requires every woman to either forgo a D & E procedure or undergo a procedure that I believe is more complex and risky, and may involve an injection of a medication called digoxin, with no medical benefit to the patient.

- 9. To my knowledge, there is no other context in which doctors are forced to administer an unnecessary, painful, and invasive medical procedure, with increased risks, in contravention of their expert medical opinion, the best interests of the patient, and the wishes of the patient. It would raise serious ethical concerns for me if I were faced with choosing between providing a procedure to cause fetal demise, that has risks with no benefits, or withholding the D & E procedure altogether.
- 10. Legal abortion is one of the safest medical procedures in the United States, and it is very common. Approximately 3 in 10 women obtain an abortion by the age of 45. About 61% of abortions are obtained by women who have one or more children.
- 11. In the first trimester of pregnancy, abortions are performed using medications or surgical treatments. Medication abortions, which are provided through approximately 70 days gestation LMP (last menstrual period), involve the ingestion of two medications at least one day apart. Surgical abortions in the first trimester are performed by dilating (opening) the uterine cervix and then using suction to empty the pregnant uterus.
- 12. Until 14 weeks gestation, surgical abortions are usually completed using only suction.<sup>3</sup> Beginning at approximately 14 weeks LMP, physicians begin using the D & E technique which often incorporates suction. A D & E has two steps: dilation of the cervix and then removal of the fetus, placenta and uterine tissues with surgical instruments. As with virtually all medical procedures, there is some variation among physicians as to how abortions are performed. For example, cervical preparation, the dilation and softening process, can be accomplished by various methods alone or in combination. These methods include medications similar to those used for labor induction at term, the use of graduated tapered dilators which are gently passed through the cervix and removed, and/or the insertion of small dilators, which are placed in the cervix and absorb moisture from the body to gently and gradually open the cervix over an interval of several hours. Based on the method of cervical preparation, the physician may start the dilation process for a D & E procedure one or two days before the procedure itself, or do the dilation and procedure on the same day.
- 13. Once cervical softening and dilation occur, analgesia and sedation or anesthesia is administered. In the D & E process, suction removes amniotic fluid and the placenta, and

Guttmacher Institute, Induced Abortion in the United States, Incidence of Abortipm, 2014, available at <a href="http://www.guttmacher.org/pubs/fb">http://www.guttmacher.org/pubs/fb</a> induced abortion.html#2, accessed May 18, 2015 (citing Jones RK & Kavanaugh M. Changes in abortion rates between 2000 and 2008 and lifetime incidence of abortion. Obstet & Gynecol. 2011;117:1358; Henshaw SK, Unintended pregnancy in the United States, Family Planning Perspectives, 1998, 30(1):24–29 & 46).

<sup>&</sup>lt;sup>2</sup> Guttmacher Institute, Induced Abortion in the United States, Who has Abortions?, 2014, available at http://www.guttmacher.org/pubs/fb\_induced\_abortion.html#2, accessed May 20, 2015 (citing Jones RK, Finer LB and Singh S, Characteristics of U.S. Abortion Patients, 2008, New York: Guttmacher Institute, 2010).

<sup>&</sup>lt;sup>3</sup> Sometimes the use of an instrument is necessary, in addition to suction, to complete a procedure beginning at approximately 13 weeks gestation.

forceps or the safest surgical instrument is used to remove the fetus. Usually, because the cervix is narrower than the fetal parts, some separation of fetal tissues occurs as the physician delivers the fetal part grasped in the instrument and gently brings it through the cervix. This is why all D & E's that do not involve fetal demise prior to the use of surgical instruments will violate the Act. A final suction curettage is often performed to ensure that the uterus is completely evacuated. This process takes between 10–15 minutes on average.

- 14. Second-trimester abortion is an important component of comprehensive women's health care. Women seek termination of pregnancy for a variety of medical and social reasons, including poverty, youth, and having completed one's family. Circumstances that can lead to second-trimester abortion include delays in suspecting and testing for pregnancy, delay in obtaining insurance or other funding, a medical condition requiring hospital referral, and delay in obtaining referral, as well as difficulties locating and travelling to a provider. In addition, the identification of most major anatomic or genetic anomalies in the fetus occur in the second trimester; some women seek abortion in those circumstances.<sup>4</sup>
- 15. In many areas of the United States, women have limited access to second trimester abortion. Eighty-nine percent of all U.S. counties lacked an abortion clinic in 2011.<sup>5</sup> Not all clinics provide abortions after the first trimester. In a census of abortion providers, only 64% reported providing services after 12 weeks of gestation.<sup>6</sup>
- 16. D & E is the safest form of second-trimester abortion after approximately 14-15 weeks gestation. In my experience, suction alone can be used in the second trimester up to approximately 15 weeks. Thereafter, I think that narrow forceps or another appropriate instrument are essential for safety. Physicians' first priority is patient safety, and the safest D & E is done as quickly and gently as possible to minimize bleeding and preserve health and fertility.
- 17. Because of its impressive safety record as well as patient preference, D & E remains by far the most prevalent method of second-trimester abortion, accounting for 95% of all second-trimester abortions nationally, primarily in outpatient settings.<sup>7</sup>

<sup>&</sup>lt;sup>4</sup> American College of Obstetricians and Gynecologists, Practice Bulletin Number 135: Second Trimester Abortion, Obstetrics and Gynecology, 2013, 121(6): 1394–1406.

<sup>&</sup>lt;sup>5</sup> Guttmacher Institute, Induced Abortion in the United States, Providers and Services, 2014, available at <a href="http://www.guttmacher.org/pubs/fb">http://www.guttmacher.org/pubs/fb</a> induced abortion.html#2, accessed May 18, 2015 (citing Jones RK and Jerman J, Abortion incidence and service availability in the United States, 2011, Perspectives on Sexual and Reproductive Health, 2014, 46(1):3-14).

<sup>&</sup>lt;sup>6</sup> American College of Obstetricians and Gynecologists, Practice Bulletin Number 135: Second Trimester Abortion, Obstetrics and Gynecology, 2013, 121(6): 1394–1406.

<sup>&</sup>lt;sup>7</sup> Paul M, Lichtenberg ES, Borgatta L, Grimes D, Stubblefield P, Creinin M, Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care, National Abortion Foundation, 157-58 (Wiley-Blackwell 2009); American College of Obstetricians and Gynecologists, Practice Bulletin Number 135: Second Trimester Abortion, Obstetrics and Gynecology, 2013, 121(6): 1394–1406.

- 18. D & E can be performed on an outpatient, ambulatory basis in a clinical setting at a lower cost than any other second-trimester abortion procedure performed after approximately 15 weeks gestation.
- 19. The American Congress of Obstetricians and Gynecologists ("ACOG") has stated that there is no sound medical basis for requiring abortion providers to induce fetal demise prior to performing a D & E. According to ACOG, "No evidence currently supports the use of induced fetal demise to increase the safety of second-trimester medical or surgical abortion. Techniques used to cause fetal demise include division of the umbilical cord, intraamniotic or intrafetal digoxin injection, or fetal intracardiac potassium chloride injection." Causing fetal demise therefore should not be imposed on every patient.
- 20. Some physicians, beginning around 18 to 20 weeks LMP, induce fetal demise prior to a D & E procedure by administering a pharmacologic agent. The pharmacologic agents used to induce fetal demise are intracardiac potassium chloride (KCl) and intrafetal or intraamniotic digoxin injections.
- 21. In the United States, injection of digoxin, a medication that is also used to treat certain heart conditions, is the most commonly used method of inducing fetal demise prior to a D & E procedure. While the prevalence of the use of digoxin to cause demise after 18 weeks is unknown, it is rarely used, if at all, prior to 18 weeks. After 18 weeks gestation, some physicians believe that digoxin offers safety benefits to patients, but that is not my view based on my own experience as well as my review of the medical literature.<sup>10</sup>
- 22. Much of the literature on causing demise has come in the wake of enforcement of federal and state bans on so-called partial birth abortions. As many of these studies acknowledge, many physicians began using demise not because they believed it offered medical benefits, but in order to avoid legal liability.<sup>11</sup>
- 23. An intrafetal or intraamniotic digoxin injection is not 100% effective. With a one milligram intrafetal injection, the failure rate (no demise occurs) of an experienced provider can be very low. However, the failure rate increases in intraamniotic injections. Most providers who induce demise use an 18 gauge, 20 gauge, or a 22 gauge spinal needle passed through the woman's abdomen, or her vagina and cervix, into the uterus using ultrasound guidance. After confirming correct needle placement, providers inject the digoxin intrafetally or intraamniotically. These procedures can be technically difficult for the physician and both physically and emotionally painful for the patient.

<sup>&</sup>lt;sup>8</sup> American College of Obstetricians and Gynecologists, Practice Bulletin Number 135: Second Trimester Abortion, Obstetrics and Gynecology, 2013, 121(6): 1394–1406.

<sup>&</sup>lt;sup>9</sup> Diedrich J, Drey E. Induction of fetal demise before abortion. SFP Guideline 20101. Contraception 2010; 81: 462-473.

<sup>&</sup>lt;sup>10</sup> *Id*.

<sup>&</sup>lt;sup>11</sup> Id.

- 24. The limited research to date has not shown medical benefits of digoxin before abortion; in no study has fetal demise been demonstrated to improve abortion safety for women. Reactions to digoxin include increased vomiting and nausea. In some studies, patients who were administered digoxin were also more likely to experience unplanned fetal expulsion (delivery) outside a medical facility, as well as infection and hospital admission. The injection procedure itself carries some risks. The majority of studies conclude that there is insufficient information to recommend the use of digoxin.<sup>12</sup>
- 25. Digoxin is usually administered 1–2 days before the D&E procedure when cervical preparation begins. It can take up to 24 hours to be effective. Further, administration of digoxin for pregnancies between 15–18 weeks would likely be intraamniotic, rather than intrafetal injections, because of the decreased size of the fetus. Intraamniotic injections take longer to take effect, have an increased failure rate, and are associated with higher rates of infection and extramural delivery than intrafetal injection. <sup>14</sup>
- 26. An ACOG practice bulletin finds that no evidence currently supports the use of induced fetal demise to increase the safety of second trimester surgical abortion.<sup>15</sup>
- 27. Moreover, the vast majority of studies only address the administration of digoxin at or after 18 weeks gestation prior to a D & E procedure. Prior to 18 weeks gestation, I'm aware of virtually no data addressing the use of digoxin prior to D & E. That is because prior to 18 weeks gestation, the fetal tissue is much smaller and softer, requiring less dilation, and there is no potential benefit to administering digoxin that would prompt a research study. At that point, the risk benefit ratio is extremely unfavorable. Moreover, prior to 18 weeks, in some cases, it may be technically impossible to do an intrafetal injection.
- 28. If fetal demise is not induced in the expected time period after the first digoxin injection, a second injection will be necessary. To my knowledge, there is there is no published information to demonstrate the safety of multiple, sequential doses of digoxin to induce fetal demise in pregnant women.
- 29. Less common than digoxin, some physicians with advanced training induce demise using intracardiac (fetal) KCl administration via transabdominal injection performed with ultrasound guidance. KCl is injected in the fetal heart until asystole is confirmed. KCl use includes a risk of maternal cardiac arrest if inadvertent intravascular injection occurs. There are also risks of intramniotic infection or chorioamnionitis. Due to dilution, KCl

<sup>&</sup>lt;sup>12</sup> *Id*.

<sup>&</sup>lt;sup>13</sup> Borgatta L, Betstadt S, Reed A, Feng K. Relationship of Intraamniotic Digoxin to Fetal Demise. Contraception. 2010; 81:328–330.

<sup>&</sup>lt;sup>14</sup> Diedrich J, Drey E. Induction of fetal demise before abortion. SFP Guideline 20101. Contraception 2010; 81: 462-473.

<sup>&</sup>lt;sup>15</sup> American College of Obstetricians and Gynecologists, Practice Bulletin Number 135: Second Trimester Abortion, Obstetrics and Gynecology, 2013, 121(6): 1394–1406.

<sup>&</sup>lt;sup>16</sup> G.A. Coke, et al. Maternal cardiac arrest associated with attempted fetal injection of potassium chloride, Int. J. Obstet. Anesth., 2004, 13: 287–290.

will not cause fetal demise when injected into the amniotic fluid; injection into the fetal heart or umbilical cord is required. An intracardiac injection of KCl is virtually 100% effective, but requires an extremely high level of skill to perform, and thus is typically performed only by Maternal-Fetal Medicine OB-GYNs following a specialized fellowship with extensive and lengthy advanced training. Thus, KCl is not a method of demise that can be administered by the vast majority of abortion providers without extensive additional training.

- 30. KCl administration is most commonly performed for selective termination in a multifetal pregnancy or to induce fetal demise of an abnormal fetus before labor induction, and, as discussed above, a small number of physicians possess the requisite skill and experience. Further, unlike induction of fetal demise prior to a D & E procedure, multifetal pregnancy reduction confers safety benefits for women by reducing risks associated with multifetal gestation. Further, they are never forced on women who do not wish to undergo the procedure; rather, physicians make case-by-case recommendations by weighing the respective benefits and risks for each individual woman and leave it to each individual woman to make the ultimate decision about her medical care.
- 31. Though it is rare, some women have contraindications for digoxin injections. Digoxin injections are also less likely to be successful for morbidly obese women if the needle is unable to reach the uterus.
- 32. Umbilical cord transection (separation) is another means of inducing demise prior to a D & E procedure. It is performed by using an appropriate surgical instrument or suction to grasp the cord and divide it with gentle traction. However, umbilical cord transection is not possible in every case and cannot be relied on as a method of inducing fetal demise prior to D & E. A surgeon cannot guarantee that he or she will be able to locate and grasp the umbilical cord in utero. Umbilical cord transection may also occur when the fluid from the amniotic sac is removed using suction. However, that does not occur in every, or even most, cases. Once the amniotic fluid has been removed, any attempt at umbilical cord transection becomes a blind procedure that cannot be guided using ultrasound technology because without amniotic fluid, the cord cannot be distinguished as separate from the rest of the fetus via ultrasound. Again, were a physician to attempt to extract the umbilical cord using surgical instruments, she would risk violation of the Act. Thus, the use of umbilical cord transection to induce fetal demise is not a reliable method, and in many cases may be a technically impossible method, of inducing demise prior to a D & E procedure. Attempting intrauterine cord transection is a clinically untested procedure, without research evidence of safety. It is likely that attempting this procedure would carry risks of bleeding and uterine perforation. There is no known medical benefit to inducing demise using umbilical cord transection prior to D & E.
- In my practice, we have never routinely induced fetal demise prior to performing a standard D & E procedure. Shortly after the passage of the federal Partial Birth Abortion ban, we began administering digoxin on patients at or after 18 weeks gestation where we felt an

intact procedure was safer for patients. We administered digoxin via transabdominal intrafetal or intraamniotic injection approximately 24 hours prior to D & E. After only a few months, we abandoned the practice. We found that digoxin administration provided no safety benefits to our patients and was not effective in every case, but that it deeply upset patients to undergo the transabdominal procedure. Many of our patients had already undergone amniocentesis, a form of genetic testing that also requires a transabdominal injection procedure. During the procedure itself, many patients cried due to the pain and emotional distress of being subjected to an invasive injection. We abandoned the practice because we felt it did not put patients' best interests first and caused harm to our patients, in violation of our medical ethics. Following that decision, I developed a method of inducing fetal demise using KCl administered via the umbilical cord for cases where an intact delivery is a clearly safer option for the patient. This method is only possible in a hospital setting where the patient is under deep sedation.

- 34. The only alternative to D & E in the second trimester is an induction abortion procedure, in which physicians use medication to induce labor and delivery of a non-viable fetus. Induced labor abortions must be performed on an inpatient basis in a hospital, and the length of the procedure can vary from between 5-6 hours up to 2-3 days. Because they must take place in a hospital setting, they are far more expensive than an out-patient D & E procedure. Inductions require women to go through labor, often in a labor and delivery area, which can be physically and psychologically challenging for some women. Further, following an induction, between 10-33% of women have retained placenta and must undergo a surgical D & C after fetal expulsion, a procedure akin to a D & E, to have it removed. In some cases, the induction may fail, and a D & E must be performed urgently if infection or heavy bleeding occur. Induction abortion can cause uterine rupture, which is rare but can be life-threatening. This is especially a concern for women who have had previous cesarean deliveries. The vast majority of patients, when given the choice between a labor induction and D & E, choose D & E.
- 35. Enforcement of the Act would require physicians to induce demise for all patients who need D & E procedures, or to cease providing D & E procedures to the extent that demise is not induced. In cases where a physician uses digoxin prior to 18 weeks, it will also force physicians to administer a virtually untested procedure. Umbilical cord transection as a step to induce fetal demise before second trimester abortion is also largely unstudied, and is not always effective.
- 36. The result would be an extraordinarily negative impact on women seeking second trimester abortions. Some physicians performing D & E's would no longer be able to provide the care that they deem to be in their patients' best interests or in line with their medical ethics. Physicians would also be exposed to criminal and civil liability.

<sup>&</sup>lt;sup>17</sup> A.M. Autry, et. al, Comparison of Medical Induction and Dilation and Evacuation for Second Trimester Abortion, Amer. J. Obstetrics and Gynecology, 2002, 187: 393–97.

- Due to increased procedure times for digoxin procedures requiring multiple trips to a clinic, patients may face significant delay in accessing an abortion procedure. Although legal abortion is a very safe procedure, the risks increase as the pregnancy advances. Thus, delaying abortion until later in pregnancy increases the potential risks for patients.
- 38. Some women, deprived of access to legal abortion, forgo the abortions they would have obtained if they could and, instead, carry unwanted pregnancies to term. These women are exposed to increased risks of major complications from childbirth, including death, and they are at much greater risk of complications during pregnancy and after delivery.

39. For these reasons, the Act will harm both physicians who provide abortions affected by the Act and their patients.

Anne Davis, M.D., M.P.H.

# Exhibit A

1) Date of Preparation

1/15/2015

### 2) Personal data

Name

Anne Rachel Davis, MD, MPH, FACOG

Contact information

622 West 168th Street

Presbyterian Hospital 16-69

Department Obstetrics and Gynecology Columbia University Medical Center

New York, NY 10032

(212) 305-4951 ard4@columbia.edu

Birthplace

Rochester, NY

Citizenship U.S.

# 3) Academic appointments, hospital appointments and other work experience

# Academic appointments, Department Obstetrics and Gynecology Columbia University Medical Center

7/2008-current	Associate Professor of Obstetrics and Gynecology
7/1999-6/2008	Assistant Professor of Clinical Obstetrics and Gynecology
7/1997-6/1999	Clinical Instructor in Obstetrics and Gynecology
2012-current	Director, Kenneth Ryan Fellowship in Family Planning
7/2004-6/2012	Co-director, Kenneth Ryan Fellowship in Family Planning

## Department of Urology

2001-2004

Co-director, New York Center for Human Sexuality

#### Hospital appointment

1999-current

Attending Physician, Columbia University Medical Center

### 4) Education

9/1984-6/1988

BA, Psychology and Neurobiology Cornell University, Ithaca, NY 9/1993-6/1997

**Medical Doctor** 

College of Physicians and Surgeons, NY, NY

9/1997-6/2002

Masters of Public Health, Epidemiology

Mailman School of Public Health, NY, NY

5) Training

7/1997-6/1999

Fellow, Columbia University Medical Center Department

Obstetrics and Gynecology, Fellowship in Family

Planning, New York, NY

7/1993-6/1997

Intern and Resident, Obstetrics and Gynecology,

University of Washington, Seattle, WA

### 6) Explanation of Gaps

None

#### Licensure

1997-current

7) Licensure and board certification

New York State #207702

1993-1997

Washington State #32927

### Board qualification

2001-2014

American Board of Obstetrics and Gynecology

Certification 2001, renewed annually, last 2014

# 8) Honors and awards

2015 Benson and Pamela Harer Seminar on History. "Your" Reproductive Decision? There's a Law for That. American College of Obstetrics and Gynecology, Annual meeting, San Francisco, CA

2014 Leadership Management Institute, Columbia University Medical Center

2011 National Physician Advocacy Merit Award. Institute on Medicine as a Profession, awarded to three physicians annually

- 2010 Best Abstract in Neuroendocrinological Research. American Academy of Neurology, Neuroendocrinology Section
- 2006 Best clinical abstract in female sexual dysfunction. International Society of Sexual Medicine.
- 2005 Physician Leadership Conference, New York Presbyterian Hospital
- 2003 Elected to New York Obstetrical Society
- 2001 Early Career Women Faculty Professional Development Program, AAMC
- 1997 Outstanding Resident Teacher, Department OB/GYN, University of Washington.
- 1993 Alpha Omega Alpha, College of Physicians and Surgeons.
- 1993 Conrad Lattes Fellowship, Columbia Society and Medicine Program.
- 1990 Dean's Summer Research Fellowship, College Physicians and Surgeons.
- 1987 Ford Foundation Research Fellowship, Cornell University.
- 1984-88: Magna cum laude, Phi Beta Kappa, Phi Kappa Phi, Dean's List, Cornell University

## 9) Academic service

Local	
2013-current	Clinical Competency Committee, Department Obstetrics and Gynecology
2010-current	Institutional Review Board, alternate, Columbia University Medical Center
2008-2010	Institutional Review Board, full member, Columbia University Medical Center
2006-2008	OR Anesthesia Committee, Allen Hospital
2003-current	Department Obstetrics and Gynecology, Residency Interview Committee
2002-2007	Department Obstetrics and Gynecology, Quality Assurance Committee

# 10) Professional Organizations and Societies

Memberships and positions

Local

2003-current

**New York Obstetrical Society** 

2005 Membership Committee

2006 Committee Chair, Residency/Fellowship

Research Day

**National** 

2005-current

Society of Family Planning, Fellow

2004-current

Association for Reproductive Health Professionals,

member

National Abortion Federation, member

2003-current 1997-current

Physicians for Reproductive Choice and Health

Consulting medical director, 2011-current Chair, Rashbaum Tiller Award Committee

2008-current

Board of Directors, 1999-2008

1997-current

American Congress of Obstetrics and Gynecology, Fellow

1989-2008

American Medical Women's Association, member

International

2000-2005

International Society for Women's Sexual Health,

member. Board of Directors, 2001-2002

Consultative

Local

2014-current

NYC DOH Office of School Health- Adolescent Health Unit. Medical Advisor to School Based Health Center-

Reproductive Health Project, New York City. Office of

School Health- Adolescent Health Unit.

2011-current

Physicians for Reproductive Health. Consulting Medical

Director

2004-2006

IPAS: Trainer. NYC Health and Hospital Corporation

(HHC) initiative to improve surgical and medical

management of early pregnancy failure.

National	
2014	FDA Center for Drug Evaluation and Research. Bone, Reproductive and Urologic Drugs Advisory Committee invited member to special committee meeting, December 18, 2014
2014-current	Agile Pharmaceuticals. Pregnancy adjudication committee, contraceptive patch clinical trial
2013-2014	Fellowship in Family Planning, reviewer, fellow research proposals
2013	TEACH project. Development of teaching and training materials for first trimester abortion.
2012	American College of Obstetrics and Gynecology, reviewer, scientific abstract submissions
2009-10	Association of Reproductive Healthcare Professionals, Mainstreaming the IUD presentation for CME, curriculum development
2005-2006	Association of Reproductive Health Professionals.  Development of post-partum provider guidelines, first and revised editions
2004-2005	American Medical Women's Association. Reproductive Health Initiative, Curriculum Development.

# International

2011	Gynuity. Research consultant for study implementation: Capacitación para el equipo del estudio: Mifepristona y misoprostol en comparación con el misoprostol solo para la interrupción del embarazo en el segundo trimestre. Medical Center of the University of San Juan, Puerto Rico		
2011	Gynuity. Chair, data safety and monitoring board, international study of misoprostol for labor induction after fetal demise		
2006	Gynuity. Research consultant for study implementation: RCT of medical versus surgical management of first trimester early pregnancy failure. Maternidad Isidro Ayalo and CEMOPLAF, Quito, Ecuador		
2005	Gynuity. Development of "Instructions for Use: Misoprostol for Treatment of Incomplete Abortion and Miscarriage". Reproductive Health Technologies Project		

#### Journal reviewer

Obstetrics and Gynecology (top 100 Reviewers, 2005)

American Journal Obstetrics and Gynecology

British Journal of Obstetrics and Gynecology

Journal of the American Medical Women's Association

Journal of the Society for Gynecologic Investigation

Women's Health in Primary Care

American Journal of Public Health

Psychoneuroendocrinology

Contraception (top reviewer, 2014)

JAMA Archives of Pediatric and Adolescent Medicine

New England Journal of Medicine

The Medical Letter

Journal of Reproductive Medicine

# 11) Fellowship and grant support

### **Present Support**

7/14-7/15

The Society of Family Planning. Combining research,

mentorship and advocacy to advance the health of special

populations. P.I. Davis (\$40,000)

8/11-7/15

Bayer Healthcare. Safety, acceptability and efficacy of the LNG

IUS in women with epilepsy. Investigator initiated. P.I. Davis

(\$218,277)

1997-current

Anonymous Foundation. Fellowship program in family planning

and contraception. (\$416,127 for year 2014-2015). Director

2012-current, renewed annually

#### Past Support

7/10-6/13

Milken Foundation. Pregnancy outcomes in women with epilepsy (WEPOD). Observational, controlled three year cohort study.

P.I. J. French, Davis Co-I.

3/2010-3/2011	The Epilepsy Foundation Epilepsy birth control registry project. On-line contraception registry for women with epilepsy. P.I. A Herzog. Co-I Davis.
7/09-2/1/11	Bayer Healthcare. Multicenter, low-dose patch contraception trial, Phase 3. Davis Co-I (\$98,657)
2/09-4/11	Bayer Healthcare. Multicenter, open-label, randomized study to assess the safety and contraceptive efficacy of two doses (in vitro 12g/24 h and 16g/24 h) of the low-dose levonorgestrel contraceptive intrauterine system (LCS) Co-I (\$32,000)
3/05-2/07	NICHD R03-HD048547-01. Oral contraceptives and cytochrome p450 inducers. P.I. Davis (\$170,500)
3/03-9/04	Wyeth. Levonorgestrel 90mg, ethinyl estradiol 20mcgs in a continuous daily regimen for oral contraception. P.I. Davis (\$123,281)
4/01 – 4/04	NICHD N01-HD13321-RCT on Management of Early Pregnancy Failure: Clinical Centers. P.I. Zhang, Davis Co-I. (\$479,006)
4/01-03/03	NICHD R03-HD39776-RCT Oral contraceptives for the management of dysmenorrhea in adolescent girls. P.I. Davis, (\$170,500)
8/01-07/03	NICHD R21-AT00836. Effects of Hypericum Perforatum on oral contraceptives. P.I Murphy, Co-I Davis (\$250,000)
7/01-6/02	Partnership for Women's Health at Columbia University An fMRI study to localize the neuropsychiatric effects of testosterone replacement in post-menopausal women. P.I. Seidman, Co-I Davis (\$200,000)
10/00-1/02	Berlex. A Multi-center, open-label, uncontrolled trial of the levonorgestrel-releasing IUS (intrauterine system) to evaluate insertion and counseling procedures. P.I. Westhoff, Co-I Davis (\$82,000)
4/99-3/1/0	Gynetics. A prospective, open-label study of levonorgestrel 0.75mg tablets as an emergency contraceptive agent. P.I. Westhoff, Co-I. Davis (\$25,925).

# 12) Educational contributions

Direct teaching, precepting, supervising

# Department Obstetrics and Gynecology

- Division of Prevention and Ambulatory Care, Division research meeting 1 hour weekly 2001-current
- Fellowship weekly didactic lecture, one hour weekly 2012-current
- Clinical supervision of residents, one week per month surgical abortion services, 16 hours, 1997-current.
- Resident education lectures. Contraception, abortion, sexual dysfunction, dysmenorrhea, 1999-2008. Three hours per year.
- Resident clinical supervision. Family Planning Clinic 8-12 hours weekly, 1999-2012
- St. Vincent's Hospital OB/GYN Resident clinical supervision. 3-4 months/year, 2003-2006

# Department Family Medicine

Resident clinical supervision. Family Planning Clinic, 8 hours weekly for six months yearly, 2004-2010

### College Physicians and Surgeons

- Clinical supervisor. AMWA Reproductive Health Initiative fourth year elective, 2-3 months a year 1999-08.
- Clinical supervisor. Medical Students for Choice Student Externship, 2-3 months/year 1999-current
- Clinical supervisor. Sexuality and Reproduction (clinical practice course), first year medical students 1999-02
- Third year medical student clerkship lecturer. Contraception, abortion, sexual dysfunction. Four hours per year 1999-05.
- Third year medical student clerkship. Clinical supervision, surgical abortion service. Eight hours monthly 2008-current.
- Lecturer. Pharmacology, endocrine block. Hormonal contraception 2009-current

#### School of Public Health

- Population and Family Health P6621, Guest lecturer, Fall 2001.
- Secondary reader, candidates for Masters Degree in Public Health:

Dr. Katharine O'Connell, 2004 Sarah Kaufman, 2005

Tina Robilotto, 2005

Dr. Paula Castano, 2005

Dr. Noa'a Shimoni, 2009 Dr. Karla Maguire, 2011

### Advising and mentorship

New York Presbyterian Hospital

Leadership program mentor. Dr. Dara Matseone. 2013-current

Department Obstetrics and Gynecology

- Fellowship Director. Research and clinical mentor since 2012, Co-director 2004-12.
- Research mentor, Dr. Sarah Horvath 2014-current.
- Resident mentor, Dr. Julie Kupferman 2011.

## College Physicians and Surgeons

- Medical student research mentor. Jasmine Heva Saadatmand 2013-current.
- Medial student research mentor. Lauren Osborne 2003-06.

#### 13) Report of Clinical and Public Health Activities and Innovations

None

#### 14) Patents and inventions

None

#### 15) Publications

#### Peer-Reviewed Research Publications in Print or other media

- 1. Shimoni N, **DAVIS AR**, Westhoff CW. Can ultrasound predict IUD expulsion after medication abortion? Contraception. 2014;89(5):434-9.
- 2. Maguire K, Morrell K, Westhoff C, **DAVIS AR**. Accuracy of providers' assessment of pain during intrauterine device insertion. Contraception. 2014 Jan;89(1):22-4.
- 3. Amoroso MW, Croft G, Roybon L, Oakley D, Williams D, **DAVIS AR**, Henderson C, and Wichterle H. Accelerated high-yield generation of limb-innervating motor neurons from human stem cells using small molecules. Journal of Neuroscience. 2013;33(2):574-586.

- Maguire K, DAVIS AR, Tejeda LR, Westhoff C. Intracervical lidocaine gel for intrauterine device insertion: a randomized controlled trial. Contraception. 2012;86(3):214-9.
- Shimoni N, DAVIS AR, Ramos ME, Rosario L and Westhoff CL. Timing of intrauterine device insertion after medical abortion. Obstet Gynecol. 2011 Sep;118(3):623-8.
- 6. **DAVIS AR**, Westhoff CL, Stanczyk FZ. Carbamazepine co-administration with an oral contraceptive: Effects on steroid pharmacokinetics, ovulation, and bleeding. Epilepsia. 2011;52(2):243-247.
- 7. Pack, A, **DAVIS AR**, Kritzer J, Yoon A and Camus A. Anti-epileptic drugs: are women aware of interactions with oral contraceptives and potential teratogenicity? Epil and Behav. 2009; 14(4):640-4.
- 8. **DAVIS AR**, Kroll R, Soltes B, Zhang N, Grubb GS, Constantine GD. Return to menses after cessation of a continuous oral contraceptive. Fert Steril. 2008; 89:1059-63.
- 9. **DAVIS AR**, Pack A, Yoon A, Kritzer J, Camus A. Reproductive history, sexual behavior and use of contraception in women with epilepsy. Contraception 2008;77:405-409.
- 10. Edwards S, Tureck R, Frederick M, Huang X, Zhang J, Barnhart K for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Manual Vacuum Aspiration Compared with Electric Vacuum Aspiration for Early Pregnancy Loss. J Womens Health 2007; 16(10):1429-36.
- 11. C Robledo, J Zhang, J Troendle, K Barnhart, M D Creinin, C Westhoff, X Huang, and M Frederick for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Clinical indicators for success of misoprostol treatment after early pregnancy failure. Int J Gynaecol Obstet 2007;99(1):46-51.
- 12. O'Connell K, **DAVIS AR**, Kerns J. Oral contraceptives, side effects and depression among adolescent girls. Contraception. 2007;75(4):299-304.
- 13. Westhoff CL, S Heartwell, S Edwards, M Zieman, G Stuart, C Cwiak, **DAVIS AR**, T Robilotto, L Cushman and D Kalmuss. Oral contraceptive discontinuation: do side effects matter? AJOG. 2007; 196:412.e1-412.e7.
- 14. DAVIS AR, Hendlish SK, Westhoff C, Zhang J, Fredricks M, Gilles J, Barnhart K, Creinin M for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Bleeding patterns after medical versus surgical management of early pregnancy failure: results from a randomized trial. AJOG 2007;196:31e1-31.e7.
- 15. DAVIS AR, Osborne L, Westhoff C and O'Connell K. A placebo-controlled

- trial of oral contraceptives in adolescents: methodological challenges. J Adol Health. 2006; 39: 607-609.
- 16. **DAVIS AR**, O'Connell K, Westhoff C. Self-treatment patterns for dysmenorrhea in adolescents. J Ped Adol Gynecol. 2006;19:285-289.
- 17. Creinin MD, Huang X, Westhoff C, Barnhart K, Gilles JM, Zhang J. For the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Factors related to successful misoprostol treatment for early pregnancy failure. Obstet Gynecol 2006;107(4):901-7, 2006.
- 18. **DAVIS AR**, WESTHOFF CL, O'Connell K, Gallagher N. Oral contraceptives for dysmenorrhea in adolescent girls: a randomized trial. Obstet Gynecol. 2005; 106:97-104.
- 19. Schafer J, Westhoff C, Osbourne L, **DAVIS AR**. Acceptability and satisfaction using quick start with a contraceptive vaginal ring versus an oral contraceptive. Contraception. 2006; 73:488-492.
- 20. Zhang J, Gilles J, Barnhart K, Creinin M, Westhoff C, Frederick M, for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. A comparison of medical management with misoprostol and surgical management for early pregnancy failure. NEJM 2005; 353 (8):761-769.
- 21. **DAVIS AR**, O'Connell K, Westhoff C, Gallagher N. Oral contraceptives and dysmenorrhea in adolescent girls: a randomized, placebo-controlled trial. Obstet Gynecol 2005; 106:97-104.
- 22. DAVIS AR, Robilotto CM, Westhoff CL, Forman S and Zhang J for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Bleeding patterns after vaginal misoprostol for early pregnancy failure. Human Rep 2004;19:1655-1658.
- 23. Barnhart KT, Bader T, Huang X, Frederick M, Timbers, K, Zhang J for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Hormone patterns after misoprostol administration for a non-viable first-trimester gestation. Fertil Steril 2004; 81:1099-1105.
- 24. Creinin MD, Harwood B, Guido R, Fox M, Zhang J for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. Endometrial thickness after misoprostol use for early pregnancy failure. Inter J Gynecol Obstet 2004; 86: 22-26.
- 25. Gilles JM, Creinin MD, Barnhart K, Westhoff C, Frederick M, Zhang J for the National Institute of Child Health and Human Development Management of Early Pregnancy Failure Trial Group. A randomized trial of saline solution-

- moistened misoprostol versus dry misoprostol for first-trimester pregnancy failure. Amer J Obstet Gynecol 2004;190:389-394.
- 26. Anastasiadis AG, **DAVIS AR**, Sawczuk IS, Fleming M, Perelman MA, Burchardt M, Shabsigh R. Quality of life aspects in kidney cancer patients: data from a national registry. Support Care in Cancer 2003:11:700-706.
- 27. **DAVIS AR**, Nowygrod S, Westhoff C, Shabsigh R. The influence of vaginal bleeding on the sexual behavior of urban, Hispanic women and men. Contraception 2002;65:351-355.
- 28. **DAVIS AR**, Westhoff C. Primary dysmenorrhea in adolescent girls and treatment with oral contraceptives. J Ped Adol Gyn. 2001;14:3-8.
- 29. **DAVIS AR**, Westhoff C, DeNonno L. Bleeding after early abortion with mifepristone or manual vacuum aspiration (MVA). JAMWA 2000;55:141-144.
- 30. **DAVIS AR**, Miller LA, Tamimi H, Gown A. Methotrexate or mercaptopurine for early abortion. Obstet Gynecol 1999;93:904-909.
- 31. Killackey MA, **DAVIS AR**. Papillary serous carcinoma of the peritoneal surface: matched case comparison with papillary serous ovarian carcinoma. Gynecol Onc 1993;51:171-174.

#### Other peer-reviewed publications in print or other media

- 1. Morrell K, **DAVIS AR**. Location, location, location: where you live determines your access to abortion. Columbia Medical Review, submitted 12/14.
- 2. Higgins J and **DAVIS AR**. Contraceptive sex-acceptability: a commentary, synopsis and agenda for future research. Contraception 2014;90(1): 4-10.
- Guiahi M, DAVIS AR. Society for Family Planning Guideline. First-trimester abortion in women with medical conditions: Contraception. 2012 Dec;86(6):622-30.
- 4. Dragoman M, DAVIS AR, Banks E. Contraceptive options for women with preexisting medical conditions. J Womens Health (Larchmt). 2010;19(3):575-580.
- 5. **DAVIS AR** and Castano P. Oral contraceptives and libido in women. Ann Rev Sex Res 2004; 15: 297-312.
- 6. Westhoff C, **DAVIS AR**. Tubal sterilization: focus on U.S. experience. Fertil Steril 2000;73:913-922.

#### Reviews, chapters, monographs, editorials

1. DAVIS AR and Pennell P. Selecting contraception for women on anti-

- epileptic drugs. Editors O'Neal, Walters, In *Neurologic Illness in Pregnancy*. 2014.
- 2. **DAVIS AR**, Pack A and Dennis A. Contraception for women with epilepsy. Editors: Allen R and Cwiak CA. In *Contraception for the Medically Challenging Patient*. Springer. New York, 2014 (135-46).
- 3. Pennell P and **DAVIS AR**. Selection of contraception for women with epilepsy. Editors: Esther Bui and Autumn Klein. In *Women with Epilepsy*. Cambridge University Press, 2014.
- DAVIS AR, Morrell KM. Epilepsy and Contraception. Editors: Harden CL, Thomas SV, and Tomson T. In *Epilepsy and Women*. Wiley-Blackwell, West Sussex, UK, 2013 (64-74).
- 5. Higgins J and **DAVIS AR**. Sexuality and Contraception. Editors: Hatcher B et al. In *Contraceptive Technology*, 20<sup>th</sup> Edition. Ardent Media, Inc, 2011 (1-20).
- 6. **DAVIS AR**. Abortion in adolescents. Editors: Fisher, Alderman, Keipe, Rosenfeld. In *Textbook of Adolescent Health Care*. American Academy of Pediatrics, 2011(526-30).
- 7. Shulman LP, **DAVIS AR**, Jensen JT, Moore A. Heavy menstrual bleeding: from recognition to resolution. A supplement to *The Clinical Advisor* and to *MPR Obstetrician & Gynecologist Edition*. April 2010.
- 8. **DAVIS AR** and Beasley A. Abortion in adolescents: epidemiology, confidentiality and methods. Curr Opin Obstet Gynecol. 2009; 21:390-395.
- 9. Grimes D, **DAVIS AR**, Ramos D. Heavy menstrual bleeding. Assessing impact, evaluating management options. Supplement to OBG management. October, 2009.
- 10. **DAVIS AR** and Easterling TE. Medical evaluation and management. Editors: Paul M, Lichtenberg S, Borgatta L, Grimes D, Stubblefield, Creinen M. In *Management of unintended and abnormal pregnancy: comprehensive abortion care.* Blackwell, U.K. 2009 (78-89).
- 11. Dempsey-Fanning A and **DAVIS AR**. Medical management of early pregnancy failure: how to treat and what to expect. Semin Reprod Med 2008; 5:401-10.
- 12. Dragoman M and **DAVIS AR**. Abortion care for adolescents. Clinical Obstet Gynecol 2008;51: 281-9.
- 13. **DAVIS AR**. Pregnancy prevention in epilepsy: assessing the options. Practical Neurology 2006;5:28-33.
- 14. **DAVIS AR** and Castano P. Oral contraceptives and libido. Editors: Goldstein I, Meston C, Davis S, Traish A. In *Women's Sexual Function and Dysfunction:* Study, Diagnosis and Treatment. Taylor and Francis, UK, 2005 (290-6).

- 15. **DAVIS AR** and Schnare S. Hormonal contraceptives and libido. Dialogues in Contraception. Volume 9, 2005.
- Anastasiadis A, Droggin D, DAVIS AR, Salomon L and Shabsigh R. Male and female sexual dysfunction: epidemiology, pathophysiology, classification and treatment. Editor: Marianne J. Legato. In *Principals of Gender Specific Medicine*. Elsevier Science, San Diego, CA, 2004 (573-585).
- 17. **DAVIS AR**, Teal S. Controversies in adolescent hormonal contraception. Infert Reprod Med Clin N Am 2003;14:141-156.
- 18. Anastasiadis AG, **DAVIS AR**, Ghafar MA, Burchardt M, Shabsigh R. The epidemiology and definitions of female sexual disorders. World J Urol, 2002;20:74-78.
- 19. Anastasiadis AG, **DAVIS AR**, Salomon L, Burchardt, Shabsigh. Hormonal factors in female sexual dysfunctional. Curr Opin. Urol. 2002; 12:503-7.
- 20. **DAVIS AR**. Recent advances in female sexual dysfunction. Curr Psych Reports 2000;2:211-214.
- 21. **DAVIS AR**. Book review. A Clinician's Guide to Medical and Surgical Abortion. NEJM. 2000;343(3):227-228.

# Books/textbooks for medical or scientific community

None

#### Case reports

None

#### Letters to the editor

- DAVIS AR. (2013, November 5<sup>th</sup>). [Letter to the editor, in response to "In reversal, court allows Texas law on abortion" news article, Nov 1] <u>The New York Times</u>, p. A28.
- 2. **DAVIS AR**. (2011, January 9) [Letter to the editor, in response to "The Unborn Paradox"] <u>The New York Times</u>, p. WK9.
- 3. **DAVIS AR** and Pack A. . [Letter to the editor, in response to "Initial management of epilepsy"] NEJM 2008; 359:2499-250.
- 4. DAVIS AR and Winikoff B. Abortion is for women. Lancet 2007; 9: 369.

#### Other media

- DAVIS AR, Boyd-Bragadeste K, Cheney B, Plumbo M, Sunyecz J and Thomas M. Postpartum counseling: a quick reference guide for clinicians. Association of Reproductive Health Professionals. March, 2003, revised 2006.
- 2. DAVIS AR, Harden C and Pennell P. Women with Epilepsy: Hormones, Contraception and Treatment Options. Supplement to OB/GYN News. Summer 2005.
- 3. DAVIS AR. Contraception: making the right choice. In Women with epilepsy: hormones, contraception and treatment options. Supplement to Clinical Neurology News. August, 2005.
- **4.** Scheinfeld N, **DAVIS AR**. Teratology and drug use during pregnancy. Emedicine Journal, 2003. http://author.emedicine.com/MED/topic3242.htm.
- **5. DAVIS AR**, Engle C. Sexual Function. Reproductive Health Initiative Model Curriculum, 2<sup>nd</sup> Edition, Psychosocial module. American Medical Women's Association. 2003.
- 6. DAVIS AR. Early pregnancy loss, recurrent pregnancy loss and ectopic pregnancy. Resident study guide for CREOG exams. 2003, 2004, 2005.

#### Thesis

None

# Other non-peer reviewed publications in print or other media

- 1. Herzog A, **DAVIS AR**, Hauser A, Contraceptive Practices of Women with Epilepsy: Findings of the Epilepsy Birth Control Registry. Platform presentation at the American Academy of Neurology 67<sup>th</sup> Annual Meeting, April, 2015.
- 2. Harden C, Lau C, Pennell P, Bagiella E, Huynh J, Kashambwa R, Llewellyn N, Kaufman B, **DAVIS AR** and French J. Menstrual cycle length in women with epilepsy trying to conceive compared to healthy controls. Poster presentation. American Epilepsy Society Annual Meeting, 2014.
- 3. **DAVIS AR**, Saadatmand J and Pack A. Seizure control, satisfaction, and drug interactions during use of the levonorgestrel intrauterine device in women with epilepsy. Poster presentation. American Epilepsy Society Annual Meeting, 2014.
- 4. **DAVIS AR**, Pack A, Saadatmand J. Contraception with the levonorgestrel IUS in women with epilepsy: results from the WE SAIL study. Poster presentation. North American Forum on Family Planning Annual Meeting,

2014.

- 5. Nippita S, Castano P and **DAVIS AR**. Text Messages Versus Monthly Paper Diaries: Collecting Bleeding Data Following IUD Insertion. Poster presentation. ACOG Annual Clinical Meeting, 2014.
- Nippita S, Castano P and DAVIS AR. 90-Day Bleeding Patterns After Intrauterine Device Insertion: A Prospective Parallel Cohort Study. Poster presentation. ACOG Annual Clinical Meeting, 2014.
- 7. Herzog A, **DAVIS AR**, Hauser A. Relative Risks of Changes in Seizure Frequency with Hormonal Contraception Vary by Antiepileptic Drug Category. Platform presentation American Academy of Neurology Annual Meeting, 2013.
- 8. Herzog A, **DAVIS AR**, Hauser A. Relative Risks of Changes in Seizure Frequency with Hormonal Versus Non-Hormonal Contraception. Platform presentation. American Academy of Neurology Annual Meeting, 2013.
- Maguire, K, Morrell K, Davis AR, Westhoff CL. Oral presentation: Accuracy of Providers' Assessment of Pain during IUD Insertion. ACOG's 60th Annual Clinical Meeting May 07, 2012.
- 10. Llewellyn N, Harden CL, French J, Pennell PB, Bartfeld E, Davis AR, Lau C, Lee JK, Kirshenbaum A, Bagiella E. Poster presentation. Maintenance of subject adherence to daily diary entry facilitated by use of a mobile application in the WEPOD study Annual Meeting of the American Epilepsy Society, 2012.
- 11. Pennell, P French, J, Harden, CL, Bartfeld, E, **DAVIS AR**, Llewellyn, LG, Staley, BA, Lau, C, Keenan, HA. Poster presentation. Evaluation of a mobile application tool in the WEPOD study. American Academy of Neurology Annual Meeting, 2011.
- 12. Tsai S, **DAVIS AR**, Wade C. Case Series: Acupuncture point injection with vitamin K for treatment of dysmenorrhea. Oral presentation: The Pediatric Academic Societies Annual Meeting 2010.
- 13. **DAVIS AR**, Westhoff C, Stanczyk F. Carbamazepine co-administration with an oral contraceptive: effects on steroid pharmacokinetics, bleeding and ovulation. Poster presentation: American Academy of Neurology Annual Meeting, 2010.
- Hall KS, O'Connell K, DAVIS AR, Rickert V, Reame N, Westhoff C. Psychological Symptoms, Perceived Side Effects, and Oral Contraceptive

- Discontinuation in Minority Adolescent and Young Adult Women. Poster presentation. Eastern Nursing Research Society Conference, 2009.
- 15. Osorio J, Reddy S, **DAVIS AR**, O'Connell K, Castano P, Simpson L, Yamashiro D and Mital S. Department Pediatric Cardiology and Obstetrics and Gynecology. Growth signaling pathways in the developing human heart. Poster presentation. Pediatric Academic Societies, 2007.
- 16. **DAVIS AR**, Pack A, Camus A, Yoon A, Kritzer J. Patient knowledge of teratogenicity and contraceptive interactions of anti-epileptic drugs. Poster presentation. American College of Obsterics and Gynecology annual meeting, 2007.
- 17. **DAVIS AR**, Pack A, Camus A, Yoon A, Kritzer J. Patient knowledge of teratogenicity and contraceptive interactions of anti-epileptic drugs. American Epilepsy Society Annual Meeting, 2007.
- 18. **DAVIS AR**, Kroll R, Soltes B, Haudiquet V, Zhang N, Grubb GS, Constantine GD. Return to menses after use of a continuous low-dose oral contraceptive. Oral presentation: American College of Obstetricians and Gynecologists annual meeting, 2006.
- 19. **DAVIS** AR, Pack A, Camus A, Yoon A, Kritzer J. Contraception in women with epilepsy. Poster presentation: Association of Reproductive Health Professionals meeting, 2006.
- O'Connell K, Kerns J, DAVIS AR. Oral contraceptives and depression in adolescent girls. Poster presentation: Association of Reproductive Health Professionals Annual Meeting, 2005.
- 21. **DAVIS AR**, O'Connell K, Westhoff C. Oral contraceptives for dysmenorrhea in adolescent girls: a randomized, controlled trial. Oral presentation: Association of Reproductive Health Professionals Annual Meeting, 2004.
- 22. Seidman S, **DAVIS AR**, Shabsigh R, Small S. The central acute effect of testosterone in post-menopausal women assessed by fMRI. International Society of Sexual Medicine 2004, Buenos Aires. Published: Journal of Sexual Medicine volume 1, supplement 3, 2004. Awarded prize: ISSM award for best clinical abstract in female sexual dysfunction.
- 23. O'Connell K, Kearns J, **DAVIS AR**. Self-treatment of moderate and severe dysmenorrhea in adolescent girls. Poster presentation: Society of Adolescent Medicine, 2004.

- 24. **DAVIS AR**, O'Connell K, Westhoff C. A double-blind randomized trial of an oral contraceptive vs. placebo for dysmenorrhea in adolescents. Poster presentation. ACOG Annual Clinical Meeting 2004.
- 25. **DAVIS AR**, Osborne L, Westhoff C and O'Connell K. A placebo-controlled trial of oral contraceptives for dysmenorrhea in adolescent girls: methodological challenges and surprises. Poster presentation: The Association for Reproductive Health Professional Annual Meeting 2003.
- 26. Seidman S, **DAVIS AR**, Shabsigh R, Small S. The acute effect of testosterone replacement in post-menopausal women as measured by fMRI. Oral presentation: International Society for Women's Sexual Health, 2003.
- 27. Anastasiadis AG, **DAVIS AR**, Sawczuk IS, Fleming M, Perelman MA, Burchardt M, Shabsigh R. Sexual functioning in kidney cancer patients: data from a national registry. Poster presentation: American Society of Clinical Oncology Annual meeting, 2002.
- 28. Anastasiadis AG, **DAVIS AR**, Sawczuk IS, Fleming M, Perelman MA, Burchardt M, Shabsigh R. High quality of life and relationship scores in men and women with high stage and metastatic kidney cancer? Poster presentation: Annual Scientific Program of the Sexual Medicine Society of North America, 2002.
- 29. The MEPF Study Group NICHD. Bleeding patterns after vaginal misoprostol for management of early pregnancy failure. Oral presentation: The Association for Reproductive Health Professionals Annual meeting, 2002.
- 30. Anastasiadis AG, **DAVIS AR**, Sawczuk IS, Fleming M, Perelman MA, Burchardt M, Shabsigh R. Sexual functioning, depression and quality of life in men and women with renal cancer. Poster presentation: The Female Sexual Function Forum annual meeting, 2001.
- 31. Murphy P, **DAVIS AR**, Westhoff C, Soren K. Contraception for adolescent girls with chronic illnesses: a demonstration project. Oral presentation: The Society for Adolescent Medicine, 2000.
- 32. **DAVIS AR**, Nowygrod S, Westhoff C, Shabsigh R. The influence of vaginal bleeding on the sexual behavior of Hispanic women and men. Poster presentation: The Association for Reproductive Health Professionals annual meeting, 2000.

- 33. **DAVIS AR**, Nowygrod S, Westhoff C, Shabsigh R. The influence of vaginal bleeding on the sexual behavior of urban Hispanic women. Oral presentation: Conference on Female Sexual Dysfunction, 1999.
- 34. **DAVIS AR**, Miller LA, Tamimi H, Gown A. Methotrexate vs. 6-Mercaptopurine for early abortion using the immunohistochemical assay Ki-67. Oral presentation: National Abortion Federation, 1997.
- 35. Killackey M and **DAVIS AR**. Case-control comparison of papillary serous ovarian CA and papillary serous ovarian CA of the peritoneal surface. Oral presentation: Annual meetings of the American College of Obstetricians and Gynecologists and The Society of Memorial Gynecologic Oncologists, 1992.

# 16) Invited and/or peer selected presentations at regional, national or international levels

Grand rounds speaker Departments Obstetrics and Gynecology

#### International

Grand rounds speaker, Department OB/GYN. Early surgical abortion. University of Puerto Rico at San Juan, San Juan, Puerto Rico, 1998.

#### National

- 1. University of Washington, Seattle, WA. Contraception for women with epilepsy: does it work? will it help? May 2014.
- 2. Dartmouth Hitchcock Medical Center. The pill for the ill? Contraception for women with medical conditions. December, 2009.
- 3. University of Utah. The pill for the ill? Contraception for women with medical conditions, September 2009.
- 4. Grand rounds speaker Departments Obstetrics and Gynecology
- 5. Northwestern University. Contraception and women with medical problems, 2007.
- 6. St. John's Hospital, Detroit, MI. Gynecologic uses of misoprostol, 2005.
- 7. University of Illinois at Chicago. Chicago, IL. Gynecologic uses of misoprostol, 2005.
- 8. Cedars-Sinai Medical Center, Los Angeles, CA. Medical management of pregnancy termination, 2002.
- 9. Kaiser Los Angeles Medical Center, Los Angeles, CA. Medical abortion regimens, 2002.

# Regional

- 1. Staten Island Hospital Center. Intrauterine progestins for common gynecologic problems. Staten Island, NY. December 2011.
- 2. Advances in Contraception. Winthrop Hospital, Long Island. November 2012.
- 3. A Clinical update in intrauterine contraception. North Shore LIJ Medical Center. April 3, 2013.
- 4. University of Rochester. The pill for the ill? Contraception for women with medical conditions. April 2009.
- 5. Long Island Jewish University. Update on intrauterine contraception. November 2009.
- 6. North Shore, Long Island Jewish. A Clinical Update on Intrauterine Contraception, 2008.
- 7. New York University. Contraception for Women with Medical Problems, 2008.
- 8. NYU Bellevue. Mainstreaming intrauterine contraception, 2008. Harlem Hospital
- 9. Medical Center. The levonorgestrel IUS. New York, NY, 2007.
- Beth Israel Medical Center. Gynecologic uses of misoprostol. New York, NY, 2006.
- 11. Woodhull Medical Center. Surgical management of abortion and miscarriage in the first trimester, 2006.
- 12. Lutheran Medical Center, Brooklyn, NY. Medical abortion, 2005.
- 13. Bronx Lebanon Medical Center. Bronx, NY. Intrauterine contraception, 2005.
- 14. Harlem Hospital Center, NY, NY. Intrauterine contraception: expelling the myths and dealing with the dilemmas, 2005.
- 15. Maimonides Medical Center. Medical abortion regimens, complications, and side effects, 2005.
- 16. NY Methodist Hospital. Medical abortion, 2005.
- 17. Staten Island Medical Center. Emergency Contraception, 2004.
- 18. Queens Medical Center, Jamaica, NY. Early options for pregnancy termination, 2004.
- 19. Columbia University Medical Center, NY, NY. Oral contraceptives and

- dysmenorrhea in adolescent girls, 2004.
- 20. University of Medicine and Dentistry of New Jersey. Newark, NJ. Second trimester abortion, 2004.
- 21. Elmhurst Medical Center, Queens, NY. New options for pregnancy termination, 2003.
- 22. New York University, NY. Overview of Abortion 2003.
- 23. Jersey Shore Medical Center, NJ. Abortion in the United States, 2002.
- 24. Albany Medical College, Albany, NY. Overview of medical abortion, 2002.
- 25. St. Vincent's Hospital, New York, NY. Recent Advances in Contraception and the levonorgestrel intra-uterine system, 2002.
- 26. Columbia University Medical Center, New York, NY. Female sexual dysfunction: an update, 2001.
- 27. Columbia University Medical Center, New York, NY. Tubal sterilization, 1998.

# Hospital presentations

# Regional

- 1. Department of Pediatrics Grand rounds. Medical Abortion Overview. Albany Medical Center, 2006.
- 2. Department of Pediatrics Grand Rounds. Adolescents, dysmenorrhea and oral contraceptives. Columbia University Medical Center, New York, NY, 2002.
- 3. Sexual dysfunction 2002: Update on female sexual dysfunction. Columbia University. New York, NY, 2002.
- 4. New Developments in Contraception: Counseling and insertion procedures for the levonorgestrel IUS. Multiple locations in New York, NY, 2001.

# Presentations at meetings

#### International

- 1. National Abortion Federation. Challenging abortion cases: best practices Halifax, Nova Scotia, 2008.
- 2. International Society of Women's Sexual Health. Adolescent Sexuality, Vancouver, CA, 2002.

# Regional

- 1. Sloane Symposium: Current Issues in Obstetrics and Gynecology. The IUD: How don't became do, 2008. Health and Hospitals Corporation Family Planning Update Conference.
- 2. Medical conditions affecting abortion care Jacobi Medical Center, NY, 2003.

#### National

- 1. Contraception after medication abortion: what do we know? North American Forum on Family Planning annual meeting 2013.
- 2. Management of early pregnancy failure. North American Forum on Family Planning annual meeting 2013.
- 3. Microadvocacy: what you can do with a few facts in a few minutes.

  Association for Reproductive Health Professionals. Las Vegas, 2011.
- 4. Heavy Menstrual bleeding: assessing the impact, evaluating management options, ACOG Annual Clinical Meeting, 2009.
- 5. Florida Academy of Physician Assistants. A Clnical Update on Intrauterine Contraception, 2008.
- 6. American Epilepsy Society. Contraception and epilepsy. Annual meeting, New Orleans, LA, 2004.
- 7. Early options for pregnancy termination. Breakfast round table meeting, ACOG Annual Clinical Meeting, 2003.
- 8. National Abortion Federation Risk Management Seminar. Medical conditions affecting abortion care. Bal Harbour, FL, 2002.
- 9. American Society for Reproductive Medicine. Clinical symposium. The utility and efficacy of monthly injectable contraception, 2001.
- 10. Female Sexual Function Forum. Oral contraceptives and libido. Boston, MA, 2000.

# Seminars

# Regional

- Update on emergency contraception and contraception for women with medical problems. School based reproductive health project. Department of Health. New York, NY. April 2014.
- 2. The time is now: providing adolescent friendly sexual and reproductive

- healthcare. For NYPATH New York Promoting and Advancing Teen Health. Segundo Ruiz Belvis Diagnostic & Treatment Center Healthcare Network of Health and Hospitals Corporation. January 15, 2014.
- 3. The time is now: providing adolescent friendly sexual and reproductive healthcare. For NYPATH New York Promoting and Advancing Teen Health. Renaissance Healthcare Network of Health and Hospitals Corporation. December 2, 2013.
- 4. Medical aspects of abortion. Center for Reproductive Rights. New York, NY. December 10, 2013.
- 5. Intrauterine progestins for common gynecologic problems. The Sloane Symposium: current issues and controversies in obstetrics and gynecology. Columbia University Medical Center Department OB/GYN 2011.
- 6. Reproductive rights at risk: frame the issue, make it law. Co-presenter with Attorney General Eric Schneiderman and New York City Council Speaker Christine Quinn. Congregation Rodeph Sholom, New York City, NY, 2011.
- 7. What can she use? Contraception for women with medical problems. New York Nurse Practitioners in Women's Health. New York City, NY, 2011.
- 8. What can she use? Adolescents, contraception and the new CDC guidelines. Mt. Sinai Medical Center, 2010.
- Contraception and women with medical problems. Ryan Health Center, 2008.
- 10.15<sup>th</sup> Annual Comprehensive Gynecology 2007: A clinical Update for the Practicing Physician. An update on the vaginal contraceptive ring: factors affecting choice and complicance, 2007.
- 11. Mainstreaming intrauterine contraception. Columbia University School of Nursing, 2007.
- 12. Cicatelli Incorporated. Depo Provera and bone health. New York, New York, 2006.
- 13. Clinical issues in reproductive health care. Cicatelli Associates Incorporated. New Methods of Hormonal Contraception. New York, NY, 2003.
- 14. New York Association of Nurse Practitioners. Beyond Oral Contraception. New York, NY, 2002.
- 15. Medical Students for Choice. New York University Regional Conference. Keynote speaker, 2002.
- 16. Westchester OB/GYN Society. Medical abortion overview, Westchester, NY, 2002.
- 17. Sexual Dysfunction 2001. Multidisciplinary update on ED, premature ejaculation, Peyronie's & Female Sexual Dysfunction. Columbia University,

New York, NY, 2001.

- 18. Medical Abortion Education Project. Evaluation, management, and administration of medical abortion. Department OB/GYN, Syracuse, NY, 2001
- 19. Adolescent Medicine Society of New York. Medical abortion, New York, NY, 2001.
- 20. New York City Department of Health. Vaginitis. New York, NY, 2000.
- 21. Downstate Medical Center Comprehensive OB/GYN Review Course. Contraception. Brooklyn, NY, 2000-2004.

#### National

Contraceptive options and management. Inova Healthcare System, 2010.

# Exhibit 3

# IN THE SECOND JUDICIAL DISTRICT DISTRICT COURT, SHAWNEE COUNTY, KANSAS DIVISION 7

HODES & NAUSER, MDs, P.A.; HERBERT C. HODES, M.D.; and TRACI LYNN NAUSER, M.D.,	) ) ) ) ) ) )
Plaintiffs,	) Case No.
v.  DEREK SCHMIDT, in his official capacity as Attorney General of the State of Kansas; and STEPHEN M. HOWE, in his official capacity as District Attorney for Johnson County,	) ) ) ) ) ) ) ) ) ) ) ) ) ) ) ) )
Defendants.	)

# AFFIDAVIT OF DAVID ORENTLICHER, M.D., J.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR TEMPORARY INJUNCTION AND/OR TEMPRORARY RESTRAINING ORDER

DAVID ORENTLICHER, M.D., J.D., of lawful age and being duly sworn, states as follows:

1. I submit this affidavit in support of Plaintiffs' Motion for Temporary Injunction and/or Temporary Restraining Order against enforcement of Kansas Senate Bill

95.

- 2. I provide the following opinions as an expert in medical ethics. I received a medical degree from Harvard University in 1981 and a juris doctor degree from Harvard University in 1986. After medical school, I continued my training for twelve months as a first-year resident in internal medicine at the University of Michigan Medical Center, and then cared for patients in a solo general practice and at a general medicine clinic for about nine months. I am the Samuel R. Rosen Professor of Law and Co-director of the William S. and Christine S. Hall Center for Law and Health at Indiana University Robert H. McKinney School of Law. I am also an adjunct professor of medicine at Indiana University School of Medicine. I previously served as director of the division of medical ethics at the American Medical Association (AMA) for six-and-a-half years. In that position I led the drafting of the AMA's first patients' bill of rights and helped develop many other AMA ethical positions, including positions on end-of-life matters, reproductive decisions, and organ transplantation. A copy of my curriculum vitae, which summarizes my background, experience and publications, is attached hereto as Exhibit A.
- 3. The opinions expressed below are based on my years of experience in caring for patients; teaching medical ethics to undergraduates, medical students, and law students at major universities; research on medical decision making by patients and physicians; and review of the professional and academic literature on principles of medical ethics.

- 4. I have reviewed S.B. 95 (the "Act"), and understand that it will ban a second-trimester abortion procedure known as dilation and evacuation or D & E on a living fetus with limited exceptions.
- 5. In order to avoid the Act's criminal penalties and civil liability, a physician wishing to perform a D & E procedure would have to ensure fetal demise prior to beginning the abortion. Based on my review of the expert declaration of Dr. Anne Davis and discussions with Plaintiffs' attorneys, I understand that it is neither common practice nor the standard of care to induce demise prior to performing a D & E procedure at less than 18 weeks LMP. I further understand that after 18 weeks, some physicians induce demise, most commonly using an injection of digoxin. Some do this because they think it provides medical benefits. Others do it to avoid violating federal or state bans on so-called partial-birth abortions. I understand that there are virtually no studies on the use of digoxin prior to 18 weeks. I further understand that an alternative means of inducing demise—umbilical cord transaction—cannot be relied on as a method of inducing fetal demise because it cannot be accomplished in every case, nor is it known how frequently the procedure will be successful.
- 6. The American College of Obstetricians and Gynecologists Second Trimester

  Practice Bulletin (No. 135, June 2013) states: "No evidence currently supports
  the use of induced fetal demise to increase the safety of second trimester
  medical or surgical abortion. Techniques used to cause fetal demise include
  division of the umbilical cord, intra-amniotic or intrafetal digoxin injection, or
  fetal intracardiac potassium chloride injection."

7. The Act violates several fundamental principles of medical ethics by 1) forcing physicians to subject women seeking D & E procedures to what the physicians believe is a more complex and risky medical procedure and that may include an additional invasive injection; 2) forcing physicians to subject women seeking D & E procedures prior to 18 weeks to untested and unstudied practices; 3) denying physicians and women seeking D & E procedures the ability to freely choose among medically appropriate treatment options; and 4) forcing physicians to comply with a government mandate that a physician may not believe is in the patient's best interest, as a prerequisite to providing care.

# The Act Subjects Women to Unnecessary Medical Risks

- 8. The principle of non-maleficence, that patients must not be exposed to unnecessary risks, is one of the most longstanding concepts of medical ethics, deriving from the admonition that doctors must first do no harm. Whether in the context of medical treatment or medical research, threats to patient welfare must be minimized. As a corollary, when there are two medical treatments that offer the same level of benefit, patients must be able to choose the treatment with the lower level of risk.
- 9. The Act will require physicians to induce demise prior to a D & E procedure, which will most likely be accomplished through either umbilical cord transection or an injection of digoxin or KCl. Whichever means the physician undertakes makes the procedure more complex and risky. Moreover, because the success rate of umbilical cord transection is unknown, every woman faces the possibility of having to undergo an invasive injection in order to obtain a D

- & E procedure. Thus, prior to 18 weeks and after 18 weeks for those physicians who do not believe that inducing demise offers any medical benefits, the Act requires many women to undergo a more complex and risky procedure that her physician does not believe offers any medical benefit.
- 10. The Act denies women seeking, and physicians wishing to provide, D & E procedures of any meaningful ability to avoid the imposition of these unnecessary risks, and provides no tangible benefit to the unwilling patient.
- 11. It is not consistent with good medical ethics to force doctors to perform a procedure that they think subjects patients to risk with no medical benefit.
  Here, my understanding of the available data supports physicians' concerns that SB 95 mandates the provision of an unnecessary medical procedure that confers no benefit to the patient.
- 12. The Act represents a significant violation of these principles because it would require women to accept an unnecessary medical procedure, and therefore an increased risk, in support of an intangible benefit—a legislative policy decision wholly unrelated to what is in the woman's medical best interests.

# The Act Subjects Women to an Experimental Procedure

13. Medical ethics provide particular protections for patients involved in experimental treatments or practices. By definition, the benefits and risks of an experimental treatment are unknown, and thus the physician does not know if he or she will inadvertently violate the principle of non-maleficence. Patient informed consent and autonomy are therefore critical, and when researchers conduct studies of an experimental procedure, their studies are subject to

- independent review to ensure that the risks of participation are "reasonable in relation to the potential benefits." National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, vol. 1, page ii (August 2001).
- 14. It is my understanding that fetal demise is not typically induced for abortion procedures prior to 18 weeks and that there is a dearth of literature addressing demise via either umbilical cord transection or digoxin injection prior to 18 weeks. Thus, physicians wishing to provide D & E procedures prior to 18 weeks would have to subject their patients to largely untested and unstudied practices in order to avoid violating the Act.
- 15. The Act thus places women in the position of taking part in experimental medical practices in order to obtain the D & E abortion services they desire.

  Any patient participating in an experiment like this must be able to consent freely. Here, however, the Act denies patients the ability to provide meaningful consent because a patient who does not wish to undergo a procedure to cause demise must either forgo a D & E procedure or choose the wholly different procedure of induction of labor, which, even if available, requires an inpatient process that is lengthier, riskier, and more expensive.
- 16. The departure from ethical principles is even starker here where women are being forced to accept a demise procedure, and the published data as I understand it, so far show no benefit to the patient in the contexts in which demise procedures have been tried.

17. Even as to digoxin procedures after 18 weeks, it is inappropriate as a matter of medical ethics to force women to accept the procedure when her physician believes that the procedure imposes risks without any benefit. The fact that some physicians are inducing demise after 18 weeks does not support mandating that all physicians do so. This is particularly so here, where some physicians who induce demise do not believe it is medically justified, but do so as a means of avoiding liability under bans on so-called partial-birth abortions. A practice driven by legal, rather than medical concerns, should not lend support to a mandate that women seeking standard D & E procedures also accept the fetal demise procedure.

# The Act Undermines the Informed Consent Process

- 18. A fundamental tenet of medical ethics is that mentally competent patients must give informed consent to medical treatment. The requirement of informed consent reflects the facts that a person's bodily integrity may not be violated without the person's permission and that patients are ultimately the most appropriate persons to make treatment decisions. The practitioner's role in the informed consent process is to provide the patient with all of the relevant considerations that will allow the patient to make a voluntary and informed choice among the medically sound treatment options and to respect the preferences of patients about what they want to do.
- 19. These principles have been incorporated into the standards for virtually all professional associations in medicine. For example, the AMA's Code of Ethics states:

The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent.

AMA, Code of Medical Ethics, Opinion E-8.08.

In addition, a recent statement by the American College of Obstetricians

& Gynecologists' Committee on Ethics (ACOG) provides:

Seeking informed consent expresses respect for the patient as a person; it particularly respects a patient's moral right to bodily integrity... Consenting freely is incompatible with being coerced or unwillingly pressured by forces beyond oneself. It involves the ability to choose among options and to select a course other than what may be recommended.... Informed consent includes freedom from external coercion, manipulation, or infringement of bodily integrity. It is freedom from being acted on by others when they have not taken account of and respected the individual's own preference and choice.

ACOG, Committee on Ethics, Committee Opinion Number 439, Informed Consent (Aug. 2009).

20. The Act prevents women seeking D & E abortions who do not wish to undergo a demise procedure from giving truly informed consent. If not for the Act, they would be able to choose freely among the options and follow their physician's recommendation as to whether to have a demise procedure or not. For many women this would likely result in choosing not to have a demise procedure if they felt, after being informed of the relevant information, that they did not want to expose themselves to the potential risks of the procedure.

21. Here, the Act prevents physicians from "help[ing] the patient make choices from among the therapeutic alternatives consistent with good medical practice," by foreclosing the option that the physician may believe is the best practice. It also fails to respect the patient's right to bodily integrity by introducing external coercion that prevents the patient from protecting her own bodily integrity while still receiving medical care that she desires.

# The Act Interferes with the Physician-Patient Relationship

- 22. The integrity of the physician-patient relationship is a cornerstone of medical ethics. The physician owes the patient a fiduciary duty by virtue of his or her professional role. This duty requires the physician to act in the patient's interests. As the World Medical Association's International Code of Medical Ethics states, "A physician shall owe his/her patients complete loyalty and all the scientific resources available to him/her."
- 23. The physician-patient relationship is also founded on trust and recognition of the patient's pro-active role in the process. ACOG's Committee on Ethics has found that "patients' active role as primary guardian of their own health is more conducive to their well-being than is a passive and submissive 'sick role.'" ACOG, Informed Consent, supra. When patients are involved in the decision-making process, they report lower levels of anxiety about their condition, a greater sense of control, less discomfort and, most importantly, greater improvement in their medical condition. Jaime Staples King & Benjamin W. Moulton, Rethinking Informed Consent: The Case for Shared Medical Decision-Making, 32 Am. J. L. and Med. 429, 469-470 (2006).

- 24. The Act interferes with both of these aspects of the physician-patient relationship. By requiring physicians to perform an unnecessary, and in some instances experimental, procedure on women in order to provide abortion care, S.B. 95 forces doctors to act against the patient's best interests. This undermines patient trust, which is critical to the provision of good care, and leaves the patient to wonder throughout the treatment whose interests the physician is serving.
- 25. In addition, the Act undermines the patient's ability to take a fully active role in her health care by precluding her ability to choose the course of treatment that she believes is best for her. Here, in fact, the patient may be forced to accept treatment that not only she does not want, but that her physician may feel is not in her best interests.
- 26. For these reasons, S.B. 95 conflicts with fundamental principles of medical ethics and its enforcement will harm both physicians who provide abortions affected by the Act and their patients.

Dated May 28, 2015

David Orentlicher, M.D., J.D.

# Exhibit A

# DAVID ORENTLICHER, MD, JD david.orentlicher@yahoo.com (317) 658-1674

#### **CURRENT POSITIONS**

Indiana University Robert H. McKinney School of Law Samuel R. Rosen Professor of Law (July 1999 - present) Professor of Law (July 1998 - present), Associate Professor of Law (August 1995 - June 1998)

Co-Director, Center for Law and Health (August 1996 - present)

Courses in bioethics and law, constitutional law, professional responsibility, trusts and estates

Indiana University School of Medicine Adjunct Professor of Medicine (July 1999 - present) Adjunct Associate Professor of Medicine (October 1995 - June 1998)

#### VISITING CHAIRED PROFESSORSHIPS

Princeton University Visiting DeCamp Professor of Bioethics (September 1997 - June 1998)

T.C. Williams School of Law, University of Richmond George E. Allen Professor of Law (March 1995)

DePauw University Frederick Distinguished Visiting Professor of Ethics (Fall 2005)

#### PREVIOUS ACADEMIC APPOINTMENTS

Northwestern University Medical School Adjunct Assistant Professor of Medicine (September 1992 - July 1995) Faculty, Medical Ethics and Humanities Program (February 1990 - July 1995)

University of Chicago Law School Lecturer in Law (1992-93, 1993-94 and 1994-95 academic years)

University of Iowa College of Law Visiting Professor (August 2010 – June 2011)

#### **EDUCATION**

Harvard Law School

J.D., 1986, Magna Cum Laude

Editor, Harvard Law Review (1984-86), Commentary and Book Review Office Chair (1985-86)

Harvard Medical School

M.D., 1981, Founder, Harvard Public Interest Health Foundation

**Brandeis University** 

B.A., 1977, Magna Cum Laude with High Honors in Economics

#### PROFESSIONAL ACTIVITIES

American Law Institute
Elected Member (October 1995 - present)
Adviser, Project on Principles of Government Ethics (2010 - present)

American Society of Law, Medicine & Ethics President (2015), President-Elect (2014), Executive Board Member (2012 – present)

Cambridge Dictionary of Bioethics, Cambridge University Press Editorial Board (August 2009 – present)

American Association of Bioethics Executive Board Member (1992-95), Secretary-Treasurer (1994-95)

#### PREVIOUS EMPLOYMENT

#### **Public Office**

State Representative, Indiana General Assembly House District 86 (November 2002 – November 2008)

Ways and Means, Public Health, Small Business and Economic Development, and Education Committees Authored legislation to make health care insurance more affordable, increase the pool of venture capital for new businesses, and ensure better protection of children from abuse and neglect.

#### **Ethics**

American Medical Association

Director, Division of Ethics Standards (October 1994 - July 1995)

Ethics and Health Policy Counsel (January 1989 - September 1994)

Supervised development of the AMA's Code of Medical Ethics. Prepared reports on the full range of ethical issues in medicine, including health care access and rationing, end-of-life decisions, organ transplantation, genetic testing, and conflicts of interest. Also wrote amicus briefs for cases involving health policy issues, including withdrawal of life-sustaining treatment and maternal-fetal conflicts.

Led drafting of AMA's first patients' bill of rights and many other guidelines that have been incorporated into federal and state law and cited by courts and government agencies in their decision-making.

#### Law

Sidley & Austin, Washington, District of Columbia Associate (October 1987 - January 1989)

Hon. Alvin B. Rubin, U.S. Court of Appeals, Fifth Circuit, Baton Rouge, Louisiana Law Clerk (August 1986 - August 1987)

#### Medicine

Private General Practice of Medicine, Detroit and Trenton, Michigan Solo Practitioner (July 1982 - February 1983)

University of Michigan Medical Center House Officer I, Internal Medicine (June 1981 - June 1982)

#### MAJOR PUBLICATIONS

#### Books

Orentlicher, Two Presidents Are Better than One: The Case for a Bipartisan Executive Branch (NYU Press 2013)

Orentlicher, Matters of Life and Death: Making Moral Theory Work in Medical Ethics and the Law (Princeton University Press 2001)

Orentlicher, Bobinski and Hall, Bioethics and Public Health Law (3<sup>rd</sup> ed., Wolters Kluwer 2013; 2<sup>nd</sup> ed., Aspen Publishers 2008)

Hall, Bobinski and Orentlicher, *Health Care Law and Ethics* (8<sup>th</sup> ed., Wolters Kluwer 2013; 7<sup>th</sup> ed., Aspen Publishers 2007; 6<sup>th</sup> ed. Aspen Law & Business 2003); Curran, Hall, Bobinski and Orentlicher, *Health Care Law and Ethics* (5th ed. Aspen Law & Business 1998)

Hall, Ellman and Orentlicher, Health Care Law and Ethics in a Nutshell (3rd ed., West 2011)

Health Care Crisis? The Search for Answers (Misbin, Jennings, Orentlicher and Dewar, eds., University Publishing Group 1995)

Articles (\* = peer-reviewed publication)

\*Orentlicher, "Abortion and Compelled Physician Speech," 43 Journal of Law, Medicine & Ethics 9-21 (2015) (invited for symposium on free speech and the regulation of reproductive health)

Orentlicher, "Medicaid at 50: No Longer Limited to the "Deserving" Poor?," 15 Yale Journal of Health Policy, Law, and Ethics 185-195 (2015) (invited for symposium on the 50th anniversary of Medicare and Medicaid)

Orentlicher, "Aging Populations and Physician Aid in Dying: The Evolution of State Government Policy," 48 *Indiana Law Review* 111-123 (2014) (invited for symposium on state governments and aging populations)

Orentlicher, "Employer-Based Health Care Insurance: Not So Exceptional After All," 36 *University of Arkansas at Little Rock Law Review* 541-553 (2014) (invited for symposium issue on the Affordable Care Act)

Orentlicher, "Concussions and Sports: Introduction," 42 Journal of Law, Medicine & Ethics 281-283 (2014) (introduction to symposium issue that I edited)

\*Orentlicher, Pope and Rich, "The Changing Legal Climate for Physician Aid in Dying," 311 JAMA 1961-1962 (2014)

Orentlicher, "Health Care Reform and Efforts to Encourage Healthy Behavior by Individuals," 92 North Carolina Law Review 1637-1657 (2014) (invited for symposium issue on health care decision making)

Orentlicher, "The Future of the Affordable Care Act: Protecting Economic Health More Than Physical Health?," 51 Houston Law Review 1057-1079 (2014) (invited for conference on health care reform)

Orentlicher, "A Restatement of Health Care Law," 79 Brooklyn Law Review 435-456 (2014) (invited for symposium issue on Restatements of law)

Orentlicher, "NFIB v. Sebelius: Proportionality in the Exercise of Congressional Power," 2013 Utah Law Review 463-477

Articles (continued) (\* = peer-reviewed publication)

Orentlicher, "The FDA's Graphic Tobacco Warnings and the First Amendment," 369 New England Journal of Medicine 204-206 (2013) (invited)

Orentlicher, "Deactivating Implanted Cardiac Devices: Euthanasia or the Withdrawal of Treatment?," 39 William Mitchell Law Review 1287-1294 (2013) (invited for symposium issue on medical device law)

Orentlicher and David, "Concussion and Football: Failures to Respond by the NFL and the Medical Profession," 8 FIU Law Review 17-30 (2013) (invited for symposium issue on NFL concussion litigation)

Kesselheim & Orentlicher, "Insights from a National Conference: 'Conflicts of Interest in the Practice of Medicine," 40 Journal of Law, Medicine & Ethics 436-440 (2012) (introduction to a symposium issue that I co-edited)

Orentlicher, "Rights to Health Care in the United States: Inherently Unstable," 38 American Journal of Law & Medicine 326-347 (2012)

Orentlicher, "Toward Acceptance of Uterus Transplants," 42(6) Hastings Center Report 12-13 (2012) (invited)

Orentlicher, "Constitutional Challenges to the Health Care Mandate: Based in Politics, Not Law," 160 University of Pennsylvania Law Review PENNumbra 19-32 (2011) (invited)

Orentlicher, "Controlling Health Care Costs through Public, Transparent Processes: The Conflict between the Morally Right and the Socially Feasible," 36 Journal of Corporation Law 807-821 (2011) (invited)

Orentlicher, "Can Congress Make You Buy Broccoli? And Why It Really Doesn't Matter," 84 Southern California Law Review Postscript 9-15 (2011)

Orentlicher, "The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm," 37 American Journal of Law & Medicine 299-314 (2011)

Orentlicher, "Cost Containment and the Patient Protection and Affordable Care Act," 6 FIU Law Review 65-83 (2011) (invited)

\*Hall, Hager and Orentlicher, "Using Payroll Deduction to Shelter Individual Health Insurance from Income Tax, 46 Health Services Research 348-364 (2011)

Orentlicher, "The Legislative Process Is Not Fit for the Abortion Debate," 41(4) Hastings Center Report 13-14 (2011) (invited)

Orentlicher, "Rationing Health Care: It's a Matter of the Health Care System's Structure," 19 Annals of Health Law 449-464 (2010) (invited)

Orentlicher, "Prescription Data Mining and the Protection of Patients' Interests," 38 Journal of Law, Medicine & Ethics 74-84 (2010) (invited)

Orentlicher, "Discrimination Out of Dismissiveness: The Example of Infertility," 85 Indiana Law Journal 143-186 (2010)

Articles (continued) (\* = peer-reviewed publication)

Orentlicher, "Multiple Embryo Transfers: Time for Policy," 40(3) Hastings Center Report 12-13 (2010) (invited)

Orentlicher, "Health Care Law: A Field of Gaps, 19 Annals of Health Law 1-5 (2010) (invited)

\*Orentlicher, "Health Care Reform: Beyond Ideology," 301 JAMA 1816-1818 (2009)

Orentlicher, "Presumed Consent to Organ Donation: Its Rise and Fall in the United States," 61 Rutgers Law Review 295-331 (2009)

\*Orentlicher, "Making Research a Requirement of Treatment: Why We Should Sometimes Let Doctors Pressure Patients to Participate in Research," 35(5) Hastings Center Report 20-28 (2005)

Orentlicher, "Diversity: A Fundamental American Principle," 70 Missouri Law Review 777-812 (2005)

Orentlicher and Callahan, "Feeding Tubes, Slippery Slopes and Physician-Assisted Suicide," 25 Journal of Legal Medicine 389-409 (2004) (invited)

Orentlicher, "The Rise and Fall of Managed Care: A Predictable Tragic Choices Phenomenon," 47 St. Louis University Law Journal 411-421 (2003) (invited)

\*Orentlicher, "Universality and Its Limits: When Research Ethics Can Reflect Local Conditions," 30 Journal of Law, Medicine & Ethics 403-410 (2002)

Orentlicher, "Conflicts of Interest and the Constitution," 59 Washington and Lee Law Review 713-766 (2002)

Orentlicher, "Placebo-Controlled Trials of New Drugs: Ethical Considerations," 24 Diabetes Care 771-772 (2001) (invited)

Orentlicher, "Beyond Cloning: Expanding Reproductive Options for Same-Sex Couples," 66 Brooklyn Law Review 651-683 (2000-2001)

\*Orentlicher and Caplan, "The Pain Relief Promotion Act of 1999: A Serious Threat to Palliative Care," 283 JAMA 255-258 (2000)

\*Orentlicher and Snyder, "Can Assisted Suicide be Regulated?," 11 Journal of Clinical Ethics 358-366 (2000)

Orentlicher, "Medical Malpractice: Treating the Causes Instead of the Symptoms," 38 Medical Care 247-249 (2000) (invited editorial)

Orentlicher, "Third Party Payments to Criminal Defense Lawyers: Revisiting <u>United States v. Hodge and Zweig</u>," 69 Fordham Law Review 1083-1110 (2000) (invited)

Orentlicher, "The Implementation of Oregon's Death with Dignity Act: Reassuring, but More Data Are Needed," 6 Psychology, Public Policy, and Law 489-502 (2000) (invited)

Orentlicher, Book Review, Euthanasia and Law in the Netherlands, 25 Journal of Health Politics, Policy and Law 387-391 (2000) (invited)

Articles (continued) (\* = peer-reviewed publication)

\*Orentlicher and Hehir, "Advertising Policies of Medical Journals: Conflicts of Interest for Journal Editors and Professional Societies," 27 Journal of Law, Medicine & Ethics 113-121 (1999)

Orentlicher, "Representing Defendants on Charges of Economic Crime: Unethical When Done for a Fee," 49 Emory Law Journal 1339-1376 (1999)

Orentlicher, "Cloning and the Preservation of Family Integrity," 59 Louisiana Law Review 1019-1040 (1999) (invited)

Orentlicher, "The Misperception that Bioethics and the Law Lag behind Advances in Biotechnology," 33 *Indiana Law Review* 163-172 (1999) (invited)

\*Orentlicher, "Practice Guidelines: A Limited Role in Resolving Rationing Decisions," 46 Journal of the American Geriatrics Society 369-372 (1998)

Orentlicher, "The Alleged Distinction between Euthanasia and the Withdrawal of Life-Sustaining Treatment: Conceptually Incoherent and Impossible to Maintain," 1998 *University of Illinois Law Review* 837-859 (invited)

Orentlicher, "Affirmative Action and Texas' Ten Percent Solution: Improving Diversity and Quality," 74 Notre Dame Law Review 181-210 (1998)

Orentlicher, "Spanking and Other Corporal Punishment of Children by Parents: Undervaluing Children, Overvaluing Pain," 35 Houston Law Review 147-185 (1998) (invited)

\*Orentlicher, "The Supreme Court and Physician-Assisted Suicide--Rejecting Assisted Suicide But Embracing Euthanasia," 337 New England Journal of Medicine 1236-1239 (1997)

Orentlicher, "The Supreme Court and Terminal Sedation: Rejecting Assisted Suicide, Embracing Euthanasia," 24 Hastings Constitutional Law Quarterly 947-968 (1997) (invited)

Orentlicher, "The Legalization of Physician-Assisted Suicide: A Very Modest Revolution," 38 Boston College Law Review 443-475 (1997) (cited in a concurring opinion in Washington v. Glucksberg, 521 U.S. 702, 805 (1997))

\*Orentlicher, "The Legalization of Physician-Assisted Suicide," 335 New England Journal of Medicine 663-667 (1996)

\*Orentlicher, "Psychosocial Assessment of Organ Transplant Candidates and the Americans with Disabilities Act," 18 General Hospital Psychiatry 5S-12S (1996)

Orentlicher, "Destructuring Disability: Rationing of Health Care and Unfair Discrimination Against the Sick," 31 Harvard Civil Rights-Civil Liberties Law Review 49-87 (1996)

Orentlicher, "Paying Physicians More to Do Less: Financial Incentives to Limit Care," 30 *University of Richmond Law Review* 155-197 (1996) (invited) (cited in the Supreme Court's unanimous opinion in Pegram v. Herdrich, 530 U.S. 211, 220 (2000))

Orentlicher, "Health Care Reform and the Threat to the Patient-Physician Relationship," 5 Health Matrix: Journal of Law-Medicine 141-180 (1995) (invited)

Articles (continued) (\* = peer-reviewed publication)

Orentlicher, "Managed Care and the Threat to the Patient-Physician Relationship," 10 Trends in Health Care, Law & Ethics 19-24 (1995) (invited)

Orentlicher, "Organ Retrieval from Anencephalic Infants: Understanding the AMA's Recommendations," 23 Journal of Law, Medicine & Ethics 401-402 (1995)

Orentlicher, "Physician Advocacy for Patients under Managed Care," 6 Journal of Clinical Ethics 333-334 (1995)

\*Orentlicher, "Rationing and the Americans with Disabilities Act," 271 JAMA 308-314 (1994).

Orentlicher, "The Limitations of Legislation," 53 Maryland Law Review 1255-1305 (1994) (invited for symposium issue on trends in health care)

Orentlicher, "The Influence of a Professional Organization on Physician Behavior," 57 Albany Law Review 583-605 (1994) (invited for symposium issue on innovative medical technology)

Glasson and Orentlicher, "Caring for the Poor and Professional Liability: Is There a Need for Tort Reform?," 270 JAMA 1740-1741 (1993) (invited editorial)

- \*Orentlicher, "The Illusion of Patient Choice in End-of-Life Decisions," 267 JAMA 2101-2104 (1992)
- \*Orentlicher, "Corporal Punishment in the Schools," 267 JAMA 3205-3208 (1992)
- \*Wolf, Boyle, Callahan, Fins, Jennings, Nelson, Barondess, Brock, Dresser, Emanuel, Johnson, Lantos, Mason, Mezey, Orentlicher and Rouse, "Sources of Concern About the Patient Self-Determination Act," 325 New England Journal of Medicine 1666-1671 (1991)
- \*Orentlicher, "HIV-Infected Surgeons: Behringer v Medical Center," 266 JAMA 1134-1137 (1991)
- \*La Puma, Orentlicher and Moss, "Advance Directives on Admission: Clinical Implications and Analysis of the Patient Self-Determination Act of 1990," 266 JAMA 402-405 (1991)
- \*Orentlicher, "Denying Treatment to the Noncompliant Patient," 265 JAMA 1579-1582 (1991)
- \*Orentlicher, "The Right to Die After Cruzan," 264 JAMA 2444-2446 (1990)
- \*Orentlicher, "Drug Testing of Physicians," 264 JAMA 1039-1040 (1990)
- \*Orentlicher, "Advance Medical Directives," 263 JAMA 2365-2367 (1990)
- \*Orentlicher, "Genetic Screening by Employers," 263 JAMA 1005, 1008 (1990)
- \*Winters, McIntosh, Cheitlin, Elon, Graboys, King, Murdaugh, Orentlicher, Ports and Rainer, "Ethics in Cardiovascular Medicine. Task Force II: The Relation of Cardiovascular Specialists to Patients, Other Physicians and Physician-Owned Organizations," 16 Journal of the American College of Cardiologists 11-16 (1990)

Articles (continued) (\* = peer-reviewed publication)

\*Orentlicher, "Cruzan v Director of Missouri Department of Health: An Ethical and Legal Perspective," 262 JAMA 2928-2930 (1989)

\*Orentlicher, "Physician Participation in Assisted Suicide," 262 JAMA 1844-1845 (1989)

Johnson, Phillips, Orentlicher and Hatlie, "A Fault-Based Administrative Alternative for Resolving Medical Malpractice Claims," 42 Vanderbilt Law Review 1365-1406 (1989)

Orentlicher, "Does Mother Know Best?," 40 Hastings Law Journal 1111-1122 (1989) (reviewing M. Field, Surrogate Motherhood (1988))

Note, "Organizational Papers and the Privilege Against Self-Incrimination," 99 Harvard Law Review 640-654 (1986)

Note, "Organizational Papers and the Privilege Against Self-Incrimination," 99 Harvard Law Review 640-654 (1986)

Book Note, Medical Malpractice: Theory, Evidence, and Public Policy, 99 Harvard Law Review 2001-2007 (1986)

Supreme Court Case Comment, "Monopolization and the Duty to Cooperate: Aspen Skiing Co. v. Aspen Highlands Skiing Corp.," 99 Harvard Law Review 275-283 (1985)

\*Graves, Hudgins, DeLung, Burnett, Scanlon and Orentlicher, "Computerized Patient-Flow Analysis of Local Family Planning Clinics," 13 Family Planning Perspectives 164-170 (1981)

# Book Chapters

Orentlicher, "Presumed Consent to Organ Donation," in Nudging Health: Health Law and Behavioral Economics (Cohen, Lynch & Robertson eds., Johns Hopkins University Press, forthcoming 2015)

Orentlicher, "Societal Disregard for the Needs of the Infertile," in Oxford Handbook of Reproductive Ethics (Francis ed., Oxford University Press, forthcoming 2015)

Orentlicher, "Principle and Practice for Palliative Sedation: Gaps between the Two," in Continuous Sedation at the End of Life: Clinical, Legal and Ethical Aspects 116-131 (Sterckx, Raus & Mortier eds., Cambridge University Press 2013)

Orentlicher, "Human Immunodeficiency Viral Syndrome: Legal and Public-Policy Perspectives," in *The Child:* An Encyclopedic Companion (Shweder, Bidell, Dailey, Dixon, Miller & Modell, eds., University of Chicago Press 2009)

Orentlicher, "Bioethics and Society: From the Ivory Tower to the State House," in *The Ethics of Bioethics:* Mapping the Moral Landscape 74-82 (Eckenwiler & Cohn, eds., Johns Hopkins University Press 2007)

Orentlicher, "Utility, Equality, and Health Care Needs of Persons with Disabilities: Interpreting the ADA's Requirement of Reasonable Accommodations," in *Americans with Disabilities: Exploring Implications of the Law for Individuals and Institutions* 236-243 (Francis & Silvers, eds., Routledge 2000)

#### Book Chapters (continued)

Orentlicher, "Medical Ethics and the Law," in Advances in Bioethics: Bioethics for Medical Education, Vol. 5, 101-112 (Edwards & Bittar, eds., JAI Press 1999)

Orentlicher, "The Supreme Court and Terminal Sedation: An Ethically Inferior Alternative to Physician-Assisted Suicide," in *Physician Assisted Suicide: Expanding the Debate* 301-311 (Battin, Rhodes & Silvers, ed., Routledge Press 1998)

Orentlicher, "Genetic Privacy in the Patient-Physician Relationship," in Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era 77-91 (Rothstein, ed., Yale University Press 1997)

Orentlicher, "The Role of Professional Self-Regulation," in Regulation of the Healthcare Professions 129-148 (Jost ed., Health Administration Press 1997)

Orentlicher, "Organ Donation--the Willing Donor," in Ethics in Emergency Medicine 214-222 (Iserson, Sanders and Mathieu, eds., 2d ed., Galen Press 1995)

Orentlicher, "Physician-Assisted Dying: The Conflict with Fundamental Principles of American Law," in *Medicine Unbound: The Human Body and the Limits of Medical Intervention* 256-268 (Blank and Bonnicksen, eds., Columbia University Press 1994)

Orentlicher & Halkola, "The Growing Inaccessibility to Prenatal Care for Poor and Minority Women: A Crucial Problem for Makers of National Health Policy," in Citizens' Commission on Civil Rights, *One Nation, Indivisible: The Civil Rights Challenge for the 1990s*, 216-246 (Govan & Taylor, eds., L&B Limited 1989)

### Staff Authorship (\* = peer-reviewed publication)

- \*Council on Ethical and Judicial Affairs, "Ethical Issues in the Patenting of Medical Procedures," 53 Food and Drug Law Journal 341-351 (1998) (with Jarrard)
- \*Council on Ethical and Judicial Affairs, "Managed Care Cost Containment Involving Prescription Drugs," 53 Food and Drug Law Journal 25-34 (1998) (with Quigley)
- \*Council on Ethical and Judicial Affairs, "The Use of Anencephalic Neonates as Organ Donors," 273 JAMA 1614-1618 (1995) (with O'Neill)
- \*Council on Ethical and Judicial Affairs, "Financial Incentives for Organ Procurement: Ethical Aspects of Future Contracts for Cadaveric Donors," 155 Archives of Internal Medicine 581-589 (1995) (with Leslie)
- \*Council on Ethical and Judicial Affairs, "Ethical Issues in Managed Care," 273 JAMA 330-335 (1995) (with Harwood and Johnson)
- \*Council on Ethical and Judicial Affairs, "Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients," 155 Archives of Internal Medicine 29-40 (1995) (with Leslie)
- \*Council on Ethical and Judicial Affairs, "Disputes Between Medical Supervisors and Trainees," 272 JAMA 1861-1865 (1994) (with Leslie and Halkola)
- \*Council on Ethical and Judicial Affairs, "Reporting Adverse Drug and Medical Device Events," 49 Food and Drug Law Journal 359-365 (1994) (with Leslie)

Staff Authorship (continued) (\* = peer-reviewed publication)

- \*Council on Ethical and Judicial Affairs, "Ethical Issues in Health Systems Reform: The Provision of Adequate Health Care," 272 JAMA 1056-1062 (1994) (with Harwood)
- \*Council on Ethical and Judicial Affairs, "Strategies for Cadaveric Organ Procurement: Mandated Choice and Presumed Consent," 272 JAMA 809-812 (1994) (with Leslie)
- \*Council on Ethical and Judicial Affairs, "Ethical Issues Related to Prenatal Genetic Testing," 3 Archives of Family Medicine 633-642 (1994) (with Leslie, Halkola and Feigenbaum)

Council on Ethical and Judicial Affairs, "Physician Assisted Suicide," 10 Issues in Law & Medicine 91-97 (1994)

- \*Council on Ethical and Judicial Affairs, "Gender Discrimination in the Medical Profession," 4 Women's Health Issues 1-11 (1994) (with Harwood)
- \*Council on Ethical and Judicial Affairs, "Physician Participation in Capital Punishment," 270 JAMA 365-368 (1993) (with Halkola)
- \*Council on Ethical and Judicial Affairs, "Caring for the Poor," 269 JAMA 2533-2537 (1993) (with Johnson and Conley)
- \*Council on Ethical and Judicial Affairs, "Mandatory Parental Consent to Abortion," 269 JAMA 82-86 (1993)
- \*Council on Ethical and Judicial Affairs, "Guidelines on Gifts to Physicians from Industry: An Update," 47 Food and Drug Law Journal 445-458 (1992) (with Johnson)
- \*Council on Ethical and Judicial Affairs, "Confidentiality of HIV Status on Autopsy Reports," 116 Archives of Pathology & Laboratory Medicine 1120-1123 (1992) (with Halkola)
- \*Council on Ethical and Judicial Affairs, "Physicians and Domestic Violence: Ethical Considerations," 267 JAMA 3190-3193 (1992) (with Schweickart and Halkola)
- \*Council on Ethical and Judicial Affairs, "Conflicts of Interest: Physician Ownership of Medical Facilities," 267 JAMA 2366-2369 (1992) (with Johnson and Conley)
- \*Council on Ethical and Judicial Affairs, "Decisions Near the End of Life," 267 JAMA 2229-2233 (1992) (with Schweickart and Halkola)
- \*Board of Trustees, "Requirements or Incentives by Government for the Use of Long-Acting Contraceptives," 267 JAMA 1818-1821 (1992)
- \*Council on Ethical and Judicial Affairs, "Sexual Misconduct in the Practice of Medicine," 266 JAMA 2741-2745 (1991) (with Halkola)
- \*Council on Ethical and Judicial Affairs, "Use of Genetic Testing by Employers," 266 JAMA 1827-1830 (1991)
- \*Council on Ethical and Judicial Affairs, "Gender Disparities in Clinical Decision Making," 266 JAMA 559-562 (1991) (with Halkola)

Staff Authorship (continued) (\* = peer-reviewed publication)

\*Council on Ethical and Judicial Affairs, "Guidelines for the Appropriate Use of Do-Not-Resuscitate Orders," 265 JAMA 1868-1871 (1991) (with Knight)

Council on Ethical and Judicial Affairs, "Gifts to Physicians From Industry," 265 JAMA 501 (1991) (an editorial)

\*Board of Trustees, "Legal Interventions During Pregnancy: Court-Ordered Medical Treatments and Legal Penalties for Potentially Harmful Behavior by Pregnant Women," 264 JAMA 2663-2670 (1990) (with Halkola)

\*Council on Scientific Affairs and Council on Ethical and Judicial Affairs, "Conflicts of Interest in Medical Center/Industry Research Relationships," 263 JAMA 2790-2793 (1990) (with Loeb)

\*Board of Trustees, "Frozen Pre-embryos," 263 JAMA 2484-2487 (1990)

\*Council on Ethical and Judicial Affairs, "Black-White Disparities in Health Care," 263 JAMA 2344-2346 (1990)

\*Council on Scientific Affairs and Council on Ethical and Judicial Affairs, "Medical Applications of Fetal Tissue Transplantation," 263 JAMA 565-570 (1990) (with Evans)

\*Council on Scientific Affairs and Council on Ethical and Judicial Affairs, "Persistent Vegetative State and the Decision to Withdraw or Withhold Life Support," 263 JAMA 426-430 (1990) (with Evans)

#### MINOR PUBLICATIONS

Orentlicher, "End Predatory Traffic Stops," Indianapolis Star, May 15, 2015

Orentlicher, "There Is an Option on Health Care," Indianapolis Star, April 17, 2015

Orentlicher, "Senators Should Have a Say, Too," Indianapolis Star, March 23, 2015

Orentlicher, "HIP 2.0 Counterproductive in Helping the Poor," Indianapolis Star, February 20, 2015

Orentlicher, "Health Care Costs Shifted to Patients," Indianapolis Star, January 16, 2015

Orentlicher, "Don't Curb Authority of Schools Official," Indianapolis Star, December 19, 2014

Orentlicher, "Does America Need More Than One President?," TIME.org, December 3, 2014

Orentlicher, "Ruthless Synagogue Killings," Indianapolis Star, November 21, 2014

Orentlicher, "No Labels Are Needed on GM Food," Indianapolis Star, October 17, 2014

Orentlicher, "Brawn vs. Brains," Indianapolis Star, September 19, 2014

Orentlicher, "Too Much Power in the White House," Indianapolis Star, August 15, 2014

Orentlicher, "The Right Call in Hobby Lobby Case," Indianapolis Star, July 18, 2014

Orentlicher, "University Censors Run Risk of Intolerance," Indianapolis Star, June 20, 2014

Orentlicher, "Off-Balance Over Public Prayer," Indianapolis Star, May 19, 2014

Orentlicher, "Wealthy Donors Can Buy More Votes," Indianapolis Star, April 18, 2014

Orentlicher, "Making the Case for Gay Marriage," Indianapolis Star, March 21, 2014

Orentlicher, "Doctors, Hospitals Key to Health-Care Costs," Indianapolis Star, February 21, 2014

Orentlicher, "Honor Beliefs in End-of-Life Decisions," Indianapolis Star, January 17, 2014

Orentlicher, "Corporate Speech vs. Public Health," Indianapolis Star, December 20, 2013

Orentlicher, "No Guarantees of Health Because of Insurance," Indianapolis Star, November 16, 2013

Orentlicher, "Health Law May Penalize the Poor," Indianapolis Star, October 18, 2013

Orentlicher, "Syria's Lesson for Obama," Indianapolis Star, September 20, 2013

Orentlicher, "The Real Roots of Polarization," Indianapolis Star, August 16, 2013

Orentlicher, "Filibusters Are Worth Protecting," Indianapolis Star, July 19, 2013

Orentlicher, "Edward Snowden Has Done Great Service to Nation," Indianapolis Star, June 14, 2013

Orentlicher, "Assisted Suicide Becomes More Legally Accepted," Indianapolis Star, May 17, 2013

Orentlicher, "Soda Ban Is Unlikely to Reduce Obesity," Indianapolis Star, April 19, 2013

Orentlicher, "Do What's Best for the Poor," Indianapolis Star, March 15, 2013

Orentlicher, "How to Make Weak Schools Strong," Indianapolis Star, February 15, 2013

Orentlicher, "Plan Ahead for End-of-Life Decisions," Indianapolis Star, January 21, 2013

Orentlicher, "A Time to Share Power," Indianapolis Star, December 21, 2012

Orentlicher, "Uterus Transplants Offer Women Hope," Indianapolis Star, November 30, 2012

Orentlicher, "The Dangers of Early Voting," Indianapolis Star, October 19, 2012

Orentlicher, "When Presidents Overreach," Indianapolis Star, September 22, 2012

Orentlicher, "Opting Out Isn't the Right Call," Indianapolis Star, July 20, 2012

Orentlicher, "Court Returns the Debate to Rightful Place: Congress," Indianapolis Star, July 1, 2012

Orentlicher, "Slippery Slopes at Life's End," Indianapolis Star, June 15, 2012

Orentlicher, "Bloodshed vs. Nudity," Indianapolis Star, May 18, 2012

#### MINOR PUBLICATIONS (continued)

Orentlicher, "Health Care's Unique Rules," Indianapolis Star, April 20, 2012

Orentlicher, "Goodbye to Public Servant," Indianapolis Star, March 16, 2012

Orentlicher, "Give Help to Infertile Couples," Indianapolis Star, February 17, 2012

Orentlicher, "No Right to Be a Freeloader," Indianapolis Star, January 20, 2012

Orentlicher, "Let's Embrace Full Disclosure," Indianapolis Star, December 16, 2011

Orentlicher, "It's Not Perfect, but It's Valid," Indianapolis Star, November 19, 2011

Orentlicher, "Corporate Speech Rights Trump the Public's Health, 18(3) Lahey Clinic Journal of Medical Ethics 4 (2011)

Orentlicher, "Common Ground on Abortion," Indianapolis Star, October 21, 2011

Orentlicher, "A Misguided Shot at Vaccine," Indianapolis Star, September 16, 2011

Orentlicher, "Fair Warning for Smokers," Indianapolis Star, August 19, 2011

Orentlicher and Stotland, "Danger for Pregnant Women," Indianapolis Star, July 15, 2011

Orentlicher, "Mandate's Good for America," Indianapolis Star, June 17, 2011

Orentlicher, "Abandoning Our Moral Code," Indianapolis Star, May 20, 2011

Orentlicher, "Medicare Plan Starts Dialogue," Indianapolis Star, April 11, 2011

Orentlicher, "Walkout Stands Up for Voters," Indianapolis Star, March 18, 2011

Orentlicher, "Despite Ruling, the Law Ultimately Will Be Upheld," Indianapolis Star, December 19, 2010

Orentlicher, "Clearly, Congress Acted within Its Constitutional Authority," Indianapolis Star, April 18, 2010

Orentlicher and Caplan, "Legislation and End-of-Life Care," 283 JAMA 2934-2935 (2000) (reply to letters to the editor)

Orentlicher, "Principle, Practice, and the Right to Die," 2(3) ASBH Exchange 1 (1999)

Orentlicher, "Mother deserves murder charge," USA Today, May 24, 1999

Orentlicher, "Hope for those in need of marrow transplants," Indianapolis Star, December 29, 1998

Orentlicher, "With proper safeguards, a medical ID will be a lifesaving health policy," *Insight*, August 24, 1998, 24

Orentlicher, "Terminal Sedation," 338 New England Journal of Medicine 1230 (1998) (reply to letters to the editor)

Orentlicher, "Medical Trials for Assisted Suicide," Louisville Courier-Journal, September 3, 1997

#### MINOR PUBLICATIONS (continued)

Orentlicher, "Trends suggest 'duty to die' may supplant 'right' question," Portland Oregonian, June 27, 1997

Orentlicher, "Why we must preserve the right to die," Baltimore Sun, October 29, 1996

Orentlicher, "Navigating the Narrows of Doctor-Assisted Suicide," Technology Review 62-63 (July 1996)

Orentlicher, "Learning Lessons of Life and Death from Kevorkian," Chicago Tribune, May 21, 1996

Glasson and Orentlicher, "Mandated Choice for Organ Donation," 273 JAMA 1176-1177 (1995) (letter to the editor)

Glasson and Orentlicher, "Essential vs Discretionary Health Care in System Reform," 273 JAMA 919 (1995) (reply to a letter to the editor)

Orentlicher, "Rationing and the Americans with Disabilities Act," 271 JAMA 1903-1904 (1994) (reply to a letter to the editor)

Glasson and Orentlicher, "HIV Testing: AMA Code of Ethics," 271 JAMA 1160 (1994) (letter to the editor)

Glasson and Orentlicher, "Gifts From Industry: Laundering Money or Supporting Education?," 271 JAMA 505 (1994) (reply to a letter to the editor)

Clarke and Orentlicher, "Parental Consent for Abortion," 269 JAMA 2211 (1993) (reply to a letter to the editor)

Clarke and Orentlicher, "Self-Referral by Physicians," 328 New England Journal of Medicine 1278 (1993) (letter to the editor)

Clarke and Orentlicher, "Reporting Abuse of Competent Patients," 268 JAMA 2378 (1992) (reply to a letter to the editor)

Clarke and Orentlicher, "'Futility' as a Criterion in Limiting Treatment," 327 New England Journal of Medicine 1240 (1992) (letter to the editor)

Clarke and Orentlicher, "Diagnosis of Brain Death and Organ Donation," 268 JAMA 1859-1860 (1992) (reply to a letter to the editor)

Emanuel, Emanuel and Orentlicher, "Advance Directives," 266 JAMA 2563 (1991) (letter to the editor)

### PROFESSIONAL LICENSURE

Medicine: Washington, DC Law: Illinois, Indiana and Washington, DC

# Exhibit 4

# IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANS DIVISION

2011 NOV 10 P 5 14

HODES & NAUSER, MDs. P.A.; HERBERT C. HODES, M.D.; and TRACIEVNN NAUSER M.D.

Plaintiffs.

Case No. 11 C 1298

ROBERT MOSER, M.D., in his official capacity as Secretary of the Kansas Department of Health and Environment STEPHEN HOWE, in his official capacity as District Attorney for Johnson County; Kansas; and DEREK SCHMIDI, in his official capacity as Attorney General for the State of Kansas.

Defendants.

Order Granting Temporary Restraining Order Rending Hearing on Application for Restraining Order | 1200 | 1200 (Prisuant to KES Av Chapter 60)

On this / U day of November, 2011, this matter comes before the Court on Plaintiffs MB TELEPTONE LONTEVENCE Verified Petition and Application for Restraining Order/ Plaintiffs seek a Restraining Order on Ve behalf of themselves and their patients, restraining, enjoining and prohibiting Defendants Robett Moser, M.D., Secretary of the Kantas Department of Health and Environment (\*KDHE\*), Stephen Howe, District Afformey of Johnson County, and Derek Schmidt, Kansas Attorney General, along with their offices, agencies, agents and successors, from enforcing K.A.R. § 28-34-126 - 144 (2011) (the "Permanent Regulations") regarding the licensing of facilities performing abortion, until such time as this Court rules on Plaintiffs' Application for a Temporary Injunction. The Court having reviewed Plaintiffs! Verified Petition and Application

Plaintiffs, and monetary damages are inadequate to compensate Plaintiffs or their patients for services will cause illeparable harm to both Plaintiffs and Women secting adoption services from Exuecology practice, in which they have provided such services for decades. This cessation of Regulations will force Plaintiffs to cease provide abortion services in their private obstetriosand will cause irreparable harmen Plandills and their passons. Specifically, the Permanent immediate injunctive relief, the Permanent Regulations will take offeet on Moyember 14, 2011, 2. Based on the allegations contained in the Wenned Febrior, the Court finds that absent ss this Court rules on Plaintiffs. Application for a Temporary Infunction. from enforcing K.A.R. § 28-34-126 -144:00 10 10 Permanent Regulations Funtil such time Schmidt, Kansas Attorney-General, along with Inche offices, agendies, agents and successors, Health and Environment Stephen Howe Denete August of Johnson County, and Derek temporarily results Beferdands Robert Wasse, Will Escretary of the Kansas Department of Hodes, and Dr. Track Nauger, who seek on behalf of themselves and their patients, to 1. The Restraining Order is sought by Paintiffs Hodos & Nauser, MDs, PA, Dr. Herbert arina Siviry I To Findings of Eact resed on review of the Verified Periformand Application for Regusting Order, succeed on the melits on one of more of then dannay. The Court makes the following findings の行いればんなつれまないのうれて that Plaintiffs have alleged sufficient tacks to make an initial showing that they are likely to the Court also concludes that the issuance of this Order will merely maintain the status que, and at law/ Based on review of Plainths Ventied Petition and Application for Restraining Order, 125141 Decure the administrative processes irreparable barm were this Order not entered, and that Plainhiffshave no other adequate remedy or Restraining Order, and being fully advised in the premises, finds that Plaintiffs would sustain Do 1 Col 3, Purkulaly NS

harms that will ensue absent relief.

- 3. Based on the allegations contained in the Verified Petition, the Court finds that the threatened harm to Plaintiffs and their patients outweighs any potential harm to Defendants because the Restraining Order imposes no affirmative obligation, administrative burden, or cost upon Defendants and will merely maintain the status quo, allowing Plaintiffs to continue providing abortion services in their medical office subject to multiple layers of government regulation and oversight (including by the Kansas Beard of Healing Arts and KDHE), as they have for many years.
- 4. This Restraining Order is not adverse to the public interest in that it will protect Plaintiffs' current practice, and patients' access to the health-services provided in that practice, and in that Plaintiffs' practice is already subject to povernment regulation and oversight by the Kansas state agencies referenced above.

## Restraining Order

Based on the foregoing-findings and for good cause shown, the Court does hereby enter a Restraining Order that:

Defendants Robert Moser, M.D., Secretary of the Kansas Department of Health and Environment, Stephen Howe, District Attorney of Johnson County, and Derek Schmidt, Kansas Actorney General, along with their offices, agencies, agents and successors, are hereby testralited, enjoying and prohibited from enforcing the Permanent Regulations, K.A.R. § 28-32-126—144 (2011) until further order of this Court. This Order will issue without bond as allowed pursuant to K.S.A. §§ 60-902 and 903. A hearing on Plaintiffs Application for Temporary Injunction is scheduled for December 120 CV.

9:30 am

DISTRICA COURT JUDGE

# Exhibit 5

# IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS TOPEKA. KS. DIVISION ONE

		864-	
		) 2013 JUN 28	P 3: 59
	HODES & NAUSER, MDS, P.A.;	)	
	HERBERT C. HODES, M.D.; and	)	
	TRACI LYNN NAUSER M.D., Plaintiffs,	)	
	i iamuiis,	) }	
v.		) Case No. 13C705	
	DEREK SCHMIDT, in his official capacity	)	
	as Attorney General of the State of Kansas;	) )	
	ROBERT MOSER, M.D., in his official	) <sub>.</sub>	
	capacity as Kansas Secretary of Health and	)	
	Environment; and NICK JORDAN, in his official capacity as Kansas Secretary of	) `	
	Revenue	)	
	Defendants.	)	•
		)	

# MEMORANDUM DECISION AND ORDER

The above matter comes before the Court on Plaintiffs' Motion for Temporary Restraining Order and Temporary Injunction to enjoin the Defendants, their agents, and their successors in office from enforcing Kansas House Bill 2253 (2013). After careful consideration of the evidence, the relevant law, and the arguments of the parties, the Court finds and concludes as follows.

#### **NATURE OF THE CASE**

This case arises out of Plaintiffs' petition seeking declaratory and injunctive relief from Kansas House Bill 2253 (2013) ("the Act"), which was signed into law on April 19, 2013. The Act is scheduled to take effect July 1, 2013. Plaintiffs assert that the Act imposes punitive and discriminatory requirements on women seeking abortions and abortion providers, which Plaintiffs allege to be in violation of the Kansas Constitution.

#### STANDARD OF REVIEW

A preliminary injunction is an extraordinary remedy that is not awarded as a matter of right. Winter v. National Resources Defense Council, Inc., 555 U.S. 7, 24, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008). Granting temporary injunctive relief is appropriate when four prerequisites are met: (1) substantial likelihood exists that the movant will eventually prevail on the merits; (2) the Court is satisfied the movant will suffer irreparable injury unless the injunction issues; (3) the movant proves the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing parties; and (4) the movant makes a showing that the injunction, if issued, would not be adverse to the public interest. Wichita Wire, Inc. v. Lenox, 11 Kan. App. 2d 459, 462, 726 P.2d 287 (1986). The main purpose of a temporary injunction is to maintain the status quo until such time that the court can render a meaningful decision. Waste Connections of Kansas, Inc. v. City of Bel Aire, Kan., 191 F. Supp. 2d 1238, 1241 (D. Kan. 2002). It is not to determine any controverted right, but merely to prevent injury to a claimed right pending final determination of the controversy on its merits. Steffes v. City of Lawrence, 284 Kan. 380, 394, 160 P.3d 843 (2007).

## **DISCUSSION AND CONCLUSION OF LAW**

Plaintiffs have not met their burden to establish the four required elements for granting a temporary injunction in respect to the Act in its entirety. Rather, due to the severability clause contained in section 23 of the Act, this Court must review each individual provision of the Act challenged and determine individually if any of the challenges substantiate injunctive relief.

Defendants admit, and this Court agrees, that the State has a vested interest in preserving human life. The U.S. Supreme Court has reviewed the States' power to regulate abortion and has held the States possess certain power to regulate abortions so long as the law contains

exceptions for pregnancies that endanger the woman's life or health. Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 846, 112 S. Ct. 2791, 120 L. Ed. 2d 674 (1992). Without an adequate medical emergency provision, the health and lives of pregnant women are endangered. Plaintiffs are board-certified physicians in the field of Obstetrics and Gynecology. They have asserted and supported that provisions of the Act effectively eliminate any meaningful exception for medical emergencies from the requirement that women seeking abortions observe a 24-hour waiting period. The Kansas Supreme Court has not taken the occasion to recognize the Due Process considerations of Casey as applied to the Kansas Constitution. However, it indicated, "we customarily interpret its provisions to echo federal standards." Alpha Med. Clinic v. Anderson, 280 Kan. 903, 920, 128 P.3d 364, 377 (2006). Further, Defendants have failed to cite any instance of a state refusing to recognize the Casey standard.

In Agency for International Development v. Alliance for Open Society International, Inc., 570 U.S. \_\_\_\_\_, 133 S. Ct. 2321 (2013), the U.S. Supreme Court recently addressed compelled speech. In analyzing a policy statement that was required for obtaining federal funding, the Supreme Court held that compelling speech as a condition for receiving funds was unacceptable. In authoring the majority opinion, Chief Justice Roberts remarked, "Were it enacted as a direct regulation of speech, the Policy Requirement would plainly violate the First Amendment." Agcy. for Int'l. Dev. 570 U.S. \_\_\_\_\_, 133 S. Ct. 2321 (2013). Here, the State attempts to mandate that the Plaintiffs certify the material found on a state-maintained website as "objective, nonjudgmental, [and] scientifically accurate." The Plaintiffs have established a substantial likelihood that this certification is a direct regulation of speech, in violation of the First Amendment of the U.S. Constitution. The Kansas Constitution protects freedom of speech in a

manner coextensive with the U.S. Constitution through Section 11 of the Kansas Bill of Rights.

State v. Russell, 227 Kan. 897, 899, 610 P.2d 1122, 1126 (1980).

Absent injunctive relief, the Act will take effect on July 1, 2013. The Court finds that the threatened harm to Plaintiffs and their patients outweighs any potential harm to Defendants because the injunction imposes no affirmative obligation, administrative burden, or cost upon Defendants and will merely maintain the status quo pending further hearings on the merits of the case. The Court further finds that absent injunctive relief, irreparable harm to Plaintiffs and their patients will occur and monetary damages would be inadequate to compensate them. Further, granting injunctive relief is not adverse to the public interest in that: it will protect the Plaintiffs' current practice, it will protect patients' access to the health services provided in that practice, and in that Plaintiffs' practice is already subject to government regulation and oversight by the Kansas state agencies referenced above.

The Court does not grant injunctive relief only as an adjudication on the merits; rather, it is only necessary that plaintiffs establish a reasonable probability of success, and not an overwhelming likelihood of success, in order for a preliminary injunction to issue.

Atchison, T. & S. F. Ry. Co. v. Lennen, 640 F.2d 255, 261 (10th Cir. 1981). Therefore, the Court determines, for the issues involving the medical emergency exception and compelled speech, there is a substantial likelihood of success and enjoins section 12(g), and any other relevant provisions pertaining to medical emergencies, and section 14(l) of the Act.

In respect to the remaining challenges to the Act, the Plaintiffs have not met the burden of proving the four elements to establish that injunctive relief is appropriate at this time. The Court, therefore, denies temporary injunction in respect to the remaining portions not specifically

addressed herein. The Court, however, grants a temporary injunction to the sections and provisions as described above.

# **CONCLUSION**

For the reasons stated above, Plaintiffs' Motion for Temporary Injunction is GRANTED in part and DENIED in part. This Memorandum Decision and Order shall serve as the journal entry of judgment. No further journal entry is required.

IT IS SO ORDERED.

Dated this <u>28</u> day of <u>Quni</u>, 2013.

Hon. Rebecca W. Crotty

District Judge

# **CERTIFICATE OF MAILING**

I hereby certify that a copy of the above and foregoing MEMORANDUM DECISION AND ORDER was mailed, hand delivered, or placed in the pick-up bin this 15<sup>+</sup> day of 2013, to the following:

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