No. 23-10362

United States Court of Appeals for the Fifth Circuit

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

U.S. FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D.; JANET WOODCOCK, M.D.; PATRIZIA CAVAZZONI, M.D.; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA,

Defendants-Appellants,

v.

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant.

On Appeal from the United States District Court
for the Northern District of Texas

BRIEF FOR *AMICI CURIAE* NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH AND AMERICAN COLLEGE OF NURSE-MIDWIVES IN SUPPORT OF APPELLANTS AND OF VACATUR OF PRELIMINARY INJUNCTION ORDER

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STATEMENT OF INTERESTED PERSONS (5TH CIR. R. 29.2)

No persons or entities other than the National Association of Nurse Practitioners in Women's Health and the American College of Nurse-Midwives have an interest in this *amicus* brief requiring disclosure.

Respectfully Submitted,

/s/ Simona G. Strauss

Simona G. Strauss
Counsel for *Amici Curiae* National Association of Nurse Practitioners in Women's Health and American College of Nurse-Midwives

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INTEREST OF *AMICI CURIAE*

Amicus curiae National Association of Nurse Practitioners in Women's Health ("NPWH") is the national professional association for women's health nurse practitioners and advanced practice registered nurses who provide women's and gender-related health care. NPWH sets a standard of excellence by translating and promoting the latest women's health care research and evidence-based clinical guidance, providing high quality continuing education, and advocating for patients, providers, and the women's health nurse practitioner profession. NPWH's mission includes protecting and promoting women's and all individuals' rights to make their own choices regarding their health and well-being within the context of their lived experience and their personal, religious, cultural, and family beliefs.

Amicus curiae American College of Nurse-Midwives ("ACNM") is the professional association that represents certified nurse-midwives and certified midwives in the United States. ACNM sets the standard for excellence in midwifery education and practice in the United States and strengthens the capacity of midwives in developing countries. Members of ACNM are primary care providers for women throughout their lifespans, with a special emphasis on pregnancy, childbirth, and gynecologic and reproductive health. ACNM's mission is to support midwives, advance the practice of midwifery, and achieve optimal,

equitable health outcomes for the people and communities midwives serve through inclusion, advocacy, education, leadership development, and research.

Amici are interested in this matter because they care deeply about not only the advanced practice clinicians ("APCs") they represent, but also the well-being of the women served by the APCs. *Amici* have extensive experience providing reproductive health care, including aspiration and medication abortion, which they have been doing for many years. *Amici* highlight the overwhelmingly positive outcomes for the hundreds of thousands of women treated by APCs in reproductive health each year. *Amici* have an interest in dispelling the misinformed assumption, seemingly shared by Appellees and the court below, that women have more favorable health outcomes when any medication abortion care they may receive is provided by physicians rather than APCs.[1]

SUMMARY OF ARGUMENT

Mifepristone is an essential component of the safe and effective provision of reproductive health care and has been used regularly by health care providers

[1] Pursuant to Federal Rule of Appellate Procedure 29, counsel for *Amici* NPWH and ACNM certify that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person or entity, other than NPWH, ACNM, or their counsel, contributed money intended to fund the preparation or submission of this brief. All parties have consented to *Amici* filing this brief.

nationwide for more than two decades. Advanced practice clinicians have safely prescribed mifepristone under physician supervision since 2000 and, since the Food & Drug Administration's ("FDA") 2016 regulatory change, have regularly prescribed the medication independently, where permitted to do so by state law.

Despite the overwhelming evidence that APCs have been independently, effectively, and safely prescribing mifepristone for years, the stay decision issued by a panel of this Court would have prohibited APCs from prescribing this medication as part of their independent scope of practice—and the district court's preliminary injunction order would prevent APCs from providing this important medication to their patients at all.

These rulings ignore that APCs are crucial providers of reproductive health care and are as qualified to provide and successful in providing medication abortion as physicians, if not more so. In addition to regularly providing medication abortion and aspiration abortion care, APCs provide care and perform procedures that are far more complex than medication abortion. It is in part for this reason that mainstream medical and public health groups overwhelmingly support the provision of medication abortion by APCs.

This Court should vacate the lower court's preliminary injunction order.

ARGUMENT

I. Advanced Practice Clinicians Must Satisfy Rigorous Education And Certification Requirements To Provide The Broad Scope Of Health Care They Routinely Provide.

APCs, which include certified women's health nurse practitioners and certified nurse-midwives, are vital participants in the U.S. health care system and are licensed to provide a broad range of health services consistent with their heightened educational standards and rigorous certification and continuing education requirements. For instance, APCs have prescriptive authority in every state in the nation, including for controlled substances. *See* Am. Med. Ass'n, *State Law Chart: Nurse Practitioner Prescriptive Authority* (2017), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/specialty%20group/arc/ama-chart-np-prescriptive-authority.pdf. They are key providers of primary, gynecological, maternity, acute, and chronic care across the country, including for low-income patients and those living in rural and medically underserved areas.

NPs provide an extensive range of health services, including diagnosing and treating acute and chronic illnesses, prescribing and managing medications and other therapies, providing immunizations, performing procedures, ordering and interpreting lab tests and x-rays, coordinating patient care, and providing health education. Am. Assoc. Nurse Prac., *Discussion Paper: Scope of Practice for Nurse Practitioners* (revised 2022),

https://storage.aanp.org/www/documents/advocacy/position-papers/Scope-of-Practice.pdf. NPs dispense these essential health services in a wide variety of practice areas, including family medicine, pediatrics, geriatrics, and women's health, among others. *See* Nat'l Governors Assoc., THE ROLE OF NURSE PRACTITIONERS IN MEETING INCREASING DEMAND FOR PRIMARY CARE 4 (2012).

NPs must satisfy rigorous educational and certification requirements. First, NPs must obtain a registered nurse license and complete several years of graduate education at the masters, post-masters, or doctoral level. *Id.* at 8. Second, in the vast majority of states, they, like physicians, subsequently gain board certification.[2] Nat'l Governors Assoc., *supra*, at 8. Certification testing assesses the "applicant's knowledge and skill in diagnosing, determining treatments, and prescribing for their patient population of focus." *Id.*

The women's health nurse practitioner ("WHNP") is prepared at the master's or doctoral level to provide holistic, client-centered primary care for women from puberty through the adult lifespan, with a focus on common and

[2] In forty-seven states, NPs must receive a certification from a nationally recognized certified body; in the remaining three states (California, Kansas and New York), NPs must complete a board-approved master's degree with similar course requirements to those accepted by one of the national certifying bodies. Am. Ass'n Nurse Pract., *State Practice Environment*, https://www.aanp.org/advocacy/state/state-practice-environment (last visited Apr. 28, 2023).

complex gynecologic, sexual, reproductive, menopause-transition, and post-menopause healthcare; uncomplicated and high-risk antepartum and postpartum care; and sexual and reproductive healthcare for men. The education, certification, and practice of the WHNP are congruent with the NP role and the women's health population focus. As a licensed health care provider, the WHNP functions within the scope of practice rules and regulations established by and pursuant to the nurse practice act in the state(s) in which the WHNP is licensed and works. The WHNP provides care in outpatient, inpatient, community, and other settings. The WHNP provides care independently and collaboratively as a member of the health care team. The role of the WHNP includes providing consultation services to other health care providers regarding the unique health care needs of women. The WHNP provides leadership to improve women's healthcare and health outcomes in practice settings, healthcare systems, and communities. NPWH, *Women's Health Nurse Practitioner: Guidelines for Practice and Education* 2-3 (8th ed. 2022). WHNPs maintain certification and recertify every three years through the National Certification Board and are required to meet delineated continuing education requirements.

Like NPs, certified nurse-midwives ("CNMs") offer a wide array of health services: they provide comprehensive assessment, diagnosis, and treatment care; prescribe medications, including controlled substances; admit, manage, and

discharge patients; order and interpret laboratory and diagnostic tests; and provide wellness education and counseling. *See* Am. College of Nurse-Midwives, *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives*, https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf (last updated Dec. 2021). CNMs principally focus on the provision of patient care during pregnancy, childbirth, and the postpartum period; sexual and reproductive health; gynecologic health; and family planning services, including preconception care. *Id.* CNMs also provide primary care for all ages, including newborns, adolescents, and adults. *Id.*

Education and certification requirements for CNMs are exacting. Following completion of a bachelor's degree and a graduate midwifery education program, CNMs must pass a national certification exam to receive the designation of CNM (a title conferred to those who have active RN credentials when they pass the certification exam). *Id.* CNMs must continuously demonstrate that they meet the Core Competencies for Basic Midwifery Practice of *Amicus* ACNM and are required to practice in accordance with the ACNM Standards for the Practice of Midwifery. *Id.* The ACNM competencies and standards are consistent with or exceed the International Confederation of Midwives' global midwifery competencies and standards. *Id.* CNMs must be recertified every five years

through the American Midwifery Certification Board and are required to meet delineated continuing education requirements. *Id.* The rigorous education and certification requirements for NPs and CNMs belie any notion that these groups of accomplished health professionals are unqualified to provide medication abortion.

II. Advanced Practice Clinicians Provide Safe And Effective Abortion Care.

In 2016, when the FDA was reassessing risk mitigation measures for mifepristone, it considered "data from over 3,200 women in randomized controlled trials and data on 596 women in prospective cohorts comparing medical abortion care by" APCs with that provided by physicians, all of which "clearly demonstrate[d] that efficacy is the same," if not better, with APCs compared to physicians. ECF No. 28-1, Defs.' Opp. to Pls.' Mot. for Prelim. Inj. Ex. 1A at 48. And, like physicians, APCs also regularly provide safe and effective aspiration abortions, including if necessary as follow-up care after a medication abortion. Additionally, APCs improve access to medication abortion, enabling people to access it earlier, when it is even more safe and effective. Given the overwhelming body of scientific evidence before it, the FDA unsurprisingly removed conditions restricting APCs' ability to be certified prescribers of mifepristone.

A. Advanced Practice Clinicians Achieve the Same, or Better, Health Outcomes as Physicians When Providing Medication Abortion.

Peer-reviewed studies have long established that APCs provide medication abortions as safely and effectively as physicians, if not more so. Indeed, after a comprehensive review of medical literature on the safety of abortion, the National Academies of Science, Engineering, and Medicine, the non-partisan, non-governmental institution set up to advise the nation on issues related to those disciplines, concluded that "[b]oth trained physicians (OB/GYNs, family medicine physicians, and other physicians) and APCs (physician assistants, certified nurse-midwives, and nurse practitioners) can provide medication and aspiration abortions safely and effectively." NAT. ACAD. OF SCI., ENG'G, AND MED., THE SAFETY AND QUALITY OF ABORTION CARE IN THE UNITED STATES 14 (2018), https://nap.nationalacademies.org/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states; *see also* Sharmani Barnard et al., *Doctors or mid-level providers for abortion*, COCHRANE DATABASE SYS. R. (2015) (concluding that there was no statistically significant difference in risk of failure for medication abortions performed by APCs compared with physicians in comparative review of studies assessing medication abortion outcomes).

In fact, some research shows that APCs may provide medication abortions with *greater* efficacy and patient acceptability than physicians. For example, one of the studies cited by the FDA in connection with the 2016 REMS review was a

2015 randomized study of 1180 women who received medication abortions, which concluded that nurse-midwives' provision of medication abortion had "superior efficacy" over that provided by physicians. *See* H. Kopp Kallner & R. Gomperts et al., *The Efficacy, Safety and Acceptability of Medical Termination of Pregnancy Provided by Standard Care by Doctors or by Nurse-midwives: A Randomised Controlled Equivalence Trial*, 122 BJOG: AN INT'L J. OF OBSTETRICS AND GYNECOLOGY 510, 515 (2014); ECF No. 28-1, 48. The study found that 99% of the 481 women treated by nurse-midwives did not require further intervention (*i.e.,* follow-up aspiration or surgery to complete the abortion), and 95.8% experienced no complications following the medication abortion (compared to 97.4% and 93.5%, respectively, for women treated by physicians).[3] *Id.* at 514. Moreover, women that met with nurse-midwives were significantly more likely to express a preference for nurse-midwives if they ever required another medication abortion in the future. *Id.*

Similarly, another FDA-cited randomized study of 1295 women who received medication abortions found that abortions provided by government-trained, certified nurses and auxiliary nurse midwives did not pose any higher risk of failure or incomplete abortions compared to those provided by physicians. Dr.

[3] *None* of the 1180 women participating in the study experienced any serious complications, across provider groups. *Id*. at 513.

IK Warriner et al., *Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomised controlled equivalence trial in Nepal*, 377 LANCET 9772, 1155-61 (2011); ECF No. 28-1, 48. In fact, 97.3% of the medication abortions provided by certified nurses or auxiliary nurse midwives were completed without further intervention, as compared to 96.1% of those provided by physicians. *Id*. at 1155. A later review of data collected in that same study found that of the women who received care from certified nurses and auxiliary nurse midwives, 38% reported being highly satisfied with their care and 62% reported being satisfied, reflecting a 100% satisfaction rate, compared to 35%, 64%, and 99% for physicians, respectively. Anand Tamang et al., *Comparative satisfaction of receiving medical abortion service from nurses and auxiliary nurse-midwives or doctors in Nepal: results of a randomized trial*, 14 REPRODUCTIVE HEALTH 176 (2017).[4]

Further, APCs working with physicians often find themselves in a position of leadership, educating the physicians about medication abortion or being asked to take the lead on patients who are under a physician's care. A 2022 qualitative study of NPs who provide medication abortion in Canada found that NPs

[4] Significantly, there is a conspicuous but telling absence of studies or empirical data even suggesting that medication abortion in states that prevent APCs from providing this care is any more safe or effective than in states that do not.

commonly found themselves "educating physician colleagues about mifepristone." Andrea Carson et al., *Nurse practitioners on 'the leading edge' of medication abortion care: A feminist qualitative approach*, 79 J. ADV. NURSING 686, 690 (2023). One NP who participated in the study explained that she provided a number of physician-attended information sessions and held one-on-ones to answer physician questions, and that she understood "that [her] role was to try to teach [the physicians]" about medication abortion. *Id*. at 690-91. "There's a lack of [provider] knowledge [about medication abortion]," she explained, but it's "been a lot better since I've been able to inform them" and "orient them toward the best treatment for the patient." *Id*. (alteration in original).

B. Advanced Practice Clinicians Regularly and Safely Provide Aspiration Abortions, Just as Physicians Do.

Advanced practice clinicians also safely and effectively provide aspiration abortions. Aspiration abortion involves the dilation of the cervix and the use of a curette to remove the uterine contents through gentle suction; the identical procedure is used to evacuate a patient's uterus in the event of an incomplete miscarriage. *See, e.g.*, Kate Coleman-Minahan et al., *Interest in Medication and Aspiration Abortion Training Among Colorado Nurse Practitioners, Nurse Midwives, and Physician Assistants*, WOMEN'S HEALTH ISSUES 167, 169 (2020); Amy J. Levi & Tara Cardinal, *Early Pregnancy Loss Management for Nurse Practitioners and Midwives*, WOMEN'S HEALTHCARE: A CLINICAL JOURNEY FOR

NPs 43, 44 (2016). Aspiration abortion may be performed to terminate a pregnancy or as follow-up care in the rare instance of a failed medication abortion. Am. Coll. Obstetricians and Gynecologists, *Medication Abortion Up to 70 Days of Gestation Practice Bulletin* (2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

The Court's prior panel suggested in its April 12, 2023 Order that emergency room physicians would be responsible for providing aspiration abortions in the unlikely event such care is needed following a medication abortion. ECF No. 183-2 at 13-14. In so doing, it incorrectly assumed that APCs cannot safely and effectively perform this procedure (for abortion and/or miscarriage care). That is demonstrably wrong, and evidence confirms that APCs provide aspiration abortion with the same safety and efficacy as physicians.

For example, in one study, researchers compared 5,812 aspiration procedures performed by physicians with 5,675 aspiration procedures performed by APCs and physician assistants over a span of four years. *See* Tracy A. Weitz et al., *Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 AM. J. PUB. HEALTH 454, 457 (2013). The study concluded that abortion "care provided by newly trained NPs, CNMs, and PAs was not inferior to that provided

by experienced physicians." *Id.* at 458. With regard to major complications, the study found that there was no significant difference in terms of risk between provider groups. *Id.* at 459. The results "confirm[ed] existing evidence from smaller studies that the provision of abortion[s] by [NPs, CNMs, and PAs] is safe and from larger international and national reviews that have found these clinicians to be safe and qualified health care providers." *Id.*; *see also* Eva Patil & Blair Darney et al., *Aspiration Abortion with Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians*, 61 J. MIDWIFERY & WOMEN'S HEALTH 325, 329 (2016) (finding no clinically significant differences between aspiration abortions followed by IUD insertions performed by physicians or by APCs).

C. The Ability of Advanced Practice Clinicians to Prescribe Mifepristone Improves Already Exceedingly Safe Abortion Care.

Although abortion is safe throughout pregnancy, safety increases the earlier the care is provided. ECF No. 28-2, Defendants' Opposition To Plaintiffs' Motion For A Preliminary Injunction Ex. 2 at 7. It is no surprise, then, that participation by trained APCs in abortion care improves both patient safety and overall outcomes, as it allows early diagnosis and management of unintended pregnancies and integrated abortion and early pregnancy care, thereby reducing delays and unnecessary referrals. D. Taylor et al., *Advanced practice clinicians as abortion*

providers: preliminary findings from the California primary care initiative, 80 CONTRACEPTION 2, 199 (2009).

APCs are, and will likely continue to be, easier to access than physicians for health care. Demand for health care is projected to continue to outpace supply. Significantly, however, the number of physicians is expected to increase annually by only 1.1% from 2016-2030, while the number of APCs is expected to increase more rapidly, with a predicted 6.8% increase in NPs annually during that same period. David I. Auerbach, Douglas O. Staiger, and Peter I. Buerhaus, *Growing Ranks of Advanced Practice Clinicians — Implications for the Physician Workforce*, 378 N. ENGL. J. MED. 25, 2359 (2018); *see also* Tim Dall et al., *The Complexities of Physician Supply and Demand: Projections from 2018 to 2030*, ASSOCIATION OF AMERICAN MEDICAL COLLEGES (2020). Thus, the relative availability of APCs as compared to physicians means that patients seeking medication abortion can access professional health care earlier, thus lowering already low complication rates.

III. Advanced Practice Clinicians Regularly Provide Health Care, Including Childbirth Care, That Is Equally Or More Complex Than Medication Abortion.

As part of their everyday practice, APCs routinely provide health care services that are comparable to or more complex than medication abortion. These services include reproductive health-related care, including aspiration abortions

and miscarriage management, and non-reproductive health-related procedures. APCs also regularly prescribe controlled substances and assist in complicated surgeries and medical procedures. Moreover, studies have demonstrated that obstetrical care (including labor and delivery) provided by APCs actually results in better outcomes than that provided by physicians despite the serious risks associated with such care, underscoring APCs' excellent provision of complex care to patients.

A. Medication Abortion Is More Straightforward Than Much of the Health Care Provided by APCs.

APCs routinely provide health care, including reproductive health-related care, that is equally or more complicated than medication abortion. Miscarriage treatment provided by APCs frequently calls for the use of the same course of medication used in medication abortion (mifepristone followed by misoprostol). *See* Am. College of Obstetricians and Gynecologists, *Early Pregnancy Loss Practice Bulletin* (2018), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss. Further, as discussed above, APCs perform aspiration procedures both for abortion and miscarriage management. *See, e.g.*, Weitz, et al., *supra*, at 457-58; Levi & Cardinal, *supra*, at 44.

Reproductive health APC services also often involve the insertion and removal of intrauterine contraceptive devices ("IUDs") and other contraceptive implants and performing endometrial biopsies. Courtney B. Jackson, *Expanding*

the Pool of Abortion Providers: Nurse-Midwives, Nurse Practitioners, and Physician Assistants, WOMEN'S HEALTH ISSUES 21-3S, S42 (2011); *see also* Am. Pub. Health Ass'n, PROVISION OF ABORTION CARE BY ADVANCED PRACTICE NURSES AND PHYSICIAN ASSISTANTS (2011). Inserting and removing an IUD involves placing an instrument through the cervix, and complicated removals may necessitate cervical dilation. *See* Aimee C. Holland & Brandi Shah et al., *Preparing for Intrauterine Device Consults and Procedures*, WOMEN'S HEALTHCARE 39 (2020). All of these procedures exceed the complexity involved in medication abortion.

APCs also provide non-reproductive health care services that are far more complex than medication abortion, including neuraxial anesthesia, central line insertions, arterial line insertions, intubations, chest tube insertions, surgical first assistance, colonoscopies, and endoscopies. APCs with Drug Enforcement Administration licenses can also prescribe controlled substances, which are potentially dangerous and addictive and thus carry greater risk than the medications used in medical abortions. *See* U.S. Dep't of Justice, Diversion Control Division, *Mid-Level Practitioners Authorized by State*, https://www.deadiversion.usdoj.gov/drugreg/practioners/index.html (last visited Apr. 25, 2023). They also provide vital assistance in complex specialist procedures, including orthopedic surgeries, cardiology procedures, and plastic surgery. *See* Grant R.

Martsolf et al., *Employment of Advance Practice Clinicians in Physician Practice*, 178 JAMA INTERN. MED. (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6126674/.

APCs provide these health care services, all of which are akin to or even more complicated than medication abortion, as a routine part of their everyday practice. Given that reality, there is no principled basis for disallowing APCs from continuing to independently prescribe mifepristone, where permitted by state law, as they have successfully done since 2016.

B. Advanced Practice Clinicians Provide Prenatal and Labor Care That Is as Safe and Effective, If Not More So, As the Care Provided by Physicians.

Childbirth is far more dangerous to women than abortion, and APCs routinely attend and manage deliveries. Significantly, studies comparing the outcomes of prenatal and labor care provided by APCs and physicians demonstrate that care provided by APCs is often more effective than care provided by physicians. *See, e.g.*, Y. Tony Yang, Laura B. Attanasio, and Katy B. Kozhimannil, *State Scope of Practice Laws, Nurse-Midwifery Workforce, and Childbirth Procedures and Outcomes*, 26 WOMEN'S HEALTH ISSUES 3 (2016) (finding that women in states with autonomous practice laws for nurse-midwives have lower rates of cesarean delivery, preterm births, and low birth weight, as compared to women in states without such laws).

For example, one study comparing the outcomes of midwife- and obstetrician-provided care in low-risk pregnancies found that midwife care resulted in "less intervention in labor, higher rates of physiologic birth, and similar hospital length of stay" as compared to physician-provided care. Vivienne Souter et al., *Comparison of Midwifery and Obstetric Care in Low-Risk Hospital Births*, 134 OBSTETRICS & GYNECOLOGY 5 (2019). The study found that care provided by midwives lowered the risk of caesarian delivery in patients who had no prior births by 30% and in patients who had had at least one prior birth by 40%. *Id*. Another similar study found that women receiving maternal and neonatal care from a midwife were at a lower risk of cesarean and preterm birth and did not have any increased odds of neonatal intensive care admissions, neonatal deaths, or severe maternal morbidity. Yiska Lowenberg Weisband et al., *Birth Outcomes of Women Using a Midwife versus Women Using a Physician for Prenatal Care*, 63 J. OF MIDWIFERY & WOMEN'S HEALTH 399 (2018); *see also* Mary Huynh, *Provider Type and Preterm Birth in New York City Births, 2009-2010*, 25 J. OF HEALTH CARE FOR THE POOR AND UNDERSERVED, 1520 (2014) (finding that "preterm birth was significantly lower for women who received care from a midwife led model than for those with a physician led model (2.8% vs 4.6%)").

With respect to NPs, one study of women at high risk of delivering low-birth-weight infants found notably better outcomes and rates of satisfaction for

those receiving prenatal care from NPs at home than from physicians at hospital clinics. Dorothy Brooten et al., *A Randomized Trial of Nurse Specialist Home Care for Women with High-Risk Pregnancies: Outcomes and Costs*, 7 AM. J. OF MANAGED CARE 8, 793 (2008). The study found a 2% infant mortality rate and 31% preterm delivery rate where care was provided by NPs, as compared with 9% and 41%, respectively, where care was provided by physicians. *Id*. at 797.

As with abortion care, physicians themselves recognize the significant benefits of allowing APCs to provide women's health care. Physicians in the study comparing outcomes for women at high risk of delivering low-birth-weight infants actually "approached the APNs [advanced practice nurses] with a patient they believed needed the [APN-led care] program and the APN expertise; the APNs had to remind them that this was a randomized controlled trial." *Id*. at 802.

IV. Mainstream Medical And Public Health Groups Overwhelmingly Support The Provision Of Medication Abortion Care By APCs.

Major medical and public health groups support the provision of medication abortions by APCs as a means of providing greater access to qualified health care providers.

The American Public Health Association ("APHA") is the largest organization of public health professionals dedicated to addressing public health issues and public health policies backed by science. For more than a decade, APHA has recommended that appropriately trained and competent nurse

practitioners and certified nurse-midwives be permitted to provide medication and aspiration abortion. *See* Am. Pub. Health Ass'n, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (2011), https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2014/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants. APHA notes that the Institute of Medicine Committee on the Future of Primary Care and the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (known together as the Affordable Care Act of 2010) have defined NPs and CNMs as "primary care clinicians." *Id*. APHA also cites evidence to conclude that "these clinicians are well positioned within the health care system to address women's needs for comprehensive primary care and preventive reproductive health services that include abortion care." *Id.*

The American College of Obstetricians and Gynecologists ("ACOG") is the leading professional organization of physicians specializing in obstetrics and gynecology. ACOG recommends "support[ing] . . . clinical training for residents and advanced practice clinicians in abortion care in order to increase the availability of trained abortion providers." Am. Coll. of Obstetricians and Gynecologists, *Abortion Training and Education*, *Committee Opinion No. 612* (2014, reaffirmed 2022), https://www.acog.org/Clinical-Guidance-and-

Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Abortion-Training-and-Education. ACOG also has called for the cease and repeal of "requirements that only physicians or obstetrician-gynecologists may provide abortion care . . . ." *Id*.

The American Medical Women's Association ("AMWA") is an organization that functions at the local, national, and international level to advance women in medicine and improve women's health, by providing and developing leadership, advocacy, education, expertise, mentoring, and strategic alliances. AMWA has pledged to "work to increase the number of abortion providers by supporting initiatives to improve and increase training for medical students, residents and physicians in the full range of abortion procedures, and to add adequately trained Nurse-Midwives, Nurse Practitioners and Physician Assistants to the pool of potential abortion providers." Am. Med. Women's Ass'n, *Position Paper on Principals of Abortion & Access to Comprehensive Reproductive Health Services*, https://www.amwa-doc.org/wp-content/uploads/2018/05/Abortion-and-Access-to-Comprehensive-Reproductive-Health-Services.pdf.

The positions of these leading, mainstream medical and public health organizations reflect and support the recommendations that organizations representing APCs have long asserted in terms of APCs' ability to provide abortion care. For example, since 1991, *amicus* NPWH has maintained that abortion care is

within women's health nurse practitioners' scope of practice. Washington, DC, National Abortion Federation, SYMPOSIUM REPORT: STRATEGIES FOR EXPANDING ABORTION ACCESS: THE ROLE OF PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, AND NURSE-MIDWIVES IN PROVIDING ABORTIONS 22 (1997). This policy has been reaffirmed to the present day, with NPWH stating in their guidelines "[t]he breadth and depth of a WHNP program curriculum in these areas prepares the [NP] with distinct competencies to provide advanced assessment, diagnosis, and management" including the ability to "[p]rovide medication abortion." NPWH, *Guidelines for Practice and Education*, *supra*, at 13-14; *see also* NPWH, Reproductive Rights Policy Summary (2022), https://cdn.ymaws.com/npwh.org/resource/resmgr/positionstatement/npwh_reproductive_rights_pol.pdf.

Similarly, in 2019, *amicus* ACNM updated and approved a position statement on "Midwives as Abortion Providers" that affirmed that "medication abortion may be safely provided by trained advance practice clinicians (APCs), including midwives." Am. Coll. of Nurse-Midwives, *Midwives as Abortion Providers* (2019), at 1, http://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000314/PS-Midwives-as-Abortion-Providers-FINAL-August-2019.pdf.

The views of the professional medical, health, and nursing organizations above are shared by global health organizations. Since at least 2012, the World

Health Organization, an agency of the United Nations tasked with promoting the health of people internationally, has emphasized the importance of having medical professionals other than physicians provide abortion care. In a policy guidance paper citing heavily to medical studies, the WHO noted that "[s]ince the advent of vacuum aspiration and medical abortion, [] abortion can be safely provided by a wide range of health workers in diverse settings" and recommended that APCs be permitted to deliver medication abortion using mifepristone plus misoprostol, or misoprostol alone, at up to 12 weeks gestational age. World Health Organization, *Abortion Care Guideline*, at 59 (2022), https://www.who.int/publications/i/item/9789240039483.

Additionally, the International Confederation of Midwives ("ICM"), a multinational organization representing 150 midwives' associations in over 100 countries, has consistently endorsed midwives providing abortion care. ICM expressly stated in a position paper that "ICM affirms that a woman who seeks or requires abortion-related services is entitled to be provided with such services by midwives." Int'l Confed. of Midwives, *Position Statement: Midwives' Provision of Abortion-Related Services*, at 1 (2008, reaffirmed 2014), https://www.internationalmidwives.org/assets/files/statement-files/2018/04/midwives-provision-of-abortion-related-services-eng.pdf.

The message of these mainstream professional and public health organizations is clear: the provision of medication abortion involving mifepristone falls well within APCs' scope of practice. Promoting women's health, which *Amici* aim to do, is best achieved by allowing APCs to provide medication abortion as they have been doing for many years. In short, the court below erred when it assumed that allowing physicians but not APCs to prescribe mifepristone is a "restriction[] protect[ing] women and girls." ECF No. 137, Memorandum Opinion and Order at 59 (Apr. 7, 2023).

CONCLUSION

Turning back the clock to prohibit APCs from being certified mifepristone prescribers, or otherwise reducing access to mifepristone, would provide no health or safety benefits. Indeed, doing so would be more likely to increase negative outcomes for women seeking abortion. Thus, for all the reasons set forth herein, *Amici* respectfully asks the Court to reverse the district court's order.

May 1, 2023

Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(A) because it contains 5,233 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f). This motion complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman typeface.

Dated: May 1, 2023

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CERTIFICATE OF SERVICE

I hereby certify that on May 1, 2023, I electronically filed the foregoing document using the Court's CM/ECF system. Because all parties in the case are CM/ECF users, service will be accomplished through the CM/ECF system.

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