Nos. 23-235, 23-236

In The
Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,

Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

Respondents.

DANCO LABORATORIES, L.L.C.,

Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,

Respondents.

On Petitions For Writs Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF OF *AMICI CURIAE* NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH, AMERICAN COLLEGE OF NURSE-MIDWIVES, AMERICAN ACADEMY OF PHYSICIAN ASSOCIATES, AND ASSOCIATION OF PHYSICIAN ASSOCIATES IN OBSTETRICS AND GYNECOLOGY IN SUPPORT OF PETITIONERS' PETITIONS FOR WRITS OF CERTIORARI

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TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF AUTHORITIES

Page

OTHER AUTHORITIES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

Page

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

RECORD

INTEREST OF *AMICI CURIAE*[1]

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 healthcare. NPWH sets a standard of excellence by translating and promoting the latest women's healthcare 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.

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[1] Pursuant to Rule 37.6 of the Supreme Court of the United States, counsel for *Amici* certify that no party's counsel authored this brief in whole or in part; no party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief; and no person or entity other than *Amici* or their counsel made such a monetary contribution. Pursuant to Rule 37.2, counsel of record for the parties received timely notice of *Amici*'s intent to file this brief.

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.

Amicus curiae American Academy of Physician Associates ("AAPA") is the national professional association for physician associates/physician assistants ("PAs"). AAPA advocates and educates on behalf of the profession and the patients and communities PAs serve. Its mission includes enhancing PAs' ability to improve the quality, accessibility, and cost-effectiveness of patient-centered healthcare, as well as ensuring the professional growth, personal excellence, and recognition of PAs.

Amicus curiae Association of Physician Associates in Obstetrics and Gynecology ("APAOG") is the professional association representing Obstetrics and Gynecologic Physician Associates in the United States. APAOG supports PAs practicing obstetrics, gynecology, and all of its subspecialties by advancing the role of PAs to serve patients throughout their lifespan. APAOG's mission is to promote equitable patient care through education, research, advocacy, inclusivity, and leadership.

Amici are interested in this matter because they care deeply about not only the advanced practice

clinicians ("APCs") and qualified practitioners they represent, but also the well-being of the women served by APCs. *Amici* have extensive experience providing reproductive healthcare, 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 Respondents and the Fifth Circuit, that women have better health outcomes when any medication abortion care they may receive is provided by physicians rather than APCs.

SUMMARY OF ARGUMENT

Mifepristone is an essential component of the safe and effective provision of reproductive healthcare and has been used regularly 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 changes to mifepristone's approved conditions of use, have routinely 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 opinion issued

by the Fifth Circuit would prohibit APCs from prescribing this medication as part of their scope of practice.

This ruling ignores that APCs are crucial providers of reproductive healthcare and are as qualified to provide and as 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. Moreover, depriving women of medication abortion care by APCs would result in many women being unable to receive the healthcare they require. It is in part for these reasons that mainstream medical and public health groups overwhelmingly support the provision of medication abortion by APCs.

The petitions for writs of certiorari should be granted.

ARGUMENT

I.

ADVANCED PRACTICE CLINICIANS MUST SATISFY RIGOROUS EDUCATION AND CERTIFICATION REQUIREMENTS TO PROVIDE THE BROAD SCOPE OF HEALTHCARE THEY ROUTINELY PROVIDE.

APCs, which include certified women's health nurse practitioners, certified nurse-midwives, and physician associates, are vital participants in the U.S.

healthcare system. They are licensed to provide a broad range of health services consistent with their heightened educational standards and rigorous certification and continuing education requirements. APCs have prescriptive authority in every state, including for controlled substances.[2] 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.[3] NPs dispense these essential health services in a wide variety of practice areas, including family medicine, pediatrics, geriatrics, and women's health, among others.[4]

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[2] *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; Am. Acad. PAs, *PA Prescribing* (2020), https://www.aapa.org/download/61323/?tmstv=1696531381.

[3] Am. Ass'n Nurse Pract., *Discussion Paper: Scope of Practice for Nurse Practitioners* (2022), https://storage.aanp.org/www/documents/advocacy/position-papers/Scope-of-Practice.pdf.

[4] *See* Nat'l Governors Ass'n, 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.[5] NPs must pass a national certification exam to receive the designation of Board-certified NP (NP-BC) which is required for practice in a vast majority of states.[6] Certification testing assesses the "applicant's knowledge and skill in diagnosing, determining treatments, and prescribing for their patient population of focus."[7]

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 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

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[5] *Id.* at 8.

[6] *Id.*; Adv. Pract. Educ. Ass'n, *How Should Nurse Practitioners List Their Credentials*, https://www.apea.com/blog/How-Should-Nurse-Practitioners-List-Their-Credentials-26/. 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 Oct. 7, 2023).

[7] Nat'l Governors Ass'n, *supra*, at 8.

with the NP role and the women's health population focus. As a licensed healthcare 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, both independently and collaboratively as a healthcare team member. The role of the WHNP includes providing consultation services to other healthcare providers regarding the unique healthcare needs of women. The WHNP provides leadership to improve women's healthcare and health outcomes in practice settings, healthcare systems, and communities.[8] WHNPs maintain certification and recertify every three years through the National Certification Board and are required to meet 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.[9]

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[8] NPWH, Women's Health Nurse Practitioner: Guidelines for Practice and Education 2-3 (8th ed. 2022).

[9] *See* Am. Coll. Nurse-Midwives, *Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives* (2021), https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf.

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.[10] CNMs also provide primary care for all ages.[11]

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 on those who have active RN credentials when they pass the certification exam).[12] 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.[13] The ACNM competencies and standards are consistent with or exceed the International Confederation of Midwives' global midwifery competencies and standards.[14] CNMs must be recertified every five years through the American Midwifery Certification Board and are required to meet continuing education requirements.[15]

Similarly, PAs' generalist clinical practice includes taking medical histories, performing physical examinations, ordering and interpreting

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[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

laboratory tests, diagnosing illness, developing and managing treatment plans, prescribing medication, including controlled substances, and assisting in surgery.[16] PAs play an integral role in a broad array of clinical settings, including obstetrics and gynecology, in both outpatient and in-hospital settings, providing a wide range of care from the diagnosis and treatment of acute and chronic gynecological conditions to independently performing critical clinical procedures such as vaginal deliveries, amniotomies, inseminations, endometrial and vulvar biopsies, and loop excision electrocoagulation procedures, and assisting in surgeries.[17]

In order to become certified and licensed to practice, PAs must first graduate from an accredited master's degree program, which spans three academic years and employs a rigorous curriculum modeled on the medical school program.[18] Students take more than 75 hours in pharmacology, 175 hours in behavioral sciences, 400 or more hours in basic sciences, and nearly 580 hours of clinical medicine, and complete over 2,000 hours of supervised clinical practice.[19] PAs must then pass the Physician Assistant National Certifying Exam, become state-licensed, and, in order to maintain national certification, must complete 100

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[16] Am. Acad. PAs, *PA Scope of Practice* (2019), https://www.aapa.org/download/61319/?tmstv=1696532297.

[17] *See* Am. Acad. PAs, *PAs in Obstetrics and Gynecology* (2021), https://www.aapa.org/download/19515/.

[18] *Id.*; *PA Scope of Practice, supra*.

[19] *PAs in Obstetrics and Gynecology*, *supra*.

hours of continuing medical education every two years and take a recertification exam every ten years.[20]

The rigorous education and certification requirements for NPs, CNMs, and PAs belie any notion that these groups of accomplished health professionals are in any way unqualified to provide medication abortion.

II.

ADVANCED PRACTICE CLINICIANS PROVIDE SAFE AND EFFECTIVE ABORTION CARE.

In 2016, when the FDA approved a supplemental new drug application from mifepristone's sponsor that changed the drug's conditions for use and the FDA Risk Evaluation and Mitigation Strategy ("REMs") to allow licensed healthcare providers (*i.e.*, APCs) to prescribe and dispense mifepristone, it considered "data from over 3200 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. Defs.' Opp. to Pls.' Mot. for Prelim. Inj., ECF No. 28-1 at 48-49, *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration* (N.D. Tex. No. 2:22-cv-99223-Z) ("Defs.' Opp."). And, like physicians, APCs also regularly provide safe and effective aspiration abortions, including, if necessary, as follow-up care after a medication

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[20] *PA Scope of Practice*, *supra.*

abortion. Additionally, APCs enable people to access abortion care earlier in a pregnancy, when such care 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."[21] A ten-year retrospective review of patients who initiated

[21] Nat. Acad. Sci., Eng'g 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).

medication abortion from 2009 to 2018 further supports the safe and effective outcomes of medication abortion provided by APCs.[22] The researchers concluded that these outcomes were well within the published benchmarks for medication abortion effectiveness and safety for medication abortion provided by physicians.[23]

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 randomized study of 1180 women who received medication abortions that concluded that nurse-midwives' provision of medication abortion had "superior efficacy" over that provided by physicians.[24] 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,

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[22] *See* L. Porsch et al., *Advanced practice clinicians and medication abortion safety: A 10-year Retrospective Review*, 101 Contraception 357, 357 (2020).

[23] *Id.*

[24] *See* H. Kopp Kallner 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: Int'l J. Obstetrics & Gynecology 510, 515 (2015).

for women treated by physicians).[25] Moreover, women who 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.[26]

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.[27] 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.[28] 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.[29]

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[25] *Id.* at 514. *None* of the 1180 women participating in the study experienced any serious complications, across provider groups. *Id*. at 513.

[26] *Id.*

[27] Dr. 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, 1155, 1155-61 (2011).

[28] *Id.*

[29] Anand Tamang et al., *Comparative satisfaction of receiving medical abortion service from nurses and auxiliary nurse-midwives*

Further, APCs working with physicians often take on leadership roles, 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 commonly "educat[ed] physician colleagues about mifepristone."[30] 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.[31] "There's a lack of [provider] knowledge [about medication abortion]," she explained, but it has "been a lot better since I've been able to inform them" and "orient them toward the best treatment for the patient."[32]

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

APCs also safely and effectively provide aspiration abortions. Aspiration abortion involves the dilation of

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or doctors in Nepal: results of a randomized trial, 14 Reproductive Health 1, 1 (2017). Significantly, there is a conspicuous but telling absence of studies or empirical data suggesting that medication abortion in states that prohibit APCs from providing this care is any more safe or effective than in states that allow APCs to do so.

[30] 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).

[31] *Id*. at 690-91.

[32] *Id*. (alteration in original).

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.[33] Aspiration abortion may be performed to terminate a pregnancy or as follow-up care in the rare instance of a failed medication abortion.[34]

The Fifth Circuit suggested that emergency room physicians would be responsible for providing aspiration abortions in the unlikely event such care is needed following a medication abortion. *See* Pet. U.S. Food & Drug Administration App'x at 17a. 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

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[33] *See* 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).

[34] Am. Coll. Obstetricians & 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.

over a span of four years.[35] The study concluded that abortion "care provided by newly trained NPs, CNMs, and PAs was not inferior to that provided by experienced physicians."[36] With regard to major complications, the study found that there was no significant difference in terms of risk between provider groups.[37] 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."[38]

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[35] *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).

[36] *Id.* at 458.

[37] *Id.* at 459.

[38] *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); Amy Levi et al., *Training in aspiration abortion care: An observational cohort study of achieving procedural competence*, 88 Int'l J. Nursing Studies 55, 57 (2018) (concluding that "complication rates did not differ significantly between [aspiration abortion] procedures performed by [APC trainees] and physician residents" and there was "no difference between the complications experienced in training and those found when the clinicians worked without direct supervision" following a study of a competency-based training model teaching NPs, CNMs, and PAs to perform vacuum aspiration abortion care).

Further buttressing these studies, PAs have a long history of successfully providing aspiration abortions, and performed surgical abortions in states such as Vermont and Montana as early as 1973.[39] An early study analyzing the outcomes of first-trimester surgical abortions performed in a Vermont clinic found that of 2,458 first trimester abortions, those performed by physician assistants presented a 2.74% complication rate as compared with a 3.08% complication rate for abortions performed by physicians.[40]

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

Although abortion is safe at any stage of pregnancy, safety increases the earlier the care is provided. *See* Defs.' Opp., ECF No. 28-2, at 21. 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

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[39] Carole Joffe & Susan Yanow, *Advanced Practice Clinicians as Abortion Providers: Current Developments in the United States*, 12 Reproductive Health Matters Supp. 198, 199 (2004).

[40] Mary Anne Freedman et al., *Comparison of Complication Rates in First Trimester Abortions Performed by Physician Assistants and Physicians*, 76 Am. J. Public Health 550, 550 (1986).

integrated abortion and early pregnancy care, thereby reducing delays and unnecessary referrals.[41]

APCs are, and will likely continue to be, easier to access than physicians for healthcare as a general matter. Demand for healthcare is projected to continue to outpace supply. Significantly, the number of physicians is expected to increase annually by only 1.1% from 2016 to 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 and a predicted 35% increase of clinically active PAs from 2020 to 2035.[42]

With respect to reproductive healthcare specifically, from 2000 to 2009 alone, the percentage of women who reported receiving maternity care from a midwife, NP, or PA increased 4% annually, indicating a cumulative increase of 48% over the decade.[43] APCs also are "important contraception providers" in the

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[41] D. Taylor et al., *Advanced practice clinicians as abortion providers: preliminary findings from the California primary care initiative*, 80 Contraception 199, 199 (2009).

[42] David I. Auerbach et al., *Growing Ranks of Advanced Practice Clinicians – Implications for the Physician Workforce*, 378 N. Engl. J. Med. 2358, 2359 (2018); Tim Dall et al., *The Complexities of Physician Supply and Demand: Projections from 2018 to 2030* (2021), https://www.aamc.org/media/54681/download; Roderick S. Hooker et al., *Forecasting the physician assistant/ associate workforce: 2020-2035*, 9 Future Healthcare J. 57, 57 (2022).

[43] Katy Backes Kozhimannil et al., *Recent trends in clinicians providing care to pregnant women in the United States*, 57 J. Midwifery Womens Health 433, 433 (2012).

reproductive healthcare landscape.[44] The increased role of APCs in providing reproductive healthcare is especially pronounced in rural areas, where lower OB-GYN availability means patients rely on NPs and PAs at higher rates for their reproductive healthcare needs.[45] The relative availability of APCs as compared to physicians means that patients seeking medication abortion can access professional healthcare earlier, thereby lowering already low complication rates.

III.

ADVANCED PRACTICE CLINICIANS REGULARLY PROVIDE HEALTHCARE, INCLUDING CHILDBIRTH CARE, THAT IS EQUALLY OR MORE COMPLEX THAN MEDICATION ABORTION.

As part of their everyday practice, APCs routinely provide healthcare 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

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[44] *See* Candice Chen et al., *Who is providing contraception care in the United States? An observational study of the contraceptive workforce*, 226 Am. J. Obstetrics & Gynecology E1, E5 (2021).

[45] *See* Hyungjung Lee et al., *Determinants of rural-urban differences in health care provider visits among women of reproductive age in the United States*, 15 PLoS ONE, e0240700 (2020); *see also* Chen et al., *supra*, at E5 (suggesting that "advanced practice nurses," *i.e.*, NPs and CNMs, are "especially" important for provision of contraceptive care in rural areas).

procedures. APCs also regularly prescribe controlled substances and assist in complicated surgeries and medical procedures. Moreover, studies have demonstrated that APC-provided obstetrical care (including labor and delivery) results in better outcomes than that provided by physicians despite the inherent, 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 Healthcare Provided by APCs.

APCs routinely provide reproductive health-related care that is akin to medication abortion. APCs provide miscarriage treatment, for example, which frequently calls for the use of the same course of medication used in medication abortion (mifepristone followed by misoprostol).[46] Further, as discussed above, APCs perform aspiration procedures both for abortion and for miscarriage management.[47]

As a routine part of their everyday practice, APCs also provide reproductive and non-reproductive healthcare services that are far more complex than medication abortion. For example, APCs insert and remove intrauterine contraceptive devices ("IUDs")

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[46] *See* Am. Coll. Obstetricians & Gynecologists, *Early Pregnancy Loss Practice Bulletin* (2018), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss.

[47] *See*, *e.g.*, Weitz et al., *supra*, at 457-58; Levi & Cardinal, *supra*, at 44.

and other contraceptive implants and perform endometrial biopsies.[48] Inserting and removing an IUD involves placing an instrument through the cervix, and complicated removals may necessitate cervical dilation.[49] These procedures exceed the complexity involved in medication abortion.

Non-reproductive healthcare services provided by APCs that are far more complex than medication abortion include but are not limited to neuraxial anesthesia, central line insertions, arterial line insertions, intubations, chest tube insertions, surgical first assistance, colonoscopies, and endoscopies. All PAs, as well as other APCs with Drug Enforcement Administration registrations, can prescribe controlled substances, which are potentially dangerous and addictive and thus carry greater risk than the medications used in medical abortions.[50] They also

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[48] Courtney B. Jackson, *Expanding the Pool of Abortion Providers: Nurse-Midwives, Nurse Practitioners, and Physician Assistants*, Women's Health Issues S42, S42 (2011); *see also* 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 (noting the same).

[49] *See* Aimee C. Holland et al., *Preparing for Intrauterine Device Consults and Procedures*, Women's Healthcare 37, 39 (2020).

[50] *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 Oct. 7, 2023); *see also PA Prescribing*, *supra* ("PAs are authorized to prescribe medications in all jurisdictions where they are licensed. Where PAs have prescriptive authority, that authority includes controlled medications.").

provide vital assistance in complex specialist procedures, including orthopedic surgeries, cardiology procedures, and plastic surgery.[51]

In light of the complexity of the healthcare provided by APCs, there is no principled basis for disallowing APCs from continuing to 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.[52]

For example, one study comparing the outcomes of midwife- and obstetrician-provided care in low-risk

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[51] *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/MC6126674/.

[52] *See*, *e.g.*, Y. Tony Yang et al., *State Scope of Practice Laws, Nurse-Midwifery Workforce, and Childbirth Procedures and Outcomes*, 26 Women's Health Issues 262, 262 (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).

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.[53] 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%.[54] 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.[55]

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.[56] The study found a

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[53] Vivienne Souter et al., *Comparison of Midwifery and Obstetric Care in Low-Risk Hospital Births*, 134 Obstetrics & Gynecology 1056, 1057 (2019).

[54] *Id.*

[55] Yiska Lowenberg Weisband et al., *Birth Outcomes of Women Using a Midwife versus Women Using a Physician for Prenatal Care*, 63 J. Midwifery & Women's Health 399, 399 (2018); *see also* Mary Huynh, *Provider Type and Preterm Birth in New York City Births, 2009-2010*, 25 J. Health Care for the Poor and Underserved, 1520, 1520 (2014) ("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%, p<.0001).").

[56] Dorothy Brooten et al., *A Randomized Trial of Nurse Specialist Home Care for Women with High-Risk Pregnancies: Outcomes and Costs*, 7 Am. J. Managed Care 793, 798-99 (2008).

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.[57] As with abortion care, physicians themselves recognize the significant benefits of APCs providing women's healthcare. Physicians in the NP 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."[58]

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 healthcare 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 NPs, CNMs, and

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[57] *Id*. at 797.

[58] *Id*. at 802.

PAs be permitted to provide medication and aspiration abortion.[59] 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) has defined NPs, CNMs, and PAs as "primary care clinicians."[60] APHA also cites evidence to conclude that "these clinicians are well positioned within the healthcare system to address women's needs for comprehensive primary care and preventive reproductive health services that include abortion care."[61]

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."[62] ACOG also has called for the cease and repeal of "requirements

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[59] *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.

[60] *Id.*

[61] *Id.*

[62] Am. Coll. Obstetricians & Gynecologists, *Abortion Training and Education*, *Committee Opinion No. 612* (2022), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Abortion-Training-and-Education.

that only physicians or obstetrician-gynecologists may provide abortion care. . . ."[63]

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."[64]

The positions of these leading 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. Since 1991, *Amicus* NPWH has maintained that abortion care is within women's health nurse practitioners' scope of practice.[65] This

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[63] *Id.*

[64] 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.

[65] 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).

policy has been reaffirmed to the present day, with NPWH stating in its guidelines that "[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."[66] 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."[67] *Amicus* AAPA has also affirmed PAs' ability to provide abortion care, stating that "the PA profession is a natural fit for team-oriented obstetrics and gynecology (OBGYN) practice. PAs increase patient access and contribute to improved quality by providing medical care and care coordination."[68]

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[66] 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 (NPWH supports "the full spectrum of reproductive health" including "abortion services").

[67] Am. Coll. Nurse-Midwives, *Midwives as Abortion Providers* (2019), http://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/000000000314/PS-Midwives-as-Abortion-Providers-FINAL-August-2019.pdf.

[68] *PAs in Obstetrics and Gynecology*, *supra*; *see also* Am. Acad. PAs, 2023-2024 Policy Manual 97 (2023), https://www.aapa.org/download/116915/?tmstv=1690405277 ("AAPA believes all PAs should advocate for and promote equitable and confidential access to comprehensive, evidence-based, developmentally appropriate, and culturally sensitive sexual and reproductive health information and services.").

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 APCs provide abortion care. In a well-researched policy guidance paper, 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.[69]

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 positpion paper that "ICM affirms that a woman who seeks or requires abortion-related services is entitled to be provided with such services by midwives."[70]

The message of these mainstream professional and public health organizations is clear: the provision

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[69] World Health Org., Abortion Care Guideline 59 (2022), https://iris.who.int/bitstream/handle/10665/349316/9789240039483-eng.pdf?sequence=1.

[70] Int'l Confed. Midwives, Position Statement: Midwives' Provision of Abortion-Related Services 1 (2014), https://www.internationalmidwives.org/assets/files/statement-files/2018/04/midwives-provision-of-abortion-related-services-eng.pdf.

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. The FDA reached this conclusion in 2016 when it approved changes to mifepristone's conditions of use to allow APCs to prescribe and dispense mifepristone. There is no reason to disturb that conclusion now.

CONCLUSION

The petitions for a writ of certiorari should be granted.

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Respectfully submitted,

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