Case Nos. 24-1576(L), 24-1600, 24-1617

In the United States Court of Appeals for the Fourth Circuit

AMY BRYANT, M.D., *Plaintiff–Appellee*,

v.

TIMOTHY K. MOORE, et al., *Intervenors/Defendants–Appellants*

and

JOSHUA H. STEIN, in his official capacity as Attorney General for the State of North Carolina, et al., *Defendants–Appellees*.

On Appeal from the United States District Court for the Middle District of North Carolina at Greensboro, The Honorable Catherine C. Eagles,
Case No. 1:23-cv-00077

BRIEF OF *AMICI CURIAE* THE NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH AND AMERICAN COLLEGE OF NURSE-MIDWIVES IN SUPPORT OF APPELLEE AMY BRYANT, M.D.

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STATEMENT OF INTEREST OF AMICI[1]

Amicus curiae The National Association of Nurse Practitioners in Women's Health ("NPWH") is the national professional association representing over 13,100 board-certified women's health nurse practitioners ("WHNP-BCs") in the United States. WHNP-BCs are advanced practice registered nurses licensed as independent practitioners who plan and deliver a full range of women's and gender-related healthcare services, starting at puberty and continuing throughout the lifespan. 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, clinicians, 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 ("CNMs") and

[1] Pursuant to Federal Rule of Appellate Procedure 29, counsel for *Amici* The National Association of Nurse Practitioners in Women's Health and American College of Nurse-Midwives 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 *Amici* or their counsel, contributed money intended to fund the preparation or submission of this brief.

certified midwives ("CMs") 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 APCs. *Amici* have extensive experience providing reproductive healthcare, including medication abortion, which they have been doing for many years. *Amici* highlight the overwhelmingly positive outcomes for the hundreds of thousands of patients treated by APCs in reproductive health each year. *Amici* have an interest in dispelling Appellants' misinformed argument that patient "safety" is protected when medication abortion care is provided by physicians rather than APCs. *Amici* also have an interest in making clear that, counter to Appellants' assertions, APCs provide safe and effective medication abortion care and play a critically important role as healthcare providers with respect to medication abortion and reproductive healthcare more generally.

INTRODUCTION AND SUMMARY OF ARGUMENT

Advanced practice clinicians, which include board-certified women's health nurse practitioners, certified nurse-midwives, and other advanced practice registered nurses, are critical participants in the provision of healthcare in this country. APCs offer a broad range of care to their patients, including primary care. APCs specializing in women's health are sometimes the only clinicians a woman may meet in connection with reproductive health, as they offer contraceptive counseling, prenatal care, STI screenings, annual exams, miscarriage treatment, and, when appropriate and lawful, abortion services.

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. APCs have safely prescribed mifepristone under physician supervision since 2000 where permitted by state law and, since the Food & Drug Administration's ("FDA") 2016 changes to mifepristone's REMS permitting non-physician licensed healthcare providers with prescribing authority under state law to become certified prescribers of mifepristone, have routinely prescribed the medication independently.

Despite the overwhelming evidence that APCs across the country have been independently, effectively, and safely prescribing mifepristone for years, in 2023, the North Carolina state legislature passed an act—entitled "Abortion Laws"—that

would, among other restrictions, disallow the prescription of mifepristone by all healthcare providers except physicians in the state. The District Court correctly recognized that this restriction "ha[s] been explicitly rejected by the FDA as unnecessary for safe administration and as unnecessary burdens on the health care system and patient access" and held that this requirement is preempted by the FDA's explicit judgment that APCs may safely prescribe mifepristone. *See* Memorandum Opinion and Order at 38, *Bryant v. Stein*, No. 1:23-CV-77 (M.D.N.C. Apr. 30, 2024), ECF No. 193 ("District Court Opinion & Order").

Appellants nonetheless seek to uphold this restriction (and others) in the Abortion Laws. In so doing, they ignore 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. APCs also prescribe medications and perform procedures that are far more complex than medication abortion. Depriving patients of medication abortion care by APCs would result in many women being unable to receive the healthcare they require. For these reasons, among others, mainstream medical and public health groups overwhelmingly support the provision of medication abortion by APCs.

The Court should rule in favor of Appellee Amy Bryant, M.D.

ARGUMENT

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

APCs, which include board-certified women's health nurse practitioners and certified nurse-midwives, are vital participants in the United States healthcare system.[2] 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.[3] 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. They consistently outperform physicians on metrics of patient satisfaction, patient compliance, and

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[2] APCs also include physician associates ("PAs").

[3] 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. In North Carolina, NPs' prescriptive authority is indicated in the written practice agreement they enter into with a collaborating physician. *See State Law Chart: Nurse Practitioner Prescriptive Authority*, at 11.

health promotion.[4] They are, as one physician put it, the ones who "keep the lights on. . . ."[5]

Nurse practitioners ("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.[6] NPs dispense these essential health services in many practice areas, including family medicine, pediatrics, geriatrics, and women's health, among others.[7]

NPs must satisfy rigorous educational and certification requirements. First, NPs must obtain a registered nurse license and complete graduate education at the masters, post-masters, or doctoral level.[8] NPs must pass a national certification exam to receive the designation of board-certified NP ("NP-BC"), which is required

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4 Elena Kraus & James M. DuBois, *Knowing Your Limits: A Qualitative Study of Physician and Nurse Practitioner Perspectives on NP Independence in Primary Care*, 32 J. Gen. Internal Med. 284, 284 (2017).

5 *Id.*

6 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.

7 Nat'l Governors Ass'n, The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care 4 (2012).

8 *Id*. at 8.

for practice in the vast majority of states, including North Carolina.[9] Certification testing assesses the "applicant's knowledge and skill in diagnosing, determining treatments, and prescribing for their patient population of focus."[10] NPs' training and testing for licensure is highly effective. Data suggest that NPs are capable of providing approximately 90% of primary care services commonly provided by physicians, with comparable outcomes.[11] Once licensed, NPs in North Carolina practice under a collaborative practice agreement with a licensed physician.[12]

WHNP-BCs are advanced practice registered nurses who obtain education at the master's, post-master's, or doctoral level, equipping them with the knowledge, skills, and abilities to provide full-scope and evidence-based women's and gender-related healthcare autonomously.[13] WHNP education, certification, and practice are congruent with the NP role and the women's health population focus. WHNP academic programs follow educational standards ensuring the attainment of core

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9 *Id*.; Adv. Pract. Educ. Ass'n, *How Should Nurse Practitioners List Their Credentials* (Oct. 20, 2023), https://www.apea.com/blog/How-Should-Nurse-Practitioners-List-Their-Credentials-26/. In forty-seven states, including North Carolina, NPs must receive certification from a nationally recognized certified body. Am. Ass'n Nurse Pract., *State Practice Environment*, https://www.aanp.org/advocacy/state/state-practice-environment (last visited Oct. 10, 2024); Am. Ass'n Nurse Pract., AANP State Fact Sheet North Carolina (Oct. 2023).

10 Nat'l Governors Ass'n, at 8.

11 Kraus & DuBois, at 284.

12 *Applications – Nurse Practitioner*, North Carolina Board of Nursing, https://www.ncbon.com/nurse-practitioner-0 (last visited Oct. 3, 2024).

13 NPWH, *Scope of Practice for the Board-certified Women's Health Nurse Practitioner (WHNP-BC)* (Sept. 2024).

competencies for the advanced practice registered nurse and NP roles, and additional population-focused didactic education and clinical experiences provide WHNP students with expanded competencies dedicated to women's and gender-related healthcare.[14] Graduates of accredited WHNP programs are eligible for national certification through the National Certification Corporation as board-certified WHNPs.[15]

The WHNP functions within the scope of practice rules and regulations established by the nurse practice act in the state(s) in which the WHNP is licensed and works.[16] The WHNP provides independent and collaborative care in outpatient, inpatient, community, and other settings and offers consultation services to other healthcare providers regarding women's unique healthcare needs. WHNP-BCs perform assessments; order, perform, and interpret diagnostic and laboratory tests; make diagnoses; and provide pharmacologic and nonpharmacologic treatments.[17] They offer routine and complex gynecologic, sexual, reproductive, menopause transition, and post-menopause healthcare.[18] WHNPs must recertify every three

[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*

years through the National Certification Board and are required to meet continuing education requirements.[19]

Like WHNPs, 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.[20] 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.[21] CNMs also provide primary care for all ages.[22]

Education and certification requirements for CNMs are exacting. Following completion of a bachelor's degree and a graduate midwifery program, CNMs must pass a national certification exam to receive the designation of CNM (a title referring to individuals with active RN credentials when they pass the exam).[23] CNMs must continuously demonstrate that they meet the Core Competencies for Basic

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[19] *Id.*

[20] 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.

[21] *Id.*

[22] *Id.*

[23] *Id.*

Midwifery Practice of *Amicus* ACNM and are required to practice in accordance with the ACNM Standards for the Practice of Midwifery.[24] The ACNM competencies and standards are consistent with or exceed the International Confederation of Midwives' global midwifery competencies and standards.[25] CNMs must be recertified every five years and are required to meet continuing education requirements.[26] In North Carolina, CNMs may practice independently upon reaching 24 months of practice as a CNM and 4,000 practice hours; before reaching that threshold, they practice under a collaborative practice agreement with a licensed physician.[27]

The rigorous education and certification requirements for NPs, WHNP-BCs, and CNMs make clear that these accomplished healthcare professionals are well-qualified to provide medication abortion, as they have been doing for years.

II. ADVANCED PRACTICE CLINICIANS PROVIDE SAFE AND EFFECTIVE ABORTION CARE.

In 2016, the FDA approved a supplemental new drug application from mifepristone's sponsor that changed the drug's conditions for use and the FDA REMS to allow licensed healthcare providers (*i.e.*, APCs) to prescribe and dispense

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[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *See Applications – Certified Nurse Midwife*, North Carolina Board of Nursing, https://www.ncbon.com/certified-nurse-midwife (last visited Oct. 3, 2024).

mifepristone. And, like physicians, APCs also regularly provide safe and effective aspiration abortions, including, if necessary, as follow-up care after a medication abortion.[28]

APCs enable patients to access abortion care earlier in pregnancy when such care is even safer and more effective. They are ideally positioned to deliver abortion care as the first point of contact for women with contraception and pregnancy-related issues. For many patients, especially those living in rural areas, APCs are not just their provider of choice, but also the only possible provider. Given the overwhelming body of scientific evidence before it, the FDA unsurprisingly removed conditions restricting APCs' ability to be certified prescribers of mifepristone. The restriction on APC-provision of medication abortion in the Abortion Laws is thus not only preempted by federal law, but also ignores that APCs provide safe and effective abortion care.

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

[28] 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).

Academies of Science, Engineering, and Medicine, the nonpartisan, nongovernmental institution established to advise the nation on issues related to those disciplines, concluded: "[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."[29] A retrospective review of patients who initiated medication abortion from 2009 to 2018 further supports the safe and effective outcomes of medication abortion provided by APCs.[30] The researchers concluded that these outcomes were well within the published benchmarks for medication abortion effectiveness and safety for medication abortion provided by physicians.[31]

In fact, some research shows that APCs provide medication abortions with *greater* efficacy and patient acceptability than physicians. For example, one of the studies cited by the FDA in connection with its 2016 REMS review was a randomized study of 1,180 women receiving medication abortions that concluded

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[29] Nat. Acad. Sci., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States 14 (2018), https://nap.national academies.org./catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states; Sharmani Barnard et al., *Doctors or Mid-Level Providers for Abortion*, Cochrane Database (2015) (no statistically significant difference in risk of failure for medication abortions performed by APCs compared with physicians in comparative review of medication abortion outcome studies).

[30] *See* L. Porsch et al., *Advanced Practice Clinicians and Medication Abortion Safety*, 101 Contraception 357, 357 (2020).

[31] *Id*.

that nurse-midwives' provision of medication abortion had "superior efficacy" over that provided by physicians.[32] 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%, for women treated by physicians).[33] Women randomized to meet with nurse-midwives were more likely to prefer their allocated provider than women randomized to meet with physicians, and were significantly more likely to express a preference for nurse-midwives if they ever required medication abortion in the future.[34]

Similarly, another FDA-cited randomized study of 1,295 women who received medication abortions found that abortions provided by nurses and auxiliary nurse midwives who received government-certified training did not pose any higher risk of failure or incomplete abortions compared to abortions provided by physicians.[35] In fact, 97.3% of the medication abortions provided by certified nurses or auxiliary nurse midwives were completed without further intervention, as

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[32] 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*, 122 BJOG: Int'l J. Obstetrics & Gynecology 510, 515 (2015).

[33] *Id*. at 513-14. None of the 1,180 women participating in the study experienced any serious complications, across provider groups. *See id.*

[34] *Id*.

[35] 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).

compared to 96.1% of those provided by physicians.[36] A later review of data collected in that same study found that of the women receiving 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.[37]

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 study of NPs who provided medication abortion in Canada found that NPs commonly "educat[ed] physician colleagues about mifepristone."[38] 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.[39]

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[36] *Id.*

[37] 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 1 (2017). 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—contrary to Appellants' characterization of such laws as "safeguards" protecting public health. *See* Opening Br. of Appellants (ECF No. 21) at 32.

[38] 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).

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

B. Advanced Practice Clinicians Regularly And Safely Provide Aspiration Abortions, Just As Physicians Do.

APCs safely and effectively provide aspiration abortions, which involve the dilation of the cervix and the use of a curette to remove uterine contents through gentle suction; the *identical* procedure is used in the event of an incomplete miscarriage.[40] Aspiration abortion may be performed to terminate a pregnancy or as follow-up care in the rare instance of an incomplete medication abortion.[41]

Evidence confirms that APCs provide aspiration abortion with the same safety and efficacy as physicians. In one study, researchers compared 5,812 aspiration procedures performed by physicians with 5,675 aspiration procedures performed by APCs over four years.[42] The study concluded that abortion "care provided by newly trained NPs, CNMs, and PAs was not inferior to that provided by experienced physicians."[43] The study found no significant difference in terms of risk of major complications between provider groups.[44] The results "confirm[ed] existing

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[40] 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).

[41] 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.

[42] Weitz et al., at 457.

[43] *Id*. at 458.

[44] *Id*. at 459.

evidence from smaller studies that the provision of abortion[s] by [APCs] is safe and from larger international and national reviews that have found these clinicians to be safe and qualified health care providers."[45]

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 care is provided. It is no surprise that participation in abortion care by trained APCs improves patient safety and overall outcomes, as it allows early diagnosis and management of unintended pregnancies and integrated abortion care, thereby reducing delays and unnecessary referrals.[46]

APCs are, and will continue to be, easier to access than physicians for healthcare. Demand for healthcare is projected to continue to outpace supply. 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

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[45] *Id.*; Eva Patil 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 versus APCs); Amy Levi et al., *Training in Aspiration Abortion Care*, 88 Int'l J. Nursing Studies 55, 57 (2018) (no significant difference in complication rates in aspiration abortions performed by APC trainees versus physician residents).

[46] D. Taylor et al., *Advanced Practice Clinicians as Abortion Providers: Preliminary Findings from the California Primary Care Initiative*, 80 Contraception 199 (2009).

predicted 6.8% increase in NPs annually during that same period.[47] In North Carolina, from 2000 to 2023, the number of physicians per 10,000 residents increased by 28.4%; the number of NPs per 10,000 residents increased far more, *by 475.6%*.[48]

In the field of reproductive healthcare, from 2000 to 2009 alone the percentage of women who reported receiving maternity care from a midwife, NP, or a PA increased 4% annually, indicating a cumulative increase of 48% over the decade.[49] APCs also are "important contraception providers" in the reproductive healthcare landscape.[50] The increased role of APCs in reproductive healthcare is especially

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[47] 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 (2022).

[48] *See North Carolina Health Professional Supply Data*, Sheps Health Workforce NC, the University of North Carolina at Chapel Hill, https://nchealthworkforce.unc.edu/interactive/supply/ (last visited Oct. 3, 2024).

[49] Katy Backes Kozhimannil et al., *Recent Trends in Clinicians Providing Care to Pregnant Women in the United States*, 57 J. Midwifery Women's Health 433, 433 (2012).

[50] 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).

pronounced in rural areas, where lower physician availability means that patients rely on NPs at higher rates for their reproductive healthcare needs.[51]

Approximately 25% of women will face the difficult decision to terminate a pregnancy in their lifetime.[52] They are often young, unmarried, low-income women seeking abortion care within the first six weeks of gestation.[53] Some women seek abortion care not from hospitals or physicians, but from health clinics. For many women, especially those living in remote locations hours away from any physician providing abortion care, APCs are the only providers reasonably available.[54] These women depend on healthcare clinics and develop trusting relationships with APCs,

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[51] 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); Chen et al., at E5 ("advanced practice nurses," *i.e.*, NPs and CNMs, are "especially" important for provision of contraceptive care in rural areas).

[52] Asvini K. Subasinghe et al., *Primary Care Providers' Knowledge, Attitudes and Practices of Medical Abortion: A Systematic Review*, 47 BMJ Sex & Reproductive Health 9 (2021), https://srh.bmj.com/content/familyplanning/47/1/9.full.pdf.

[53] Margot Sanger-Katz et al., *Who Gets Abortions in America?*, N.Y. Times (Dec. 14, 2021), https://www.nytimes.com/interactive/ 2021/12/14/upshot/who-gets-abortions-in-america.html.

[54] *See, e.g.*, Decl. of Helen Weems in Support of Pls.' Mot. for Prelim. Inj. at 1, *Whole Woman's Health All. v. U.S. Food & Drug. Admin.*, No. 3:23-cv-00019 (W.D. Va. May 8, 2023), ECF No. 10-3 ("Weems Decl.") ("I am also the only clinician providing abortion care in Northwest Montana. The next closest abortion provider is almost a 3-hour drive away, each way. Before [the clinic] opened in 2018, the Northwest region had been without an abortion provider since 2014. And, prior to 2014, another [APC] was the only abortion provider in the region for many years.").

who are often their reproductive healthcare providers well before they seek abortion care.

In 2020, clinics, including abortion clinics, made up only 50% of abortion providers in the United States but administered 96% of all abortions.[55] One study showed that of 9,087 women who sought a first-trimester aspiration abortion, 81% of women who were offered APC care accepted such care, and the majority received an abortion provided by an APC.[56] Further, as a result of the COVID-19 pandemic, the practice of medicine drastically shifted in favor of telehealth when appropriate.[57] Medication abortion is one area that has been shown to be particularly appropriate for telehealth for eligible patients, and many women have expressed gratitude that APCs are more available to provide that care.

The relative availability of APCs compared to physicians, coupled with APCs' authority to prescribe mifepristone, means that patients seeking an abortion can access healthcare earlier, facilitating the provision of safe critical care.

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[55] Jeff Diamat & Besheer Mohamed, *What the Data Says About Abortion in the U.S.*, Pew Rsch. Ctr. (Jan. 11, 2023), https:// www.pewresearch.org/short-reads/2023/01/11/what-the-data-says-about-abortion-in-the-u-s-2/.

[56] Diana Taylor et al., *Multiple Determinants of the Abortion Care Experience: From the Patient's Perspective*, 28 Am. J. Med. Quality 510, 511-14 (2013).

[57] Julia Shaver, *The State of Telehealth Before and After the COVID-19 Pandemic*, 49 Primary Care: Clinics in Office Practice 517, 517 (2022).

Reverting to a physician-only prescriber requirement would leave many women without such care.[58]

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 provide healthcare services that are essentially the same as, comparable to, or more complex than medication abortion. These services include reproductive health-related care and non-reproductive health-related procedures. APCs also regularly prescribe controlled substances and assist in complicated surgeries and medical procedures. Finally, studies have demonstrated that APC-provided obstetrical care 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.

As a part of their everyday practice, APCs provide reproductive and non-reproductive healthcare that is far more complex than medication abortion. APCs insert and remove intrauterine contraceptive devices ("IUDs") and other contraceptive implants and perform endometrial biopsies.[59] Inserting and removing

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[58] *See* Weems Decl. at 8.

[59] Courtney B. Jackson, *Expanding the Pool of Abortion Providers: Nurse-Midwives, Nurse Practitioners, and Physician Assistants*, Women's Health

an IUD involves placing an instrument through the cervix, and complicated removals may necessitate cervical dilation.[60] These procedures exceed the complexity involved in medication abortion.

Other non-reproductive healthcare provided by APCs that is more complex than medication abortion includes neuraxial anesthesia, central line insertions, arterial line insertions, intubations, chest tube insertions, surgical first assistance, colonoscopies, and endoscopies. NPs and CNMs with Drug Enforcement Administration registrations, and all PAs, can prescribe controlled substances which are potentially dangerous and addictive and carry far greater risk than the medications used in medical abortions.[61] APCs also provide vital assistance in complex specialist procedures, including orthopedic, cardiac, and plastic surgery.[62]

Issues S42 (2011); 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] Aimee C. Holland et al., *Preparing for Intrauterine Device Consults and Procedures*, Women's Healthcare 37, 39 (2020).

[61] *See* U.S. Dep't of Justice, *Mid-Level Practitioners Authorized by State*, https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf; Am. Acad. PAs, *PA Prescribing* (2020), https://www.aapa.org/download/61323/?tmstv=1696531381.

[62] Grant R. Martsolf et al., *Employment of Advance Practice Clinicians in Physician Practice*, 178 JAMA Intern. Med. 988, 990 (2018).

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 manage deliveries.[63] Significantly, studies comparing the outcomes of prenatal and labor care provided by APCs and physicians demonstrate that APC care is often more effective than physician care.[64]

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.[65] Another study found that women receiving care from a midwife were at lower risk of cesarean and preterm birth and did not have increased risk of neonatal intensive care admissions, neonatal deaths, or severe maternal morbidity.[66]

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[63] *See* Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 217 (2012); 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).

[64] Yang et al., at 262 (women in states with autonomous practice laws for nurse-midwives have lower rates of cesarean delivery, preterm births, and low birth weight compared to women in states without such laws).

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

[66] 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).

With respect to NPs, one study of women at high risk of delivering low-birth-weight infants found notably better outcomes and satisfaction rates for those receiving prenatal care from NPs at home than from physicians at hospital clinics.[67] As with abortion care, physicians themselves recognize the significant benefits of APCs providing women's healthcare. Physicians in the study "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."[68]

Given the far greater complexity of the other procedures and medical care that APCs routinely provide patients, including prenatal and labor care, there is no principled basis to uphold the Abortion Laws' prohibition of APCs' prescription of mifepristone.

IV. MAINSTREAM MEDICAL AND PUBLIC HEALTH GROUPS OVERWHELMINGLY SUPPORT THE PROVISION OF MEDICATION ABORTION CARE BY APCS.

Leading medical and public health groups support provision of medication abortions by APCs as a means of providing patients greater access to qualified healthcare providers.

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67 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).

68 *Id*. at 802.

The American Public Health Association ("APHA") is the largest organization of professionals dedicated to addressing public health issues and policies backed by science. For more than a decade, APHA has recommended that APCs be permitted to provide medication abortion and has advocated for the provision of abortion care by APCs since 1999.[69] APHA also cites evidence to conclude that APCs "are well positioned within the healthcare system to address women's needs . . . includ[ing] abortion care."[70]

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."[71] ACOG also has called for the cease and repeal of "requirements that only physicians or obstetrician-gynecologists may provide abortion care. . . ."[72]

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69 *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants*.

70 *Id*.

71 Am. Coll. Obstetricians & Gynecologists, *Abortion Training and Education, Committee Opinion No. 612* (2014) (reaffirmed 2022), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/11/abortion-training-and-education.

72 *Id*.

The American Medical Women's Association ("AMWA") is dedicated to the advancement of women in medicine and the improvement of women's health. 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 [APCs] to the pool of potential abortion providers."[73]

The positions of these medical and public health organizations reflect and support the recommendations that organizations representing APCs have long asserted regarding APCs' ability to provide abortion care. Since 1991, *Amicus* NPWH has maintained that abortion care is within WHNPs' scope of practice.[74] This policy has been reaffirmed, with NPWH stating in its guidelines that "a WHNP program curriculum . . . prepares the [NP] with distinct competencies to provide advanced assessment, diagnosis, and management," including the ability to "[p]rovide medication abortion."[75] In 2019, *Amicus* ACNM affirmed that

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[73] 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.

[74] Nat'l Abortion Fed., Strategies for Expanding Abortion Access: The Role of Physician Assistants, Nurse Practitioners, and Nurse-Midwives in Providing Abortions 22 (1997).

[75] NPWH, Guidelines for Practice and Education 13-14 (2022).

"medication abortion may be safely provided by trained advance practice clinicians (APCs), including midwives."[76]

The views of these professional organizations are shared more globally. Since 2012, the World Health Organization ("WHO") has emphasized the importance of APC-provided abortion care. In a policy guidance paper, the WHO noted: "[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.[77]

The message of these organizations is clear: the provision of medication abortion involving mifepristone falls well within APCs' scope of practice. Limiting the prescription of mifepristone to physicians is, as the District Court made clear, a "restriction[] that impose[s] unnecessary burdens on the health care system and patient access." District Court Opinion & Order at 39. 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 correctly reached this

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[76] 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.

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

same conclusion in 2016. There is no basis for allowing North Carolina's Abortion Laws to disturb that conclusion now.

CONCLUSION

For the foregoing reasons, the Court should rule for Appellee Amy Bryant, M.D.

Respectfully submitted,

/s/ *Jonathan K. Youngwood*

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Dated: October 17, 2024

/s/ *Jonathan K. Youngwood*
Jonathan K. Youngwood

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I hereby certify that on October 17, 2024, I electronically filed the foregoing *amicus curiae* brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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Jonathan K. Youngwood

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COUNSEL FOR: The National Association of Nurse Practitioners in Women's Health;

American College of Nurse-Midwives as the
(party name)

☐ appellant(s) ☐ appellee(s) ☐ petitioner(s) ☐ respondent(s) ☑ amicus curiae ☐ intervenor(s) ☐ movant(s)

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Signature: /s/ Jonathan K. Youngwood Date: 10/17/2024

Counsel for: Nat'l Ass'n of NPs in Women's Health

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