Nos. 23-235 and 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 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

JONATHAN K. YOUNGWOOD
Counsel of Record
SIMONA G. STRAUSS
CLAIRE E. CAHOON
ISABEL R. MATTSON
JACOB M. MADDEN
SIMPSON THACHER & BARTLETT LLP
425 Lexington Avenue
New York, NY 10017
JYoungwood@stblaw.com
SStrauss@stblaw.com
Claire.Cahoon@stblaw.com
Isabel.Mattson@stblaw.com
Jacob.Madden@stblaw.com
(212) 455-2000

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

TABLE OF CONTENTS

Page

TABLE OF CONTENTS i

TABLE OF AUTHORITIES iii

INTEREST OF *AMICI CURIAE* 1

SUMMARY OF ARGUMENT 3

ARGUMENT 5

I. ADVANCED PRACTICE CLINICIANS MUST SATISFY RIGOROUS EDUCATION AND CERTIFICATION REQUIREMENTS TO PROVIDE THE BROAD SCOPE OF HEALTHCARE THEY ROUTINELY OFFER 5

II. ADVANCED PRACTICE CLINICIANS PROVIDE SAFE AND EFFECTIVE ABORTION CARE 11

A. Advanced Practice Clinicians Achieve The Same, Or Better, Health Outcomes As Physicians When Providing Medication Abortion 13

B. Advanced Practice Clinicians Regularly And Safely Provide Aspiration Abortions, Just As Physicians Do........ 17

C. The Ability Of Advanced Practice Clinicians To Prescribe Mifepristone Improves Already Exceedingly Safe Abortion Care 20

D. Advanced Practice Clinicians Providing Medication Abortion Give Follow-Up Care And Support As Indicated..... 24

TABLE OF CONTENTS – Continued

Page

III. ADVANCED PRACTICE CLINICIANS REGULARLY PROVIDE HEALTHCARE, INCLUDING CHILDBIRTH CARE, THAT IS EQUALLY OR MORE COMPLEX THAN MEDICATION ABORTION 28

A. Medication Abortion Is Essentially Equivalent To Care For Early Pregnancy Loss 29

B. Medication Abortion Is More Straightforward Than Much Of The Healthcare Provided By APCs 31

C. Advanced Practice Clinicians Provide Prenatal And Labor Care That Is As Safe And Effective, If Not More So, As The Care Provided By Physicians 32

IV. MAINSTREAM MEDICAL AND PUBLIC HEALTH GROUPS OVERWHELMINGLY SUPPORT THE PROVISION OF MEDICATION ABORTION CARE BY APCS 34

CONCLUSION 38

TABLE OF AUTHORITIES

Page

RULES

Sup. Ct. R. 37.6 1

CASE MATERIALS AND RECORDS

Decl. of Helen Weems in Support of Pls.' Mot. for Prelim. Inj., ECF No. 10-3, *Whole Woman's Health All. v. U.S. Food & Drug. Admin*., No. 3:23-cv-00019 (W.D. Va. May 8, 2023)..............22, 24

Defs.' Opp. to Pls.' Mot. for Prelim. Inj., ECF No. 28-1, *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration* (N.D. Tex. No. 2:22-cv-99223-Z)...11, 12, 20

Pet. U.S. Food & Drug Administration Cert. App'x..18

INTERVIEWS

Interview with Alexi Child, MMS, PA-C (Jan. 24, 2024)...20, 22, 25, 29

Interview with Brittania McDonald, BS, MS, MPAS (Jan. 24, 2024)............................22, 29, 30, 31

Interview with Christie Pitney, MS, RN, WHNP-BC, CNM (Jan. 10, 2024) 25, 26, 27

Interview with Debbie Barish, DNP, RN, WHNP-BC (Jan. 16, 2024).............. 22, 25, 26, 27, 28

TABLE OF AUTHORITIES – Continued

Page

Interview with Julie Jenkins, DNP, APRN, WHNP-BC (Jan. 18, 2024) ... 16-17, 18, 23, 24, 27, 37

Interview with Lindsey Piper, MSN, WHNP-BC (Jan. 11, 2024) 16, 23, 25, 28, 29

OTHER AUTHORITIES

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/ 7

Aimee C. Holland et al., *Preparing for Intrauterine Device Consults and Procedures*, Women's Healthcare 37 (2020)...31

Am. Acad. PAs, *PA Prescribing* (2020), https://www.aapa.org/download/61323/?tmstv=1696531381 ....6, 32

Am. Acad. PAs, *PA Scope of Practice* (2019), https://www.aapa.org/wp-content/uploads/2017/01/Issue-brief_Scope-of-Practice_0117-1.pdf 10, 11, 25

Am. Acad. PAs, *PAs in Obstetrics and Gynecology* (2021), https://www.aapa.org/download/19515/ 10, 11, 36

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 6

TABLE OF AUTHORITIES – Continued

Page

Am. Ass'n Nurse Pract., *State Practice Environment*, https://www.aanp.org/advocacy/state/state-practice-environment 7

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/acnmlibrary data/uploadfilename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf.....8, 9

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 36

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 35

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 29

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 17-18

TABLE OF AUTHORITIES – Continued

Page

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..........................6

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.................... 35-36

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 31, 34, 35

Amy J. Levi & Tara Cardinal, *Early Pregnancy Loss Management for Nurse Practitioners and Midwives*, Women's Healthcare: A Clinical Journey for NPs 43 (2016) 17

Amy Levi et al., *Training in Aspiration Abortion Care: An Observational Cohort Study of Achieving Procedural Competence*, 88 Int'l J. Nursing Studies 55 (2018)..19

TABLE OF AUTHORITIES – Continued

Page

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)............................15

Andrea Carson et al., *Nurse Practitioners on 'the Leading Edge' of Medication Abortion Care: A Feminist Qualitative Approach*, 79 J. Adv. Nursing 686 (2023) 16

Anthony W. Chow et al., *IDSA Clinical Practice Guidelines for Acute Bacterial Rhinosinusitis in Children and Adults*, 54 Clinical Infectious Diseases e72 (2012)...30

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 22

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 (2021) 21

Carole Joffe & Susan Yanow, *Advanced Practice Clinicians as Abortion Providers: Current Developments in the United States*, 12 Reproductive Health Matters Supp. 198 (2004)....................19

TABLE OF AUTHORITIES – Continued

Page

Courtney B. Jackson, *Expanding the Pool of Abortion Providers: Nurse-Midwives, Nurse Practitioners, and Physician Assistants*, Women's Health Issues S42 (2011) 31

D. Taylor et al., *Advanced Practice Clinicians as Abortion Providers: Preliminary Findings from the California Primary Care Initiative*, 80 Contraception 199 (2009) 20

David I. Auerbach et al., *Growing Ranks of Advanced Practice Clinicians – Implications for the Physician Workforce*, 378 N. Engl. J. Med. 2358 (2018) 21

Diana Taylor et al., *Multiple Determinants of the Abortion Care Experience: From the Patient's Perspective*, 28 Am. J. Med. Quality 510 (2013) 23

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 (2008) 33, 34

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 (2017) 6, 7

Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (2012) 32

TABLE OF AUTHORITIES – Continued

Page

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 (2016)....................19

Grant R. Martsolf et al., *Employment of Advance Practice Clinicians in Physician Practice*, 178 JAMA Intern. Med. 988 (2018)....................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: A Randomised Controlled Equivalence Trial*, 122 BJOG: Int'l J. Obstetrics & Gynecology 510 (2015)....................14, 26

Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 Am. Fam. Physician 473 (2021)....................30

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)....................21

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 (2011)....................15

TABLE OF AUTHORITIES – Continued

Page

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/ 23

Julia Shaver, *The State of Telehealth Before and After the COVID-19 Pandemic,* 49 Primary Care: Clinics in Office Practice 517 (2022) 23

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 (2020) 17

Katy Backes Kozhimannil et al., *Recent Trends in Clinicians Providing Care to Pregnant Women in the United States*, 57 J. Midwifery Womens Health 433 (2012) 21

L. Porsch et al., *Advanced Practice Clinicians and Medication Abortion Safety: A 10-Year Retrospective Review*, 101 Contraception 357 (2020) 13, 14

Leah S. Honigman et al., *National Study of Non-Urgent Emergency Department Visits and Associated Resource Utilization*, 14 West. J. Emergency Med. 609 (2013) 27

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 22

TABLE OF AUTHORITIES – Continued

Page

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 (1986)..............20

Medication Guide, Danco Lab. (2016), https://www.earlyoptionpill.com/wp-content/uploads/2016/01/DAN_MedGuideEng_FINAL.pdf...............25

Nat. Acad. Sci., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States (2018), https://nap.nationalacademies.org./catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states 13

Nat'l Abortion Fed., Strategies for Expanding Abortion Access: The Role of Physician Assistants, Nurse Practitioners, and Nurse-Midwives in Providing Abortions (1997).................................36

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

NPWH, Guidelines for Practice and Education (2022)...36

Robin M. Weinick et al., *How Many Emergency Department Visits Could be Managed at Urgent Care Centers and Retail Clinics?*, 29 Health Affairs (Millwood) 1630 (2010)...................27

Roderick S. Hooker et al., *Forecasting the Physician Assistant/Associate Workforce: 2020-2035*, 9 Future Healthcare J. 57 (2022) 21

TABLE OF AUTHORITIES – Continued

Page

Sharmani Barnard et al., *Doctors or Mid-Level Providers for Abortion*, Cochrane Database (2015) 13

Tim Dall et al., *The Complexities of Physician Supply and Demand: Projections from 2018 to 2030* (2021), https://www.aamc.org/media/54681/download 21

Toshiyuki Kakinuma et al., *Safety and Efficacy of Manual Vacuum Suction Compared with Conventional Dilation and Sharp Curettage and Electric Vacuum Aspiration in Surgical Treatment of Miscarriage: A Randomized Controlled Trial*, 20 BMC Pregnancy & Childbirth 1 (2020) 18

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 (2013) 12, 18, 19, 26

U.S. Dep't of Justice, *Mid-Level Practitioners Authorized by State*, https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf 32

Vivienne Souter et al., *Comparison of Midwifery and Obstetric Care in Low-Risk Hospital Births*, 134 Obstetrics & Gynecology 1056 (2019) 33

World Health Org., Abortion Care Guideline (2022), https://iris.who.int/bitstream/handle/10665/349316/9789240039483-eng.pdf?sequence=1 37

TABLE OF AUTHORITIES – Continued

Page

Y. Tony Yang et al., *State Scope of Practice Laws, Nurse-Midwifery Workforce, and Childbirth Procedures and Outcomes*, 26 Women's Health Issues 262 (2016)..32, 33

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 (2018).....................33

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 ("CNM") and certified midwives ("CM") 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

---

[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.

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") 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 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. *Amici* also have an interest in making clear that they are committed to and are involved in continuity of care, including with respect to medication abortion administered by telehealth. Finally, *Amici* have an interest in educating the Court and the public that APCs address follow-up needs after medication abortion, primarily through counseling and *not* by pointing their patients to the ER.

SUMMARY OF ARGUMENT

Advanced practice clinicians, which include women's health nurse practitioners, advanced practice registered nurses, certified nurse-midwives, and physician associates, are critical participants in the provision of healthcare in this country. APCs offer a broad range of care, often serving as primary care providers for their patients. 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, early 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 where permitted by state law. In providing medication abortion, APCs also educate their patients and offer comprehensive care, initially to determine whether a prescription is appropriate and thereafter remaining involved in follow-up care and support as needed. Post-medication abortion care typically can be handled through counseling, and true complications from medication abortion are exceedingly rare. In the case of a true complication, ERs are a last resort.

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 being independent certified prescribers of the medication, including for miscarriage management.

The Fifth Circuit's 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. APCs also prescribe medications and perform procedures that are far more complex than medication abortion. Depriving women 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 Petitioners.

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 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. They regularly see patients independently, and many run their own clinics.[3] They consistently outperform physicians on metrics of patient satisfaction, patient compliance, and health promotion.[4] They are, as one physician puts it, the ones who "keep the lights on. . . ."[5]

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

---

[2] 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] 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, 287 (2017).

[4] *Id.* at 284.

[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.

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 for practice in the vast majority of states.[9] Certification testing assesses the "applicant's knowledge and skill in diagnosing, determining treatments, and prescribing for their patient population of focus."[10] This training and testing 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]

---

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

[8] *Id.* at 8.

[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, NPs must receive 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.

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

[11] Kraus & DuBois, at 284.

The women's health nurse practitioner ("WHNP") is prepared at the master's or doctoral level to provide primary care for women from puberty through adulthood, with a focus on gynecologic, sexual, reproductive, menopause-transition, and post-menopause healthcare; uncomplicated and high-risk antepartum and postpartum care; and sexual and reproductive healthcare for men. WHNP education, certification, and practice are congruent with the NP role and the women's health population focus. 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, and provides consultation services to other healthcare providers regarding women's unique healthcare needs. WHNPs maintain certification and recertify every three years through the National Certification Board and also 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.[12] CNMs principally

---

[12] 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/upload

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.[13] CNMs also provide primary care for all ages.[14]

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).[15] 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.[16] The ACNM competencies and standards are consistent with or exceed the International Confederation of Midwives' global midwifery competencies and standards.[17] CNMs must be recertified every five years and are required to meet continuing education requirements.[18]

---

filename/000000000266/Definition%20Midwifery%20Scope%20of%20Practice_2021.pdf.

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

PAs' generalist clinical practice, spanning from the beginning to the completion of care, includes taking medical histories, performing physical examinations, ordering and interpreting diagnostic tests, diagnosing illness, developing and managing treatment plans, prescribing medication (including controlled substances), and assisting in surgery.[19] PAs play an integral role in a broad array of clinical settings, including obstetrics and gynecology, in outpatient and in-hospital settings; they provide a wide range of reproductive 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.[20]

To become licensed, 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.[21] 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

---

[19] Am. Acad. PAs, *PA Scope of Practice* (2019), https://www.aapa.org/wp-content/uploads/2017/01/Issue-brief_Scope-of-Practice_0117-1.pdf.

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

[21] *Id.*; *PA Scope of Practice*.

clinical practice.[22] PAs must then pass the Physician Assistant National Certifying Examination, become state-licensed, and, in order to maintain national certification, complete 100 hours of continuing medical education every two years and take a recertification exam every ten years.[23]

The rigorous education and certification requirements for NPs, CNMs, and PAs support the conclusion that these groups of 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 mifepristone. In assessing the appropriateness of the approval, 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.'

---

[22] *PAs in Obstetrics and Gynecology*.

[23] *PA Scope of Practice.*

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 abortion.[24]

APCs enable people 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.

Finally, APCs remain involved in their patients' care well beyond the prescription stage, ensuring continuity of care following medication abortion. They provide any follow-up care, typically through counseling and reassurance, needed after an abortion medication, and they remain trusted providers for their patients' future healthcare needs.

---

[24] 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).

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 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."[25] 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.[26] The researchers concluded that these outcomes were well within the published benchmarks for medication

---

[25] 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; 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).

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

abortion effectiveness and safety for medication abortion provided by physicians.[27]

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 the 2016 REMS review was a randomized study of 1,180 women receiving medication abortions that concluded that nurse-midwives' provision of medication abortion had "superior efficacy" over that provided by physicians.[28] 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).[29] 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 another medication abortion in the future.[30]

---

[27] *Id.*

[28] 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).

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

[30] *Id.*

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.[31] 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.[32] 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.[33]

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

---

[31] 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).

[32] *Id.*

[33] 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.

NPs who provided medication abortion in Canada found that NPs commonly "educat[ed] physician colleagues about mifepristone."[34] 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.[35] Similarly, Lindsey Piper, a WHNP who has been providing abortion care for over 20 years, "is often called upon by physicians to provide assistance and guidance in difficult abortion procedures" and is often shadowed by medical residents as part of their training. Piper reports that she "is not the only one. Many of [her] colleagues regularly work with physicians and physicians-in-training in order to teach them best practices [with respect to abortion medication]."[36] WHNP Julie Jenkins, who has been involved in abortion care for over 30 years, also trains physicians, NPs, and PAs in medication

---

[34] 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).

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

[36] Interview with Lindsey Piper, MSN, WHNP-BC (Jan. 11, 2024). Piper is a Board-Certified WHNP with a Master of Science in Nursing. She has served on the faculty of an abortion training program at a health center in Maine, as a guest lecturer at the University of Maine and Northeastern University, and has been involved in programs providing abortion training of family medicine residents, medical students, NP students, and others. All interviews cited herein were conducted by counsel for *Amici*, and the interviewed APCs reviewed and approved information attributed to them.

abortion. After Jenkins trained 18 practitioners of a healthcare center in 2023 on medication abortion, the physician-medical director of the center told her, "I've been providing abortions since the 1980s and medication abortions since 2000. I learned so much from you today."[37]

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

APCs also 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.[38] Aspiration abortion thus may be performed to terminate a pregnancy or as follow-up care in the rare instance of an incomplete medication abortion.[39]

---

[37] Interview with Julie Jenkins, DNP, APRN, WHNP-BC (Jan. 18, 2024). Jenkins, who has a Doctor of Nursing Practice degree, has taught in nursing programs at UCSF, University of Maine, and MGH Institute of Health Professions, and is currently a member of the nursing faculty at Yale University.

[38] 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).

[39] Am. Coll. Obstetricians & Gynecologists, *Medication Abortion Up to 70 Days of Gestation Practice Bulletin* (2020), https://

The Fifth Circuit suggested that ER physicians sometimes are required to perform an aspiration abortion in the unlikely event such care is needed following a medication abortion. Pet. U.S. Food & Drug Administration Cert. App'x at 17a. In so doing, the court incorrectly assumed that APCs cannot or do not safely and effectively perform this procedure, whether for abortion or miscarriage care. That assumption is wrong, and evidence confirms that APCs provide aspiration abortion with the same safety and efficacy as physicians.[40]

In one study, researchers compared 5,812 aspiration procedures performed by physicians with 5,675 aspiration procedures performed by APCs over four years.[41] The study concluded that abortion "care provided by newly trained NPs, CNMs, and PAs was not

---

www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[40] An ER visit can lead to a dilation and curettage, a more invasive and often unnecessary procedure in the event of an incomplete abortion. Interview with Julie Jenkins. This is one of many reasons patients are counseled to first contact their APC following medication abortion rather than going to the ER. *Id.*; Toshiyuki Kakinuma et al., *Safety and Efficacy of Manual Vacuum Suction Compared with Conventional Dilation and Sharp Curettage and Electric Vacuum Aspiration in Surgical Treatment of Miscarriage: A Randomized Controlled Trial*, 20 BMC Pregnancy & Childbirth 1, 2 (2020) (World Health Organization and the International Federation of Gynecology and Obstetrics "do not recommend the use of dilation and sharp curettage" for "abortion [or] treatment of miscarriage during the first trimester").

[41] Weitz et al., at 457.

inferior to that provided by experienced physicians."[42] The study found no significant difference in terms of risk of major complications between provider groups.[43] The results "confirm[ed] existing 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."[44]

Further buttressing these studies, PAs have a long history of successfully providing aspiration abortions, and have performed surgical abortions in some states as early as 1973.[45] An early study analyzing the outcomes of first-trimester surgical abortions performed in a Vermont clinic found that of 2,458 first trimester abortions, PA-performed abortions presented a 2.74%

---

[42] *Id.* at 458.

[43] *Id.* at 459.

[44] *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).

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

complication rate, even lower than the 3.08% complication rate for physician-performed abortions.[46]

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. Defs.' Opp., ECF No. 28-2, at 21. 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.[47] Ending APCs' ability to prescribe mifepristone would compromise safe abortion care and miscarriage management.[48]

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

---

[46] 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 (1986).

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

[48] Interview with Alexi Child, MMS, PA-C (Jan. 24, 2024) ("Being able to prescribe both mifepristone and misoprostol for medication abortion and for miscarriage management of early pregnancy loss enables me to give my patients the best evidence-based medical care they need given their individual circumstances.").

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.[49]

In reproductive healthcare, 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.[50] APCs also are "important contraception providers" in the reproductive healthcare landscape.[51] The increased role of APCs in reproductive healthcare is especially pronounced in rural areas, where lower physician availability means that patients rely on NPs and PAs at higher rates for their reproductive healthcare needs.[52]

---

[49] 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).

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

[51] 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).

[52] 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

Approximately 25% of women will face the difficult decision to terminate a pregnancy in their lifetime.[53] They are often young, unmarried, low-income women seeking abortion care within the first six weeks of gestation.[54] 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.[55] These women depend on healthcare clinics and develop trusting relationships with APCs, who are

---

CNMs, are "especially" important for provision of contraceptive care in rural areas).

[53] 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.

[54] 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.

[55] Decl. of Helen Weems in Support of Pls.' Mot. for Prelim. Inj. 1, ECF No. 10-3, *Whole Woman's Health All. v. U.S. Food & Drug. Admin.*, No. 3:23-cv-00019 (W.D. Va. May 8, 2023) ("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."); Interview with Brittania McDonald, BS, MS, MPAS (Jan. 24, 2024); Interview with Alexi Child; Interview with Debbie Barish, DNP, RN, WHNP-BC (Jan. 16, 2024). Barish is a WHNP with 30 years of experience who has provided thousands of medication abortions and has been performing aspiration abortions for over 17 years.

often their reproductive healthcare providers well before they seek abortion care.[56]

In 2020, clinics, including abortion clinics, made up only 50% of abortion providers in the U.S. but administered 96% of all abortions.[57] One study showed that of 9,087 women who sought a first-trimester aspiration abortion from 22 California clinics, 81% of women who were offered APC care accepted such care, and the majority received an abortion provided by an APC.[58]

As a result of the COVID-19 pandemic, the practice of medicine drastically shifted in favor of telehealth when appropriate.[59] 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. As one APC stated, allowing women to obtain abortion care without being required to leave their communities and drive many hours to see a physician – none of which is warranted

---

[56] Interview with Julie Jenkins; Interview with Lindsey Piper.

[57] 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/.

[58] 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).

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

for medication abortion – has been a "silver lining of the pandemic."[60]

The relative availability of APCs compared to physicians, coupled with APCs' authority to independently prescribe mifepristone, means that patients seeking an abortion can access healthcare earlier, facilitating the provision of safe critical care. Reverting to a physician-only prescriber requirement would leave many women without such care.[61] As one WHNP states, "it simply is not a good use of physicians' time to be involved in medication abortion, especially when APCs are available."[62]

D. Advanced Practice Clinicians Providing Medication Abortion Give Follow-Up Care And Support As Indicated.

APCs begin providing care well before they write a prescription for mifepristone and continue to provide care well after.

APCs or the healthcare clinics in which they practice often have preexisting relationships with medication abortion patients, providing annual exams, cancer screenings, contraception counseling, STI screenings, and other care. Whether or not they have those relationships, prior to prescribing mifepristone, APCs assess patients' medical histories and presenting signs

[60] Interview with Julie Jenkins.

[61] Declaration of Helen Weems, at 8.

[62] Interview with Julie Jenkins.

and symptoms to determine their eligibility to receive, and the appropriateness of providing, medication abortion.[63]

Before any medication is prescribed or administered, APCs provide their patients with counseling and extensive information, often including information from the manufacturer of mifepristone, regarding exactly what to expect after taking the medication and giving guidance as to when follow-up care may be indicated.[64]

After a medication abortion, APCs remain available to provide care as appropriate. Like physicians, many APCs provide telephone numbers with 24-hour on-call support; some provide patients with their direct phone numbers and encourage patients to call or text "at any time during the process."[65] As one dual-certified WHNP and CNM explained, she, like other APCs, is available to answer "medical support questions and emotional support questions throughout the [abortion care] process."[66] In the vast majority of instances

---

[63] *Id.*; Interview with Alexi Child; Interview with Debbie Barish; *PA Scope of Practice* (describing how PAs' broad, generalist medical education prepares them to take medical histories).

[64] Interview with Debbie Barish; Interview with Lindsey Piper; *Medication Guide*, Danco Lab. (2016), https://www.earlyoptionpill.com/wp-content/uploads/2016/01/DAN_MedGuideEng_FINAL.pdf.

[65] Interview with Christie Pitney, MS, RN, WHNP-BC, CNM (Jan. 10, 2024). Pitney is a dual-certified Women's Health Nurse Practitioner and Nurse-Midwife who has provided medication abortion care to thousands of women.

[66] *Id.*

where patients seek additional care or advice following a medication abortion, their concerns can be resolved completely with additional education and counseling, which APCs can provide virtually or in-person. Many patients, for example, simply need to be reassured that "bleeding is not a problem, complication, or side effect [of medication abortion], but the intended and expected mechanism of the process."[67]

Whether the medication was provided after a telehealth visit or an in-person visit, APCs frequently check in on their patients a week or so later to ensure that results are progressing as expected, to answer questions patients may have, and, often most importantly, to provide reassurance that bleeding is not an adverse effect, but rather the desired outcome.[68]

In the exceedingly rare case that a medication abortion presents issues that do not resolve on their own, APCs can provide the vast majority of necessary follow-up care, including prescribing antibiotics, performing an aspiration to "empty the uterus" of excess tissue, prescribing additional doses of mifepristone, and treating anemia.[69] Because they are capable of providing most follow-up care themselves, APCs prefer to maintain continuity of care rather than have their patients seek care elsewhere. Even APCs who provide only telehealth services often arrange for intervention as needed by collaborating with local providers who

---

67 *Id.*

68 *Id.*

69 *Id.*; Kopp Kallner et al.; Weitz et al.; Interview with Debbie Barish.

are knowledgeable about medication abortion. APCs refer patients to the ER only when necessary, but doing so is rarely warranted, and is considered a "last resort," in part because, due to ER providers' relative lack of experience in and knowledge of abortion care, patients who present to the ER may end up receiving a more invasive, unnecessary, and costly intervention than necessary.[70] One WHNP explained that in her over 30 years of experience, she has never instructed a patient who was not experiencing a true medical emergency to go to the ER, and in the rare instances where she has ultimately referred a patient to the ER, she first exhausted every other option and then made contact with the ER physicians to confirm that they were willing and able to provide the appropriate abortion-related care.[71] Many APCs explicitly tell their patients, orally and in writing, that unless there is a medical emergency, going to the local ER is "a last option."[72]

---

[70] Interview with Christie Pitney; Interview with Debbie Barish; Interview with Julie Jenkins.

[71] Interview with Julie Jenkins. As Jenkins stated, patients sometimes decide to go to the ER when they need not do so, either because they panic or because they were unprepared for the bleeding that is an expected result of medication abortion. *Id.* However, patients seeking emergency care when there is no emergency is not unique to abortion, and most non-urgent ER patients do not undergo any type of procedure. Leah S. Honigman et al., *National Study of Non-Urgent Emergency Department Visits and Associated Resource Utilization*, 14 West. J. Emergency Med. 609, 612 (2013); Robin M. Weinick et al., *How Many Emergency Department Visits Could be Managed at Urgent Care Centers and Retail Clinics?*, 29 Health Affairs (Millwood) 1630 (2010).

[72] Interview with Christie Pitney.

The medication abortion process frequently results in close, trusting relationships between APCs and their patients. Even APCs who did not already have preexisting relationships with their patients often develop relationships, and their patients return to them or their clinics for annual gynecologic exams, STI screening, contraception, and other reproductive care.[73]

In short, APCs provide medication abortion patients with an expectation of continuity of care, within the context of their medication abortion and beyond.

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

[73] Interview with Debbie Barish; Interview with Lindsey Piper (noting she has "even had patients who received abortions refer their family and friends to see [her]. It is all about building a trusting relationship").

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 Essentially Equivalent To Care For Early Pregnancy Loss.

APCs routinely provide reproductive health-related care that is akin to medication abortion. APCs provide miscarriage care, for example, which frequently calls for the use of the same course of medication used in medication abortion.[74]

The clinically indicated medication regimen now used to manage miscarriages is a combination of mifepristone and misoprostol. Brittania McDonald, who has been a certified physician assistant for 18 years, provides miscarriage care but does not provide medication abortion.[75] She used to give patients undergoing

---

[74] 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; Interview with Lindsey Piper; Interview with Alexi Child. Child is an Illinois PA who, in addition to providing obstetric and medication abortion care, regularly serves as a preceptor and educates PA and NP students on proper abortion and miscarriage management. As she informs her students, "the course of medication is the same for both medication abortion and miscarriage medication treatment." *Id*.

[75] Interview with Brittania McDonald. McDonald is Chief of Medicine at Speare Memorial Hospital in Plymouth, New Hampshire.

early pregnancy loss misoprostol, but she now provides both mifepristone and misoprostol and cautions against prescribing misoprostol alone. McDonald describes the combination of mifepristone and misoprostol as "a far more effective treatment" for miscarriage and refers to extensive data demonstrating that the rate of unplanned aspiration following treatment with misoprostol alone is nearly three times the rate of unplanned aspiration following treatment with both mifepristone and misoprostol.[76] McDonald analogizes the situation to treating sinus infections with amoxicillin rather than Augmentin (a combination of amoxicillin and clavulanic acid), contrary to Infectious Diseases Society of America clinical practice guidelines.[77] "In addition to miscarriage care," she says, "I provide primary care. If I told a patient that I was going to prescribe an antibiotic with a 23% failure rate when I could instead prescribe different medication with a far lower 8% failure rate, my patient would be outraged. Increasing the risk of needing a follow-up surgical procedure when minimizing that risk is so straightforward would not be tolerated in any other specialty."[78] McDonald says she

[76] *Id.*; Honor MacNaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 Am. Fam. Physician 473, 477 (2021) ("For early pregnancy loss, the rate of unplanned aspiration attributed to persistent pain or bleeding is 8.8% when using combined regimens of mifepristone and misoprostol and 23.5% when using misoprostol alone.").

[77] Interview with Brittania McDonald; Anthony W. Chow et al., *IDSA Clinical Practice Guidelines for Acute Bacterial Rhinosinusitis in Children and Adults*, 54 Clinical Infectious Diseases e72, e74 (2012).

[78] Interview with Brittania McDonald.

hates to think about healthcare regressing to the point that APCs would be unable to provide the gold standard of medication for early pregnancy loss.[79]

B. 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.[80] Inserting and removing an IUD involves placing an instrument through the cervix, and complicated removals may necessitate cervical dilation.[81] 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,

---

[79] *Id.*

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

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

arterial line insertions, intubations, chest tube insertions, surgical first assistance, colonoscopies, and endoscopies. All PAs, and other APCs with Drug Enforcement Administration registrations, can prescribe controlled substances, which are potentially dangerous and addictive and carry far greater risk than the medications used in medical abortions.[82] APCs also provide vital assistance in complex specialist procedures, including orthopedic, cardiac, and plastic surgery.[83]

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.

C. 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.[84]

---

[82] U.S. Dep't of Justice, *Mid-Level Practitioners Authorized by State*, https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf; *PA Prescribing*.

[83] Grant R. Martsolf et al., *Employment of Advance Practice Clinicians in Physician Practice*, 178 JAMA Intern. Med. 988, 988-90 (2018).

[84] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (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 (2016).

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.[85]

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.[86] 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.[87]

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.[88] As with abortion care,

---

[85] 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).

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

[87] 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 (2018).

[88] 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).

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."[89]

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.

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.[90] APHA also cites evidence to conclude that APCs "are well positioned

---

[89] *Id*. at 802.

[90] *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants.*

within the healthcare system to address women's needs . . . includ[ing] abortion care."[91]

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."[92] ACOG also has called for the cease and repeal of "requirements that only physicians or obstetrician-gynecologists may provide abortion care. . . ."[93]

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."[94]

---

[91] *Id.*

[92] 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.

[93] *Id.*

[94] Am. Med. Women's Ass'n, *Position Paper on Principals of Abortion & Access to Comprehensive Reproductive Health Services*,

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.[95] 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."[96] In 2019, *Amicus* ACNM affirmed that "medication abortion may be safely provided by trained advance practice clinicians (APCs), including midwives."[97] *Amicus* AAPA has also affirmed PAs' ability to provide abortion care, stating: "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."[98]

---

https://www.amwa-doc.org/wp-content/uploads/2018/05/Abortion-and-Access-to-Comprehensive-Reproductive-Health-Services.pdf.

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

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

[97] 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.

[98] *PAs in Obstetrics and Gynecology*.

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.[99]

The message of these 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 broadly and independently provide medication abortion as they have been doing for many years. The FDA correctly reached this same conclusion in 2016. There is no reason to disturb that conclusion now. Doing so would be "devastating to abortion care."[100]

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

[100] Interview with Julie Jenkins.

CONCLUSION

The Court should rule in favor of Petitioners.

January 30, 2024

Respectfully submitted,

JONATHAN K. YOUNGWOOD
Counsel of Record
SIMONA G. STRAUSS
CLAIRE E. CAHOON
ISABEL R. MATTSON
JACOB M. MADDEN
SIMPSON THACHER &
BARTLETT LLP
425 Lexington Avenue
New York, NY 10017
JYoungwood@stblaw.com
SStrauss@stblaw.com
Claire.Cahoon@stblaw.com
Isabel.Mattson@stblaw.com
Jacob.Madden@stblaw.com
(212) 455-2000

Counsel for 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