IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO



PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

v.

PLAINTIFFS' SECOND MOTION FOR PRELIMINARY INJUNCTION

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

Plaintiffs seek a preliminary injunction to enjoin enforcement of two categories of unconstitutional restrictions on medication abortion: *first*, a series of laws which prohibit qualified and skilled advanced practice clinicians ("APCs") from providing medication abortion, regardless of their education, training, and experience, R.C. 2317.56(B), 2919.11, 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm. Code 4723.9.10(K), 4730-2-07(E) (collectively, the "APC Ban"); and *second*, R.C. 2919.123 (the "Evidence-Based Use Ban," and with the APC Ban, "the Bans"), which prohibits providers from prescribing mifepristone for abortion in any way that differs from the U.S. Food and Drug Administration's label for the drug, despite the fact that other evidence-based uses of mifepristone are common, safe, and effective.¹

These restrictions violate Ohioans' right to reproductive freedom, which voters enshrined in the Ohio Constitution. Article I, Section 22 of the Ohio Constitution (the "Amendment") now

¹ In the Amended Complaint, Plaintiffs additionally challenge a ban on the provision of medication abortion via telemedicine (the "Telemedicine Ban"). See SB 260, 2020 Ohio Laws File 113 (adding R.C. 2919.124); Am. Compl. ¶¶ 71−98. On April 19, 2021, this Court granted a preliminary injunction enjoining enforcement of the Telemedicine Ban before it went into effect. Plaintiffs request that the preliminary injunction against the Telemedicine Ban remain in place, particularly given that, as set forth in this Motion, the Ohio Constitution now explicitly protects abortion.

explicitly protects every Ohioan's "right to make and carry out [their] own reproductive decisions," including decisions related to abortion. The State "shall not, directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against" either: (1) "[a]n individual's voluntary exercise of this right," or (2) "[a] person or entity that assists an individual exercising this right," unless the State can satisfy the heavy burden of showing that it is using the least restrictive means to advance patient health in accordance with widely accepted and evidence-based standards of care. Ohio Constitution, Article I, Section 22(B).

As set forth in the accompanying Memorandum, the affidavits and exhibits attached thereto, and the Amended Complaint and its attached exhibits, Plaintiffs satisfy all of the factors for obtaining preliminary injunctive relief against the Bans. To start, Plaintiffs have established a substantial likelihood of success on the merits of their claim that the Bans violate the Amendment. The evidence shows that the Bans, individually and collectively, burden, penalize, interfere with, and discriminate against both Ohioans who seek to exercise their constitutional right to abortion and Plaintiffs who assist Ohioans in exercising that right by providing abortion care. In some cases, these restrictions may even prohibit Ohioans from making and carrying out their own reproductive decisions entirely. Moreover, these restrictions provide no countervailing benefit to patient health, let alone through the least restrictive means.

Preliminary injunctive relief is also necessary and appropriate to prevent irreparable harm to Plaintiffs' patients—namely, the stark, ongoing violation of their constitutional rights. Every day that the Bans remain in effect, medication abortion is less accessible and available in Ohio. The Bans force patients to remain pregnant against their will for longer periods, subjecting them to all the risks associated with pregnancy and delayed abortion care, along with the financial and logistical burdens associated with traveling longer distances to obtain care. These restrictions also

impose serious, irreparable harms on Plaintiffs as providers of reproductive health care by preventing them from providing timely, evidence-based care to their patients. A preliminary injunction is necessary to stop these ongoing and irreparable constitutional, medical, emotional, psychological, dignitary, and other harms. Finally, an injunction will not harm any third parties and will serve the public interest by preventing the ongoing violation of Ohioans' constitutional rights.

Accordingly, Plaintiffs respectfully request that this Court issue an order enjoining Defendants, as well as their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them, from enforcing the Bans and/or any other Ohio statute or regulation that could be understood to give effect to these provisions, including, but not limited to, R.C. 2903.09,² during the pendency of this litigation, as well as from taking any later enforcement action premised on conduct that occurred while such relief was in effect.

A proposed order will be submitted separately.

R.C. 2903.09 defines "[u]nlawful termination of another's pregnancy," "[a]nother's unborn," and "such other person's unborn," for purposes of Ohio's homicide and assault statutes. See R.C. 2903.01-2903.08, 2903.11-2903.14, 2903.21, 2903.22. In so doing, R.C. 2903.09 makes clear that "in no case" shall the homicide and assault offenses detailed in R.C. 2903.01-2903.08, 2903.11-2903.14, 2903.21, and 2903.22 be "applied or construed... in a manner so that the offense prohibits or is construed as prohibiting any pregnant woman or her physician from performing an abortion" with appropriate consent from the patient or someone authorized to act on their behalf. R.C. 2903.09(C)(1) (emphasis added). Plaintiffs do not understand the terms "[u]nlawful termination of another's pregnancy," "[a]nother's unborn," and "such other person's unborn," as used in Ohio's homicide and assault statutes, to encompass lawful termination of pregnancies via medication abortion. However, given that the exclusion contained in R.C. 2903.09(C)(1) on its face applies only to abortions performed by a pregnant woman or her "physician," it is conceivable that those tasked with enforcement may seek to prosecute APCs for providing medication abortion under such provisions. Accordingly, Plaintiffs request that any order of this Court granting relief from the APC Ban also encompass R.C. 2903.09 and the homicide and assault statutes referenced therein, making clear that the homicide and assault offenses detailed in R.C. 2903.01-2903.08, 2903.11-2903.14, 2903.21, and 2903.22 also cannot be applied or construed as prohibiting an APC from providing a medication abortion with the requisite consent.

Respectfully submitted,

/s/ Michelle Nicole Diamond
Michelle Nicole Diamond (Pro Hac Vice)
Peter Neiman (Pro Hac Vice)
Maura Douglas (Pro Hac Vice)
Meghan Koushik (Pro Hac Vice)
Zach Blair (Pro Hac Vice)
Nicole Castillo (Pro Hac Vice)
WilmerHale LLP
7 World Trade Center
New York, NY 10007
(212) 230-8800
michelle.diamond@wilmerhale.com
peter.neiman@wilmerhale.com
Counsel for Plaintiffs

Alyssa Milstead (Pro Hac Vice) WilmerHale LLP 2600 El Camino Real, Suite 400 Palo Alto, CA 94306 (650) 858-6000 alyssa.milstead@wilmerhale.com Counsel for Plaintiffs

Catherine Humphreville (Pro Hac Vice)
Vanessa Pai-Thompson (Pro Hac Vice)
Planned Parenthood Federation of America
123 William Street, 9th Floor
New York, NY 10038
(212) 541-7800 (Pai-Thompson)
(212) 247-6811 (fax)
catherine.humphreville@ppfa.org
vanessa.pai-thompson@ppfa.org
Counsel for Planned Parenthood
Southwest Ohio Region, Sharon Liner,
M.D., Julia Quinn, and Planned
Parenthood of Greater Ohio

B. Jessie Hill (0074770)
Margaret Light-Scotece (0096030)
Freda J. Levenson (0045916)
ACLU of Ohio Foundation
4506 Chester Ave.
Cleveland, OH 44103
(216) 368-0553
(614) 586-1974 (fax)
bjh@cwru.edu
margaret.light-scotece@case.edu
flevenson@acluohio.org
Counsel for Preterm-Cleveland and
Women's Med Group Professional
Corporation

David J. Carey (0088787)
ACLU of Ohio Foundation
1108 City Park Ave., Ste. 203
Columbus, OH 43206
(380) 215-0997
dcarey@acluohio.org
Counsel for Preterm-Cleveland and
Women's Med Group Professional
Corporation

Meagan Burrows*
Johanna Zacarias*
American Civil Liberties Union
125 Broad St., 18th Fl.
New York, NY 10004
(212) 549-2601
mburrows@aclu.org
jzacarias@aclu.org
Counsel for Preterm-Cleveland and
Women's Med Group Professional
Corporation

Fanon A. Rucker #0066880 The Cochran Firm 527 Linton Street Cincinnati, OH 45219 (513) 381-4878

(513) 672-0814 (fax)
frucker@cochranohio.com
Counsel for Planned Parenthood
Southwest Ohio Region, Sharon Liner,
M.D., Julia Quinn, and Planned
Parenthood of Greater Ohio

*Motion for pro hac vice forthcoming

Dated: May 22, 2024

IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

v.

PLAINTIFFS' MEMORANDUM IN

, [

SUPPORT OF SECOND MOTION FOR PRELIMINARY INJUNCTION

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

INTRODUCTION

In November 2023, Ohioans voted by an overwhelming margin to enshrine an affirmative right to abortion in the Ohio Constitution. Ohio Constitution, Article I, Section 22 (the "Amendment"). The Ohio Constitution now explicitly protects every Ohioan's "right to make and carry out [their] own reproductive decisions," including decisions related to abortion. Given this unequivocal constitutional protection, the Amendment further mandates that the State "shall not, directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against" either: (1) "[a]n individual's voluntary exercise of this right," or (2) "[a] person or entity that assists an individual exercising this right," unless the State can satisfy the extremely heavy burden of showing that it is using the least restrictive means to advance patient health in accordance with widely accepted and evidence-based standards of care. *Id.* § 22(B).

Despite explicit constitutional protections for abortion access, Ohio continues to enforce a host of medically unjustified abortion restrictions, including the restrictions on medication abortion at issue in this case. As set forth in the Amended Complaint, Planned Parenthood Southwest Ohio Region ("PPSWO"); Sharon Liner, M.D.; Julia Quinn, MSN, WHNP-BC;

Planned Parenthood of Greater Ohio ("PPGOH"); Women's Med Group Professional Corporation ("WMGPC"); and Preterm-Cleveland ("Preterm") (collectively, "Plaintiffs"), who are all reproductive health care providers in Ohio, challenge three categories of restrictions on medication abortion that violate the Ohio Constitution: (1) a series of laws that together prohibit qualified and skilled health care providers known as advanced practice clinicians ("APCs") from providing medication abortion, regardless of their education, training, and experience, R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm.Code 4723-9-10(K), 4730-2-07(E) (collectively, the "APC Ban"); (2) a ban on prescribing mifepristone—one of two drugs used in the most common medication abortion regimen—for abortion in any way that differs from the formulation set forth in the U.S. Food and Drug Administration's ("FDA") label for the drug, including in otherwise safe, widely-accepted and evidence-based "off-label" formulations, R.C. 2919.123 (the "Evidence-Based Use Ban"); and (3) a ban on the provision of medication abortion via telemedicine, R.C. 2919.124(B) (the "Telemedicine Ban").

This Court previously found that Plaintiffs were substantially likely to succeed on the merits of their claim challenging the Telemedicine Ban, in part because it "denies [pregnant Ohioans] access to safe, effective health care via telemedicine, and all the benefits such care brings, without any countervailing benefit," and thus irreparably harms Plaintiffs' patients. *See* Entry Granting Plaintiffs' Motion for a Preliminary Injunction ("PI Order") at 7 (Apr. 19, 2021). As set forth herein, Plaintiffs are similarly likely to succeed on the merits of their claim that the APC and Evidence-Based Use Bans (together, "the Bans") are unconstitutional under the Amendment because they, like the Telemedicine Ban, restrict, impede, and deny Ohioans' access to safe, effective reproductive health care with no countervailing benefit to patient health.

The Bans, collectively and individually, violate the Ohio Constitution because they "burden, penalize, interfere with . . . and discriminate against" patients seeking abortion and providers who assist them. In some cases, the Bans may prohibit patients from making and carrying out their reproductive decisions altogether—by preventing them from having the medication abortion they prefer, or medically need-with no countervailing benefit to patient health. The APC Ban prevents experienced APCs from providing medication abortions, even though APCs can legally prescribe the exact same drugs for other purposes, including miscarriage management. It thus unnecessarily restricts the number of available abortion providers and the number of available appointments and locations from which abortion can be provided, and delays patients' access to abortion care, thereby risking harm to patient health and well-being. The Evidence-Based Use Ban similarly singles out medication abortion for differential treatment by criminalizing the prescription of mifepristone for abortion in any formulation that departs from the FDA label (i.e., "off-label" or "evidence-based" prescribing), notwithstanding the fact that offlabel use of FDA-approved drugs-including mifepristone-is common, safe, and effective in the medical field. Indeed, Plaintiffs are not aware of any state besides Ohio which permits medication abortion but applies a similar restriction on off-label prescriptions of mifepristone for abortion. The Evidence-Based Use Ban thus needlessly restricts how mifepristone may be used for abortion care, prohibiting Plaintiffs from prescribing it in a safe and effective evidence-based manner for their patients. This ultimately prevents some patients from obtaining medication abortion in Ohio altogether.

It is well established that the violation of a constitutional right constitutes irreparable harm, and Plaintiffs can demonstrate a litany of other irreparable harms stemming from the Bans. By forcing patients to unnecessarily delay time-sensitive medication abortion care, travel further

distances to receive that care, and potentially lose access to medication abortion in the State entirely, the Bans inflict numerous medical, emotional, financial, psychological, and other harms on patients. And the remaining factors warranting preliminary relief also weigh in Plaintiffs' favor: the State cannot claim harm from being unable to enforce unconstitutional laws, and there is a clear public interest in preventing ongoing violations of constitutional rights.

For these reasons, Plaintiffs respectfully request a preliminary injunction enjoining the enforcement of the Bans.

PROCEDURAL BACKGROUND

On April 1, 2021, PPSWO, Dr. Liner, and PPGOH brought this action, seeking a temporary restraining order followed by a preliminary injunction, as well as a declaratory judgment and permanent injunctive relief, against the Telemedicine Ban. The initial complaint asserted claims for violations of the Ohio Constitution's equal protection and benefit guarantee under Article I, Section 2, and the Ohio Constitution's protections for individual liberty under Article I, Sections 1, 2, 16, 20, and 21. After entering a temporary restraining order, the Court issued a preliminary injunction on April 19, 2021, recognizing the serious, irreparable harm to patients' physical, psychological, and emotional well-being if the Telemedicine Ban was permitted to go into effect. See PI Order. On July 13, 2022, the Court stayed this case pending resolution of State ex rel. Preterm-Cleveland v. Yost, No. 2022-0803 (Ohio June 29, 2022), challenging an Ohio law banning abortion after detection of embryonic or fetal cardiac activity. See Entry Granting Plaintiffs' Motion to Stay Proceedings (July 13, 2022). After the Amendment took effect, the Ohio Supreme Court dismissed the State's appeal in State ex rel. Preterm-Cleveland v. Yost, 2023 WL 8663888, No. 2023-0004 (Ohio Dec. 15, 2023), attached as Exhibit 11. This Court thereafter lifted the stay in this case.

In light of the Amendment, Plaintiffs filed an Amended Complaint to add new parties and additional challenges, including challenges to the APC and Evidence-Based Use Bans. Plaintiffs now seek to preliminarily enjoin the Bans as violations of Article I, Section 22 of the Ohio Constitution. Plaintiffs also respectfully request that the preliminary injunction against the Telemedicine Ban remain in place, given that, as set forth in this Memorandum, the Ohio Constitution now explicitly protects abortion.

STATEMENT OF FACTS³

A. Abortion is Essential Health Care in Ohio

Abortion is extremely common in the United States: approximately one in four women in this country will have had an abortion by age 45. Expert Affidavit of Daniel Grossman, M.D., in Support of Plaintiffs' Motion for Temporary Restraining Order Followed by Preliminary Injunction ("Grossman 2021 PI Aff."), attached as Exhibit 8, ¶ 6. Patients make the deeply personal decision to have an abortion for diverse reasons. *See* Affidavit of W.M. Martin Haskell, M.D., in Support of Plaintiffs' Second Motion for Preliminary Injunction ("Haskell Aff."), attached as Exhibit 2, ¶ 13; Affidavit of Bethany Lewis, LISW-S, in Support of Plaintiffs' Second Motion for Preliminary Injunction ("Lewis Aff."), attached as Exhibit 4, ¶ 13; Affidavit of Sharon Liner, M.D., in Support of Plaintiffs' Motion for a Temporary Restraining Order Followed by Preliminary Injunction ("Liner 2021 PI Aff."), attached as Exhibit 10, ¶ 30; Grossman 2021 PI Aff. ¶ 7. Some patients seek an abortion because they determine it is not the right time to add a

³ Drs. Sharon Liner and Daniel Grossman previously submitted affidavits and expert reports in support of Plaintiffs' first motion for a preliminary injunction. As set forth in their affidavits appended to this Motion, both Dr. Liner and Dr. Grossman reviewed their prior submissions and have represented that they continue to rely on the facts outlined in those submissions and that those facts, and any opinions offered based on those facts, have not changed except as set forth in their 2024 affidavits. Plaintiffs attach Dr. Liner's and Dr. Grossman's 2021 affidavits as Exhibits 8 and 10 to this motion. Dr. Adarsh Krishen also previously submitted an affidavit in support of Plaintiffs' first motion for a preliminary injunction, attached as Exhibit 9.

child to their family because of insufficient financial resources, caretaking responsibilities for their existing children, or a lack of partner or familial support. Grossman 2021 PI Aff. ¶ 7; Liner 2021 PI Aff. ¶ 30; Haskell Aff. ¶ 13; Lewis Aff. ¶ 13. Indeed, the majority of Plaintiffs' abortion patients are already parents. See, e.g., Lewis Aff. ¶ 12; Affidavit of Adarsh E. Krishen, M.D., in Support of Plaintiffs' Second Motion for a Preliminary Injunction ("Krishen Aff."), attached as Exhibit 3, ¶ 24; Affidavit of Sharon Liner, M.D., in Support of Plaintiffs' Second Motion for a Preliminary Injunction ("Liner Aff."), attached as Exhibit 5, ¶ 21. In addition, a significant proportion of Plaintiffs' abortion patients are low-income, e.g., Liner 2021 PI Aff. ¶ 14; Haskell Aff. ¶ 12; Lewis Aff. ¶ 12, as are the majority of patients trying to access abortion care nationwide, see Grossman 2021 PI Aff. ¶ 49. Some may become pregnant as a result of rape, incest, or abuse and do not wish to be further bound to their abuser or to bring a child into an unsafe environment. Haskell Aff. ¶ 13; Lewis Aff. ¶ 13. Others decide to have an abortion to pursue education or career goals. Liner 2021 PI Aff. ¶ 30.

Two types of abortion are available in Ohio: medication and procedural abortion. See Lewis Aff. ¶ 9; Krishen Aff. ¶ 13; see also Liner 2021 PI Aff. ¶ 22. This case concerns medication abortion. The most common regimen of medication abortion involves a combination of two medications: mifepristone and misoprostol. See Grossman 2021 PI Aff. ¶ 12; Liner 2021 PI Aff. ¶ 23; Affidavit of Julia Quinn, MSN, WHNP-BC, in Support of Plaintiffs' Second Motion for a Preliminary Injunction ("Quinn Aff."), attached as Exhibit 6, ¶ 10. Medication abortion patients first take mifepristone orally, which blocks the hormone progesterone, which is necessary to maintain pregnancy. Quinn Aff. ¶ 10; Grossman 2021 PI Aff. ¶ 12. Then, typically 24 to 48 hours later, patients take misoprostol, which causes the uterus to contract and expel its contents, in a

manner similar to a miscarriage. Grossman 2021 PI Aff. ¶ 12; Quinn Aff. ¶ 10; Liner 2021 PI Aff. ¶ 23.

B. Medication Abortion Is Extremely Safe

Abortion in general, and medication abortion specifically, are among the safest treatments in contemporary medical practice. Expert Affidavit of Daniel Grossman, M.D., in Support of Plaintiffs' Motion for a Preliminary Injunction ("Grossman Aff."), attached as Exhibit 1, ¶ 50; see also Grossman 2021 PI Aff. ¶ 8. In the rare, limited cases where complications occur from medication abortion, they usually can be managed safely in an outpatient clinical setting. Grossman Aff. ¶ 36; Liner 2021 PI Aff. ¶ 47. While abortion overall is extremely safe, the risks associated with it increase as pregnancy progresses. Grossman Aff. ¶ 50.

Abortion is also substantially safer than continuing a pregnancy through childbirth. Grossman 2021 PI Aff. ¶ 9; Liner 2021 PI Aff. ¶ 55. Every pregnancy-related complication is more common among women giving birth than among those having abortions. Liner 2021 PI Aff. ¶ 55; Grossman 2021 PI Aff. ¶ 9. The national risk of maternal mortality associated with live birth is approximately 14 times higher than that of induced legal abortion. Grossman 2021 PI Aff. ¶ 9. And these harms do not fall on all populations equally—women of color, particularly Black and Indigenous women, face heightened risks of maternal mortality and pregnancy-related complications. *Id.* ¶ 10. For example, statistics from the Ohio Department of Health show that Black women in Ohio are 1.5 to 2.5 times more likely than white women to die of pregnancy-related causes. ⁴

⁴ According to Ohio statistics from 2008 to 2016, non-Hispanic Black women were more than 2.5 times as likely to die from pregnancy-related causes than their white counterparts. Ohio Dept. of Health, *A Report on Pregnancy-Associated Deaths in Ohio 2008–2016*, at 19 (2019), https://bit.ly/3uZraej (accessed May 8, 2024). However, in 2017 and 2018, due to the adoption of new criteria employed by ODH "to determine the pregnancy-relatedness of unintentional overdose deaths, an increased number of unintentional overdose deaths were determined to be pregnancy related in 2017 and 2018," and the majority of those occurred among non-Hispanic white women. Ohio Dept. of

C. Many Patients Prefer—or Require—Medication Abortions Over Procedural Abortions

Many patients strongly prefer medication abortion over procedural abortion for a host of reasons. Liner Aff. ¶ 25; Grossman 2021 PI Aff. ¶¶ 52–53. Patients may prefer medication abortion because they can end their pregnancy at home at the best time for them and because it allows them more privacy. Grossman 2021 PI Aff. ¶ 52; Liner 2021 PI Aff. ¶ 29. For patients who have experienced sexual assault or abuse, procedural abortions may feel especially traumatic or invasive; such patients may choose medication abortion to feel more in control of the experience and to avoid re-traumatization from the insertion of instruments into the body. Grossman 2021 PI Aff. ¶ 52; Liner Aff. ¶ 25; Krishen Aff. ¶ 35. Other patients may require medication abortions based on medical contraindications for procedural abortions. For example, some patients have medical conditions that make medication abortions significantly safer than procedural abortions, including uterine fibroids, congenital abnormalities, severe obesity, or an extremely flexed uterus. Grossman 2021 PI Aff. ¶ 53; Liner 2021 PI Aff. ¶ 29.

D. The Bans Negatively Impact Access to Abortion Care

1. The APC Ban

a) Overview of the Ban

Under the APC Ban, only physicians can provide abortion care, including medication abortion, in Ohio. See R.C. 2317.56(B), 2919.11, 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1); Ohio Adm.Code 4723-9-10(K), 4730-2-07(E). APCs, which include Nurse Practitioners ("NPs"), Certified Nurse

Health, A Report on Pregnancy-Related Deaths in Ohio 2017–2018, at 4, 28 (2022), https://odh.ohio.gov/know-our-programs/pregnancy-associated-mortality-review/reports/pregnancy-related-deaths-ohio-2017-2018 (accessed May 8, 2024). Nevertheless, in 2017 and 2018, ODH noted that "pregnancy-related deaths due to causes other than overdose occurred disproportionately among non-Hispanic Black women," with Black women being 1.5 times as likely to die from pregnancy-related causes other than overdose than their white counterparts. *Id.*

Midwives ("CNMs"),⁵ and Physician Assistants ("PAs"), are expressly prohibited from prescribing any "drug or device to perform or induce an abortion." R.C. 4723.44(B)(6), 4730.02(E); Ohio Adm.Code 4723-9-10(K), 4730-2-07(E). In addition, non-physicians are prohibited from providing, selling, dispensing, or administering mifepristone "for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person." R.C. 2919.123(A). Ohio law also requires that, at least 24 hours prior to an abortion, a physician (and not an APC) must meet in person with a patient to inform them of the nature and purpose of the abortion as well as its medical risks, in addition to other information. R.C. 2317.56(B).⁶ APCs face severe consequences for violating the APC Ban's physician-only restrictions, including possible criminal charges, civil penalties, civil forfeiture, and professional sanctions. R.C. 4723.28(B)(30), 4723.99(A), 4730.25(B)(24), 4730.252, 4730.99(A).

b) APCs Are Highly Skilled and Capable of Safely and Effectively Providing Medication Abortion Care

APCs play an increasingly important role in the health care workforce throughout the United States and in Ohio specifically. Expert Affidavit of Joanne Spetz, Ph.D., in Support of Plaintiffs' Second Motion for Preliminary Injunction ("Spetz Aff."), attached as Exhibit 7, ¶¶ 14–16, 97. APCs are highly skilled, comprehensively regulated, and qualified health professionals. See id. ¶¶ 90–95. They are subject to rigorous educational and certification requirements, id. ¶¶ 19–22, 90–95; Grossman Aff. ¶¶ 20, and are delegated broad authority by the State Medical Board of Ohio in the case of PAs and the Ohio Board of Nursing in the case of NPs and CNMs, Spetz Aff. ¶¶ 20–22. In Ohio, APCs collaborate with physicians under standard care agreements,

 $^{^5}$ NPs and CNMs are both types of advanced practice registered nurses ("APRNs"). Spetz Aff. \P 13.

⁶ R.C. 2317.56 is currently subject to a separate constitutional challenge in the Franklin County Court of Common Pleas. *Preterm-Cleveland, et al. v. Dave Yost, et al.*, Franklin C.P. No. 24-cv-2634 (Mar. 29, 2024). Plaintiffs challenge it here to the extent that it prohibits APCs from conducting this visit.

which allow for physician supervision and consultation as necessary but do not require physicians to be physically present when APCs provide care. Quinn Aff. ¶ 8. Dozens of states give APCs full practice independence without any physician oversight. Spetz Aff. ¶ 25.

Numerous studies have shown that APCs can provide medication abortion at least as safely as physicians. Grossman Aff. ¶ 23; Spetz Aff. ¶ 84. Research shows no difference in outcomes between a medication abortion provided by an APC and one provided by a physician, and there is no evidence that patients who receive medication abortions from an APC have a higher risk of experiencing complications than if they had received them from a physician. Grossman Aff. ¶ 23; Spetz Aff. ¶¶ 84-85. Based on this medical evidence, numerous professional organizations, including the American College of Obstetricians and Gynecologists, the American Public Health Association, the World Health Organization, and the National Academies of Sciences, Engineering, and Medicine support the provision of medication abortion by appropriately trained APCs. Grossman Aff. ¶¶ 24-25; Spetz Aff. ¶¶ 72-78. Indeed, the FDA does not require provision of mifepristone under physician supervision, basing its conclusion on studies that the FDA recognized "found no differences in efficacy, serious adverse events, ongoing pregnancy or incomplete abortion between" physicians and APCs providing the drug. Grossman Aff. ¶ 28. Today, 21 states and the District of Columbia allow APCs to provide medication abortion. Id. ¶ 29; Spetz Aff. ¶ 43. In fact, APCs (including APCs at PPGOH and PPSWO) currently perform a variety of reproductive health interventions of equal or greater technical complexity and that carry equal or greater risk than medication abortion. Quinn Aff. ¶¶ 15-17; Liner Aff. ¶¶ 33-34; Krishen Aff. ¶ 19.

Nevertheless, despite this extensive evidence and despite APCs' training and qualifications, Ohio law prohibits APCs from prescribing medication to induce an abortion. This

is so even though nothing in Ohio law prevents APCs from legally prescribing the same medications used in medication abortion—mifepristone and misoprostol—for other purposes, including miscarriage management. Grossman Aff. ¶ 32. Miscarriage management requires essentially the same clinician skill and knowledge and carries the same risk to patients as medication abortion. *Id.*

c) Impact of the APC Ban

In practice, the APC Ban significantly restricts and delays access to abortion by limiting the pool of available medication abortion providers in Ohio. Because APCs are prohibited from providing medication abortions, patients are forced to rely exclusively on physicians to provide them with that care in Ohio. *Id.* ¶¶ 41–42; *see also* Liner Aff. ¶¶ 37–38; Haskell Aff. ¶¶ 18; Lewis Aff. ¶¶ 18. This limits the number of available medication abortion appointments, the timing of such appointments, and the number of sites where medication abortions are offered. Grossman Aff. ¶¶ 43–44; Haskell Aff. ¶¶ 18; Lewis Aff. ¶¶ 18–20; Krishen Aff. ¶¶ 15.

At PPSWO and PPGOH, APCs provide the majority of patient care. Liner Aff. ¶ 33; Krishen Aff. ¶ 14, 17. Their health centers, other than their ambulatory surgical facilities ("ASFs"), are all currently staffed with APCs, rather than physicians. Liner Aff. ¶ 4, 33; Krishen Aff. ¶ 15–17. However, because of the APC Ban, PPGOH can only offer medication abortion at its two ASFs in Bedford Heights and Columbus where there are physicians on staff. This is so, even though PPGOH has 13 other health centers in Ohio staffed by APCs who could otherwise provide medication abortion, but for the APC Ban. Krishen Aff. ¶ 13, 16. This forces some patients to travel up to 60 miles each way to receive medication abortions. *Id.* ¶ 23. Likewise, PPSWO can only offer medication abortion at its ASF, where there are physicians on staff; it cannot provide such care at its four other health centers. Liner Aff. ¶¶ 37–38, 44. WMPGC and

Preterm similarly only have two and four physicians, respectively, who are able to provide medication abortion care, and patients often struggle to find available appointments with those providers that match their needs. Haskell Aff. ¶ 19; Lewis Aff. ¶ 20.

These restrictions on availability mean that many patients must ultimately travel farther and/or wait longer to access abortion. This, in turn, requires them to make arrangements for missed work or child care, and overcome the heightened financial and logistical burdens associated with increased travel. Liner Aff. ¶ 21–22, 47; Grossman Aff. ¶ 43–48. These burdens are further heightened for low-income patients, patients with children, and patients in unstable living situations, including those experiencing homelessness or intimate partner violence. For people experiencing intimate partner violence, for instance, delayed abortion care requires them to keep their pregnancies secret for longer and make more complex arrangements to cover their absence; it also increases the likelihood their abuser could detect their pregnancy as a result of the delay, endangering them further. Grossman Aff. ¶ 47–48, 55–56; Krishen Aff. ¶ 26–28.

Indeed, in some cases, as a result of the difficulty of obtaining an appointment and/or overcoming the transportation and logistical barriers necessary to attend that appointment, a patient may be delayed past the gestational age limit for medication abortion entirely. Grossman Aff. ¶ 52; Krishen Aff. ¶ 30; Lewis Aff. ¶ 23. To obtain an abortion, such patients will either need to have a procedural abortion, contrary to their preference or medical indication; leave the State to get the medication abortion they desire, as some of Dr. Liner's patients have done; or may even be forced to carry a pregnancy to term against their will. Liner Aff. ¶ 26; see also Grossman Aff. ¶ 52.

Forcing patients to remain pregnant against their will subjects them to exacerbated physiological stressors and emotional distress, including health risks associated with pregnancy

complications, that ultimately harm patient well-being. Krishen Aff. ¶ 29; Grossman Aff. ¶ 54; Liner Aff. ¶ 24. And though abortion overall remains extremely safe, the risks do increase as pregnancy progresses, meaning that patients are subjected to those heightened risks if and when they do obtain abortion care. Grossman Aff. ¶ 50; Haskell Aff. ¶ 18 n.1. The APC Ban also harms the Plaintiff clinics' providers and staff, given their deep commitment to providing timely, compassionate, patient-centered care. See Krishen Aff. ¶ 31; Quinn Aff. ¶ 23. By forcing these clinics to turn away patients they would otherwise be able to serve, or to witness their patients face significant and unnecessary hurdles to get the care they need and deserve, the APC Ban causes emotional distress and psychological harm to Plaintiffs as providers. See Krishen Aff. ¶ 31; Quinn Aff. ¶ 23.

APCs at PPSWO's and PPGOH's health centers, including Plaintiff Quinn, are highly qualified and trained clinicians who, but for the APC Ban, would be trained to provide safe medication abortion care. Liner Aff. ¶ 42; Krishen Aff. ¶ 22. Without the APC Ban, PPSWO and PPGOH would be able to offer more appointments and greater flexibility to patients and to provide medication abortion care in a larger number of geographic locations, thereby reducing patient travel and associated financial, logistical, and emotional burdens. Liner Aff. ¶¶ 44–48; Krishen Aff. ¶¶ 22–24. Similarly, without the APC Ban, both WMPGC and Preterm would seek to hire and train APCs to provide medication abortion care. Haskell Aff. ¶¶ 19; Lewis Aff. ¶¶ 19, 21. WMPGC would potentially even be able to open a second health center located in the greater Cincinnati area, staffed by APCs, further increasing accessibility. Haskell Aff. ¶¶ 17. Allowing APCs to provide medication abortions thus would not only expand the number of clinicians who could offer medication abortions, it would also increase physician availability to provide

procedural abortions at these clinics, increasing access for all abortion patients. E.g., Liner Aff. ¶ 45; Haskell Aff. ¶ 18.

2. The Evidence-Based Use Ban

a) Overview of the Ban

The Evidence-Based Use Ban, enacted in 2004 as a first-of-its-kind restriction on mifepristone, prohibits abortion providers from prescribing mifepristone for abortion care in any way that differs from the express terms of mifepristone's final printed labeling as incorporated by the drug's FDA approval letter, a common practice known as "evidence based" or "off-label" use of a drug. R.C. 2919.123. Thus, an Ohio health care provider prescribing mifepristone for the purpose of inducing an abortion may do so "only by using the dosage indications and treatment protocols expressly approved by the FDA in the drug's printed labeling as incorporated by the drug approval letter." *Cordray v. Planned Parenthood Cincinnati Region*, 122 Ohio St.3d 361, 2009-Ohio-2972, 911 N.E.2d 871, ¶ 35 (interpreting R.C. 2919.123). The current final printed labeling for mifepristone specifies a regimen, approved by the FDA in 2016, of 200 mg of mifepristone taken orally, followed 24 to 48 hours later by 800 μg of misoprostol taken buccally through 70 days from the first day of a pregnant person's last menstrual period ("LMP"). Liner Aff. ¶ 15; Grossman Aff. ¶ 67.

Failure to prescribe mifepristone for abortion in accordance with this regimen—even where a provider determines, based on the best-available medical evidence, that an off-label use of mifepristone is more medically appropriate for a particular patient—exposes providers to felony criminal penalties, fines, and professional sanctions. R.C. 2919.123(E).

b) Evidence-Based, Off-Label Use of FDA-Approved Drugs, Including Mifepristone, Is Common, Safe, and Effective "Evidence-based" or "off-label" use of medications is a common and essential part of medical practice, which allows providers to care for patients according to the best medical evidence. Grossman Aff. ¶59; Liner Aff. ¶¶7, 13. Common off-label uses for medications include prescribing aspirin to prevent heart attacks and Wellbutrin, approved by the FDA as an antidepressant, for smoking cessation. Grossman Aff. ¶60.

In approving drugs for distribution in the United States, the FDA itself does not test medications. Grossman Aff. ¶ 64. Instead, manufacturers submit evidence from clinical trials to the FDA to demonstrate that the drug is safe and effective for a particular intended use. *Id.* The FDA then reviews those studies, *id.*, and reviews and approves the drug's labeling, *see* Grossman 2021 PI Aff. ¶ 14. If the FDA determines that the drug's health benefits outweigh its known risks for that particular use, the FDA approves the drug for sale along with its proposed label, sometimes with an accompanying Risk Evaluation and Mitigation Strategy ("REMS") to ensure the drug's benefits continue to outweigh the risks. 21 U.S.C. § 355-1(a)(1).⁷ Once the FDA approves a drug, health care providers may generally prescribe the drug for unapproved or off-label use when "they judge that it is medically appropriate for their patient."

To Plaintiffs' knowledge, Ohio only restricts off-label use of drugs in two instances: the use of mifepristone for abortion care and the use of certain Schedule III anabolic steroids, R.C. 3719.06(B), which exhibit significantly higher rates of adverse effects than mifepristone, *see* Spetz Aff. ¶ 40. Notably, Ohio law does not impose similar restrictions on the off-label use of

FDA, Understanding Unapproved Use of Approved Drugs "Off Label" (Feb. 8, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

⁷ The FDA implemented restrictions for mifepristone when first approving its use under a provision then known as "subpart H," 21 C.F.R. §§ 314.500–560, and later under a REMS. Grossman Aff. ¶ 68. Despite the proven safety of mifepristone in the two decades since its approval, and despite broad calls from the medical community to eliminate it based on mifepristone's safety record, the FDA has kept a REMS for mifepristone in place. See ACOG, Updated Mifepristone REMS Requirements, Practice Advisory (Jan. 2023), https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2023/01/updated-mifepristone-rems-requirements.

mifepristone for purposes other than abortion, including miscarriage management. Haskell Aff. ¶ 22; Lewis Aff. ¶ 24. In addition, providers outside of Ohio routinely prescribe mifepristone for off-label use in accordance with evidence-based standards of care. See Grossman Aff. ¶¶ 17, 61.

Mifepristone itself is a case in point of how off-label use can become the standard of medical care well before the FDA formally approves a protocol. The FDA approved a 600mg dosage of mifepristone for abortion in 2000. See id. ¶¶ 64–65. But by the time mifepristone was made available in the United States, research had conclusively demonstrated that a lower dosage of mifepristone (when combined with a different dosage and manner of administering misoprostol⁹) was equally effective through 63 days LMP. Id. ¶ 66. As a result, the overwhelming majority of abortion providers began—and continued—to offer their patients a formulation that differed from the FDA label at the time when mifepristone was actually made available. Id. And in 2016, the FDA approved several changes to mifepristone labeling, expressly relying on this evidence-based regimen, which—by then—was the standard of care in clinical practice. Id. ¶ 67.

Evidence of additional, safe off-label uses of mifepristone for abortion care has emerged since 2016. For example, clinical research has demonstrated—and use throughout the United States has confirmed—that mifepristone is a safe and effective way to terminate a pregnancy beyond 70 days LMP. See id. ¶¶ 69–70 (noting that 37% of facilities providing medication abortion offer it past 70 days LMP); Liner Aff. ¶ 16. In addition, evidence indicates that varying the use of misoprostol from what is indicated on the final printed labeling may also benefit patients. See Grossman Aff. ¶¶ 17, 71. But under the Evidence-Based Use Ban, Ohio providers are

⁹ The use of misoprostol is similarly a case in point for the safety and efficacy of off-label use where supported by medical evidence. Misoprostol was originally approved to treat ulcers but has been shown to have several off-label gynecological uses, including for medication abortion. Grossman Aff. ¶ 60; Liner Aff. ¶ 13. The FDA's inclusion of an off-label use of misoprostol in the label for mifepristone is further evidence of the safety and commonness of off-label uses. Grossman Aff. ¶¶ 66–67.

prohibited from prescribing mifepristone based on these research advances, meaning that Ohioans cannot benefit from these advancements in medical research and best practice.

c) Impact of the Evidence-Based Use Ban

The Evidence-Based Use Ban prohibits Plaintiffs from using evidence-based medical practices in providing medication abortion services for their patients after 70 days LMP. See, e.g., id. ¶¶ 17, 69. Absent the Evidence-Based Use Ban, Plaintiffs would provide mifepristone to their patients for medication abortion beyond 70 days LMP, consistent with the best-available medical evidence. Haskell Aff. ¶ 27; Liner Aff. ¶ 17; Lewis Aff. ¶ 26; Krishen Aff. ¶ 34.

As discussed, there are numerous reasons why patients beyond 70 days LMP may choose or need medication abortion over procedural abortion. See supra at 8. The APC Ban itself may make it more difficult for individuals to get a medication abortion before 70 days LMP, due to restrictions on availability and access. See Krishen Aff. ¶ 36. Under the Evidence-Based Use Ban, these patients are forced to travel out-of-state to obtain medication abortion, often at greater expense and logistical complexity; obtain a procedural abortion against their preference or medical indication; attempt to manage their own medication abortion outside the medical system; or remain pregnant against their will. Liner Aff. ¶¶ 18–27; Haskell Aff. ¶ 25. And again, barriers to access are exacerbated for patients who are low-income, or who may already have children. See, e.g., Liner Aff. ¶¶ 21–22; Krishen Aff. ¶¶ 26–27. As set forth above, patients who face such delays in accessing abortion care are exposed to a host of physiological stressors, health risks, and emotional distress, that are ultimately harmful to their health and well-being. See supra at 12–13.

The Evidence-Based Use Ban also harms Plaintiffs' providers, by impinging on the patient-provider relationship, Liner Aff. ¶ 28, and forcing providers to deny patients safe, evidence-based care that many patients desperately want, with no medical justification—causing them moral and

emotional distress. See Krishen Aff. ¶ 38. Providers, at best, can offer their patients past 70 days LMP a procedural abortion, even where it is medically less safe for that patient, and despite the providers' awareness that the patient does not want to undergo such a procedure. See Liner Aff. ¶¶ 25–26. Otherwise, providers must turn such patients away, knowing this means the patients will suffer from delays in receiving the care they need and the associated harms of such delay.

LEGAL STANDARD

A. Preliminary Injunction Standard

Courts in Ohio grant preliminary injunctive relief where the moving party demonstrates that (1) there is a "substantial likelihood that [it] will prevail on the merits"; (2) it will "suffer irreparable injury if the injunction is not granted"; (3) "no third parties will be unjustifiably harmed if the injunction is granted"; and (4) "the public interest will be served by the injunction." *Proctor & Gamble Co. v. Stoneham*, 140 Ohio App.3d 260, 267, 747 N.E.2d 268 (1st Dist.2000).

B. Ohio's Robust Constitutional Right to Reproductive Freedom

The Ohio Constitution now broadly protects an individual's "right to make and carry out one's own reproductive decisions, including but not limited to decisions on . . . abortion." Ohio Constitution, Article I, Section 22(A). Under the Amendment, the State shall not "directly or indirectly, burden, penalize, prohibit, interfere with, or discriminate against" either Ohioans exercising their right to reproductive freedom or people or entities assisting Ohioans in exercising that right, unless it can "demonstrate[] that it is using the least restrictive means to advance the individual's health in accordance with widely accepted and evidence-based standards of care." *Id.* §§ 22(A)–(B). As Ohio Attorney General Dave Yost acknowledged prior to its passage, the Amendment "create[s] a new . . . standard" that "goes further" beyond the "strict scrutiny" test announced in *Roe v. Wade*, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147 (1973), or the "undue

burden" test described in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992).¹⁰

ARGUMENT

A preliminary injunction is necessary and appropriate to stop the ongoing constitutional, medical, emotional, financial, psychological, and other harms currently being inflicted by the Bans, and Plaintiffs have amply demonstrated that they satisfy all four factors necessary for obtaining such relief. The Bans unconstitutionally restrict access to medication abortion. They do not comport with widely accepted and evidence-based standards of care and do nothing to advance patient health, let alone by employing the "least restrictive means" to do so. Ohio Constitution, Article I, Section 22(B). Instead, these restrictions only harm patients by unnecessarily delaying their access to time-sensitive medication abortion, including (for some) to the point of entirely foreclosing access to medication abortion in Ohio. Plaintiffs are therefore substantially likely to succeed on the merits. And because all other factors warranting injunctive relief also weigh in Plaintiffs' favor, their request for preliminary injunctive relief should be granted.

A. Plaintiffs Are Substantially Likely to Succeed on the Merits of Their Claims that the Bans Are Unconstitutional

The Bans burden, interfere with, penalize, discriminate against, and in some cases, may prohibit individuals from exercising their right to make their own reproductive choices, including about medication abortion. They also restrict and interfere with providers' ability to assist their patients in vindicating these rights. Accordingly, for the Bans to survive constitutional scrutiny, Defendants must demonstrate that they are "using the least restrictive means to advance the individual's health in accordance with widely accepted, evidence-based standards of care." Ohio

¹⁰ Ohio Atty. Gen., Issue 1 on the November 2023 Ballot: A Legal Analysis by the Ohio Attorney General, 5–7 (Oct. 5, 2023), https://www.ohioattorneygeneral.gov/SpecialPages/FINAL-ISSUE-1-ANALYSIS.aspx.

Constitution, Article I, Section 22(B). Defendants cannot do so here, because well-established medical evidence demonstrates that the Bans not only fail to advance patient health, but by delaying and constraining access to medication abortion, they serve only to harm patient health and well-being. Plaintiffs are, therefore, substantially likely to succeed on the merits of their claims.

1. The APC Ban Violates Ohioans' Constitutional Right to Abortion

a) The APC Ban Burdens, Penalizes, Interferes with, Discriminates Against, and in Some Cases, May Prohibit Patients from Making and Carrying Out Their Own Reproductive Decisions

The APC Ban indiscriminately bars all APCs from providing medication abortion regardless of their training or ability to safely provide such care. This prohibition serves only to burden, penalize, and interfere with Ohioans' reproductive decisionmaking, with no benefit to patient health. Moreover, by singling out medication abortion for differential and unfavorable treatment as compared to virtually all other types of medical care, the APC Ban discriminates against both abortion patients and providers. And, by delaying patients' access to medication abortion, the APC Ban may, in some cases, prevent patients from accessing medication abortion entirely, even if preferred or medically indicated.

The APC Ban results in an arbitrary limitation on the number of providers that are hired, trained, and available to provide medication abortion services in the state of Ohio; the number of physical locations where medication abortion is available; and the number and timing of appointments—all of which only unnecessarily constrain and restrict access to this essential service. See supra at 11–12; see also Order Granting Plaintiff's Motion for Preliminary Injunction, Planned Parenthood Great Nw. v. State, Alaska Super. Ct. No. 3AN-19-11710CI ("Alaska PI Order") at 8 (Nov. 2, 2021) (granting preliminary injunction allowing APCs to provide medication

abortion where law had the effect of "limiting the days each month that medication abortion appointments [were] available"), attached as Exhibit 12. As a result, patients for whom medication abortion is preferred or medically indicated, may be delayed in accessing abortion, deal with greater logistical and financial burdens, and have to travel farther to access such care. See supra at 11-12; Weems ex rel. Knudsen v. Montana, 529 P.3d 798, 804 (Mont. 2023) (finding that limits on APCs providing abortions in Montana had resulted in "limited provider availability," causing patients seeking abortion care to "travel great distances, requiring long travel times to access a provider [and] find[] the funds and means to travel"). This is particularly burdensome for lowincome patients, patients with children, and patients in unstable or unsafe living situations, including homeless patients or victims of abuse. See supra at 12. Without the APC Ban, Plaintiffs could expand medication abortion services significantly by training APCs like Plaintiff Quinn to provide medication abortion, by hiring additional APCs, and/or by expanding the number of locations and appointments where medication abortion is available. See supra at 13-14. This would allow the clinics to serve more patients across Ohio-including by freeing up their physicians to perform more procedural abortions—resulting in more flexibility and faster access to time-sensitive care for patients. Id.

By unnecessarily delaying patient access to abortion care, the APC Ban only results in greater health risks to patients. These risks include the physiological stressors and risks associated with remaining pregnant against their will, the risks associated with obtaining abortion later in pregnancy than desired, and the increased likelihood they will ultimately need to undergo more complex procedures to terminate their pregnancies—not to mention the costs and logistical burdens associated with being forced to travel greater distances than necessary in order to obtain care, including identifying and arranging transportation, reliable child care, and paid time off work.

See supra at 11–13; In re Hodes & Nauser MDS PA v. Kobach, D.Kan. No. 23CV03140, 2023 WL 7130406, at *21 (Jan. 1, 2023) ("Delays . . . increase the costs, logistics, and risks to the pregnant woman seeking to avail herself of her fundamental rights, and likely decrease or eliminate access to [abortion-related] services[.]"), attached as Exhibit 13; Weems, 529 P.3d at 804–05 (finding that "scarcity of providers can cause women to experience delays accessing care," requiring them to seek an abortion later in their pregnancies, which can result in "comparatively higher risk, greater financial expenses, and even ineligibility for medical abortion"). Moreover, in certain cases, the APC Ban may delay patients seeking to access medication abortion past Ohio's 70-day LMP legal limit, 11 thus barring them entirely from receiving their preferred, or medically indicated, method of abortion care in the State. See supra at 12–13; Weems, 529 P.3d at 812 (recognizing that limiting the pool of providers can lead to patients becoming ineligible for medication abortions).

In sum, forcing patients to remain pregnant unless and until they can secure an accessible appointment with a physician who can provide medication abortion—when qualified APCs could provide the same care—serves only to burden, penalize, and interfere with patients' right to make and carry out their own reproductive decisions, specifically, choosing a medication abortion. In some cases, this may prohibit Ohio patients from obtaining a medication abortion entirely. The APC Ban also discriminates against pregnant patients seeking abortions because patients in Ohio can receive the same underlying medications from an APC for other reasons, including miscarriage management. See supra at 11; Alaska PI Order at 9–10 (enjoining Alaska's APC ban because it

¹¹ By imposing an arbitrary, outdated limit of 70 days LMP on medication abortion in the State, the Evidence-Based Use Ban exacerbates the harms of the APC Ban. Without the Evidence-Based Use Ban, patients who, notwithstanding delays attributable to the APC Ban, could otherwise attend an appointment beyond 70 days LMP would be able to obtain medication abortion care. However, the harms imposed by the APC Ban would still exist even absent the Evidence-Based Use Ban.

"results in different treatment for . . . pregnant patients" seeking abortions versus those experiencing miscarriage and "dictates a patient's access to care based on their decision to obtain an abortion").

b) The APC Ban Burdens, Penalizes, Interferes with, Discriminates Against, and in Some Cases, May Prohibit Providers from Assisting Their Patients in Obtaining Medication Abortions

The APC Ban imposes punitive consequences on providers who run afoul of its provisions, including criminal and civil penalties and professional discipline. See R.C. 4723.28(B)(30), 4723.99(A), 4730.25(B)(24), 4730.252, 4730.99(A). It forces Plaintiffs and their providers to turn away patients they otherwise would be able to assist and to deny those patients time-sensitive care they desperately want. See supra at 13–14. In so doing, it burdens, interferes with, and prohibits the Plaintiff clinics and APCs like Plaintiff Quinn from assisting their patients in obtaining medication abortion and penalizes them for doing so. The APC Ban also discriminates against APCs who seek to provide abortion care by singling them out for differential and unfavorable treatment, prohibiting them from providing care that they are trained and qualified to provide and that is otherwise within their scope of practice, solely because it is abortion care. This discrimination is made especially stark by the fact that Ohio permits APCs to prescribe the same medications utilized for medication abortion for other, non-abortion purposes, including miscarriage management. See supra at 11.

c) The APC Ban Does Not Advance Patient Health

As detailed above, the APC Ban serves only to burden, penalize, interfere with, discriminate against, and in some cases prohibit patients seeking to exercise their right to make and carry out their own reproductive decisions, including the decision to obtain medication abortion—and the providers assisting them in doing so. Accordingly, Defendants bear the heavy

burden of showing that the APC Ban is the least restrictive means of advancing patient health in accordance with widely accepted and evidence-based standards of care. Ohio Constitution, Article I, Section 22(B). They cannot meet that burden here because the APC Ban has no medical justification whatsoever, does nothing to advance patient health, and instead only risks harming patient health and well-being.

As already explained, APCs, like Plaintiff Quinn, are highly skilled and qualified clinicians, who complete advanced education and training and generally have a broad scope of practice. See supra at 9–10. APCs already provide services that are more technically complex and carry more risk to patient health than medication abortion. See supra at 10–11. The medical evidence and medical consensus are clear: APCs can—and do, in many other states—provide medication abortion just as safely and effectively as physicians. See id.

Even if the APC Ban had some marginal health benefit (it does not), Defendants cannot show that categorically banning several types of highly-trained, well-credentialed, competent clinicians from providing medication abortion care within their scope of practice constitutes the "least restrictive means" of advancing patient health as constitutionally required. *Cf. Portage Cty. Educators Assn. v. State Emp. Relations Bd.*, 169 Ohio St.3d 167, 2022-Ohio-3167, 202 N.E.3d 690, ¶ 32 (concluding that a statute prohibiting a labor-dispute picketing could not survive strict scrutiny, because the state could not demonstrate that a "categorical prohibition" served the state's interests "in the least restrictive way available"). Thus, Defendants cannot possibly satisfy their stringent burden under the Amendment, and Plaintiffs are substantially likely to succeed on their claim that the APC Ban is unconstitutional.

2. The Evidence-Based Use Ban Violates Ohioans' Constitutional Right to Abortion

a) The Evidence-Based Use Ban Burdens, Penalizes, Interferes with, Discriminates Against, and in Some Cases May Prohibit Patients from Making and Carrying Out Their Own Reproductive Decisions

The Evidence-Based Use Ban also plainly violates the Amendment. Research demonstrates that mifepristone can be used safely and effectively for medication abortions beyond 70 days LMP. Grossman Aff. ¶ 69–70; Liner Aff. ¶ 16. Yet, under the Evidence-Based Use Ban, Ohio providers may only prescribe mifepristone as specified on the FDA label, thus barring patients beyond 70 days LMP from obtaining a medication abortion, even where preferred or medically indicated. See R.C. 2919.123. To Plaintiffs' knowledge, Ohio is the sole outlier in this regard: no state that allows abortion past 70 days LMP restricts the use of mifepristone for abortion care based on the FDA's label.

Restricting the availability of medication abortion for patients beyond 70 days LMP with no medical justification interferes with Ohioans' reproductive decisions and burdens and penalizes them for choosing medication abortions. As discussed, many patients strongly prefer—or even medically require—medication over procedural abortions due to other medical conditions or health history. See supra at 8. But after 70 days LMP, those patients cannot access medication abortion in Ohio, which forces them to make the difficult choice between traveling outside the State to obtain care; 12 managing their own medication abortion outside of the medical system; undergoing a procedural abortion, which may be contraindicated, traumatizing, or significantly less manageable for certain patients; or in some cases, potentially even carrying an unwanted

25

¹² Even patients who decide to travel outside the State may not end up being able to obtain a medication abortion, because the same barriers that may bar them from accessing medication abortion by 70 days LMP—including financial barriers, inflexible work or school schedules, and caretaking obligations—are only exacerbated by the need to travel out-of-state. *See supra* at 17–18.

pregnancy to term. See supra at 17–18. No matter what they choose, such patients must contend with the stressors and risks associated with remaining pregnant against their will for longer and any increased risks associated with obtaining an abortion when they are further along in their pregnancies. See supra at 13, 18.

Finally, the Evidence-Based Use Ban discriminates against patients who choose medication abortion. Ohio law singles out off-label use of mifepristone only when it is prescribed "for inducing abortions," R.C. 2919.123(A), and does not impose similar restrictions on its use for other medical purposes, including miscarriage management. *See supra* at 16. As such, Ohioans can access off-label uses of virtually any drug, including mifepristone when it is used for purposes other than abortion, without restrictions, benefiting from the latest clinical research and medical expertise. Only patients seeking abortions are subjected to stigmatizing, discriminatory treatment and an outdated, one-size-fits-all medication abortion regimen due to the Evidence-Based Use Ban. *See, e.g., Cline v. Okla. Coalition for Reproductive Justice*, 313 P.3d 253, 262 (Okla.2013), *superseded by statute* (citing with approval district court finding that prohibition on off-label use of abortion-related medications was "so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do").

b) The Evidence-Based Use Ban Burdens, Penalizes, Interferes with, Discriminates Against, and in Some Cases May Prohibit Providers from Assisting Their Patients in Obtaining Abortion Care

The Evidence-Based Use Ban similarly burdens, penalizes, interferes with, and in some cases prohibits providers from assisting their patients in obtaining medication abortion care. As set forth above, the Evidence-Based Use Ban threatens providers with imprisonment, fines, and professional discipline if they prescribe mifepristone for an abortion to patients beyond 70 days

LMP, even when doing so represents an exercise of their best medical judgment in accordance with evidence-based standards of medical care. It forces providers to offer only procedural abortion to patients beyond 70 days LMP, even where that patient may have medical conditions, a history of trauma, or other challenges that would make procedural abortion contraindicated or riskier than a medication abortion. Otherwise, these providers must turn their patients away entirely, knowing the burdens and barriers that await them if they attempt to access medication abortion out-of-state or outside the medical system. *See supra* at 18.

The Evidence-Based Use Ban also discriminates against providers assisting their patients in making and carrying out reproductive health decisions. Ohio providers do not face similar constraints on off-label prescriptions for virtually any other drug. In fact, they remain free to prescribe mifepristone consistent with off-label practices for other purposes, including miscarriage management. See supra at 16. The Evidence-Based Use Ban criminalizes the exercise of providers' reasonable medical judgment, instead forcing them to disregard their patients' individualized histories and medical profiles and to take an outdated, one-size-fits-all approach, potentially subjecting their patients to unwanted or medically contraindicated procedural abortions.

In essence, the Evidence-Based Use Ban converts the FDA's labeling for mifepristone into a stringent legal requirement, notwithstanding the fact that, as courts have recognized, the label "w[as] not intended to limit or interfere with the practice of medicine, nor to preclude physicians from using their best judgment in the interest of the patient." Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir.1989).

c) The Evidence-Based Use Ban Does Not Advance Patient Health

The Evidence-Based Use Ban does nothing to advance patient health in accordance with widely-accepted, evidence-based standards—let alone as the least restrictive means of doing so, as required by the Ohio Constitution. As demonstrated through historical practice and clinical research, evidence-based, off-label use of mifepristone for abortion—including for patients beyond 70 days LMP—is safe, common, and well-accepted in medical practice across the nation. See supra at 16. In fact, providers outside Ohio routinely prescribe mifepristone for abortion care in off-label formulations in accordance with evidence-based standards of care. See id. The fact that Ohio is an outlier in imposing such restrictions on mifepristone for use in abortion, and that Ohio law permits off-label use of mifepristone in other contexts, including for managing miscarriages, only underscores the absence of any medical justification for this restriction. See supra at 16–17.

Far from advancing patient health, the Evidence-Based Use Ban actively harms patient health. By unnecessarily precluding patients from obtaining a desired medication abortion in Ohio, the Evidence-Based Use Ban forces them either to obtain a potentially medically contraindicated procedural abortion at greater risk to their physical and mental health; delay their care (and, in so doing, risk harm to their health and well-being) while they attempt to travel out-of-state for a medication abortion; attempt to obtain medications and self-induce an abortion outside of the medical system; or carry their pregnancy to term, along with all the attendant risks and stressors associated with pregnancy and childbirth. *See supra* at 17–18. Accordingly, the Evidence-Based Use Ban cannot pass muster under the stringent standard imposed by the Amendment.

B. Plaintiffs and Their Patients Are Suffering and Will Continue to Suffer Irreparable Harm Because of the Bans

Every day that the Bans remain in effect, Plaintiffs and their patients suffer irreparable harm. Under the broad protections of the Amendment, the Bans are a patent violation of Ohioans' constitutional right to reproductive decision-making, including decision-making related to abortion, and their providers' ability to assist them in effectuating those decisions. As this Court has previously recognized, violations of constitutional rights are, in and of themselves, an irreparable harm. See PI Order at 11–12 ("'[I]mpair[ment]' of a constitutional right 'mandates a finding of irreparable injury." (citation omitted)); see also Magda v. Ohio Elections Comm., 2016-Ohio-5043, 58 N.E.3d 1188, ¶ 38 (10th Dist.) ("A finding that a constitutional right has been threatened or impaired mandates a finding of irreparable injury[.]" (citing Bonnell v. Lorenzo, 241 F.3d 800, 809 (6th Cir.2001))); Mich. State A. Phillip Randolph Inst. v. Johnson, 833 F.3d 656, 669 (6th Cir.2016) ("When constitutional rights are threatened or impaired, irreparable injury is presumed." (citation omitted)). Accordingly, Plaintiffs' patients currently suffer, and will continue to suffer, irreparable harm, stemming from the violation of their constitutional rights, each day the Bans remain in effect.

Moreover, as set forth above, the Bans' restrictions on medication abortion in Ohio engender numerous other harms to the physical and mental health and dignity of Plaintiffs' patients that are not compensable or remediable at law. The direct and ongoing impact of the Bans is to make medication abortion significantly less accessible and available in Ohio. In combination and separately, the Bans compel patients to remain pregnant against their will; to travel further and contend with more complex financial and logistical challenges to obtain medication abortion; and to face a host of additional medical risks, physiological stressors, and emotional distress from remaining pregnant longer against their will. *See supra* at 12–13, 17–18. In some cases, the Bans

force patients to undergo procedural abortions to get their desired outcome, even where procedural abortions may be more invasive, traumatizing, or even medically contraindicated for some patients. See supra at 8. Courts have repeatedly recognized that harms of this nature are irreparable. See, e.g., Taverns for Tots, Inc. v. City of Toledo, 307 F.Supp.2d 933, 945 (N.D.Ohio 2004) (harm to health constitutes irreparable harm); Doe v. Franklin Cty. Children's Servs., S.D.Ohio No. 2:20-CV-4119, 2020 WL 4698801, at *3 (Aug. 13, 2020) (weighing "serious harm to [individuals'] health or wellbeing absent injunctive relief" in finding irreparable harm), attached as Exhibit 14; Planned Parenthood of Kan. v. Andersen, 882 F.3d 1205, 1236 (10th Cir.2018) ("A disruption or denial of . . . patients' health care cannot be undone after a trial on the merits." (internal quotations omitted)); cf. Bd. of Edn. of Highland Local School Dist. v. United States Dept. of Edn., 208 F.Supp.3d 850, 878 (S.D.Ohio 2016) (finding stigma to be a type of irreparable harm). Moreover, Plaintiffs themselves have suffered—and will continue to suffer—the emotional and moral distress that arises from being forced to act contrary to the standard of care, evidence-based medical practice, and their ethical duties, and from the ensuing deterioration of the patient-provider relationship. See supra at 11–12, 18.

C. The Other Factors Relevant to Preliminary Relief Weigh in Plaintiffs' Favor

As to the other relevant factors here, there will be no harm to third parties if the Bans are enjoined. Research shows—and practices in other states confirm—that abortion is common, safe, and effective beyond 70 days LMP, and trained APCs can safely and effectively provide it. Defendants will not suffer any harm from an injunction, as the State is not harmed by being unable to enforce unconstitutional laws. The Bans do not further the only State interest that can justify a restriction under the Amendment: advancing patient health through evidence-based means.

Instead, these laws only impair patient health and well-being and violate Ohioans' constitutional rights. *See supra* at 19–29.

Additionally, the public interest will be served by stopping the Bans' violation of Ohioans' fundamental rights. A "great[] public interest exists in ensuring governments and governmental officials operate within the confines of constitutional restrictions and prohibitions," and as such, "it is always in the public interest to prevent violation of a party's constitutional rights." Lamar Advantage GP Co., LLC v. City of Cincinnati, Hamilton C.P. No. A-18-04105, 114 N.E.3d 805, 829 (quoting Miller v. City of Cincinnati, 709 F.Supp.2d 605, 627 (S.D.Ohio 2008)); Am. Freedom Defense Initiative v. Suburban Mobility Auth. for Regional Transp., 698 F.3d 885, 896 (6th Cir.2012) ("[T]he public interest is promoted by the robust enforcement of constitutional rights"); G & V Lounge, Inc. v. Mich. Liquor Control Comm., 23 F.3d 1071, 1079 (6th Cir.1994). Because a preliminary injunction against these laws will prevent future violations of Ohioans' rights under Article I, Section 22, it clearly serves the public interest.

D. The Injunction Should Issue Without Bond

This Court has discretion to waive the bond requirement set forth in Civil Rule 65(c). See Vanguard Transp. Sys. Inc. v. Edwards Transfer & Storage Co., 109 Ohio App.3d 786, 793, 673 N.E.2d 182 (10th Dist.1996). The Court should exercise that discretion here and waive the bond requirement, because the relief sought will result in no monetary loss to Defendants, there is a strong public interest in the case, and Plaintiffs are likely to succeed on the merits. See Molton Co. v. Eagle-Pitcher Industries, 55 F.3d 1171, 1176 (6th Cir.1995) (affirming decision to require no bond because of "the strength of [the plaintiff's] case and the strong public interest involved").

CONCLUSION

For the foregoing reasons, Plaintiffs ask this Court to issue a preliminary injunction, and enjoin Defendants, as well as their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them, from enforcing the Bans and/or any other Ohio statute or regulation that could be understood to give effect to these provisions¹³ during the pendency of this litigation, as well as from taking any later enforcement action premised on conduct that occurred while such relief was in effect.

Respectfully submitted,

/s/ Michel<u>le Nicole Diamond</u>

Michelle Nicole Diamond (Pro Hac Vice)

Peter Neiman (Pro Hac Vice)

Maura Douglas (Pro Hac Vice)

Meghan Koushik (Pro Hac Vice)

Zach Blair (Pro Hac Vice)

Nicole Castillo (Pro Hac Vice)

WilmerHale LLP

7 World Trade Center

New York, NY 10007

(212) 230-8800

michelle.diamond@wilmerhale.com

peter.neiman@wilmerhale.com

Counsel for Plaintiffs

Alyssa Milstead (Pro Hac Vice)

WilmerHale LLP

2600 El Camino Real, Suite 400

Palo Alto, CA 94306

(650) 858-6000

alyssa.milstead@wilmerhale.com

Counsel for Plaintiffs

B. Jessie Hill (0074770)

Margaret Light-Scotece (0096030)

Freda J. Levenson (0045916)

ACLU of Ohio Foundation

4506 Chester Ave.

Cleveland, OH 44103

(216) 368-0553

(614) 586-1974 (fax)

bjh@cwru.edu

margaret.light-scotece@case.edu

flevenson@acluohio.org

Counsel for Preterm-Cleveland and

Women's Med Group Professional

Corporation

David J. Carey (0088787)

ACLU of Ohio Foundation

1108 City Park Ave., Ste. 203

Columbus, OH 43206

(380) 215-0997

dcarey@acluohio.org

Counsel for Preterm-Cleveland and

Women's Med Group Professional

Corporation

32

¹³ As set forth in Plaintiffs' Motion, this includes, but is not limited to R.C. 2903.09. Plaintiffs' Second Motion for Preliminary Injunction at 3 n.2.

Catherine Humphreville (Pro Hac Vice)
Vanessa Pai-Thompson (Pro Hac Vice)
Planned Parenthood Federation of America
123 William Street, 9th Floor
New York, NY 10038
(212) 541-7800 (Pai-Thompson)
(212) 247-6811 (fax)
catherine.humphreville@ppfa.org
vanessa.pai-thompson@ppfa.org
Counsel for Planned Parenthood
Southwest Ohio Region, Sharon Liner,
M.D., Julia Quinn, and Planned
Parenthood of Greater Ohio

Meagan Burrows*
Johanna Zacarias*
American Civil Liberties Union
125 Broad St., 18th Fl.
New York, NY 10004
(212)-549-2601
mburrows@aclu.org
jzacarias@aclu.org
Counsel for Preterm-Cleveland and
Women's Med Group Professional
Corporation

Fanon A. Rucker #0066880
The Cochran Firm
527 Linton Street
Cincinnati, OH 45219
(513) 381-4878
(513) 672-0814 (fax)
frucker@cochranohio.com
Counsel for Planned Parenthood
Southwest Ohio Region, Sharon Liner,
M.D., Julia Quinn, and Planned
Parenthood of Greater Ohio

*Motion for pro hac vice forthcoming

Dated: May 22, 2024

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2024, the foregoing was electronically filed via the Court's e-filing system. I further certify that a copy of the foregoing was served via electronic mail upon counsel for the following parties:

OHIO DEPARTMENT OF HEALTH

246 N. High Street Columbus, OH 43215

Email: Amanda.Narog@OhioAGO.gov

BRUCE T. VANDERHOFF, M.D., MBA

Director, Ohio Department of Health

246 N. High Street Columbus, OH 43215

Email: Amanda.Narog@OhioAGO.gov

KIM G. ROTHERMEL, M.D.

Secretary, State Medical Board of Ohio

30 E. Broad Street, 3rd Floor

Columbus, OH 43215

Email: Kim.Rothermel@Med.Ohio.gov

HARISH KAKARALA, M.D.

Supervising Member, State Medical Board of Ohio

30 E. Broad Street, 3rd Floor

Columbus, OH 43215

Email: harish.kakarala@med.ohio.gov; kakarah@ccf.org

ERIN KEELS, DNP, APRN-CNP

President, Ohio State Board of Nursing

8995 East Main Street

Reynoldsburg, OH 43068

Email: BoardMembers@Nursing.Ohio.gov

CANDY SUE RINEHART, DNP, APRN-CNP

Supervising Member for Disciplinary Matters, Ohio State Board of Nursing

8995 East Main Street

Reynoldsburg, OH 43068

Email: BoardMembers@Nursing.Ohio.gov

MELISSA POWERS

Hamilton County Prosecutor

230 E. Ninth Street, Suite 4000

Cincinnati, OH 45202

Email: melissa.powers@hcpros.org

G. GARY TYACK

Franklin County Prosecutor

373 S. High Street, 14th Floor

Columbus, OH 43215

Email: gtyack@franklincountyohio.gov

MICHAEL C. O'MALLEY

Cuyahoga County Prosecutor

Justice Center, Courts Tower

1200 Ontario Street, 9th Floor

Cleveland, OH 44113

Email: mcomalley@prosecutor.cuyahogacounty.us

MATHIAS H. HECK, JR.

Montgomery County Prosecutor

301 W. Third St., 5th Floor

P.O. Box 972

Dayton, OH 45402

Email: heckm@mcohio.org

ELLIOT KOLKOVICH

Summit County Prosecutor

175 S. Main Street

Akron, OH 44308

Email: ekolkovich@prosecutor.summitoh.net

KELLER J. BLACKBURN

Athens County Prosecutor

Athens County Courthouse

1 South Court Street, First Floor

Athens, OH 45701

Email: kim@athenscountyprosecutor.org

KYLE L. STONE

Stark County Prosecutor

110 Central Plaza South, Suite 510

Canton, OH 44702

Email: klstone@starkcountyohio.gov

VICTOR V. VIGLUICCI

Portage County Prosecutor

The Portage County Prosecutor's Office 241 South Chestnut Street

Ravenna, OH 44266

Email: vvigluicci@portageco.com

JODIE M. SCHUMACHER

Richland County Prosecutor

38 South Park Street, 2nd Floor

Mansfield, OH 44902

Email: Jschumacher@richlandcountyoh.us

JULIA R. BATES

Lucas County Prosecutor

Common Pleas Court 700 Adams Street

Toledo, OH 43604

Email: jbates@co.lucas.oh.us

GINA DEGENOVA

Mahoning County Prosecutor

21 W Boardman Street, 6th Floor

Youngstown, OH 44503

Email: gina.degenova@mahoningcountyoh.gov

MICHAEL T. GMOSER

Butler County Prosecutor

315 High Street, 11th Floor

P.O. Box 515

Hamilton, OH 45012

Email: gmosermt@butlercountyohio.org

DANIEL P. DRISCOLL

Clark County Prosecutor

50 E. Columbia Street, Suite 449

Springfield, OH 45502

Email: ddriscoll@clarkcountyohio.gov

Respectfully submitted,

/s/ Michelle Nicole Diamond

Michelle Nicole Diamond (Pro Hac Vice)

Exhibit 1

doc**v**erify



Grossman Affidavit.pdf

DocVerify ID:

FFD8E6E0-859C-4BE4-9A45-056483EB9FE4

Created:

April 10, 2024 08:48:30 -5:00

Pages:

30

Remote Notary:

Yes / State: OH

This document is a DocVerify VeriVaulted protected version of the document named above. It was created by a notary or on the behalf of a notary, and it is also a DocVerify E-Sign document, which means this document was created for the purposes of Electronic Signatures and/or Electronic Notary. Tampered or altered documents can be easily verified and validated with the DocVerify veriCheck system. This remote online notarization involved the use of communication technology.

Go to www.docverify.com at any time to verify or validate the authenticity and integrity of this or any other DocVerify VeriVaulted document.

E-Signature Summary

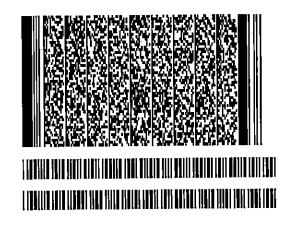
E-Signature 1: Daniel Grossman (DG)

April 10, 2024 09:26:09 -5:00 [D247D5E07B09] [79.153.31.46] danielgrossman12468@gmail.com (Principal) (ID Verified)

E-Signature Notary: Theresa M Sabo (TMS)

April 10, 2024 09:26:09 -5:00 [D2C32BA0CEB7] [74.142.214.254] tess.sabo@gmail.com

I, Theresa M Sabo, did witness the participants named above electronically sign this document.



DocVerify documents cannot be altered or tampered with in any way once they are protected by the DocVerify VeriVault System. Best viewed with Adobe Reader or Adobe Acrobat.

All visible electronic signatures contained in this document are symbolic representations of the persons signature, and not intended to be an accurate depiction of the persons actual signature as defined by various Acts and/or Laws.



FFD8E6E0-859C-4BE4-9A45-056483EB9FE4 --- 2024/04/10 08:48:30 -5:00 --- Remote Notary

IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

v.

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

EXPERT AFFIDAVIT OF DANIEL GROSSMAN, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Pursuant to Ohio Rule of Civil Procedure 26, Daniel Grossman, M.D., makes the following disclosures:

PRIOR AFFIDAVITS SUBMITTED IN THIS CASE I.

- I have submitted two expert affidavits in this case: (1) an expert affidavit dated 1. March 30, 2021, in support of Plaintiffs' Motion for Temporary Restraining Order Followed by a Preliminary Injunction; Request for Hearing, Ex. 8 ("PI Aff."); and (2) a reply expert affidavit dated April 15, 2021 in support of Plaintiff's Reply in Support of Preliminary Injunction, Ex. 1. I also prepared an expert report, dated April 28, 2022, which I understand has been disclosed to the defendants in this case.
- I have reviewed all three documents in preparing this expert affidavit. Except as 2. noted below, my understanding is that the facts regarding the Plaintiffs' practices and challenged restrictions upon which I based the opinions I offered in my prior expert affidavits and expert report have not changed. I continue to rely upon the unchanged facts as supplemented by the additional facts discussed below. My opinions outlined in those affidavits have not changed.

II. MY QUALIFICATIONS

My March 30, 2021, expert affidavit outlined my qualifications. In 2023, I was 3. named the Vice Chair for Advocacy of the UCSF Department of Obstetrics, Gynecology & Reproductive Sciences. I was also awarded the UCSF Chancellor Award for Public Service in 2022. I currently have 240 peer-reviewed publications. An updated curriculum vitae (CV) is attached to this affidavit as Exhibit A.

ADDITIONAL FACTUAL BASIS FOR OPINIONS III.

- Planned Parenthood Plaintiffs' Telemedicine Practices for Abortion Α.
 - Planned Parenthood of Greater Ohio 1.
- In my March 30, 2021, affidavit, I described my understanding of Planned 4. Parenthood of Greater Ohio's ("PPGOH") procedure for allowing some qualified patients to have their Day 2 medication abortion appointment via site-to-site telemedicine. PI Aff. ¶ 27. Plaintiff PPGOH's counsel informs me that PPGOH discontinued this site-to-side telemedicine practice due to staffing shortages. Plaintiffs' counsel further informs me that PPGOH has piloted a new telemedicine procedure for some qualified patients to complete their second medication abortion appointment via telemedicine.
- I understand that, under the new protocol, rather than having to travel to a health 5. center to complete their second appointment via a site-to-site telemedicine model, patients are now able to complete their second appointment at their homes or another private place of their choosing. Plaintiff's counsel informs me that this option is only available to Ohio resident patients who can access a secure telemedicine platform via the internet. Under the new protocol, patients receive a combination-coded secure containing doses of mifepristone and

misoprostol at their first, in-person appointment (a "lockbox"), which they take home with them from the appointment.

- 6. I further understand that, as with the prior protocol, during the telemedicine visit, which occurs at least 24 hours after the patient's first, in-person visit, the physician confirms the patient's decision to seek an abortion, confirms that they have not had a change in their symptoms or other medical concerns, and answers any questions the patient may have. The physician then gives the patient the combination code to the lockbox, from which the patient removes the mifepristone and shows it to the physician. The physician then observes the patient ingesting the mifepristone. The patient then takes the misoprostol 24 to 48 hours later.
- I understand that, under the pilot protocol, nothing has changed about the 7. medication abortion eligibility screening, patient education, and informed consent processes that occur during the patient's first appointment. My understanding is that the only difference at the first appointment from the process I previously described is that patients who complete their second medication abortion appointment via telemedicine now need to pay their portion of the cost for both appointments at their first appointment.

Planned Parenthood Southwest Ohio Region 2.

In my March 30, 2021 affidavit, I also described my understanding of Planned 8. Parenthood Southwest Ohio Region's ("PPSWO") procedure for allowing some qualified patients to have their Day 2 medication abortion appointment via site-to-site telemedicine, which was the same as PPGOH's procedure. PI Aff. ¶ 27. Plaintiff PPSWO's counsel informs me that PPSWO also discontinued this procedure for administrative reasons. I understand that PPSWO has also initiated the same lockbox procedure pilot program for some qualified patients to complete their second medication abortion appointment via telemedicine.

Additional Laws Plaintiff's Challenge in the Amended Complaint C.

My understanding is that the Plaintiffs in this case have amended their complaint 9. to challenge two additional restrictions Ohio law places on abortion, alongside their continued challenge the Telemedicine Ban.

Ohio's Advanced Practice Clinician Ban 1.

- I understand that Plaintiffs challenge a number of Ohio Revised Code provisions, 1 10. which effectively forbid physician assistants, nurse practitioners, and certified nurse-midwives (collectively, "APCs") from providing abortions, including medication abortions, even when they are otherwise trained, qualified, and competent to do so. Through my clinical and academic work, I am intimately familiar with the medical standard of care for abortion. In particular, I am familiar with developments in the various methods of abortion provision, including medication abortion, and with the practice capabilities of APCs in the context of obstetrics and gynecology generally, as well as abortion care more specifically.
- I understand that the scope of practice of APCs in Ohio is consistent with their 11. general scope of practice nationally. I further understand that Ohio's state practice and licensure laws allow for nurse practitioners ("NPs"), certified nurse midwives ("CNMs") and physician assistants ("PAs"), the types of APCs relevant here, to have practice and prescribing rights, including prescribing for controlled substances.2 APCs are highly qualified medical professionals whose qualifications are based on their advanced education, training, and experience.

Ohio's Evidence-Based Use Ban 2.

I understand that Plaintiffs also challenge Ohio Revised Code 2919.123. I 12. understand that this law, as interpreted by the Ohio Supreme Court, restricts mifepristone's use to

¹ Together referred to herein as the "APC Ban."

² R.C. 4723.43 (NPs and CNMs), 4730.20(A) (PAs).

the specific protocol detailed in the current FDA-approved label, including its gestational limit, which is 70 days (10 weeks) from a patient's last menstrual period ("LMP"). The Evidence-Based Use Ban prohibits providers from prescribing mifepristone in an evidence-based, "off-label" manner, which is a common part of modern medical practice.

III. SUMMARY OF OPINIONS

- 13. In good medical practice, health care decisions are based on the best medical evidence, the patient's particular health circumstances, and the clinician's individual training and experience. It should be no different for abortion, which is an essential medical service,³ is safe and effective,⁴ is in fact safer than carrying a pregnancy to term, and is "a mental health imperative with major social and mental health implications,"⁵
- 14. Laws that categorically bar APCs from providing abortions, such as Ohio's APC Ban, prevent APCs from providing to their patients the highest level of care within their scope of practice and restrict abortion availability by unnecessarily limiting the pool of available, competent providers.

⁴ Natl. Academies of Sciences, Eng. & Medicine, *The Safety & Quality of Abortion Care in the United States, at 77 (2018)*, https://www.nap.edu/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states (accessed Apr. 9, 2024) [hereinafter "Natl. Academies"].

⁵ Am. Psych. Assn., APA Official Actions: Abortions and Women's Reproductive Health Care Rights, 167 Am. Journal of Psychiatry 726, 726 (2010); see also Am. Psychological Assn., Abortion Resolutions, http://www.apa.org/about/policy/abortion.aspx (accessed Apr. 9, 2024) (affirming that "freedom of choice and a woman's control over her critical life decisions promotes psychological health.").

5056483EB9FE4

³ Am. College of Obstetricians & Gynecologists ("ACOG"), Joint Statement on Abortion Access During the COVID-19 Outbreak (Mar. 18, 2020), https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak (accessed Apr. 9, 2024); see also ACOG, Committee Opinion Number 815: Increasing Access to Abortion, 136 Obstetrics & Gynecology e107, e108 (Dec. 2020) ("Safe, legal abortion is a necessary component of women's health care."); see also Am. Academy of Pediatrics, Commt. on Adolescence, The Adolescent's Right to Confidential Care When Considering Abortion, 139 Pediatrics 1, 1 (2017) (stating that access to abortion is important for adolescent health and well-being "because of the significant medical, personal, and social consequences of adolescent childbearing").

- It is my opinion that Ohio's APC Ban does not enhance patient safety but instead 15. reduces patient access to important, time-sensitive medical care, and therefore undermines both public health and individual patient health and well-being.
- It is my further opinion that the APC Ban has no medical benefit and is contrary 16. to the best medical evidence about the scope of practice of APCs. As described in more detail below, there is no medical reason to single out medication abortion from all other health care for specialized scope-of-practice regulation. Doing so does not benefit patients. Instead, it limits patients' access to care, and exposes them to substantial financial, logistical, emotional, and physical burdens.
- Moreover, it is my opinion that the Evidence-Based Use Ban restricts physicians 17. in Ohio from providing evidence-based care. In particular, there are ample studies supporting the use of medication abortion past 10 weeks' gestation, the use of a different route of administration for misoprostol when used with mifepristone as part of the two-drug regimen for medication abortion, and the use of different intervals between taking the mifepristone and misoprostol than those detailed in the FDA-approved label. According to the Advancing New Studies in Reproductive Health ("ANSIRH") Abortion Facilities Database, in 2022, 789 facilities nationwide offered medication abortion, of which 292 (37%) offered the service past 10 weeks' gestation.6 Currently, patients in Ohio who present seeking medication abortion past 10 weeks' gestation are denied this service, leaving them the option of having a procedural abortion or traveling to another state. Those who are interested in shortening the interval between mifepristone and misoprostol using non-buccal routes of administering the second medication are similarly denied access to this evidence-based treatment. The effect of these restrictions is to

6056483EB9FE4

⁶ ANSIRH, Trends in Abortion Facility Gestational Limits Pre- and Post-Dobbs (June 2023), https://www.ansirh.org/sites/default/files/2023-06/ Gestational%20Limits%20Brief%206-14-23%20Final.pdf (accessed Apr. 9, 2024).

FFD8E6E0-859C-4BE4-9A45-056483EB9FE4 — 2024/04/10 08:48:30 -5:00 — Remote Notary

limit patient options and reduce their satisfaction with care; they may also delay care if patients decide to seek care out of state.

IV. OPINIONS

- 18. I submit my opinions in this affidavit based on my education, my clinical training, my many years of experience as a practicing physician, my attendance at professional conferences, my own research, and my regular review of other research in my field. The literature considered in forming my opinions includes, but is not limited to, the sources cited in the footnotes of this report and in my curriculum vitae. All opinions stated herein are to a reasonable degree of professional certainty.
 - A. APCs Provide Medication Abortion as Safely and Effectively as Physicians.
- 19. In my opinion, the APC Ban offers no health or safety benefits to abortion patients. Rather, the APC Ban harms people seeking abortion care by unnecessarily limiting its availability and delaying access to care.
 - 1. APCs Are Highly Trained Medical Professionals with a Long History of Safely Providing Reproductive Health Care.
- 20. APCs are highly trained medical professionals who practice autonomously in health care settings throughout the country. I understand that, as in other states, to obtain an Advanced Practice Clinician license in Ohio, whether as a NP, a CNM, or as a PA, a clinician must meet rigorous educational, certification, and continuing education requirements.⁷
- 21. Experience and training, rather than any particular specialty or title, determines an individual clinician's competence to provide medical care, including abortion.

⁷ R.C. 4734.41(A) (NPs and CNMs), 4730.11 (PAs).

- APCs have a long history of providing reproductive health care, and they already 22. provide the majority of women's health care across the country.8 As described further below, APCs routinely provide care of similar or greater complexity and carrying similar or greater risk than medication abortion.
- Numerous studies have also shown that APCs provide both medication and 23. aspiration abortion as safely as, or more safely than, physicians.9 This research demonstrates that medication abortion is just as effective when provided by APCs as when it is provided by physicians, and there is no evidence that patients who receive medication abortion from an APC have a higher risk of experiencing complications associated with abortion than those who receive the same care from a physician.¹⁰

⁸ See, e.g., Susan Yanow, It Is Time to Integrate Abortion into Primary Care, 103 Am. Journal of Pub. Health 14, 15 (2013).

⁹ See, e.g., Lauren Porsch et al., Advanced Practice Clinicians and Medication Abortion Safety: A 10-year Retrospective Review, 101 Contraception 357 (2020); 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 Randomized Controlled Equivalence Trial, 122 Royal College of Obstetricians & Gynaecologists 510, 515 (2014); Brooke Ronald Johnson Jr. et al., Provision of Medical Abortion by Midlevel Healthcare Providers in Kyrgyzstan: Testing an Intervention to Expand Safe Abortion Services to Underserved Rural and Periurban Areas, 97 Contraception 160 (2018); Mary Anne Freedman et al., Comparison of Complication Rates in First Trimester Abortions Performed by Physician Assistants and Physicians, 76 Am. Journal of Pub. Health 550, 552-53 (1986); Tracy A. Weitz et al., Letters: Research Informs Abortion Care Policy Change in California, 104 Am. Journal of Pub. Health e3, e3 (2014); 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. Journal of Pub. Health 454, 456, 458, tbl. 2 (2013) (establishing that Advanced Practice Clinicians are "comparably safe providers" and determining that there is a 0.05% risk of major complications following an abortion performed by Advanced Practice Clinicians); Natl. Academies, supra note 4, at 118. 10 Claudia Diaz Olavarrieta et al., Nurse Versus Physician-Provision of Early Medical Abortion in Mexico: A Randomized Controlled Non-Inferiority Trial, 93 Bulletin World Health Org. 249, 256 (2015); Ina K. 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, 1159-60 (2011).

- Based on the medical evidence, numerous professional organizations, including 24. American College of Obstetricians and Gynecologists ("ACOG"),11 the American Public Health Association ("APHA"), 12 the World Health Organization ("WHO"), 13 the National Academies of Sciences, Engineering, and Medicine, 14 the American College of Nurse Midwives, 15 and the American Academy of Physician Assistants¹⁶ endorse APCs' provision of abortion care.
- For example, ACOG has recognized that "APCs have the foundational skills 25. necessary to be trained to provide medication and procedural abortion care" and that "[i]ncreasing the availability of trained clinicians who can provide abortion care will allow more patients to access quality health care in their own communities and enable patients to receive care more quickly."17 Similarly, the APHA states that laws like the APC Ban "do not acknowledge the roles and experience of NPs, CNMs, and PAs, whose scope of primary and

clinicians (APCs), including midwives.").

9056483EB9FE4

¹¹ ACOG, Committee Opinion Number. 613: Increasing Access to Abortion, 124 Obstetrics & Gynecology 1060, 1060 (2014) (recognizing that "trained advanced practice clinicians can safely provide abortion services").

¹² APHA, Provision of Abortion Care by Advanced Nurses and Physicians Assistants, APHA 2011), (Nov. Statements & Advocacy 1, Policy https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/20 14/07/28/16/00/provision-of-abortion-care-by-advanced-practice-nurses-and-physician-assistants (accessed Apr. 9, 2024).

¹³ World Health Org., Health Worker Roles in Providing Safe Abortion Care and Post-Abortion 6-10 (2015),Summary, Contraception: Executive https://apps.who.int/iris/handle/10665/181043 (accessed Apr. 9, 2024).

¹⁴ Natl. Academies, *supra* note 4, at 76.

¹⁵ Am. College of Nurse-Midwives, Position Statement, Midwives as Abortion Providers, at 1 https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/00000000314/ps-midwiv es-as-abortion-providers-final-19-mar-18.pdf (accessed Apr. 9, 2024) ("Manual vacuum aspiration abortion and medication abortion may be safely provided by trained advance practice

¹⁶ Am. Academy of Physician Assistants, PAs in Obstetrics and Gynecology, at 2 (Jan. 2021), https://www.aapa.org/download/19515 (accessed Apr. 9, 2024) ("[PAs] are safe, qualified providers of first trimester abortion care, including surgical aspiration and medication-induced terminations.").

¹⁷ ACOG, Issue Brief: Advanced Practice Clinicians and Abortion Care Provision (Oct. 2023), https://www.acog.org/-/media/project/acog/acogorg/files/advocacy/issue-briefs/advanced-practic e-clinicians-and-abortion-care-provision.pdf (accessed Apr. 9, 2024).

FFD8E6E0-869C-48E4-9A45-056483EB9FE4 -- 2024/04/10 08:48:30 -5:00 -- Remote Natary

specialty practice includes management of conditions and procedures significantly more complex than medication or aspiration abortion."¹⁸

26. The National Academies has recognized the devastating impact that laws like the APC Ban can have on patients, reporting that such laws:

can reduce the availability of providers, resulting in inequitable access to abortion care based on a woman's geography. In addition, these policies can limit patients' preferences, as patient choice is contingent on the availability of trained and experienced providers. Limiting choices impacts patient-centered care, and also negatively affects the efficiency of abortion services by potentially increasing the costs of abortion care as the result of requiring the involvement of a physician to perform a procedure that can be provided safely and effectively by an APC.¹⁹

- 27. When the FDA first approved mifepristone in 2000, it authorized its provision by or under the supervision of physicians. This clearly contemplated and encompassed provision by APCs under physician supervision. The FDA never required the supervising physician's physical presence.
- 28. When the FDA updated the labeling for mifepristone in 2016, it removed the physician supervision requirement, allowing APCs to provide medication abortion fully independently.²⁰ This conclusion was based on studies that the FDA recognized "found no differences in efficacy, serious adverse events, ongoing pregnancy or incomplete abortion between the groups."²¹

¹⁸ APHA, supra note 12.

¹⁹ Natl. Academies, supra note 4, at 14, 118.

FDA, MIFEPREX: Highlights of Prescribing Information (2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf; FDA, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation,

https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (accessed Apr. 9, 2024).

²¹ Ctr. for Drug Evaluation & Research, Application Number: 020687Orig1s020, Medical Review(s), at 79 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (accessed Apr. 9, 2024).

29. Twenty-one states and the District of Columbia permit APCs to provide medication abortion.²² These states reflect the medical consensus that there is no medical reason to prevent APCs from providing medication abortion. Because APCs with appropriate education, training, and clinical experience can provide medication abortion just as safely and effectively as physicians, there is no medical justification for a law that prevents them from doing so.

2. APCs Provide a Range of Other Complex Procedures.

- 30. It is my understanding that in Ohio, similar to my experience in California, APCs commonly perform office-based reproductive health procedures that are at least comparable in clinical complexity and risk to providing and managing a medication abortion. Although medication abortion is not a procedure, complications such as bleeding and infection may rarely occur after the treatment. These complications may also occur after other procedures, which I understand from PPGOH and PPSWO's counsel APCs in Ohio (as elsewhere) currently provide, including:
 - a. endometrial biopsy (inserting a sterile tube through a patient's cervix into the
 uterus to suction and remove tissue from the uterine lining), a procedure that is
 more complex than medication abortion in its technical requirements and risk of
 complications;
 - b. colposcopies (using instruments to magnify the cervix, identifying signs of cervical cancer or precancerous lesions, performing biopsies, and managing

AP Toolkit, State Abortion Laws and Their Relationship to Scope of Practice, https://aptoolkit.org/advancing-scope-of-practice-to-include-abortion-care/state-abortion-laws-an d-their-relationship-to-scope-of-practice/ (accessed Apr. 9, 2024) (the jurisdictions that allow APCs to provide medication abortions are Alaska, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Illinois, Maine, Maryland, Massachusetts, Minnesota, Montana, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Virginia, and Washington).

bleeding with the use of hemostatic agents), a procedure that is more complex than medication abortion in its technical requirements and risk of complications;

- c. intrauterine contraceptive device ("IUD") insertion and removal (sometimes using ultrasound guidance), a procedure that is more complex than medication abortion in its technical requirements and risk of complications, including uterine perforation. In particular, many removals of IUDs without a visible string (potentially requiring use of paracervical block, mechanical cervical dilation, ultrasound guidance, and/or use of instruments in the uterus, such as alligator forceps, IUD thread retriever, or IUD hook)—which are performed by APCs—are more complex than medication abortion. Further, certain difficult removals of contraceptive implants, which are performed by APCs, are more complex than medication abortion, as they require local anesthesia, knowledge of anatomy, and careful dissection and carry a risk of nerve or vascular injury; and
- d. Nexplanon (contraceptive implant) insertion and removal, a procedure that is more complex than medication abortion in its technical requirements and risk of complications.
- 31. CNMs also routinely care for patients giving birth and assume responsibility for managing complications from childbirth like vaginal lacerations and postpartum hemorrhage.

 This is far more complex than providing medication abortion in its technical requirements and risk of complications.
- 32. In addition to the procedures above, I understand that APCs in Ohio can prescribe medications for miscarriage management. Comparable doses of mifepristone and misoprostol,

FFD8E6E0-859C-4BE4-9A45-056483EB9FE4 --- 2024/04/10 08:48:30 -5:00 --- Remote Notary

the same medications used in medication abortion, can be used to treat miscarriage.²³ Medical miscarriage management requires essentially the same clinician skill and knowledge and carries essentially the same risk to patients as medication abortion.

- 33. I understand from their counsel that APCs at PPGOH and PPSWO prescribe misoprostol in connection with some IUD insertions and removals. And, as explained above, IUD insertions involve risk of uterine perforation, which is not present in the context of medication abortion, and require greater skill than prescription of medication abortion.
- 34. APCs have prescriptive authority in every state, including Ohio,²⁴ and in Ohio they are authorized to prescribe controlled substances,²⁵including narcotics and other medications that carry far greater risk than the two medications involved in medication abortion.²⁶
- 35. There is no medical or safety reason to prohibit APCs from providing medication abortion while allowing them to prescribe one of the same medications in another context (as with misoprostol for IUD insertion and removal) and to perform services that are clinically comparable to or of higher complexity and risk than medication abortion.

Justin J. Chu et al., Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised, Double-Blind, Placebo-Controlled Trial, 386 The Lancet 770 (2020); Courtney A. Schreiber et al., Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss, 378 New England Journal of Medicine 2161 (2018).

²⁴ Phillip Zhang & Preeti Patel, StatPearls, *Practitioners and Prescriptive Authority*, https://www.ncbi.nlm.nih.gov/books/NBK574557/#_NBK574557_pubdet_ (accessed Apr. 9, 2024).

²⁵ U.S. Dept. of Justice Drug Enforcement Administration, Diversion Control Div., Mid-Level Practitioners Authorization by State, https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (accessed Apr. 9, 2024).

U.S. Drug Enforcement Administration, *Drug Scheduling*, https://www.dea.gov/drug-information/drug-scheduling (accessed Apr. 9, 2024).

- 36. Almost all of the complications associated with medication abortion can be safely and appropriately managed by APCs in an outpatient clinic setting. For example, cases of incomplete abortion are generally managed in the health center through medication or aspiration. Managing complications of medication abortion is within the scope of practice of APCs trained in obstetric and gynecological care, particularly with a physician consistently available for consultation as I understand is the case for Ohio providers. Furthermore, it is comparable to providing miscarriage management.
- 37. In many areas of medicine, APCs now routinely provide care that was once exclusively or primarily provided by physicians. In addition to medication abortion, colposcopy and endometrial biopsy are two examples. As medical science advances and the nation's health care needs and health care delivery systems evolve, the roles, clinical skills, and competencies of APCs and other medical professionals advance and evolve in response.
- 38. In other states, APCs routinely provide medication abortion without a physician on site, reflecting confidence in properly trained APCs' capacity to provide safe and effective care to patients. The expansion of APC provision of medication abortion in other states also showcases the important role that APCs play in expanding rural access to health care.
- 39. As a liaison member of the Planned Parenthood National Medical Committee and as a physician who provided clinical services with Planned Parenthood Northern California (formerly Planned Parenthood Shasta Pacific) between 2012 and 2015, I can attest that the vast majority of medication abortions at Planned Parenthood Northern California were directly provided by APCs. In my previous work at St. Luke's Women's Center, I trained APCs to provide medication abortion, which they did with a high level of competence. It has been my

experience that APCs' expertise, judgment, and quality of care in providing medication abortions are at least equivalent to that of physicians.

- B. The APC Ban is Not Evidence-Based and Harms Patients.
- 40. It is my opinion that Ohio's APC Ban unnecessarily restricts willing and capable APCs from safely and effectively providing medication abortion care. Laws like Ohio's APC Ban restrict qualified medical professionals from providing care within their scope of practice and do not help patients. Rather, categorical scope-of-practice restrictions like Ohio's APC Ban harm patients seeking medication abortion care in numerous ways given unnecessary limits they impose on the number and geographic distribution of medical professionals available to offer needed health care. These harms include, but are not limited to, harm to patient health and wellbeing associated with being delayed access to medication abortion, being forced to remain pregnant longer, and being pushed past the point in pregnancy when medication abortion is available, which may be a patient's preferred method. As an OB-GYN, I have seen how unnecessary delays in access to abortion care cause my patients medical harm.

1. APC Bans Result in Provider Shortages and Care Delays.

41. Banning APCs from providing medication abortion care in accordance with their experience, training, and scope of practice can significantly constrain when and where this care is available. This is particularly true given heightened demand for care placed on an increasingly limited number of physician abortion providers and as more and more states ban or severely restrict abortion access within their borders. By prohibiting qualified APCs from providing medication abortion, the APC Ban restricts the medical system's capacity to provide time-sensitive health care to people who need it. These differences in capacity may make the

difference for people who already face other obstacles to care, potentially leading to delay or even preventing patients from accessing medication abortion.

Particularly in the context of the nationwide shortage of both primary care 42. providers²⁷ and abortion providers, ²⁸ APC bans like Ohio's limit the number of sites where abortion is available in a given state as well as the capacity of those clinics that do provide abortion. The limited pool of abortion providers in the United States has multiple causes. Options are limited, and historically have been limited, for students and residents who want to be trained in this care.²⁹ The increase in punitive and restrictive laws being enacted and enforced in states hostile to abortion following the United States Supreme Court's decision in Dobbs v. Jackson

Kaiser Family Found., Primary Care Health Professional Shortage Areas (HPSAs), https://www.kff.org/other/state-indicator/primary-care-health-professional-shortage-areas (accessed Apr. 9, 2024) (noting that only 46.16% of need for primary care health professionals is being met nationally); Assn. of Am. Med. Colleges, The Complexities of Physician Supply and 2024), From 2021 2036 (Mar. Demand: **Projections** https://www.aamc.org/media/75236/download?attachment (accessed Apr. 9, 2024) ("Comparison of projected supply and demand for Primary Care physicians [] predicts a shortage of between 20,200 and 40,400 physicians by 2036 ").

Daniel Grossman et al., Induced Abortion Provision Among a National Sample of Obstetrician-Gynecologists, 133 Obstetrics & Gynecology 477, 477 (2019); Amanda Michelle Gomez, ThinkProgress, Medical School Training Is Exacerbating the Shortage of Abortion (Nov. 27, Across the Country https://archive.thinkprogress.org/training-the-next-generation-of-abortion-doctors-45cd46403b6a / (accessed Apr. 9, 2024); Mara Gordon, The Atlantic, The Scarcity of Abortion Training in (June 2015). Schools, The Atlantic America's Medical https://www.theatlantic.com/health/archive/2015/06/learning-abortion-in-medical-school/395075 / (accessed Apr. 9, 2024).

²⁹ Eve Espey et al., Abortion Education in Medical Schools: A National Survey, 192 Am. Journal of Obstetrics & Gynecology 640, 640-42 (2005) (17% of U.S. medical schools reported no formal education about abortion in the four years of medical school, and in the third-year OB/GYN rotation, 23% reported no formal abortion education); Jema K. Turk et al., Sources of Support for and Resistance to Abortion Training in Obstetrics and Gynecology Residency Programs, 221 Am. Journal of Obstetrics & Gynecology 156.e1 (2019) (nearly three-quarters of OB/GYN residency programs report at least some institutional or governmental restrictions to training, and reported an average of three types of restrictions); Alison Block et al., Postgraduate Experiences with an Advanced Reproductive Health and Abortion Training and Leadership Program, 49 Family Medicine 706, 707 (2017) (only 6% of family medicine residencies offered opt-out abortion training in 2016).

Women's Health Organization, 597 U.S. 215, 142 S.Ct. 2228, 213 L.Ed.2d 545 (2022), has only exacerbated this. Moreover, clinicians who do seek out and receive abortion training often face institutional barriers to incorporating that care into their practice.³⁰

APCs to provide medication abortion in particular expands the number of clinicians who can see abortion patients on a given day, thereby expanding the number and timing of available appointments. It also frees up physicians to see other patients and to focus on more technically complex procedures, allowing both APCs and physicians to provide the full range of care permitted by their training and license. In this way, permitting APCs to provide medication abortion increases patient access to abortion, particularly for people in rural and underserved urban areas. Conversely, when qualified providers are prevented from seeing patients, appointment availability is reduced, creating bottlenecks and delaying patients in accessing care. Limited appointment availability may force some patients to travel farther for abortion care (if they can do so and find a health center where they can get an appointment sooner) or wait until they find an appointment time that fits their schedule. Studies show that the number of appointments available to patients plays a significant role in how promptly patients can access abortion as well as in how many people can access care at all.³²

³⁰ Lori Freedman et al., Obstacles to the Integration of Abortion Into Obstetrics and Gynecology Practice, 42 Perspectives on Sexual & Reproductive Health 146, 147–48 (2010); Block et al., supra note 29, at 710 (stating that 29% of graduates from an advanced reproductive care training program for family medicine residents reported administrative obstruction as an obstacle to their provision of abortion care, and 27% reported clinic or hospital policies not allowing abortion service provision).

Donna Barry & Julia Rugg, Ctr. for Am. Progress, *Improving Abortion Access by Expanding Those Who Provide Care* (March 26, 2015), https://cdn.americanprogress.org/wp-content/uploads/2015/03/ExpandingAccessToAbortionBrief .pdf (accessed Apr. 9, 2024).

³² Jason Lindo et al., How Far Is Too Far? New Evidence on Abortion Clinic Closures, Access, and Abortions, 55 Journal of Human Resources 1137 (2020); Andrea M. Kelly, When Capacity Constraints Bind: Evidence from Reproductive Health Clinic Closures (Jan. 15, 2020),

- 44. As discussed in my March 30, 2021, affidavit, many people in Ohio do not live near an abortion provider and must travel for care. PI Aff. ¶¶ 37–38. Plaintiffs' counsel inform me that Plaintiffs PPGOH and PPSWO would work/seek to expand medication abortion to additional clinic locations if the APC Ban is enjoined, decreasing the distance patients have to travel to obtain an abortion.
- A5. Research demonstrates that when patients have to travel farther for abortion care, many are delayed and some are prevented from receiving it altogether.³³ Increases in distances traveled mean not only that patients must drive farther to access safe, legal, and early abortion (or, if they lack access to a car, must take public transportation), but they also must bear the increased financial, logistical, and psychological costs of reaching the nearest abortion provider. This includes making arrangements for additional childcare, missed work, and other obligations; making arrangements for additional travel; and securing additional funds.

https://amkelly15.github.io/andiemkelly.com/ReducedCapacity_Kelly_current.pdf (accessed Apr. 9, 2024).

³³ Sharon A. Dobie et al., Abortion Services in Rural Washington State, 1983-1984 to 1993-1994: Availability and Outcomes, 31 Family Planning Perspectives 241, 243 (1999); see also Jason M. Lindo & Mayra Pineda-Torres, New Evidence on the Effects of Mandatory Waiting Periods for Abortion, 80 Natl. Bur. of Economic Research 1 (2021); Joanna Venator & Jason Fletcher, Undue Burden Beyond Texas: An Analysis of Abortion Clinic Closures, Births, and Abortions in Wisconsin, 40 Journal of Policy Management 774 (2020); Stefanie Fischer, Heather Royer, and Corey White, The Impacts of Reduced Access to Abortion and Family Planning Services on Abortions, Births and Contraceptive Purchases, 167 Journal of Public Economics 43 (2018); Jason Lindo et al., supra note 32; Daniel Grossman et al., Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014, 317 JAMA 437 (2017); Troy Quast, Fidel Gonzalez, and Robert Ziemba, Abortion Facility Closings and Abortion Rates in Texas, 54 Inquiry 1 (2017); Ushma D. Upadhyay et al., Denial of Abortion Because of Provider Gestational Age Limits in the United States, 104 Am. Journal of Pub. Health 1687 (2014); Rachel K. Jones & Jenna Jerman, How Far Did US Women Travel for Abortion Services in 2008?, 22 Journal of Women's Health 706, 710 (2013) ("[R]ural women were more likely to travel greater distances relative to their counterparts" and "women at 16+ weeks gestation were twice as likely to have [traveled farther] compared with women seeking abortions at less than 12 weeks gestation.").

- 46. These logistical barriers result in delays in seeking care.³⁴ Indeed, in one study of 1,209 abortion patients, among women who said they would have preferred to have had their abortions earlier, 56% of first-trimester patients reported they were delayed because it took a long time to make arrangements, including 23% who said they needed time to raise money to have the abortion and 6% who said they could not find a place to have an abortion near where they lived and so had to arrange for transportation.³⁵
- 47. Most abortion patients are parents³⁶ and must arrange for childcare coverage, which can be harder the farther they have to travel for care. Many patients need to keep their decision confidential to avoid coercion or punishment from family or friends,³⁷ which becomes increasingly difficult if they are delayed in the process of seeking abortion care due to longer travel distances.
- 48. People with low incomes often face transportation limitations, such as lacking or sharing a car or having a low-functioning car, that make it particularly hard for them to travel long distances.³⁸

³⁴ Sarah E. Baum et al., Women's Experience Obtaining Abortion Care in Texas After Implementation of Restrictive Abortion Laws: A Qualitative Study, 11 PLOS One 1, 5–12 (2016) (observing burdens women faced due to increased travel distances, including delay, due to Texas abortion restrictions, including among women who strongly preferred medication abortion and women who obtained a surgical abortion though they preferred medication).

³⁵ Lawrence B. Finer et al., Timing of Steps and Reasons for Delays in Obtaining Abortions in the United States, 74 Contraception 334, 335 tbl. 1 (2006).

³⁶ Jenna Jerman et al., Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008, Guttmacher Inst., 1, 7 (2016); Lawrence B. Finer et al., Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives, 37 Perspectives on Sexual & Reproductive Health 110, 110, 116 tbl. 6 (2005).

³⁷ACOG, Committee Opinion Number 554: Reproductive and Sexual Coercion, 121 Obstetrics & Gynecology 1 (2013).

Vehicles (2020),Unreliable Natl. Consumer Law Ctr., Dangerous and http://www.workingcarsforworkingfamilies.org/promoting-improved -public-policy/dangerous-and-unreliable-vehicles (accessed Apr. 8, 2024); Elaine Murakami & Daily Travel by Persons with Low Income, Young, Jennifer https://www.researchgate.net/publication/239490744_Daily_Travel_by_Persons_with_Low_Inco me (accessed Apr. 8, 2024).

49. In a study I published in 2014, my colleagues and I found that, as a result of the number of abortion providers in Texas dropping from 41 to 22, there was a statistically significant increase in the proportion of abortions that occurred in the second trimester, suggesting restrictions on abortion access delayed abortions from the first into the second trimester.³⁹ We later confirmed this finding in a more detailed analysis of abortion statistics from Texas.⁴⁰

2. Delay and Increased Travel Harm Patients

cause my patients medical harm. To begin, while abortion still one of the safest medical interventions in contemporary medicine, the risks increase as pregnancy progresses. ⁴¹ Thus, restrictions on abortion provision that result in patients being unnecessarily delayed in accessing care not only force the patient to endure the physiological stressors and risks associated with pregnancy for longer, but also subject the patient to increased risks associated with abortion if and when they do obtain that care. ⁴² Additionally, as pregnancy progresses, abortion becomes more expensive, is offered at fewer locations, and there are fewer providers than there are for early abortions. ⁴³

⁴⁰ Kari White et al., Change in Second-Trimester Abortion After Implementation of a Restrictive State Law, 133 Obstetrics & Gynecology 771, 771 (2019).

³⁹ Daniel Grossman et al., Change in Abortion Services After Implementation of a Restrictive Law in Texas, 90 Contraception 496, 499–500 (2014).

⁴¹ Natl. Academies, supra note 4, at 77–78; Linda Bartlett et al., Risk Factors for Legal Induced Abortion-Related Mortality in the United States, 103 Obstetrics & Gynecology 729, 729, 733 tbl. 2, 735 (2004); Mary Gatter et al., Efficacy and Safety of Medical Abortion Using Mifepristone and Buccal Misoprostol Through 63 Days, 91 Contraception 269, 269, 272 tbl. 2; Suzanne Zane et al., Abortion-Related Mortality in the United States 1998–2010, 126 Obstetrics & Gynecology 258, 262 tbl. 4, 263 (2015).

⁴² Suzanne Zane et al., *supra* note 41, at 258.

⁴³ Rachel K. Jones et al., Differences in Abortion Service Delivery in Hostile, Middle-Ground, and Supportive States in 2014, 28 Women's Health Issues 212, 216 (2018).

- 51. Advanced practice clinicians are more likely to provide care in rural areas and underserved settings than are OB-GYNs.⁴⁴ In many community health clinics (and a number of Planned Parenthood health centers), APCs are the lead clinicians on site. Eliminating physician-only restrictions increases abortion access by allowing clinics staffed by APCs to begin providing abortion. This also promotes continuity of care, as patients are able to access abortion from the same clinician who provides their routine gynecological or primary care.⁴⁵ Care continuity benefits patients by improving communication and trust.
- 52. Sometimes, unwanted delay in a patient's ability to access an abortion can result in their preferred abortion method no longer being available because medication abortion generally is unavailable after 77 days (11 weeks) LMP and currently prohibited after 70 days (10 weeks) LMP in Ohio. Accordingly, if a patient for whom a medication abortion is preferred, for either personal or medical reasons, is delayed in accessing care past 70 days LMP, they will no longer be able to obtain a medication abortion in Ohio. If this happens, the patient will need to either seek a procedural abortion or attempt to travel out of state for care. I have cared for patients who strongly preferred medication abortion, and I believe that such patients would be harmed by a delay that forced them to have an aspiration abortion instead.
- 53. Delay is also problematic for patients who need to terminate a pregnancy due to health reasons. And, for some patients, medication abortion is safer than aspiration abortion, and laws that delay patients past the point in pregnancy when medication abortion is available

⁴⁴ One study, for example, indicates that 49% of NPs and 69% of PAs in California serve rural and vulnerable populations, compared with 35% of OB/GYNs. Diana Taylor et al., When Politics Trumps Evidence: Legislative or Regulatory Exclusion of Abortion from Advanced Practice Clinician Scope of Practice, 54 J. of Midwifery & Women's Health 4, 6 (2009); see also Amanda Van Vleet & Julia Paradise, Tapping Nurse Practitioners to Meet Rising Demand for Primary Care (Jan. 20, 2015), https://www.kff.org/medicaid/issue-brief/tapping-nurse-practitioners-to-meet-rising-demand-for-primary-care/ (accessed Apr. 8, 2024); APHA, supra note 12.

⁴⁵ See ACOG, supra note 11, at 1060.

eliminate that option. Faced with barriers to accessing facility-based care, some patients attempt to self-induce their abortion, in some cases using dangerous methods.⁴⁶

- 54. Delay can have negative effects on patients' wellbeing. 47 Indeed, in my experience patients who have decided to end a pregnancy very consistently want to do so as early in the pregnancy as possible, for a variety of personal reasons, and are distressed that delays have pushed them later into pregnancy. Unnecessary delay causes additional stress to patients. Others may fear that they will miss the window to have a medication abortion, or miss the window to have an abortion altogether, and be forced to carry an unwanted pregnancy to term. As a result, delays themselves cause some patients significant and unnecessary emotional distress.
- 55. Other patients must conceal their travel arrangements from abusive or controlling partners or family members. According to the U.S. Centers for Disease Control and Prevention, 55.7% of Ohio women experience psychological aggression from an intimate partner in their lifetime, which amounted to approximately 2,571,000 women in 2016–2017. Psychological aggression includes name calling, insulting or humiliating an intimate partner, and behaviors that are intended to monitor and control or threaten an intimate partner. Being unable to access medication abortion early in pregnancy, when their pregnancy may be less apparent, can be particularly detrimental for these patients. Loss of confidentiality is particularly harmful for the

⁴⁶ See, e.g., Jenna Jerman et al., Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States, 49 Perspectives on Sexual & Reproductive Health 95, 101 (2017); Teresa A. Saultes et al., The Back Alley Revisited: Sepsis after Attempted Self-Induced Abortion, The W. Journal of Emergency Medicine 278 (2009); Daniel Grossman et al., The Public Health Threat of Anti-Abortion Legislation, 89 Contraception 73 (2014); Lauren Ralph et al., Prevalence of Self-Managed Abortion Among Women of Reproductive Age in the United States, 3 JAMA 1 (2020).

⁴⁷ Jenna Jerman et al., *supra* note 46, at 98.

⁴⁸ Sharon G. Smith et al., Ctrs. for Disease Control & Prevention, The National Intimate Partner and Sexual Violence Survey, 2016/2017 State Report, at 67 (2022), https://www.cdc.gov/violenceprevention/pdf/nisvs/nisvsreportonipv_2022.pdf (accessed Apr. 9, 2024).

⁴⁹ *Id*. at 11.

10% of abortion patients who suffer intimate partner violence.⁵⁰ Many abusive partners coerce their victims into becoming and staying pregnant as a means of control. They often monitor their victims to prevent them from accessing abortion services.⁵¹

56. Women who are forced to carry an unwanted pregnancy to term are more likely to continue having sustained contact with an abusive partner than women who have obtained an abortion.⁵² This is likely because people who are victims of partner violence will, in many cases, face increased difficulty escaping that relationship after having a child (because of new financial, emotional, and legal ties with that partner).

3. Ohio's APC Ban Harms Patients Seeking Abortion.

57. In sum, as the National Academies has recognized, state abortion restrictions like Ohio's APC Ban "have created barriers to optimizing each dimension of quality care. The quality of care is optimal when the care is based on current evidence and when trained clinicians are available to provide abortion services."53

⁵³ Natl. Academies, *supra* note 4, at 10.

⁵⁰ Audrey F. Saftlas et al., *Prevalence of Intimate Partner Violence Among an Abortion Clinic Population*, 100 Am. Journal of Pub. Health 1412 (2010).

Flizabeth Miller et al., Pregnancy Coercion, Intimate Partner Violence, and Unintended Pregnancy, 81 Contraception 316, 316, 318–20 (2010) (finding that domestic violence is highly correlated with unintended pregnancies due to the reproductive coercion that women face in their abusive relationships, and that one in five women who disclosed domestic violence also reported having experienced pregnancy-promoting behaviors by their abusive partner); Nat'l Domestic Violence Hotline, 1 in 4 Callers to the National Domestic Violence Hotline Report Birth Control Sabotage and Pregnancy Coercion (Feb. 15, 2011), https://www.thehotline.org/news/1-in-4-callers-to-the-national-domestic-violence-hotline-report-birth-control-sabotage-and-pregnancy-coercion/ (accessed Apr. 8, 2024).

⁵² Sarah C.M. Roberts et al., Risk of Violence From the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion, 12 BMC Medicine 144, 148 (2014); Jane Mauldon et al., Effect of Abortion vs. Carrying to Term on a Woman's Relationship with the Man Involved in the Pregnancy, 47 Perspectives on Sexual & Reproductive Health 11, 11 (2015).

- 58. For all of the reasons stated above, it is my opinion that Ohio's APC Ban is not evidence-based, serves no legitimate medical purpose, does not increase safety or the quality of patient care and is in fact harmful to the health and wellbeing of patients seeking abortion.
 - Advantages of the Current Evidence-Based Mifepristone Regimen over the C. Regimen on Its Label
 - Evidence-Based, Off-Label Medication Use Is a Routine Part of Modern 1. Medical Care.
- The practice of prescribing FDA-approved medications according to different 59. evidence-based protocols, in different evidence-based dosages, or for different evidence-based uses than those for which they were approved by the FDA, is common in medicine and referred to as "off-label" or "evidence-based" use of a medication. Indeed, up to 20% of all drugs are prescribed off-label and among some classes of cardiac drugs, off-label use can be as high as 46%,54
- For example, this is how aspirin came to be used to prevent heart attacks and 60. Wellbutrin, approved by the FDA for use as an antidepressant, came to be used for smoking cessation. Indeed, misoprostol itself was only approved for the prevention and treatment of ulcers and now has a number of important off-label uses for gynecological treatments; it is used for labor induction, treatment of spontaneous early pregnancy loss, prevention and treatment of postpartum hemorrhage, and cervical priming before uterine procedures such as hysteroscopy.⁵⁵
- In almost all cases, the label for a drug does not reflect or account for all of the 61. many evidenced-based, accepted ways that the drug is prescribed and used in routine medical

⁵⁴ Natl. Task Force on CME Provider/Industry Collaboration, On-Label and Off-Label Usage of Relationship CME. and the Prescription Medicines Devices. https://www.urmc.rochester.edu/medialibraries/urmcmedia/center-experiential-learning/cme/orga nizing-activities/documents/prescription-usage.pdf (accessed Apr. 9, 2024).

⁵⁵ A. Elati & A. D. Weeks, The Use of Misoprostol in Obstetrics and Gynaecology, 116 BJOG 61 (2009).

practice. That is because only a manufacturer of a drug can apply to have a drug relabeled, the process is very expensive (the manufacturer has to submit and perhaps conduct new research to support the application and pay a large application fee), and there is simply no incentive for the manufacturer to go through this costly process since off-label use is so prevalent and so rarely restricted.56

Mifepristone Clinical Testing, FDA Approval, and Label Changes 2.

- I briefly discussed the history of mifepristone approval in my March 30, 2021, 62. affidavit. PI Aff. ¶¶ 14-16. Since Plaintiffs now challenge Ohio's Evidence-Based Use Ban, I detail below additional information about mifepristone's history and labeling that is relevant to my opinions about that law.
- Clinical testing of mifepristone began abroad in 1982, and it was licensed in 63. France and China in 1988. In 1996, Danco Laboratories filed a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA"), requesting approval of mifepristone for distribution in the United States.
- The FDA does not itself test medications. Rather, it reviews studies submitted by 64. the applicant (known as "clinical trials"). In the case of mifepristone, the clinical trials involved approximately 2,100 women who took 600 mg of mifepristone orally and returned to the clinic 36 to 48 hours later to take 400 µg of misoprostol orally. Those trials showed that this regimen was safe and effective for abortions through 49 days LMP.
- In September 2000, the FDA approved the NDA, and as part of that approval, as 65. with all medications, approved a Final Printed Labeling ("FPL"), which is an informational document that provides physicians with guidance about the use for which the drug sponsor

⁵⁶ Michael Shea et al., Outdated Prescription Drug Labeling: How FDA-Approved Prescribing Information Lags Behind Real-World Clinical Practice, 52 Therapeutic Innovation & Regulatory Science 771 (2018).

requested and received FDA approval. The mifepristone label, therefore, described the regimen used in the clinical trials.⁵⁷ Mifepristone is the only medication that has received FDA approval for marketing as an abortion-inducing drug, and therefore, the only medication with an FPL describing an abortion regimen.

- 66. By the time that mifepristone was made available in the United States, newer research had been conducted showing that a lower dosage of mifepristone (200 mg) combined with a different dosage (800 µg) and manner of administering misoprostol was equally safe and effective through 63 days LMP. This research also showed that reducing the mifepristone dose decreased side effects. Based on this research, from the time that mifepristone medication abortion became available in the United States, the overwhelming majority of abortion providers offered their patients a regimen different from the one on the FPL.⁵⁸ The regimens used have changed over time in response to further medical research. For years before the FDA label was updated in 2016, the regimen most commonly used across the country was a regimen that differed from that detailed in the FDA's approved mifepristone label at the time.
- 67. In 2016, the FDA approved an updated label for Mifeprex (the brand name for mifepristone 200 mg) based on this evidence. That label sets forth the following evidence-based regimen for medication abortion through 70 days LMP: on day one, the patient takes 200 mg of mifepristone orally; 24 to 48 hours later, the patient takes 800 µg of misoprostol buccally; and 7

⁵⁷ The FPL at the time said that on Day One, the patient read the Medication Guide, signed the Patient Agreement, and received three 200 mg tablets of Mifeprex, taken orally at the health care facility; on Day Three, the patient returned to the health care facility and, unless the abortion has already occurred, received two 200 μg tablets of misoprostol taken orally; and on Day 14, the patient returned to the health facility to confirm that a complete termination of pregnancy has occurred.

⁵⁸ Melanie Wiegerinck et al., Medical Abortion Practices: A Survey of National Abortion Federation Members in the United States 78 Contraception 486, 489 (2008) (finding that as early as 2001, just four percent of surveyed providers reported using the FPL regimen).

FFD8E6E0-859C-4BE4-9A45-056483EB9FE4 -- 2024/04/10 08:48:30 -5:00 --- Remote Notary

to 14 days later, the patient follows up with a health care provider to confirm the pregnancy has been terminated.⁵⁹

- 68. Since mifepristone was approved in 2000, an additional layer of regulatory scrutiny was applied to the drug that has limited its distribution; this is currently codified in the drug's Risk Evaluation and Mitigation Strategy (REMS). 60 The REMS requires patients to sign a Patient Agreement Form and clinicians to sign a Prescriber Agreement Form. Prior to 2021, the REMS required that mifepristone be dispensed by a certified prescriber in a hospital, clinic, or medical office. In 2021, the REMS was modified, allowing certified pharmacies to dispense mifepristone on prescription and allowing mailing of the medication; guidance for becoming a certified pharmacy was released in 2023.
 - 3. Research Demonstrates that Mifepristone Is Safe and Effective Beyond 70 Days LMP.
- 69. The current FDA label describes mifepristone use only through 70 days LMP. However, research demonstrates that it can be safely used beyond 70 days LMP. Ohio law does not allow such safe, effective, evidence-based use because of the Evidence-Based Use Ban. As noted above, nationwide in 2022, 37% of facilities providing medication abortion offered the service past 70 days' gestation.⁶¹
- 70. When used in the later first trimester, medication abortion with mifepristone is more effective when more than one dose of misoprostol is used.⁶² In one study from Mexico, use

⁵⁹ FDA, MIFEPREX: Highlights of Prescribing Information, supra note 20, at 1.

⁶⁰ See, e.g. FDA, Questions and Answers for Medical Termination of Pregnancy Through Ten Weeks Gestation (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (accessed Apr. 9, 2024).

⁶¹ Advancing New Stds. in Reproductive Health, *Trends in Abortion Facility Gestational Limits Pre- and Post-Dobbs* (June 2023), https://www.ansirh.org/sites/default/files/2023-06/Gestational%20Limits%20Brief%206-14-23%20Final.pdf (accessed Apr. 9, 2024).

⁶² Nathalie Kapp et al., Medical Abortion in the Late First Trimester: A Systematic Review, 99 Contraception 77 (2019).

of two doses of misoprostol 800 mcg four hours apart (first dose administered buccally and second administered sublingually) resulted in a complete abortion for 97.7% of patients pregnant at 71–77 days of pregnancy. ⁶³ In that study, among patients pregnant at 71–77 days, 1.4% had an ongoing pregnancy. Although the study was relatively small (218 patients pregnant at 71–77 days), a serious adverse event occurred in only one patient (0.5%). Based on this evidence, the National Abortion Federation Clinical Policy Guidelines for Abortion Care allow medication abortion through 77 days' gestation. ⁶⁴

- 5. Research Demonstrates that the Interval between Mifepristone and Misoprostol May Be Shortened When Using the Vaginal Route of Administering Misoprostol
- 71. Research has shown that the interval between mifepristone and misoprostol may be shortened when using the vaginal route of administration. In one study of 1,080 patients undergoing medication abortion with mifepristone and misoprostol administered vaginally, patients were randomized to take the misoprostol either 6-8 hours after mifepristone or 24 hours after mifepristone. Among those in the shorter interval group, complete abortion occurred in 95.8% of patients and was not statistically different from the group that used the 24-hour interval. Serious adverse events related to medication abortion occurred in 0.6% of patients in this study. Based on this evidence, the National Abortion Federation Clinical Policy Guidelines for Abortion Care allow the interval between mifepristone and misoprostol to be shortened if misoprostol is administered vaginally. My understanding is that this currently is not allowed in Ohio. In my experience, some patients have a strong preference to shorten the interval between

Hours After Mifepristone for Abortion, 103 Obstetrics & Gynecology 851 (2004).

⁶³ Ilana Dzuba et al., A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64-70 and 71-77 Days of Gestation: A Retrospective Chart Review, 102 Contraception 104 (2020).

Natl. Abortion Fedn., 2024 Clinical Policy Guidelines for Abortion Care (2024), https://prochoice.org/wp-content/uploads/2024-CPGs-FINAL-1.pdf (accessed Apr. 9, 2024).
 Mitchell Creinin et al., A Randomized Comparison of Misoprostol 6 to 8 Hours Versus 24

mifepristone and misoprostol so they can return to work sooner, care for their children, or travel, among other reasons.

- 6. Research Demonstrates that Mifepristone Can Be Used to Prepare the Cervix Before Second-Trimester Procedural Abortion.
- 72. Evidence indicates that mifepristone is safe and effective when used to dilate and soften the cervix before dilation and evacuation (D&E), which is a procedural abortion in the second trimester. Based on a review of the evidence, the Society of Family Planning concluded that "adjuvant mifepristone for D&E at 20–24 weeks' gestation has been shown to decrease procedure time and improve providers' sense of ease of procedure without increasing side effects." My understanding is that this currently is not allowed in Ohio.
 - 5. Allowing Evidence-Based, Off-Label Use of Mifepristone Benefits Patients by Increasing Access and Allowing Patient-Centered Care.
- 73. Allowing providers to prescribe mifepristone off-label beyond 70 days LMP to eligible patients would increase abortion access. This is particularly true for patients who struggle to access an abortion for the reasons I have outlined in both this and my prior affidavits. This includes, but is not limited to, patients who prefer medication abortion but cannot access care within 70 days LMP; young people and those who have not given birth previously, as well as those who get pregnant while using hormonal contraception, who may recognize pregnancy later; ⁶⁷ and poor and low-income patients that face financial and logistical barriers to access.

⁶⁶ Justin Diedrich et al., Society of Family Planning Clinical Recommendations: Cervical Preparation for Dilation and Evacuation at 20–24 Weeks' Gestation, 101 Contraception 286, 289 (2020).

⁶⁷ Diana Foster et al., *Timing of Pregnancy Discovery Among Women Seeking Abortion*, 104 Contraception 642 (2021).; Lawrence B. Finer et al., *supra* note 35.

FFD8E6E0-859C-4BE4-9A45-056483EB9FE4 --- 2024/04/10 08:48:30 -5:00 --- Remote Notary

The undersigned hereby affirms that the statements made in the foregoing affidavit are true, under penalty of perjury.

Daniel Grossman Daniel Grossman, M.D. SS/ Franklin County, Ohio 04/10/2024 Sworn to and subscribed before me this _____ day of April, 2024. Theresa M Sabo Commission # 2016-RE-619622 Electronic Notary Public State of Ohio My Comm Exp. Nov 28, 2026

Notarial act performed by audio-visual communication

Daniel A. Grossman, M. D., F. A. C. O. G.

Advancing New Standards in Reproductive Health, UCSF 1330 Broadway, Suite 1100 Oakland, CA 94612

Current position

Professor, Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco Director, Advancing New Standards in Reproductive Health (ANSIRH)

Education

Sept. 1985-May 1989Yale University-Molecular Biophysics

and Biochemistry

B.S., 1989

Sept. 1989-June 1994

Stanford University School of Medicine

M.D., 1994

June 1994-June 1998Resident and Administrative Chief Resident, Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco

Licenses/Certification

1996-Present

California medical licensure (A60282)

2001-Present

Board Certified, American Board of Obstetrics and Gynecology

2022-Present

Board Certified Subspecialist in Complex Family Planning

Principal positions held

Aug. 1998-Feb. 2003

Aug. 2005-2012

Physician, St. Luke's Women's Center, San Francisco, CA

May 2003-Aug. 2005

Health Specialist, The Population Council

Aug. 2005-Aug. 2015

Regional Office for Latin America and the Caribbean, Mexico City Senior Associate (through June 2012), Vice President for Research

(starting July 2012), Ibis Reproductive Health

Sept. 2015-Present

Professor, Department of Obstetrics, Gynecology and Reproductive

Sciences at the University of California, San Francisco

Sept. 2015-Present

Director, Advancing New Standards in Reproductive Health

(ANSIRH)

January 2023-Present

Vice Chair of Advocacy, Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco

Other positions held concurrently

Aug. 1998-Feb. 2003

Director of Medical Student Education, Department of

Obstetrics and Gynecology, St. Luke's Hospital

Aug. 1998-Feb. 2003Vice Chair, Department of Obstetrics and Gynecology, St. Luke's Hospital Aug. 1998-2015Assistant Clinical Professor, Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology and Reproductive Sciences at

the University of California, San Francisco

2012-2015Contract physician, Planned Parenthood Shasta Pacific

Senior Advisor, Ibis Reproductive Health Aug. 2015-Present

Aug. 2018-Present

Associate Investigator, SPHERE: A Centre of Research Excellence in Sexual and Reproductive Health for Women, Monash University, Melbourne, Australia

Honors and awards

- 1988 Howard W. Hilgendorf Jr. Fellowship, Yale University
- 1988 Robin Berlin Memorial Prize, Yale University
- 1989 Magna cum laude, Yale University
- 1990 Medical Scholars Award, Stanford University
- 1990 Peter Emge Traveling Fellowship, Stanford University
- 1991-1992 Foreign Language and Area Studies Fellowship, Stanford University
 - 1994 Dean's Award for Research in Infectious Diseases, Stanford University
 - 2007 Ortho Outstanding Researcher Award, Association of Reproductive Health Professionals
 - 2009 Visionary Partner Award, Pacific Institute for Women's Health
 - 2010 Scientific Paper Award, National Abortion Federation
 - 2013 Gerbode Professional Development Fellowship
 - 2013 Abstract selected as one of Top 4 Oral Abstracts at North American Forum on Family Planning
 - 2013 Felicia Stewart Advocacy Award from the Population, Reproductive and Sexual Health Section of the American Public Health Association
 - 2018 Outstanding Resident Teaching Award, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF
 - 2019 Outstanding Resident Teaching Award, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF
 - 2019 Beacon of Science Award, Society of Family Planning
 - 2021 Outstanding Resident Teaching Award, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF
 - 2022 UCSF Chancellor Award for Public Service
 - 2022 Outstanding Resident Teaching Award, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF
 - 2023 Outstanding Resident Teaching Award, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF
 - 2024 University of Utah Visiting Professor in Family Planning

Key words/areas of interest

Abortion, medication abortion, second-trimester abortion, contraception, over-the-counter access to oral contraception, integration of family planning into HIV care and treatment, Latina reproductive health in the US, misoprostol and self-induction of abortion, Mexico, Peru, Bolivia, Dominican Republic, South Africa, Kenya

PROFESSIONAL ACTIVITIES

PROFESSIONAL ORGANIZATIONS

<u>Memberships</u>

2000-Present Fellow, American College of Obstetrics and Gynecology (ACOG)

2006-Present Fellow, Society of Family Planning 2004-Present American Public Health Association

2013-Present 2004-2011	American Medical Association Association of Reproductive Health Professionals
2004-2016 2006-Present	International Consortium for Medical Abortion Liaison Member, Planned Parenthood Federation of America National Medical Committee
2005-Present	Consorcio Latinoamericano contra el Aborto Inseguro (Latin American Consortium against Unsafe Abortion)
2004-Present	Free the Pill Coalition (formerly Working Group on Oral Contraceptives Over-the-Counter)
Service to profe	essional organizations
2008-Present	Society of Family Planning, reviewer of grant proposals, abstract reviewer for annual meeting
2007-Present	American Public Health Association, Governing Councilor (2007-2009, 2010-2014), Section Secretary (2008-2009), abstract reviewer for annual meeting
2005-2012	Consorcio Latinoamericano contra el Aborto Inseguro, member of Coordinating Committee
2006-Present	Free the Pill Coalition (formerly Working Group on Oral Contraceptives Over-the-Counter), working group coordinator and member of steering committee
2010-2016	Steering Committee member, International Consortium for Medical Abortion
2016	External advisor for Marie Stopes International research strategy meeting, March 23-24, 2016, London, UK
2010-2013	Member, Committee on Practice Bulletins-Gynecology, ACOG
2014-2020	Member, Committee on Health Care for Underserved Women, ACOG (Vice Chair of Committee 2016-18, Chair 2018-20)
2017-2018	Member, Telehealth Task Force, ACOG
2018-2021	Member, Telehealth Working Group, ACOG
2019-Present	Member, Abortion Access and Training Expert Work Group, ACOG
2020	Member, Workgroup on Advancing Diversity, Equity and Inclusive Excellence, ACOG

SERVICE TO PROFESSIONAL PUBLICATIONS

2013-Present	Editorial Board, Contraception
2024	Women's Health Distinguished Reviewer, JAMA Internal Medicine
2004-Present	Ad hoc reviewer for Obstetrics and Gynecology (10 papers in past 5

years), American Journal of Public Health (4 papers in past 3 years), Reproductive Health Matters (6 articles in past 4 years), Expert Review of Obstetrics and Gynecology (3 review in past year), and Women's Health

Issues (4 articles in past 2 years), Lancet (2 reviews in past year)

INVITED PRESENTATIONS (Selected)

International

Second-trimester abortion. Optimizing the Potential for Medication in Pregnancy Termination in South America Conference, Lima, Peru, 2014 (invited talk).

- Participation in panel at Harvard University seminar: Politics, Public Health, and Abortion: Examining the Changing Legal Environment in Mexico and Central America, Cambridge, MA, 2014 (invited talk).
- Evidence for removing the prescription barrier to hormonal contraception. Annual meeting of the Associacion Française pour la Contraception, Paris, France, March 2015.
- Presentations on medical abortion and second-trimester abortion, REDAAS (Red de Acceso al Aborto Seguro) meeting, Buenos Aires, Argentina, May 2015 (invited talk).
- Panel participant in panel "Gestational limits for abortion: what purpose do they serve?" and presentations on adolescent pregnancy, telemedicine provision early medical abortion, and second-trimester abortion. Fifth Research Meeting on Unintended Pregnancy and Unsafe Abortion, Mexico City, September 2015 (invited talks).
- Moving oral contraceptives over the counter as a strategy to reduce unintended pregnancy. The Human Right to Family Planning Conference, Seattle, WA, October 2015 (invited talk).
- Over-the-counter access to hormonal contraception- what are the risks and benefits?, and Introduction of the mifepristone regimen for second-trimester medical abortion in South Africa. XXI FIGO World Congress of Gynecology and Obstetrics, Vancouver, Canada, October 2015 (oral presentations).
- Second-trimester abortion. Presentation at the First Latin American Meeting on Public Sector Providers of Legal Abortion, Buenos Aires, Argentina, August 2016 (invited talk).
- Safety, effectiveness and acceptability of telemedicine provision of medication abortion in Iowa, NAF regional meeting, Mexico City, September 2017 (invited talk).
- Abortion in the United States: A new report on safety and the effects of being denied a wanted abortion. Presentation at "Evidencias y argumentos de salud pública para la legalización del aborto en Argentina," Buenos Aires, Argentina, May 2018 (invited talk).
- Self-managed abortion in the United States. Presentation at "Abortion Beyond Bounds," Montreal, Canada, October 2018.
- Gestational age limits in the United States: legal and service delivery perspectives. Presentation at "Interrupción del embarazo y edad gestacional," Buenos Aires, Argentina, August 2019 (invited talk).
- Telemedicine and abortion care in the United States. Plenary lecture at SPHERE Annual meeting (virtual), Monash University, Melbourne, Australia, November 2020 (invited talk).
- Virtual delivery of reproductive health care. Presentation at Australasian Sexual and Reproductive Health Day (virtual), Australia, September 2021.
- Access to later abortion in the US post-Dobbs. Presentation at Abortion Providers Group of Aotearoa New Zealand (virtual), New Zealand, September 2022.

<u>National</u>

- Participation in panel entitled Abortion Scholarship: An Interdisciplinary Conversation, at UC Berkeley Symposium Speech, Symbols, and Substantial Obstacles: The Doing and "Undue"ing of Abortion Law since Casey, Berkeley, 2013 (invited talk).
- Impact of restrictive abortion law on women in Texas. North American Forum on Family Planning, Seattle, 2013 (oral presentation).
- Randomized Trial of Misoprostol versus Laminaria before Dilation and Evacuation in South Africa. Annual meeting of the National Abortion Federation, San Francisco, 2014 (oral presentation).

- Introduction of the mifepristone regimen for second-trimester medical abortion in South Africa. Annual meeting of the National Abortion Federation, Baltimore, April 2015 (oral presentation).
- Knowledge, opinion and experience related to abortion self-induction in Texas (oral abstract), and participant in panel "Addressing the global need for safe abortion after the first trimester." North American Forum on Family Planning, Chicago, November 2015 (oral presentations).
- Participant in panel "Addressing the Challenges Facing Women's Reproductive Health Care," Academy Health National Health Policy Conference, Washington, DC, February 2, 2016 (invited talk).
- Panel presentations entitled "Medical abortion restrictions: From label laws to abortion reversal," "Texas: Ground Zero in the Abortion Wars" and "Stolen Lives: Impact of early adolescent pregnancy on all aspects of health," Annual meeting of the National Abortion Federation, Austin, Texas, April 2016.
- Panel presentations entitled "Evaluating Reproductive Health Policy at the State Level" and "Translating research into policy: Contributing data to the public debate when it matters most," North American Forum on Family Planning, Denver, November 2016.
- Panel presentation entitled "Abortion Outside the Clinic: Imagining Safe and Legal Abortion in a post-Roe World," Physicians for Reproductive Health Grand Rounds, New York University School of Law, New York, March 2017.
- "Safety of medication abortion provided through telemedicine: A non-inferiority study" (oral abstract), "Evaluating the provision of early medical abortion by telemedicine" (panel presentation), and "Use of research in evaluating Texas House Bill 2" (panel presentation). Annual meeting of the National Abortion Federation, Montreal, Canada, April 2017.
- Using Evidence to Inform Policy in an Era of Alternative Facts, keynote address at Family Planning Symposium, "Family Planning Post-Election: Putting on our Fatigues," San Diego, May 2017.
- "Improving access through over-the-counter status" (panel presentation), "Building bridges, not walls: using telemedicine to expand sexual & reproductive healthcare" (panel presentation), and "Expanding access to medical abortion through clinic-to-clinic telemedicine" (panel presentation). North American Forum on Family Planning, Atlanta, October 2017.
- "Prevalence of Self-Induced Abortion Attempts among a Nationally Representative Sample of U.S. Women" (oral abstract), "What do we know about self-induced or self-managed abortion in the United States?" (panel presentation). Annual meeting of the National Abortion Federation, Seattle, April 2018.
- "Driving Health Equity Through Innovation in Health Care," panel participant at plenary at the 2018 Planned Parenthood Federation of America National Conference, Washington, DC, April 2018.
- Innovative Contraceptive Delivery Models. Presentation at National Reproductive Health Title X Conference, Kansas City, July 2018.
- "Medication abortion in the United States" and panel participant in "The NASEM Report on Abortion Safety and Quality: implications for research, training, practice and advocacy." North American Forum on Family Planning, New Orleans, October 2018.
- Research on telemedicine and abortion care, panel presentation. Annual meeting of the National Abortion Federation, Chicago, May 2019.

- Alternative provision models for medication abortion: from pharmacy dispensing to OTC. Annual meeting of the Mifepristone Coalition, New York City, June 2019.
- "Medication abortion with pharmacist dispensing of mifepristone: a cohort study" (oral abstract), "It makes sense': pharmacists' attitudes toward dispensing mifepristone for medication abortion" (poster), "Abortion referral practices among a national sample of obstetrician-gynecologists" (poster). Annual meeting of Society of Family Planning, Los Angeles, October 2019.
- Panelist at Society of Family Planning Research Fund Roundtable on medication abortion research (virtual), August 2020.
- Panelist, Evidence-Based Guidance on Telehealth Interventions to Improve Health Outcomes in Obstetrics & Gynecology: Best Practices and COVID-19 Updates, ACOG Annual Clinical and Scientific Meeting (virtual), May 2021.
- Overview of reproductive health. Meeting of the Association of Prosecuting Attorneys (virtual), October 2021.
- Self-managed abortion. Presentation for the Ryan Residency Training Program (virtual), January 2022.
- The rise of telehealth medication abortion as a possible mitigation strategy. Presentation at Legislating Abortion: Comparative Legal Perspectives on Statutory Abortion Rights, Harvard Human Rights Journal's Annual Symposium (virtual), March 2022.
- Health care provider reporting practices related to self-managed abortion (oral abstract). American Public Health Association annual meeting, Boston, November 2022.
- Participation in panel "The View from the Trenches: The Experience of Providers and the Role of Health Systems" at After Dobbs: New Directions in Reproductive Justice, University of California Davis, March 2023.
- Advance Provision of Medication Abortion. Presentation at National Abortion Federation Annual Meeting, Denver, May 2023.
- Ask the Experts: Medication abortion; Self-managed abortion; Over-the-counter access to contraception. Presentations at ACOG Annual Clinical and Scientific Meeting, Baltimore, May 2023.
- Caring for Patients in a Post-Roe World. Presentation at Endocrine Society's Annual Meeting, ENDO 2023, Chicago, June 2023.
- "Self-managed abortion: what is it and what is our role?" and "Over-the-counter contraception: first progestin-only pills, then what?" Presentations at Contraceptive Technology Conference 2023, Atlanta, September 2023.
- Care Post-Roe: Documenting poor-quality care since the Dobbs decision. Presentation at U.S. Department of Health and Human Services Roundtable Series: Facilitating reproductive health research post-Dobbs decision: Research networks documenting the consequences post-Dobbs (virtual), September 2023.
- Care Post-Roe: Documenting poor-quality care related to abortion bans since the *Dabbs* decision. Poster at Society of Family Planning Annual Meeting, Seattle, October 2023.

Regional and other invited presentations

- Impact of family planning cuts and abortion restrictions in Texas. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, 2013.
- Improving access to early medical abortion through the use of telemedicine. Office of Population Research seminar, Princeton University, 2014 (invited talk).

- Impact of family planning cuts and abortion restrictions in Texas. Grand rounds presentation, Department of Obstetrics and Gynecology, Emory University School of Medicine, Atlanta, Georgia, February 2015.
- Impact of family planning cuts and abortion restrictions in Texas. Grand rounds presentation, Department of Obstetrics and Gynecology, Baylor University School of Medicine, Houston, Texas, April 2015.
- The causes and consequences of unintended pregnancy among women in the US military. San Francisco General Hospital grand rounds, September 2015.
- Impact of family planning cuts and abortion restrictions in Texas. Grand rounds presentation, Department of Obstetrics and Gynecology, University of New Mexico School of Medicine, Albuquerque, New Mexico, October 2015.
- Using evidence and advocacy to improve second-trimester abortion care in South Africa.

 Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, December 2015.
- UCSF/UCH Consortium Annual Supreme Court Review, panel speaker on Whole Woman's Health v. Hellerstedt, San Francisco, July 2016.
- American Gynecological Club meeting, presentation on Reproductive Health in Texas and panel participant, San Francisco, September 2016.
- Speaking science to the Court: the experience of experts in Whole Woman's Health v. Hellerstedt, panel participant, UC Hastings, San Francisco, October 2016.
- How data made the difference in the Texas abortion case before the US Supreme Court. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, November 2016.
- Research That Gets Results: A Symposium on Science-Driven Policy Change, panel participant, UCSF, March 2017.
- Medication abortion: What is it and how can its potential to improve access to care be realized? Presentation for UCSF Students for Choice, April 2017.
- Medication Abortion: Supporting Women Both Inside and Outside the Clinic to Access Safe Care. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, November 2017.
- Medication Abortion: Supporting Women Both Inside and Outside the Clinic to Access Safe Care. Grand rounds presentation, Department of Obstetrics and Gynecology, Kaiser San Francisco, March 2018.
- Medication Abortion: Supporting Women Both Inside and Outside the Clinic to Access Safe Care. Grand rounds presentation, Department of Obstetrics and Gynecology, University of Arizona College of Medicine, Tucson, June 2018.
- Medication Abortion: Supporting Women Both Inside and Outside the Clinic to Access Safe Care. Presentation to Medical Students for Choice, University of Kansas Medical Center, July 2018.
- Medication Abortion: Supporting Women Both Inside and Outside the Clinic to Access Safe Care. Grand rounds presentation, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, October 2018.
- Self-managed abortion in the US: What's happening, and what is our role? Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, November 2018.
- Evidence-based advocacy to improve reproductive health. Annual Creinin Family Planning Lectureship, Department of Obstetrics, Gynecology & Reproductive Sciences, University of Pittsburgh, April 2019.

- Evidence-based advocacy to improve reproductive health. Symposium speaker at the 2019 Research Retreat, Department of Obstetrics and Gynecology, University of Colorado, October 2019.
- Demedicalizing reproductive health care: from OTC oral contraceptives to self-managed abortion. James C. and Joan Caillouette Lecture at the annual meeting of the Pacific Coast Obstetrical and Gynecological Society, San Diego, October 2019.
- Advocacy 101: How to Inform Policy Debates with Your Own Expertise in OB/GYN. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, January 2020.
- Telehealth in Obstetrics and Gynecology. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, April 2020.
- Abortion care during the COVID-19 pandemic: threats to access and opportunities for innovation. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, November 2020.
- Using research evidence to inform policy. Invited plenary for Inquiry Symposium, UCSF School of Medicine, May 2021.
- Evidence-based advocacy to improve reproductive health. Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UC San Diego, May 2021.
- Evidence-based advocacy to improve reproductive health. Grand rounds presentation, Department of Obstetrics & Gynecology, Stanford University School of Medicine, December 2021.
- Emergency Gynecological Care in a Post-Roe Landscape: Clinical and Practical Considerations. Grand rounds presentation, Department of Obstetrics & Gynecology, University of Louisville, May 2022.
- Addressing Abortion in Primary Care. Grand rounds presentation, Department of General Internal Medicine, San Francisco General Hospital, September 2022.
- Practicing in a Post-Roe World, and Social Media to Combat Misinformation. Presentations at ACOG District V, VIII, IX Annual Meeting, Maui, September 2022.
- All hands on deck: Strategies to maintain access to reproductive healthcare post-Roe.

 Presentation at 5th Annual Connors Center for Women's Health and Gender Biology
 Research Symposium, Harvard Medical School, Boston, November 2022.
- Medication Abortion: Clinical and Policy Considerations in a Post-Roe World. Grand rounds presentation, Department of Pediatrics, San Francisco General Hospital, February 2023.
- Threat to mifepristone access: How should we respond? Grand rounds presentation, Department of Obstetrics, Gynecology and Reproductive Sciences, UCSF, February 2023.
- Medication abortion with mifepristone and misoprostol: Under attack and ripe with opportunity. Grand rounds presentation, Department of Obstetrics, Midwifery and Gynecology, Alameda Health System, March 2023.
- Care Post-Roe: Documenting cases of poor-quality care post-Dobbs. Presentation at San Francisco Gynecological Society, May 2023.
- Care Post-Roe: Documenting poor-quality care since *Dobbs*. Presentation at Orange County Women's Summit, UC Irvine, October 2023.
- Update on abortion access. Invited presentation in "Healthcare in America," Warren Alpert Medical School, Brown University, November 2023.

Over-the-counter access to oral contraception: from FDA approval to equitable expansion of access. Grand rounds presentation, Department of Obstetrics and Gynecology, University of Utah, February 2024.

OTHER PROFESSIONAL SERVICE

OTIMENTING	TESSIONAL SERVICE
2007	Member of the International Planned Parenthood Federation Safe Abortion
	Action Fund Technical Review Panel
2007-2009	Steering committee member of the California Microbicide Initiative
2002-2004	Member, Medical Development Team, Marie Stopes International (London)
2013-2021:	Reviewer of fellows' research proposals for the Fellowship in Family
	Planning
2013-2015	Member of working group on Guidelines for Task Shifting in Abortion
	Provision convened by World Health Organization
2014	Discovery working group member, Preterm Birth Initiative (PTBi), UCSF
2013-2019	Board member and Secretary (2014-2016), NARAL Pro-Choice America
	Foundation
2014-2021	Board member, NAF
2015-2019	Board member, Shift/Whole Woman's Health Alliance
2017	Study section member, U54 Contraceptive Center proposal review panel,
	National Institute of Child Health and Human Development
2020	Reviewer, Health Research Council of New Zealand
2019-Present	Chair, UCSF Department of Obstetrics, Gynecology & Reproductive
	Sciences Advocacy Strategy Committee
2020-Present	Member, UCSF Department of Obstetrics, Gynecology & Reproductive
	Sciences Leadership Council
2021-Present	Member of UCSF Institutional Review Board (IRB), Laurel Heights
	Committee
2021-Present	Member, California Future of Abortion Council
2022	Reviewer, Grand Challenges Canada

TEACHING FORMAL SCHEDULED CLASSES:

Qt r	Academic Yr	Institution Course Title	Teaching Contribution	Class Size
W	2008-09	Harvard School of Public Health; GHP502 International reproductive health issues: Moving from theory to practice	Lecturer; 2 lectures	22
w	2009-10	Harvard School of Public Health; GHP502 International reproductive health issues: Moving from theory to practice	Lecturer; 1 lecture	17

Qt	Academic	Institution	Teaching Contribution	Class
r	Yr	Course Title		Size
F	2014-15	UCSF Coursera course; Abortion: Quality Care and Public Health Implications	Lecturer; 4 lectures	6,000+ (online)
F	2015-16	University of Texas at Austin; SociologyReproductive Health and Population in Texas; SS 301 Honors Social Science	Lecturer; 1 lecture	20
S	2016-17	UC Berkeley School of Law; 224.6 - Selected Topics in Reproductive Justice	Lecturer; 1 lecture	12
s	2018-19	University of Texas at Austin; Sociology—Graduate seminar in human fertility	Lecturer; 1 seminar	8
W	2019-20	UCSF: Family Planning and Reproductive Choices elective	Lecturer; 1 lecture	20
s	2020-21	Harvard Medical School; Sex- and Gender-Informed Medicine: Research, Clinical Practice, and Population Health, AISC626.0	Lecturer; 1 lecture	25

POSTGRADUATE and OTHER COURSES

Guest lecturer in "Qualitative Research Methods in Public Health," CUNY School of Public Health, September 2011

Women's health from a global perspective. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, 2007.

Expanding access to medication abortion. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, 2017.

A world post Roe v. Wade. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, 2019.

The changing landscape of abortion access. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, 2020.

Update on abortion regulations. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, 2021.

A world post-Roe. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, 2022.

Future of Abortion Care After Roe. Presentation at 46th Annual Antepartum and Intrapartum Management (AIM) CME Conference, San Francisco, June 2023.

Update on abortion access. Presentation at Obstetrics and Gynecology Update: What Does the Evidence Tell Us? UCSF CME course, San Francisco, October 2023.

TEACHING AIDS

Contributed to the development of a training slide set on medical abortion in Spanish, 2004

- Developed pocket cards on emergency contraception for use by community health workers in the State of Mexico, 2005
- Reviewed and provided input on a manual on gynecologic uses of misoprostol published by the Latin American Federation of Obstetric and Gynecologic Societies (FLASOG), 2005
- Grossman D. Medical methods for first trimester abortion: RHL commentary (last revised: 3 September 2004). The WHO Reproductive Health Library, No 8, Update Software Ltd, Oxford, 2005. Exerpt available at:

http://www.rhlibrary.com/Commentaries/htm/Dgcom.htm.

Grossman D. Medical methods for first trimester abortion: RHL practical aspects (last revised: 3 September 2004). The WHO Reproductive Health Library, No 8, Update Software Ltd, Oxford, 2005.

RESEARCH AND CREATIVE ACTIVITIES

PEER REVIEWED PUBLICATIONS

- Laudon M, Grossman DA, Ben-Jonathan N. Prolactin-releasing factor: cellular origin in the intermediate lobe of the pituitary. Endocrinology 1990; 126(6):3185-92.
- 2. Grossman DA, Witham ND, Burr DH, Lesmana M, Rubin FA, Schoolnik GK, Parsonnet J. Flagellar serotypes of <u>Salmonella typhi</u> in Indonesia: relationships among motility, invasiveness, and clinical illness. Journal of Infectious Diseases 1995; 171(1):212-6.
- 3. MacIsaac L, Grossman D, Balistreri E, Darney P. A randomized controlled trial of laminaria, oral misoprostol, and vaginal misoprostol before abortion. Obstetrics and Gynecology 1999; 93(5, pt.1):766-770.
- 4. Grossman D, Ellertson C, Grimes DA, Walker D. Routine follow-up visits after first-trimester induced abortion. Obstetrics and Gynecology 2004; 103(4):738-45.
- 5. Lafaurie MM, Grossman D, Troncoso E, Billings DL, Chávez S. Women's perspectives on medical abortion in Mexico, Colombia, Ecuador and Peru: a qualitative study. Reproductive Health Matters 2005;13(26):75-83.
- 6. Grossman D, Ellertson C, Abuabara K, Blanchard K. Barriers to contraceptive use present in product labeling and practice guidelines. American Journal Public Health 2006;96(5):791-9.
- 7. Yeatman SE, Potter JE, Grossman DA. Over-the-counter access, changing WHO guidelines, and the prevalence of contraindicated oral contraceptive use in Mexico. Studies in Family Planning 2006; 37(3):197–204.
- 8. Pace L, Grossman D, Chavez S, Tavara L, Lara D, Guerrero R. Legal Abortion in Peru: Knowledge, attitudes and practices among a group of physician leaders. Gaceta Medica de Mexico 2006; 142(Supplement 2):91-5.
- 9. Lara D, Abuabara K, Grossman D, Diaz C. Pharmacy provision of medical abortifacients in a Latin American city. Contraception 2006;74(5):394-9.
- 10. Tinajeros F, Grossman D, Richmond K, Steele M, Garcia SG, Zegarra L, Revollo R. Diagnostic accuracy of a point-of-care syphilis test when used among pregnant women in Bolivia. Sexually Transmitted Infections 2006;82 Suppl 5:v17-21.
- 11. Clark W, Gold M, Grossman D, Winikoff B. Can mifepristone medical abortion be simplified? A review of the evidence and questions for future research. Contraception 2007;75:245-50.

- 12. Garcia SG, Tinajeros F, Revollo R, Yam EA, Richmond K, Díaz-Olavarrieta C, Grossman D. Demonstrating public health at work: A demonstration project of congenital syphilis prevention efforts in Bolivia. Sexually Transmitted Diseases 2007;34(7):S37-S41.
- 13. Díaz-Olavarrieta C, García SG, Feldman BS, Polis AM, Revollo R, Tinajeros F, Grossman D. Maternal syphilis and intimate partner violence in Bolivia: a gender-based analysis of implications for partner notification and universal screening. Sex Transm Dis 2007;34(7 Suppl):S42-6.
- 14. Harper CC, Blanchard K, Grossman D, Henderson J, Darney P. Reducing Maternal Mortality due to Abortion: Potential Impact of Misoprostol in Low-resource Settings. International Journal of Gynecology and Obstetrics 2007;98:66-9.
- 15. Grossman D, Berdichevsky K, Larrea F, Beltran J. Accuracy of a semi-quantitative urine pregnancy test compared to serum beta-hCG measurement: a possible tool to rule-out ongoing pregnancy after medication abortion. Contraception 2007;76(2):101-4.
- 16. Lara D, van Dijk M, Garcia S, Grossman D. La introducción de la anticoncepción de emergencia en la norma oficial mexicana de planificación familiar (The introduction of emergency contraception into the official Mexican family planning norms). Gaceta Médica de México 2007;143(6): 483-7.
- 17. Grossman D, Blanchard K, Blumenthal P. Complications after second trimester surgical and medical abortion. Reproductive Health Matters 2008;16(31 Supplement):173-82.
- 18. Grossman D, Fernandez L, Hopkins K, Amastae J, Garcia SG, Potter JE. Accuracy of self-screening for contraindications to combined oral contraceptive use. Obstetrics and Gynecology 2008; 112(3):572-8.
- 19. Grossman D. Should the oral contraceptive pill be available without prescription? Yes. British Medical Journal 2008;337:a3044.
- 20. Levin C, Grossman D, Berdichevsky K, Diaz C, Aracena B, Garcia S, Goodyear L. Exploring the economic consequences of unsafe abortion: implications for the costs of service provision in Mexico City. Reproductive Health Matters 2009;17(33):120–132.
- Hu D, Grossman D, Levin C, Blanchard K, Goldie SJ. Cost-Effectiveness Analysis of Alternative First-Trimester Pregnancy Termination Strategies in Mexico City. BJOG 2009;116:768–779.
- 22. Távara-Orozco L, Chávez S, Grossman D, Lara D, Blandón MM. Disponibilidad y uso obstétrico del misoprostol en los países de América [Availability and obstetric use of misoprostol in Latin American countries]. Revista Peruana de Ginecologia y Obstetricia 2009;54:253-263.
- 23. Lara DK, Grossman D, Muñoz J, Rosario S, Gomez B, Garcia SG. Acceptability and use of female condom and diaphragm among sex workers in Dominican Republic: Results from a prospective study. AIDS Education and Prevention 2009;21(6):538-551.
- 24. Grossman D, Fernandez L, Hopkins K, Amastae J, Potter JE. Perceptions of the safety of oral contraceptives among a predominantly Latina population in Texas. Contraception 2010;81(3):254-60. (NIHMS155993)
- 25. Potter JE, White K, Hopkins K, Amastae J, Grossman D. Clinic versus Over-the-Counter Access to Oral Contraception: Choices Women Make in El Paso, Texas. American Journal of Public Health 2010;100(6):1130-6. (NIHMS 221745)

- 26. Phillips K, Grossman D, Weitz T, Trussell J. Bringing evidence to the debate on abortion coverage in health reform legislation: findings from a national survey in the United States. Contraception 2010;82(2):129-30.
- 27. Hu D, Grossman D, Levin C, Blanchard K, Adanu R, Goldie SJ. Cost-Effectiveness Analysis of Unsafe Abortion and Alternative First-Trimester Pregnancy Termination Strategies in Nigeria and Ghana. African Journal of Reproductive Health 2010;14(2)85-103.
- 28. Grossman D, Holt K, Peña M, Veatch M, Gold M. Winikoff B, Blanchard K. Self-induction of abortion among women in the United States. Reproductive Health Matters 2010;18(36):136–146.
- 29. Grossman D, Grindlay K. Alternatives to ultrasound for follow-up after medication abortion: A systematic review. Contraception 2011;83(6):504-10.
- 30. Liang S-Y, Grossman D, Phillips K. Women's out-of-pocket expenditures and dispensing patterns for oral contraceptive pills between 1996 and 2006. Contraception 2011;83(6):528-36.
- 31. Blanchard K, Bostrom A, Montgomery E, van der Straten A, Lince N, de Bruyn G, Grossman D, Chipato T, Ranjee G, Padian N. Contraception use and effectiveness among women in a trial of the diaphragm for HIV prevention. Contraception 2011;83(6):556-63.
- 32. Grossman D, White K, Hopkins K, Amastae J, Shedlin M, Potter JE. Contraindications to Combined Oral Contraceptives Among Over-the-Counter versus Prescription Users. Obstet Gynecol 2011;117(3):558–65.
- 33. Potter JE, McKinnon S, Hopkins K, Amastae J, Shedlin MG, Powers DA, Grossman D. Continuation of prescribed compared with over-the-counter oral contraceptives. Obstet Gynecol 2011;117(3):551–7.
- 34. Grindlay K, Yanow S, Jelinska K, Gomperts R, Grossman D. Abortion restrictions in the US military: Voices from women deployed overseas. Women's Health Issues 2011;21(4):259-64.
- 35. Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine. Obstetrics and Gynecology 2011;118(2 Pt 1):296-303.
- 36. Holt K, Grindlay K, Taskier M, Grossman D. Unintended pregnancy and contraceptive use among women in the US military: A systematic literature review. Military Medicine 2011;176(9):1056-64.
- 37. Harris LH, Grossman D. Confronting the challenge of unsafe second-trimester abortion. Int J Gynaecol Obstet 2011;115(1):77-9.
- 38. Grossman D, Constant D, Lince N, Alblas M, Blanchard K, Harries J. Surgical and medical second trimester abortion in South Africa: a cross-sectional study. BMC Health Serv Res. 2011;11(1):224.
- 39. Harries J, Lince N, Constant C, Hargey A, Grossman D. The challenges of offering public second trimester abortion services in South Africa: Health care providers' perspectives. Journal of Biosocial Science 2011;17:1-12.
- 40. Dennis A, Grossman D. Barriers to Contraception and Interest in Over-the-Counter Access Among Low-Income Women: A Qualitative Study. Perspect Sex Reprod Health 2012;44(2):84-91.

- 41. Foster DG, Higgins J, Karasek D, Ma S, Grossman D. Attitudes toward unprotected intercourse and risk of pregnancy among women seeking abortion. Women's Health Issues 2012;22(2):e149-55.
- 42. Foster DG, Karasek D, Grossman D, Darney P, Schwarz EB. Interest in using intrauterine contraception when the option of self-removal is provided. Contraception 2012;85(3):257-62.
- 43. White K, Potter JE, Hopkins K, Fernández L, Amastae J, Grossman D. Contraindications To Progestin-Only Oral Contraceptive Pills Among Reproductive Aged Women. Contraception 2012;86(3):199-203.
- 44. Harrington EK, Newmann SJ, Onono M, Schwartz KD, Bukusi EA, Cohen C, Grossman D. Fertility intentions and interest in integrated family planning services among HIV-infected women in Nyanza Province, Kenya: a qualitative study. Infectious Diseases in Obstetrics and Gynecology 2012;2012, Article ID 809682. doi:10.1155/2012/809682.
- 45. Lessard L, Karasek D, Ma S, Darney P, Deardorff J, Lahiff M, Grossman D, Foster DG. Contraceptive features preferred by women at high risk of unintended pregnancy. Perspectives on Sexual and Reproductive Health 2012;44(3):194-200.
- Grossman D, Garcia S, Kingston J, Schweikert S. Mexican women seeking safe abortion services in San Diego, California. Health Care Women Int 2012;33(11):1060-9.
- 47. Hopkins K, Grossman D, White K, Amastae J, Potter JE. Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users. Contraception 2012;86(4):376-82.
- 48. Potter JE, White K, Hopkins K, McKinnon S, Shedlin MG, Amastae J, Grossman D. Frustrated Demand for Sterilization among Low-Income Latinas in El Paso, Texas. Perspectives on Sexual and Reproductive Health 2012;44(4):228–235.
- 49. White K, Grossman D, Hopkins K, Potter JE. Cutting family planning in Texas. N Engl J Med 2012;367(13):1179-81.
- 50. Liang S-Y, Grossman D, Phillips K. User characteristics and out-of-pocket expenditures for progestin-only versus combined oral contraceptives. Contraception 2012;86(6):666-72.
- 51. Manski R, Dennis A, Blanchard K, Lince N, Grossman D. Bolstering the Evidence Base for Integrating Abortion and HIV Care: A Literature Review. AIDS Research and Treatment 2012 (2012), Article ID 802389. doi:10.1155/2012/802389.
- 52. Schwarz EB, Burch EJ, Parisi SM, Tebb KP, Grossman D, Mehrotra A, Gonzales R. Computer-assisted provision of hormonal contraception in acute care settings. Contraception 2013;87(2):242-50.
- 53. Grindlay K, Grossman D. Contraception access and use among U.S. servicewomen during deployment. Contraception 2013;87(2):162-9.
- 54. Grossman D, Grindlay K, Buchacker T, Potter JE, Schmertmann CP. Changes in service delivery patterns after introducing telemedicine provision of medical abortion in Iowa. Am J Public Health 2013;103(1):73-78.
- 55. Potter JE, Stevenson AJ, White K, Hopkins K, Grossman D. Hospital variation in postpartum tubal sterilization rates in California and Texas. Obstetrics and Gynecology 2013;121(1):152-8.
- 56. Grindlay K, Grossman D. Unintended Pregnancy Among Active Duty Women in the United States Military, 2008. Obstetrics and Gynecology 2013;121(2 Pt 1):241-6.

- 57. Hyman A, Blanchard K, Coeytaux F, Grossman D, Teixeira A. Misoprostol in women's hands: a harm reduction strategy for unsafe abortion. Contraception 2013;87(2):128-30.
- 58. Grindlay K, Grossman D, Lane K. Women's and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study. Women's Health Issues 2013;23(2):e117-22.
- Shedlin M, Amastae J, Potter J, Hopkins K, Grossman D. Knowledge & Beliefs about Reproductive Anatomy and Physiology among Mexican-Origin Women in the U.S.: Implications for Effective Oral Contraceptive Use. Cult Health Sex 2013;15(4):466-79.
- 60. Newmann SJ, Mishra K, Onono M, Bukusi E, Cohen CR, Gage O, Odeny R, Schwartz KD, Grossman D. Providers' perspectives on provision of family planning to HIV-positive individuals in HIV care in Nyanza Province, Kenya. AIDS Research and Treatment 2013;2013, Article ID 915923. http://dx.doi.org/10.1155/2013/915923.
- 61. Steinfeld R, Newmann SJ, Onono M, Cohen CR, Bukusi E, Grossman D. Overcoming Barriers to Family Planning through Integration: Perspectives of HIV-Positive Men in Nyanza Province, Kenya. AIDS Research and Treatment 2013;2013, Article ID 861983, http://dx.doi.org/10.1155/2013/861983.
- 62. Henderson JT, Puri M, Blum M, Harper CC, Rana A, Gurung G, Pradhan N, Regmi K, Malla K, Sharma S, Grossman D, Bajracharya L, Satyal I, Acharya S, Lamchhane P, Darney PD. Effects of Abortion Legalization in Nepal, 2001–2010. PLoS ONE 2013;8(5): e64775. doi:10.1371/journal.pone.0064775.
- 63. Grossman D. Moving oral contraceptives over the counter as a strategy to reduce unintended pregnancy. Annals of Internal Medicine 2013;158(11):839-40.
- 64. Committee on Practice Bulletins-Gynecology, American College of Obstetricians and Gynecologists, with Steinauer J, Jackson A, Grossman D. Practice Bulletin No 135: Second-trimester abortion. Obstet Gynecol 2013;121(6):1394-1406.
- 65. Foster DG, Biggs MA, Grossman D, Schwarz EB. Interest in a pericoital pill among women in family planning and abortion clinics. Contraception 2013;88(1):141-6.
- 66. White K, Hopkins K, Potter JE, Grossman D. Knowledge and attitudes about long-acting reversible contraception among Latina women who desire sterilization. Women's Health Issues 2013;23(4):e257-e263.
- 67. Grindlay K, Burns B, Grossman D. Prescription requirements and over-the-counter access to oral contraceptives: A global review. Contraception 2013;88(1):91-6.
- 68. McIntosh J, Wahlin B, Grindlay K, Batchelder M, Grossman D. Insurance and Access Implications of an Over-the-Counter Switch for a Progestin-Only Pill. Perspectives on Sexual and Reproductive Health 2013;45(3):164-9.
- 69. Grossman D, Grindlay K, Li R, Potter JE, Trussell J, Blanchard K. Interest in over-the-counter access to oral contraceptives among women in the United States. Contraception 2013;88(4):544-52.
- 70. Grossman D, Onono M, Newmann SJ, Blat C, Bukusi EA, Shade SB, Steinfeld RL, Cohen CR. Integration of family planning services into HIV care and treatment in Kenya: a cluster-randomized trial. AIDS 2013; 27(Suppl 1):S77-S85.
- 71. Shade SB, Kevany S, Onono M, Ochieng G, Steinfeld RL, Grossman D, Newmann SJ, Blat C, Bukusi EA, Cohen CR. Cost, Cost-efficiency and Cost-effectiveness of

- Integrated Family Planning and HIV Services in Nyanza, Kenya. AIDS 2013; 27(Suppl 1):S87-S92.
- 72. van Dijk MG, Lara Pineda D, Grossman D, Sorhaindo A, García SG. The Female Condom: A Promising but Unavailable Method for Dominican Sex Workers, Their Clients, and Their Partners. Journal of the Association of Nurses in AIDS Care 2013;24(6):521-9.
- 73. White K, Potter JE, Hopkins K, Amastae J, Grossman D. Hypertension among oral contraceptive users in El Paso, Texas. Journal of Health Care for the Poor and Underserved 2013;24(4):1511-21.
- 74. Withers M, Dworkin S, Harrington E, Kwena Z, Onono M, Bukusi E, Cohen CR, Grossman D, Newmann SJ. Fertility intentions among HIV-infected, sero-concordant Kenyan couples in Nyanza Province, Kenya. Cult Health Sex 2013;15(10):1175-90.
- 75. Newmann SJ, Grossman D, Blat C, Onono M, Steinfeld RL, Bukusi EA, Shade SB, Cohen CR. Does integrating family planning into HIV care and treatment impact intention to use contraception? Patient perspectives from HIV-infected individuals in Nyanza Province, Kenya. Int J Gynaecol Obstet 2013;123 Suppl 1:e16-23.
- 76. Grossman D, Fuentes L. Over-the-counter access to oral contraceptives as a reproductive healthcare strategy. Curr Opin Obstet Gynecol 2013;25(6):500-5.
- 77. White K, Potter JE, Hopkins K, Grossman D. Variation in postpartum contraceptive method use: Results from the Pregnancy Risk Assessment Monitoring System (PRAMS). Contraception 2014;89(1):57-62.
- 78. Burns B, Grindlay K, Holt K, Manski R, Grossman D. Military sexual trauma among U.S. servicewomen during deployment: A qualitative study. AJPH 2014;104:345-349.
- 79. Committee on Practice Bulletins-Gynecology, American College of Obstetricians and Gynecologists, with Creinin M, Grossman D. Practice Bulletin No 143: Medical management of first-trimester abortion. Obstet Gynecol 2014;123(3):676-92.
- 80. Wahlin B, Grindlay K, Grossman D. Should Oral Contraceptives Be Available Over the Counter? Food and Drug Policy Forum 2014; 4(3).
- 81. Constant D, Grossman D, Lince N, Harries J. Self-induction of abortion among women accessing second trimester abortion services in the public sector, Western Cape, South Africa: An exploratory study. South African Medical Journal 2014;104(4):302-305.
- 82. Onono M, Blat C, Miles S, Steinfeld R, Wekesa P, Bukusi EA, Owuor K, Grossman D, Cohen CR, Newmann SJ. Impact of family planning health talks by lay health workers on contraceptive knowledge and attitudes among HIV-infected patients in rural Kenya. Patient Educ Couns 2014;94(3):438-41.
- 83. Grossman D, White K, Hopkins K, Potter JE. The public health threat of anti-abortion legislation. Contraception 2014;89:73-4.
- 84. Foster DG, Grossman D, Turok DK, Peipert JF, Prine L, Schreiber CA, Jackson A, Barar R, Schwarz EB. Interest in and experience with IUD self-removal. Contraception 2014;90(1):54-9.
- 85. Manski R, Grindlay K, Burns B, Holt K, Grossman D. Reproductive health access among deployed U.S. servicewomen: a qualitative study. Military Medicine 2014;1179(6):645-52.
- 86. Grindlay K, Foster DG, Grossman D. Attitudes Toward Over-the-Counter Access to Oral Contraceptives Among a Sample of Abortion Clients in the United States. Perspect Sex Reprod Health 2014;46(2):83-9.

- 87. Grossman D, Constant D, Lince-Deroche N, Harries J, Kluge J. A randomized trial of misoprostol versus laminaria before dilation and evacuation in South Africa. Contraception 2014;90(3):234-41.
- 88. Patel R, Baum S, Grossman D, Steinfeld R, Onono M, Cohen CR, Bukusi EA, Newmann SJ. HIV-positive men's experiences with integrated family planning and HIV services in western Kenya: Integration fosters male involvement. AIDS Patient Care STDS 2014;28(8):418-24.
- 89. Blanchard K, Chipato T, Ramjee G, Nhemachena T, Harper CC, and the Provider Study Writing Committee (including Grossman D). Clinicians' perceptions and provision of hormonal contraceptives for HIV positive and at-risk women in Southern Africa: an original research article. Contraception 2014;90(4):391-8.
- 90. DePiñeres T, Baum S, Grossman D. Acceptability and clinical outcomes of first- and second-trimester surgical abortion by suction aspiration in Colombia. Contraception 2014;90(3):242-8.
- 91. Potter JE, Hopkins K, Aiken ARA, Hubert Lopez C, Stevenson AJ, White K, Grossman D. Unmet Demand for Highly Effective Postpartum Contraception in Texas. Contraception 2014;90(5):488-95.
- 92. Grossman D, Baum S, Fuentes L, White K, Hopkins K, Stevenson A, Potter JE. Change in abortion services after implementation of a restrictive law in Texas. Contraception 2014;90(5):496-501.
- 93. Raymond EG, Grossman D, Weaver MA, Toti S, Winikoff B. Mortality of induced abortion, other outpatient surgical procedures, and common activities in the United States. Contraception 2014;90(5):476-9.
- 94. Tao AR, Onono M, Baum S, Grossman D, Steinfeld R, Cohen CR, Bukusi EA, Newmann SJ. Providers' perspectives on male involvement in family planning in the context of family planning/HIV integration in Nyanza, Kenya. AIDS Care 2015;27(1):31-7.
- 95. Grindlay K, Grossman D. Women's perspectives on age restrictions for over-the-counter access to oral contraceptives in the United States. J Adolesc Health 2015;56(1):38-43.
- 96. Upadhyay UD, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of Emergency Department Visits and Complications After Abortion. Obstet Gynecol 2015;125(1):175-83.
- 97. Biggs MA, Rocca CH, Brindis CD, Hirsch H, Grossman, D. Did increasing use of highly effective contraception contribute to declining abortions in Iowa? Contraception 2015;91:167-73.
- 98. Lara D, Holt K, Pena M, Grossman D. Knowledge of abortion laws and services among low-income women in three United States cities. J Immigr Minor Health 2015;17(6):1811-8.
- 99. Hopkins K, White K, Linkin F, Hubert C, Grossman D, Potter JE. Women's Experiences Seeking Publicly Funded Family Planning Services in Texas. Perspect Sex Reprod Health 2015;47(2):63-70.
- 100. White K, Hopkins K, Aiken A, Stevenson A, Hubert C, Grossman D, Potter JE The impact of reproductive health legislation on family planning clinic services in Texas. AJPH 2015;105(5):851-8.
- 101. Foster DG, Biggs MA, Phillips KA, Grindlay K, Grossman D. Potential Public Sector Cost-Savings from Over-the-Counter Access to Oral Contraceptives. Contraception 2015;91(5):373-9.

- 102. Onono M, Guzé MA, Grossman D, Steinfeld R, Bukusi EA, Shade S, Cohen CR, Newmann SJ. Integrating family planning and HIV services in western Kenya: the impact on HIV-infected patients' knowledge of family planning and male attitudes toward family planning. AIDS Care 2015;27(6):743-52.
- 103. Withers M, Dworkin SL, Zakaras JM, Onono M, Oyier B, Cohen CR, Bukusi EA, Grossman D, Newmann SJ. 'Women now wear trousers': men's perceptions of family planning in the context of changing gender relations in western Kenya. Cult Health Sex 2015;17(9):1132-46.
- 104. Grossman D, White K, Harris L, Reeves M, Blumenthal PD, Winikoff B, Grimes DA. Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review. Contraception 2015;92:206-11.
- 105. Dennis A, Fuentes L, Douglas-Durham E, Grossman D. Barriers to and Facilitators of Moving Miscarriage Management Out of the Operating Room. Perspect Sex Reprod Health 2015;47(3):141-9.
- 106. Grossman D, Goldstone P. Mifepristone by prescription: a dream in the United States but reality in Australia. Contraception 2015;92:186-9.
- 107. Baum S, DePiñeres T, Grossman D. Delays and barriers to care in Colombia among women obtaining legal first- and second-trimester abortion. International Journal of Gynecology and Obstetrics 2015;131(3):285-8.
- 108. Lince-Deroche N, Constant D, Harries J, Blanchard K, Sinanovic E, Grossman D. The Costs of Accessing Abortion in South Africa: Women's costs associated with second-trimester abortion services in Western Cape Province. Contraception 2015;92(4):339-44.
- 109. Dzuba I, Grossman D, Schreiber CA. Off-label indications for mifepristone in gynecology and obstetrics. Contraception 2015;92:203-5.
- 110. Raymond EG, Grossman D, Wiebe E, Winikoff B. Reaching Women Where They Are: Eliminating The Initial In-Person Medical Abortion. Contraception 2015;92:190-3.
- 111. White K, Carroll E, Grossman D. Complications from first-trimester aspiration abortion: A systematic review of the literature. Contraception 2015; 92(5):422-38.
- 112. Grindlay K, Grossman D. Unintended Pregnancy among Active-Duty Women in the United States Military, 2011. Contraception 2015; 92(6):589-95.
- 113. Grossman D. Over-the-counter access to oral contraceptives. Obstetrics and Gynecology Clinics of North America 2015;42:619-29.
- 114. Newmann SJ, Zakaras JM, Tao AR, Onono M, Bukusi EA, Cohen CR, Steinfeld R, Grossman D. Integrating family planning into HIV care in western Kenya: HIV care providers' perspectives and experiences one year following integration. AIDS Care 2016; 28(2):209-13.
- 115. Potter JE, Hubert C, Stevenson AJ, Hopkins K, Aiken ARA, White K, Grossman D. Barriers to Postpartum Contraception in Texas and Pregnancy Within 2 Years of Delivery. Obstet Gynecol 2016;127:289–96.
- 116. Hubert C, White K, Hopkins K, Grossman D, Potter JE. Perceived interest in vasectomy among Latina women and their partners in a community with limited access to female sterilization. J Health Care Poor Underserved 2016; 27(2):762-77.
- 117. Baum S, Burns B, Davis L, Yeung M, Scott C, Grindlay K, Grossman D. Perspectives among a diverse sample of women on the possibility of obtaining oral contraceptives over the counter: A qualitative study. Women's Health Issues 2016;26(2):147-52.

- 118. Grindlay K, Grossman D. Prescription birth control access among U.S. women at risk of unintended pregnancy. J Womens Health (Larchmt) 2016;25(3):249-54.
- 119. Fuentes L, Lebenkoff S, White K, Gerdts C, Hopkins K, Potter JE, Grossman D. Women's experiences seeking abortion care shortly after the closure of clinics due to a restrictive law in Texas. Contraception 2016;93(4):292-7.
- 120. Newmann SJ, Rocca CH, Zakaras JM, Onono M, Bukusi EA, Grossman D, Cohen CR. Does Integrating Family Planning into HIV Services Improve Gender Equitable Attitudes? Results from a Cluster Randomized Trial in Nyanza, Kenya. AIDS Behav 2016;20(9):1883-92.
- 121. White K, deMartelly V, Grossman D, Turan JM. Experiences Accessing Abortion Care in Alabama among Women Traveling for Services. Women's Health Issues 2016;26(3):298-304.
- 122. White K, Potter JE, Stevenson A, Fuentes L, Hopkins K, Grossman D. Women's knowledge of and support for abortion restrictions in Texas: Findings from a statewide representative survey. Perspect Sex Reprod Health 2016;48(4):189-197.
- 123. Norris A, Harrington BJ, Grossman D, Hemed M, Hindin M. Abortion experiences among Zanzibari women: a chain-referral sampling study. Reprod Health 2016;13(1):23.
- 124. Gerdts C, Fuentes L, Grossman D, White K, Keefe-Oates B, Baum SE, Hopkins K, Stolp CW, Potter JE. Impact of Clinic Closures on Women Obtaining Abortion Services After Implementation of a Restrictive Law in Texas. Am J Public Health 2016;106(5):857-64.
- 125. Grossman D, Grindlay K, Burns B. Public funding for abortion where broadly legal. Contraception 2016;94(5):453-460.
- 126. Constant D, Harries J, Malaba T, Myer L, Patel M, Petro G, Grossman D. Clinical Outcomes and Women's Experiences before and after the Introduction of Mifepristone into Second-Trimester Medical Abortion Services in South Africa. PLoS One 2016;11(9):e0161843.
- 127. Grossman D, Goldstone P. Reply to: "Mifepristone by prescription: not quite a reality in Australia." Contraception 2016;94(4):379.
- 128. Dragoman MV, Grossman D, Kapp N, Nguyen MH, Habib N, Duong LD, Tamang A. Two prophylactic medication approaches in addition to a pain control regimen for early medical abortion <63 days' gestation with mifepristone and misoprostol: study protocol for a randomized, controlled trial. Reprod Health 2016;13(1):132.
- 129. Baum SE, White K, Hopkins K, Potter JE, Grossman D. Women's Experience Obtaining Abortion Care in Texas after Implementation of Restrictive Abortion Laws: A Qualitative Study. PLoS One 2016;11(10):e0165048.
- 130. Grindlay K, Grossman D. Telemedicine provision of medical abortion in Alaska: Through the provider's lens. J Telemed Telecare 2017;23(7):680-685.
- 131. Grossman D. The Use of Public Health Evidence in Whole Woman's Health v. Hellerstedt. JAMA Intern Med 2017;177(2):155-156.
- 132. Upadhya KK, Santelli JS, Raine-Bennett TR, Kottke MJ, Grossman D. Over-the-Counter Access to Oral Contraceptives for Adolescents. J Adolesc Health 2017;60(6):634-640.
- 133. Whitehouse KC, Kim CR, Ganatra B, Duffy JMN, Blum J, Brahmi D, Creinin MD, DePiñeres T, Gemzell-Danielsson K, Grossman D, Winikoff B, Gülmezoglu AM. Standardizing Abortion Research Outcomes (STAR): a protocol for developing,

- disseminating, and implementing a core outcome set for medical and surgical abortion. Contraception 2017;95(5):437-441.
- 134. White K, Campbell A, Hopkins K, Grossman D, Potter JE. Barriers to offering vasectomy at publicly funded family planning organizations in Texas. Am J Mens Health 2017;11(3):757-766.
- 135. Grossman D, White K, Hopkins K, Potter JE. Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014. JAMA 2017;317(4):437-439.
- 136. Mifeprex REMS Study Group., Raymond EG, Blanchard K, Blumenthal PD, Cleland K, Foster AM, Gold M, Grossman D, Pendergast MK, Westhoff CL, Winikoff B. Sixteen Years of Overregulation: Time to Unburden Mifeprex. N Engl J Med 2017;376(8):790-794.
- 137. Kapp N, Grossman D, Jackson E, Castleman L, Brahmi D. A research agenda for moving early medical pregnancy termination over the counter. BJOG 2017; 124(11):1646-1652.
- 138. Cohen CR, Grossman D, Onono M, Blat C, Newmann SJ, Burger RL, Shade SB, Bett N, Bukusi EA. Integration of family planning services into HIV care clinics: Results one year after a cluster randomized controlled trial in Kenya. PLoS One 2017;12(3):e0172992.
- 139. Potter JE, Coleman-Minahan K, White K, Powers DE, Dillaway C, Stevenson AJ, Hopkins K, Grossman D. Contraception After Delivery among Publicly Insured Women in Texas: Use compared with Preference. Obstet Gynecol 2017;130(2):393-402.
- 140. White K, Turan JM, Grossman D. Travel for Abortion Services in Alabama and Delays Obtaining Care. Womens Health Issues 2017;27(5):523-529.
- 141. Grossman D, Grindlay K. Safety of Medical Abortion Provided Through Telemedicine Compared With in Person. Obstet Gynecol 2017;130(4):778-782.
- 142. White K, Grossman D, Stevenson AJ, Hopkins K, Potter JE. Does information about abortion safety affect Texas voters' opinions about restrictive laws? A randomized study. Contraception 2017;96(6):381-387.
- 143. Grindlay KK, Seymour JW, Fix L, Reiger S, Keefe-Oates B, Grossman D. Abortion Knowledge and Experiences Among US Servicewomen: A Qualitative Study. Perspect Sex Reprod Health 2017;49(4):245-252.
- 144. Grossman D, Baum SE, Andjelic D, Tatum C, Torres G, Fuentes L, Friedman J. A harm-reduction model of abortion counseling about misoprostol use in Peru with telephone and in-person follow-up: A cohort study. PLoS One 2018;13(1):e0189195.
- 145. Rocca CH, Goodman S, Grossman D, Cadwallader K, Thompson KMJ, Talmont E, Speidel JJ, Harper CC. Contraception after medication abortion in the United States: results from a cluster randomized trial. Am J Obstet Gynecol 2018;218(1):107.e1-107.e8.
- 146. Rocca CH, Puri M, Shrestha P, Blum M, Maharjan D, Grossman D, Regmi K, Darney PD, Harper CC. Effectiveness and safety of early medication abortion provided in pharmacies by auxiliary nurse-midwives: A non-inferiority study in Nepal. PLoS One 2018;13(1):e0191174.
- 147. White K, Hopkins K, Grossman D, Potter JE. Providing family planning services at primary care organizations after the exclusion of Planned Parenthood from publicly funded programs in Texas: early qualitative evidence. Health Services Research 2018;53 Suppl 1:2770-2786.

- 148. Grindlay KK, Grossman D. Interest in over-the-counter access to a progestin-only pill among women in the United States. Women's Health Issues 2018;28(2):144-151.
- 149. Vu K, Rafie S, Grindlay K, Gutierrez H, Grossman D. Pharmacist Intentions to Prescribe Hormonal Contraception Following New Legislative Authority in California. Journal of Pharmacy Practice 2019;32(1):54-61.
- 150. Hopkins K, Hubert C, Coleman-Minahan K, Stevenson AJ, White K, Grossman D, Potter JE. Unmet demand for short-acting hormonal and long-acting reversible contraception among community college students in Texas. Journal of American College Health 2018;66(5):360-8.
- 151. Lince-Deroche N, Harries J, Constant D, Morroni C, Pleaner M, Fetters T, Grossman D, Blanchard K, Sinanovic E. Doing more for less: Identifying opportunities to expand public sector access to safe abortion in South Africa through budget impact analysis. Contraception 2018;97(2):167-176.
- 152. Raifman S, Anderson P, Kaller S, Tober D, Grossman D. Evaluating the capacity of California's publicly-funded universities to provide medication abortion. Contraception 2018;98(4):306-311.
- 153. Raifman S, Orlando M, Rafie S, Grossman D. Medication abortion: Potential for improved patient access through pharmacies. J Am Pharm Assoc (2003) 2018;58(4):377-381.
- 154. Lince-Deroche N, Constant D, Harries J, Kluge J, Blanchard K, Sinanovic E, Grossman D. The costs and cost effectiveness of providing second-trimester medical and surgical safe abortion services in Western Cape Province, South Africa. PLoS ONE 2018;13(6):e0197485.
- 155. Grossman D and White K. Abortion "Reversal" Legislating without Evidence. N Eng J Med 2018;379(16):1491-3.
- 156. Biggs MA, Ralph L, Raifman S, Foster DG, Grossman D. Support for and interest in alternative models of medication abortion provision among a national probability sample of U.S. women. Contraception 2019;99(2):118-124.
- 157. Seymour JW, Fix L, Grossman D, Grindlay K. Facilitators and Barriers to Contraceptive Use Among U.S. Servicewomen Who Had an Abortion. Mil Med 2019;184(5-6):e417-e423.
- 158. Zuniga C, Grossman D, Harrell S, Blanchard K, Grindlay K. Breaking down barriers to birth control access: An assessment of online platforms prescribing birth control in the USA. J Telemed Telecare 2020;26(6):322-331.
- 159. Grossman D, Grindlay K, Altshuler AL, Schulkin J. Induced Abortion Provision Among a National Sample of Obstetrician—Gynecologists. Obstet Gynecol 2019;133:477–83.
- 160. Baum SE, White K, Hopkins K, Potter JE, Grossman D. Rebound of medication abortion in Texas following updated mifepristone label. Contraception 2019;99(5):278-280.
- 161. Potter JE, Stevenson AJ, Coleman-Minahan K, Hopkins K, White K, Baum SE, Grossman D. Challenging unintended pregnancy as an Indicator of reproductive autonomy. Contraception 2019;100(1):1-4.
- 162. White K, Baum SE, Hopkins K, Potter JE, Grossman D. Change in Second-Trimester Abortion After Implementation of a Restrictive State Law. Obstet Gynecol 2019;133:771-9.
- 163. Mark A, Foster AM, Grossman D, Prager SW, Reeves M, Velásquez CV, Winikoff B. Foregoing Rh testing and anti-D immunoglobulin for women presenting for early

- abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception 2019;99(5):265-266.
- 164. Castleberry NM, Stark L, Schulkin J, Grossman D. Implementing best practices for the provision of long-acting reversible contraception: a survey of obstetrician-gynecologists. Contraception 2019;100(2):123-127.
- 165. Constant D, Kluge J, Harries J, Grossman D. An analysis of delays among women accessing second-trimester abortion in the public sector in South Africa. Contraception 2019;100(3):209-213.
- 166. Ehrenreich K, Kaller S, Raifman S, Grossman D. Women's Experiences Using Telemedicine to Attend Abortion Information Visits in Utah: A Qualitative Study. Womens Health Issues 2019;29(5):407-413.
- 167. Ralph LJ, Schwarz EB, Grossman D, Foster DG. Self-reported Physical Health of Women Who Did and Did Not Terminate Pregnancy After Seeking Abortion Services: A Cohort Study. Ann Intern Med 2019;171(4):238-247.
- 168. Kohn JE, Snow JL, Simons HR, Seymour JW, Thompson TA, Grossman D. Safety and effectiveness of medication abortion provided via telemedicine in four U.S. states. Obstet Gynecol 2019;134(2):343-350.
- 169. Grossman D. Expanding Access to Short-Acting Hormonal Contraceptive Methods in the United States. JAMA Intern Med 2019;179(9):1209-10.
- 170. Upadhyay UD, Grossman D. Telemedicine for medication abortion. Contraception 2019;100(5):351-353.
- 171. Moseson H, Filippa S, Baum SE, Gerdts C, Grossman D. Reducing underreporting of stigmatized pregnancy outcomes: results from a mixed-methods study of self-managed abortion in Texas using the list-experiment method. BMC Womens Health 2019;19(1):113.
- 172. Grossman D, Raifman S, Bessenaar T, Duong LD, Tamang A, Dragoman MV. Experiences with pain of early medical abortion: qualitative results from Nepal, South Africa, and Vietnam. BMC Womens Health 2019;19(1):118.
- 173. Ehrenreich K, Kriz R, Grossman D. Miscarriage information available on the internet: A content analysis of leading consumer websites. Contraception: X 2019;1:100010. https://doi.org/10.1016/j.conx.2019.100010.
- 174. Biggs MA, Casas L, Ramm A, Baba CF, Correa SV, Grossman D. Future health providers' willingness to provide abortion services following decriminalization of abortion in Chile: a cross-sectional survey. BMJ Open 2019;9(10):e030797.
- 175. Daniel S, Raifman S, Kaller S, Grossman D. Characteristics of patients having telemedicine versus in-person informed consent visits before abortion in Utah. Contraception 2020;101(1):56-61.
- 176. Fix L, Seymour JW, Grossman D, Johnson DM, Aiken ARA, Gomperts R, Grindlay K. Abortion Need among U.S. Servicewomen: Evidence from an Internet Service. Womens Health Issues 2020;30(3):161-166.
- 177. Fuentes L, Baum S, Keefe-Oates B, White K, Hopkins K, Potter J, Grossman D. Texas women's decisions and experiences regarding self-managed abortion. BMC Womens Health 2020;20(1):6.
- 178. DeNicola N, Grossman D, Marko K, Sonalkar S, Butler Tobah YS, Ganju N, Witkop CT, Henderson JT, Butler JL, Lowery C. Telehealth Interventions to Improve Obstetric and Gynecologic Health Outcomes: A Systematic Review. Obstet Gynecol 2020;135(2):371-382.

- 179. Mark A, Grossman D, Foster AM, Prager SW, Winikoff B. When Patients Change Their Minds After Starting an Abortion: Guidance from the National Abortion Federation's Clinical Policies Committee. Contraception 2020;101(5):283–5.
- 180. Harris LH, Grossman D. Complications of Unsafe and Self-Managed Abortion. N Engl J Med 2020;382(11):1029-1040.
- 181. Raymond EG, Grossman D, Mark A, Upadhyay UD, Dean G, Creinin MD, Coplon L, Perritt J, Atrio JM, Taylor D, Gold M. No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond. Contraception 2020;101(6):361-366.
- 182. Thompson TA, Sonalkar S, Butler J, Grossman D. Telemedicine for family planning: a scoping review. Obstet Gynecol Clin North Am 2020;47(2):287-316.
- 183. Wollum A, Trussell J, Grossman D, Grindlay K. Modeling the Impacts of Price of an Over-the-Counter Progestin-Only Pill on Use and Unintended Pregnancy among U.S. Women. Womens Health Issues 2020;30(3):153-160.
- 184. Wingo E, Raifman S, Landau C, Sella S, Grossman D. Mifepristone-misoprostol versus misoprostol-alone regimen for medication abortion at ≥24 weeks' gestation. Contraception 2020;102(2):99-103.
- 185. Seymour J, Fix L, Grossman D, Grindlay K. Pregnancy and abortion: Experiences and attitudes of deployed U.S. servicewomen. Mil Med 2020;185(9-10):e1390.
- 186. Daniel S, Schulkin J, Grossman D. Abortion Referral Practices among a National Sample of Obstetrician-Gynecologists. Womens Health Issues 2020;30(6):446-452.
- 187. Castleberry NM, Stark L, Schulkin J, Grossman D. Oral and IUD emergency contraception provision among a national sample of obstetrician-gynecologists. Contraception 2020;102(6):406-408.
- 188. Creinin MD, Grossman DA; Committee on Practice Bulletins—Gynecology; Society of Family Planning. Medication Abortion Up to 70 Days of Gestation. Obstet Gynecol 2020;136(4):e31-e47.
- 189. Wollum A, Zuniga C, Lezama N, Grossman D, Grindlay K. A randomized study evaluating the effect of evidence-based information on clinician attitudes about moving oral contraceptives over the counter. J Womens Health (Larchmt) 2021;30(11):1626-36.
- 190. Ralph L, Foster DG, Raifman S, Biggs MA, Samari G, Upadhyay U, Gerdts C, Grossman D. Prevalence of self-managed abortion among women of reproductive age in the United States. JAMA Netw Open 2020;3(12):e2029245.
- 191. Seymour J, Fix L, Grossman D, Grindlay K. Contraceptive use and access among deployed servicewomen: Findings from an online survey. BMJ Sex Reprod Health 2021;47(1):61-66.
- 192. White K, Kumar B, Goyal V, Wallace R, Roberts SCM, Grossman D. Changes in abortion in Texas following an executive order ban during the coronavirus pandemic. JAMA 2021;325(7):691-693.
- 193. Dragoman MV, Grossman D, Nguyen MH, Habib N, Kapp N, Tamang A, Bessenaar T, Duong LD, Gautam J, Yoko J-L, Hong M, Gulmezoglu M. Two prophylactic pain management regimens for medical abortion ≤63 days' gestation with mifepristone and misoprostol: a multicenter, randomized, placebo-controlled trial. Contraception 2021;103(3):163-170.
- 194. Grindlay K, Wollum A, Karver J, Grossman D. Over-the-counter oral contraceptive use among women in Mexico: Results from a national survey. BMJ Sex Reprod Health 2021;47(3):205-210.

- 195. Kohn JE, Snow JL, Grossman D, Thompson T-A, Seymour JW, Simons HR. Introduction of telemedicine for medication abortion: changes in service delivery patterns in two U.S. states. Contraception 2021;103(3):151-156.
- 196. Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, Gurazada T, Rafie S, Averbach S, Meckstroth KR, Micks EA, Berry E, Raine-Bennett TR, Creinin MD. Medication abortion with pharmacist dispensing of mifepristone. Obstet Gynecol 2021;137(4):613-622.
- 197. Constant D, Endler M, Grossman D, Petro G, Patel M. Immediate versus delayed insertion of the copper IUD after medical abortion at 17-20 gestational weeks: a randomized controlled trial. BMJ Sex Reprod Health 2022;48:28–34
- 198. Coleman-Minahan K, Ela EJ, White K, Grossman D. Contraindications to hormonal contraception among postpartum women in Texas. Obstet Gynecol 2021;137(5):907-915.
- 199. Kaller S, Daniel S, Raifman S, Biggs MA, Grossman D. Pre-abortion informed consent through telemedicine vs. in person: differences in patient demographics and visit satisfaction. Womens Health Issues 2021;31(3):227-235.
- 200. Raifman S, Baum SE, White K, Hopkins K, Ogburn T, Grossman D. Perspectives on self-managed abortion among providers in hospitals along the Texas-Mexico border. BMC Womens Health 2021;21(1):132.
- 201. Roberts SCM, Berglas NF, Schroeder R, Lingwall M, Grossman D, White K. Disruptions to abortion care in Louisiana during early months of the COVID-19 pandemic. Am J Public Health 2021;111(8):1504-12.
- 202. Raifman S, Sierra G, Grossman D, Baum SE, Hopkins K, Potter JE, White K. Border-state abortions increased for Texas residents after House Bill 2. Contraception 2021;104(3):314-8.
- 203. Daniel S, Schulkin J, Grossman D. Obstetrician-gynecologist willingness to provide medication abortion with removal of the in-person dispensing requirement for mifepristone. Contraception 2021;104(1):73-76.
- 204. Raifman S, Biggs MA, Ralph L, Ehrenreich K, Grossman D. Exploring Attitudes About the Legality of Self-Managed Abortion in the US: Results from a Nationally Representative Survey. Sexuality Research and Social Policy 2021. Doi: https://doi.org/10.1007/s13178-021-00572-z.
- 205. Raifman S, Ralph L, Biggs MA, Grossman D. "I'll just deal with this on my own": A qualitative exploration of experiences with self-managed abortion in the United States. Reprod Health 2021;18(1):91.
- 206. Constant D, Castro Lopes S, Grossman D. Could routine pregnancy self-testing facilitate earlier recognition of unintended pregnancy? A feasibility study among South African women. BMJ Sex Reprod Health 2022;48(e1):e60-e66.
- 207. Potter JE, Burke KL, Broussard K, Hopkins K, Grossman D, White K. Improving Assessment of Demand for Postpartum Tubal Ligation among Publicly Insured Women in Texas. Contraception 2021;104(5):518-523.
- 208. Dickman SL, White K, Grossman D. Affordability and Access to Abortion Care in the United States. JAMA Intern Med 2021;181(9):1157-8.
- 209. Kaller S, Morris N, Biggs MA, Baba CF, Rafie S, Raine-Bennett TR, Creinin MD, Berry E, Micks EA, Meckstroth KR, Averbach S, Grossman D. Pharmacists' knowledge, perspectives, and experiences with mifepristone dispensing for medication abortion. J Am Pharm Assoc (2003) 2021;61(6):785-794.e1.

- 210. Whitehouse KC, Stifani BM, Duffy JMN, Kim CR, Creinin MD, DePiñeres T, Winikoff B, Gemzell-Danielsson K, Blum J, Bracey Sherman R, Lavelanet AF, Brahmi D, Grossman D, Tamang A, Gebreselassie H, Gomez Ponce de Leon R, Ganatra B. Standardizing abortion research outcomes (STAR): results from an international consensus development study. Contraception 2021;104(5):484-491.
- 211. Ehrenreich K, Biggs MA, Grossman D. Making the case for advance provision of mifepristone and misoprostol for abortion in the United States. BMJ Sex Reprod Health 2022;48(4):238-42.
- 212. Thompson T-A, Seymour J, Melville C, Khan Z, Mazza D, Grossman D. An observational study of patient experiences with a direct-to-patient telehealth abortion model in Australia. BMJ Sex Reprod Health 2022;48(2):103-109.
- 213. Grossman D, Raifman S, Morris N, Arena A, Bachrach L, Beaman J, Biggs MA, Hannum C, Ho S, Schwarz EB, Gold M. Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment. Contraception 2022;107:36-41.
- 214. Upadhyay UD, Cartwright AF, Grossman D. Barriers to abortion care and incidence of attempted self-managed abortion among individuals searching Google for abortion care: A national prospective study. Contraception 2022;106:49-56.
- 215. Adams M, Kully G, Tilford S, White K, Mody S, Hildebrand M, Johns N, Grossman D, Averbach S. Time from first clinical contact to abortion in Texas and California. Contraception 2022;110:76-80.
- 216. Dickman SL, White K, Sierra G, Grossman D. Financial Hardships Caused by Out-of-Pocket Abortion Costs in Texas, 2018. Am J Public Health 2022;112(5):758-761.
- 217. Ralph LJ, Ehrenreich K, Barar R, Biggs MA, Morris N, Blanchard K, Kapp N, Moayedi G, Perritt J, Raymond EG, White K, Grossman D. Accuracy of self-assessment of gestational duration among people seeking abortion. Am J Obstet Gynecol 2022;226(5):710.e1-710.e21.
- 218. Biggs MA, Ralph L, Morris N, Ehrenreich K, Perritt J, Kapp N, Blanchard K, White K, Barar R, Grossman D. A cross-sectional survey of U.S. abortion patients' interest in obtaining medication abortion over the counter. Contraception 2022;109:25-31.
- 219. Biggs MA, Ehrenreich K, Morris N, Blanchard K, Bustamante CK, Choimorrow SY, Hauser D, Hernandez Y, Kapp N, Kromenaker T, Moayedi G, Perritt JB, Ralph L, Raymond E, Valladares ES, White K, Grossman D. Comprehension of an over-the-counter drug facts label prototype for a mifepristone and misoprostol medication abortion product. Obstet Gynecol 2022;139(6):1111-22.
- 220. Seymour JW, Melville C, Thompson TA, Grossman D. Effectiveness and safety of a direct-to-patient telehealth service providing medication abortion targeted at rural and remote populations: Cross-sectional findings from Marie Stopes Australia. Contraception 2022;115:67-68.
- 221. Kaller S, Ma M, Gurazada T, Baba CF, Rafie S, Raine-Bennett T, Averbach S, Chen M, Berry E, Meckstroth KR, Grossman D. "No Big Deal": A Qualitative Study of Pharmacists' Perspectives on Dispensing Mifepristone for Medication Abortion. Womens Health Issues 2022;32(6):571-7.
- 222. Wollum A, Zuniga C, Grindlay K, Grossman D. Who Accesses Birth Control Online? An Analysis of Requests for Contraception Submitted to an Online Prescribing Platform in the United States. Womens Health Issues 2023;33(1):25-35.

- 223. Ruggiero SP, Seymour JW, Thompson TA, Kohn JE, Snow JL, Grossman D, Fix L. Patient and provider experiences using a site-to-site telehealth model for medication abortion. Mhealth 2022;8:32.
- 224. Endler M, Petro G, Gemzell Danielsson K, Grossman D, Gomperts R, Weinryb M, Constant D. A telemedicine model for abortion in South Africa: a randomised, controlled, non-inferiority trial. Lancet 2022;400(10353):670-9.
- 225. Verma N, Goyal V, Grossman D, Perritt J, Shih G. Society of Family Planning interim clinical recommendations: Self-managed abortion. SFP 2022. https://doi.org/10.46621/ZRDX9581.
- 226. Grindlay Kelly K, Seymour J, Fix L, Grossman D. Unintended pregnancy and abortion in the US Navy, 2016. J Gen Intern Med 2022;37(Suppl 3):679-684.
- 227. Biggs MA, Serrano S, Valladares ES, Grossman D. Development of a Spanish-language drug facts label prototype for a combination mifepristone and misoprostol medication abortion product. Contraception 2023;118:109906.
- 228. Grindlay K, Key K, Zuniga C, Wollum A, Grossman D, Blanchard K. Experiences using a progestin-only pill in an over-the-counter environment in the United States: a cross-sectional survey. BMJ Sex Reprod Health 2023;49(1):27-34.
- 229. Grindlay K, Key K, Bradford RD, Amato C, Blanchard K, Grossman D. Pilot label comprehension study for an over-the-counter combined oral contraceptive pill in the United States. Perspect Sex Reprod Health 2023;55(1):28-37.
- 230. Grindlay K, Key K, Zuniga C, Wollum A, Blanchard K, Grossman D. Interest in continued use after participation in a study of over-the-counter progestin-only pills in the United States. Women's Health Reports 2022;3(1):904-914.
- 231. Baum SE, Sierra G, Grossman D, Vizcarra E, Potter JE, White K. Comparing preference for and use of medication abortion in Texas after policy changes in 2014 and 2018. Contraception 2023;119:109912.
- 232. Morris N, Ehrenreich K, Gurazada T, Grossman D. Feasibility and Acceptability of At-Home Routine Pregnancy Testing in the United States: A Pilot Study. Womens Health Issues 2023;33(3):258-65.
- 233. Sierra G, Berglas NF, Hofler LG, Grossman D, Roberts SCM, White K. Out-of-State Travel for Abortion among Texas Residents following an Executive Order Suspending In-State Services during the Coronavirus Pandemic. Int J Environ Res Public Health 2023;20(4):3679.
- 234. Raymond EG, Mark A, Grossman D, Beasley A, Brandi K, Castle J, Creinin MD, Gerdts C, Gil L, Grant M, Lockley A, Perritt J, Shochet T, Truan D, Upadhyay UD. Medication abortion with misoprostol-only: A sample protocol. Contraception 2023;121:109998.
- 235. Roberts SCM, Zaugg C, Grossman D. Health care provider reporting practices related to self-managed abortion. BMC Womens Health 2023;23(1):136.
- 236. Ehrenreich K, Baba CF, Raifman S, Grossman D. Perspectives on Alternative Models of Medication Abortion Provision Among Abortion Patients in the United States. Womens Health Issues 2023;33(5):481-8.
- 237. Ralph L, Biggs MA, Ehrenreich K, Grossman D. Accuracy of Self-assessment of Gestational Duration Among Adolescents Seeking Abortion Using Information in Addition to Date of Last Menstrual Period. JAMA Pediatr 2023;177(6):642-644.
- 238. Biggs MA, Becker A, Schroeder R, Kaller S, Scott K, Grossman D, Raifman S, Ralph L. Support for criminalization of self-managed abortion (SMA): A national representative survey. Soc Sci Med 2024;340:116433.

- 239. Grossman D, Raifman S, Morris N, Arena A, Bachrach L, Beaman J, Biggs MA, Collins A, Hannum C, Ho S, Seibold-Simpson SM, Sobota M, Tocce K, Schwarz EB, Gold M. Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person screening. In press at JAMA Internal Medicine.
- 240. Morris N, Baba F, Biggs MA, Grossman D. Interest in and support for alternative models of medication abortion provision among patients seeking abortion in the U.S. In press at Women's Health Issues.
- 241. Kapp N, Romero M, Dupte S, Shaber A, Grossman D. Comprehensive Abortion Care. In press at Oxford Encyclopedia of Sexual and Reproductive Health.
- 242. Filippa S, Jayaweera RT, Blanchard K, Grossman D. Do miscarriage care practice recommendations align with individuals' needs?: a scoping review. In press at Contraception.

NON-PEER REVIEWED PUBLICATIONS

Review articles and commentaries

- 1. Weitz T, Foster A, Ellertson C, Grossman D, Stewart F. "Medical" and "surgical" abortion: rethinking the modifiers. Contraception 2004; 69(1):77-8.
- 2. Levin C, Grossman D, Garcia SG. Unsafe abortion costs in Mexico City. In: Institute of Development Studies. id2 health focus: unsafe abortion. 2007.
- 3. Grossman D. Should oral contraceptives be sold over-the-counter? Yes. Contemporary OB/GYN 2008;53(9):63-73.
- 4. Goodman S, Gordon R, Eckhardt C, Osborne S, Grossman D, Spiedel JJ. Beyond education and training: making change stick. Contraception 2009;79(5):331-3.
- 5. Grossman D. Over-the-counter access to oral contraceptives. Expert Review of Obstetrics and Gynecology 2011; 6(5):501-8.
- 6. Grossman D. Should women have over-the-counter access to oral contraceptive pills? Expert Review of Obstetrics and Gynecology 2013; 8(5):389–391.
- 7. Grossman D. The potential impact of over-the-counter access to oral contraceptives to reduce unintended pregnancy. American Family Physician 2015;92(11):968-9.
- 8. Grossman D. Sexual and reproductive health under the Trump presidency: policy change threatens women in the USA and worldwide. J Fam Plann Reprod Health Care 2017;43(2):89-91.
- 9. Grossman D. Telemedicine for medical abortion Time to move toward broad implementation. BJOG 2019;126(9):1103.
- 10. ACOG Committee on Health Care for Underserved Women, Grossman D. Increasing Access to Abortion: ACOG Committee Opinion, Number 815. Obstet Gynecol 2020;136(6):e107-e115.
- 11. Perritt J, Grossman D. The Health Consequences of Restrictive Abortion Laws. JAMA Intern Med 2021;181(5):713-714.
- 12. Grossman D, Perritt J, Grady D. The Impending Crisis of Access to Safe Abortion Care in the US. JAMA Intern Med 2022;182(8):793-5.
- 13. Grossman D. Telemedicine Provision of Medication Abortion. Am J Public Health 2022;112(9):1282-3.
- 14. Grossman D, Verma N. Self-managed Abortion in the US. JAMA 2022;328(17):1693-1694. doi: 10.1001/jama.2022.19057.
- 15. Verma N, Grossman D. Self-managed Abortion in the United States. Curr Obstet Gynecol Rep 2023. https://link.springer.com/article/10.1007/s13669-023-00354-x.

Book and chapters

- 1. Grossman D, Díaz Olavarrieta C. "Manejo del dolor en la atención posaborto (Pain management in the post-abortion care setting)." In: Billings DL, Vernon R, editors. Avances en la atención posaborto en América Latina y el Caribe: Investigando, aplicando y expandiendo. Mexico City: The Population Council, 2007.
- 2. Lafaurie MM, Grossman D, Troncoso E, Billings DL, Chávez S, Maira G, Martinez I, Mora M, Ortiz O. "El aborto con medicamentos en América Latina: Las experiencias de las mujeres en México, Colombia, Ecuador y Perú." Bogota, 2005.
- 3. Amastae J, Shedlin M, White K, Hopkins K, Grossman DA, Potter JE. "Lessons for Border Research: The Border Contraceptive Access Study." In: Ochoa O'Leary A, Deeds CM, and Whiteford S, editors. *Uncharted Terrains: New Directions in Border Research Methodology, Ethics, and Practice.* Tucson, AZ: The University of Arizona Press, 2013. p. 249-64.
- 4. Wiebe E and Grossman D. "Telemedicine." In: Rowlands S, editor. *Abortion Care*. Cambridge: Cambridge University Press, 2014. p. 227-35.
- 5. Winikoff B and Grossman D. "Contraception." In: Goldman L, Schafer AI, editors. Goldman-Cecil Medicine, 25th edition. Philadelphia: Elsevier Saunders, 2015. p. 1604-10.
- 6. Casas Isaza X, Cabrera O, Reingold R, Grossman D. Stolen Lives: A multi-country study on the health effects of forced motherhood on girls 9-14 years old. New York, NY: Planned Parenthood Global, 2015.
- 7. Raymond E and Grossman D. "Progestin-only pills." In: Hatcher RA, et al., eds. *Contraceptive Technology*, 21st edition. New York, NY: Ayer Company Publishers, Inc., 2018. p. 317-28.
- 8. Winikoff B and Grossman D. "Contraception." In: Goldman L, Schafer AI, editors. *Goldman-Cecil Medicine*, 26th edition. Philadelphia: Elsevier, 2020. p. 1568-75.
- 9. Grossman D. Introduction to: Banish R. Focus on Abortion: Americans Share their Stories. New York, NY: Skyhorse Publishing, 2021. P. xiii-xvi.
- 10. Winikoff B and Grossman D. "Contraception." In: Goldman L, Cooney KA, editors. Goldman-Cecil Medicine, 27th edition. Philadelphia: Elsevier, 2024. p. 1610-17.

Other publications

- 1. Grossman D. Medical methods for first trimester abortion: RHL commentary (last revised: 3 September 2004). The WHO Reproductive Health Library, No 8, Update Software Ltd, Oxford, 2005. Excerpt available at: http://www.rhlibrary.com/Commentaries/htm/Dgcom.htm.
- 2. Grossman D. Medical methods for first trimester abortion: RHL practical aspects (last revised: 3 September 2004). The WHO Reproductive Health Library, No 8, Update Software Ltd, Oxford, 2005.
- 3. Potter JE and Grossman D. Make birth control available to immigrants. Op-ed in the Austin Statesman 2010. Available at http://www.statesman.com/opinion/potter-grossman-make-birth-control-available-to-immigrants-896651.html.
- 4. Grossman D. Female active duty soldiers face many barriers to care. RH Reality Check 2010. Available at:

 http://www.shreelitysheek.org/blog/2010/12/08/study-female-active-duty-soldiers.
 - http://www.rhrealitycheck.org/blog/2010/12/08/study-female-active-duty-soldiers-face-many-barriers-care.

- 5. Grossman D. Making mifepristone available and accessible in Latin America. International Consortium for Medical Abortion newsletter. January 2011; 4:3.
- 6. Wahlin B, Chin KK, Dawes Gay E, Grossman D, McGuire KI, Taylor-McGhee B, Scott C. VIEWPOINT: Why birth control needs to be both over the counter and on your insurance plan. ThinkProgress 2013. Available at http://thinkprogress.org/health/2013/04/30/1934631/viewpoint-birth-control-otc/?mobile=nc.
- 7. Raymond E, Grossman D. Dealing with breast cancer (2 letters). Letter to the Editor, New York Times, June 3, 2013. Available at http://www.nytimes.com/2013/06/04/science/dealing-with-breast-cancer-2-letters. http://www.nytimes.com/2013/06/04/science/dealing-with-breast-cancer-2-letters.
- 8. Cockrill K., Herold, S., Blanchard, K., Grossman, D., Upadhyay, U., Baum S. (2013). Addressing Abortion Stigma Through Service Delivery: A White Paper. Retrieved from Ibis Reproductive Health:

 http://www.ibisreproductivehealth.org/publications/addressing-abortion-stigma-through-service-delivery-white-paper.
- 9. Blanchard K, Grossman D, Wahlin B. The real way to improve contraceptive access. The Hill, July 30, 2014. Available at http://thehill.com/blogs/congress-blog/healthcare/213716-the-real-way-to-improve-contraceptive-access.
- 10. Grossman D. In the Obamacare birth-control debate, there's a logical path. Op-ed in the Los Angeles Times, October 18, 2014. Available at http://www.latimes.com/opinion/op-ed/la-oe-grossman-contraceptives-midterm-over-the-cou-20141020-story.html.
- 11. Grossman D. Birth control pills should not be prescription-only. Op-ed in the Los Angeles Times, June 19, 2015. Available at http://www.latimes.com/opinion/op-ed/la-oe-grossman-otc-birth-control-pills-20150619-story.html.
- 12. Grossman D. How do you make a safe abortion safer? RH Reality Check 2015. Available at
 - http://rhrealitycheck.org/article/2015/06/30/make-safe-abortion-safer/.
- 13. Grossman D. Hampering this safe abortion method is cruel and wrong. Newsweek, September 28, 2015. Available at http://www.newsweek.com/hampering-safe-abortion-method-cruel-and-wrong-377 638.
- 14. Texas Policy Evaluation Project. Abortion wait times in Texas (Research brief). November 25, 2015. http://sites.utexas.edu/txpep/files/2016/01/Abortion Wait Time Brief.pdf.
- 15. Texas Policy Evaluation Project. Knowledge, opinion and experience related to abortion self-induction in Texas (Research brief). November 25, 2015. http://liberalarts.utexas.edu/txpep/files/pdf/TxPEP-Research-Brief-KnowledgeOpinionExperience.pdf.
- 16. Texas Policy Evaluation Project. Texas women's experiences attempting self-induced abortion in Texas (Research brief). November 25, 2015. http://liberalarts.utexas.edu/txpep/files/pdf/TxPEP-Research-Brief-WomensExperiences.pdf.
- 17. Grossman D. The new face of sélf-induced abortion in Texas and beyond. Houston Chronicle, January 21, 2016. Available at

- http://www.houstonchronicle.com/opinion/outlook/article/Grossman-The-new-face-of-self-induced-abortion-6775378.php?t=3d6d5c30c9438d9cbb&cmpid=twitter-premium.
- 18. Texas Policy Evaluation Project. Change in number of physicians providing abortion care in Texas after HB2 (Research brief). February 29, 2016.

 http://liberalarts.utexas.edu/txpep/research-briefs/admitting-privileges-research-brief.php.
- 19. Grossman D. Whole Woman's Health v. Hellerstedt. Quantifying The Case's Potential Impact On Abortion Access And Women's Health. Health Affairs Blog, March 1, 2016. Available at http://bealthaffairs.org/blog/2016/03/01/whole-womans-health-v-hellerstedt-quantifying-the-cases-potential-impact-on-abortion/.
- 20. Grossman D. The sudden slump in abortions in Texas explained. Newsweek, April 7, 2016. Available at http://www.newsweek.com/sudden-slump-abortions-texas-explained-444351.
- 21. Grossman D. El aborto en el segundo trimestre. Red de acceso al aborto seguro Argentina. Available at http://www.clacaidigital.info:8080/xmlui/bitstream/handle/123456789/834/Doc5-REDAAS-2016 Grossman.pdf?sequence=1&isAllowed=v.
- 22. Grossman D. State's 'Woman's Right To Know' booklet is lacking evidence. Austin American-Statesman, August 5, 2016. Available at:

 http://www.mystatesman.com/news/news/opinion/grossman-states-womans-right-to-know-booklet-is-la/nr9iZ/.
- 23. Grossman D and Joffe C. Zika and the military. Letter to the editor, New York Times, August 15, 2016. Available at: http://www.nytimes.com/2016/08/16/opinion/zika-and-the-military.html?r=0.
- 24. Grossman D. Give Women Their Reproductive Revolution: It's long past time to remove the FDA's unscientific restrictions on the abortion pill. US News & World Report, September 30, 2016. Available at:

 http://www.usnews.com/opinion/articles/2016-09-30/its-long-past-time-to-remove-abortion-pill-restrictions.
- 25. Grossman D. Trump is wrong on abortion and Roe v. Wade. USA Today, January 22, 2017.
 - http://www.usatoday.com/story/opinion/2017/01/22/trump-wrong-abortion-roe-v-wade-texas-column/96802764/.
- Grossman D. Letter in response to "With Child," Letter from South Dakota, Harper's Magazine, February 2017. http://harpers.org/archive/2017/02/letters-853/.
- 27. Grossman D. Overregulation is forcing women to have late-term abortions. Los Angeles Times, February 28, 2017. http://www.latimes.com/opinion/op-ed/la-oe-grossman-remove-restrictions-on-medication-abortion-20170228-story.html.
- 28. Grossman D. Should over-the-counter medical abortion be available? The Guardian, April 28, 2017.

 https://www.theguardian.com/commentisfree/2017/apr/28/should-over-counter-medical-abortion-be-available.
- 29. Grossman D, Deady G. Virginia is wrong to target a woman after an abortion. Washington Post, April 28, 2017.

- https://www.washingtonpost.com/opinions/virginia-is-wrong-to-target-a-woman-after-an-abortion/2017/04/28/6f827886-26a0-11e7-a1b3-faff0034e2de_story.html?utm_term=.c2650228f034.
- 30. Grossman D. One Year After the Supreme Court's HB2 Ruling, Facts Matter More Than Ever. Huffington Post, June 27, 2017.

 http://www.huffingtonpost.com/entry/one-year-after-the-supreme-courts-hb2-ruling-facts-matter-more-than-ever-us-5952cdb1e4b02734df2e3cb5.
- 31. Bracey Sherman R, Grossman D. Abortion 'reversal': the latest sham from anti-choice activists trying to end women's rights. The Guardian, August 2, 2017. https://www.theguardian.com/commentisfree/2017/aug/02/abortion-pill-reversal-anti-choice-activism.
- 32. Grossman D. Where's the corporate outrage about restricting women's health care? Dallas Morning News, August 24, 2017. https://www.dallasnews.com/opinion/commentary/2017/08/24/corporate-outrage-restricting-womens-healthcare.
- 33. Grossman D, Grindlay Kelly K. These birth control pills should be available without a prescription. Teen Vogue, February 2, 2018. https://www.teenvogue.com/story/birth-control-over-the-counter.
- 34. Sherman RB, Grossman D. Abortion is not a thought experiment. Huffington Post, May 2, 2018.

 https://www.huffingtonpost.com/entry/opinion-sherman-grossman-abortion-us-5-ae8a7ede4b04aa23f277f2e.
- 35. Schwarz EB, Foster DG, Grossman D. Contemporary Hormonal Contraception and the Risk of Breast Cancer. N Engl J Med 2018;378(13):1263-4.
- 36. Grossman D. California public universities should make abortion pill available to students. San Francisco Chronicle, August 30, 2018. https://www.sfchronicle.com/opinion/openforum/article/California-public-universities-should-make-13195219.php.
- 37. Grossman D. Health-Care Providers Must Consider What Role We'll Play in Harm Reduction if Abortion Is Outlawed. Rewire, September 17, 2018. https://rewire.news/article/2018/09/17/health-care-providers-must-consider-what-role-well-play-in-harm-reduction-if-abortion-is-outlawed/.
- 38. Grossman D. American women should have access to abortion pills before they need them. Los Angeles Times, November 21, 2018. https://www.latimes.com/opinion/op-ed/la-oe-grossman-abortion-pills-20181121-s torv.html.
- 39. Biggs AM, Grossman D. With abortion clinic restrictions tightening, women want more access at home. Salon, November 28, 2018. https://www.salon.com/2018/11/28/with-abortion-clinic-restrictions-tightening-women-want-more-access-at-home/.
- 40. Grossman D. Conservatives Are Perpetuating Dangerous Tropes About Patients Who Need Later Abortions. Rewire, February 4, 2019. https://rewire.news/article/2019/02/04/conservatives-are-perpetuating-dangerous-tropes-about-patients-who-need-later-abortions/.
- 41. Grossman D. Ohio abortion, ectopic pregnancy bill: 'It's both bad medicine and bad law-making.' Cincinnati Enquirer, May 21, 2019.

 https://www.cincinnati.com/story/opinion/2019/05/21/ohio-abortion-bill-john-be-cker-daniel-grossman-ectopic-pregnancy-false-medicine/3753610002/.

- 42. Grossman D. OTC Birth Control Pills: Answering Attacks on Access. Women's E-news, July 24, 2019. https://womensenews.org/2019/07/otc-birth-control-pills-answering-attacks-on-access/.
- 43. Grossman D, Schickler R. Facebook took down our fact-check on medically necessary abortions. That's dangerous. Washington Post, September 15, 2019. https://www.washingtonpost.com/opinions/2019/09/15/facebook-took-down-our-fact-check-medically-necessary-abortions-thats-dangerous/.
- 44. Grossman D, Anaya Y. The myth of ectopic pregnancy transplantation. The BMJ Opinion, December 17, 2019. https://blogs.bmj.com/bmj/2019/12/17/the-myth-of-ectopic-pregnancy-transplant-ation/.
- 45. Grossman D. Why 2020 presidential candidates should support over-the-counter access to abortion pills. USA Today, December 18, 2019. https://www.usatoday.com/story/opinion/2019/12/18/abortion-pills-safe-could-ease-access-crisis-women-column/2665854001/.
- 46. Grossman D. California calls itself a 'reproductive freedom' state. Here's how it can make good on that. Los Angeles Times, January 24, 2020. https://www.latimes.com/opinion/story/2020-01-24/abortion-access-california-roe-v-wade.
- 47. Grossman D. Abortions don't drain hospital resources. Boston Review, April 17, 2020.

 http://bostonreview.net/science-nature-politics-law-justice/daniel-grossman-abortio

ns-dont-drain-hospital-resources.

- 48. White K, Grossman D. Biden should support abortion access during COVID-19 and beyond. The Hill, January 22, 2021. https://thehill.com/opinion/healthcare/535203-biden-should-support-abortion-access-during-covid-19-and-beyond.
- 49. Palacio H, Grossman D. How the Biden administration should stand up for abortion rights. Washington Post, January 28, 2021. https://www.washingtonpost.com/opinions/2021/01/27/biden-abortion-rights-ord-ers-healthcare/.
- 50. Constant D, Endler M, Grossman D, Petro G, Patel M. There's the IUD, but can it be provided conveniently to women after medical abortion? BMJ SRH Blog, February 18, 2021.

 https://blogs.bmj.com/bmjsrh/2021/02/18/theres-the-iud-but-can-it-be-provided-conveniently-to-women-after-medical-abortion/.
- 51. Grossman D, Rafie S. It's Time for the Biden Administration to Let Pharmacists Dispense the Abortion Pill. Ms. Magazine, April 6, 2021. https://msmagazine.com/2021/04/06/biden-administration-pharmacists-dispense-a-bortion-pill-pharmacy/.
- 52. Seymour JW, Snow J, Garnsey C, Thompson T-A, Kohn JE, Grossman D. Patient satisfaction with telemedicine for medication abortion: Survey data from seven US states. April 2021. Available at <a href="https://www.ibisreproductivehealth.org/sites/default/files/files/publications/Patient%20satisfaction%20with%20telemedicine%20for%20medication%20abortion.%20survey%20data%20from%20seven%20US%20states%20_0.pdf.

- 53. Grossman D. UC betrays its values when it partners with Catholic hospitals that restrict care. Los Angeles Times, June 22, 2021. https://www.latimes.com/opinion/story/2021-06-22/univeristy-of-california-uc-health-center-partnerships.
- 54. Grossman D. We need two laws to ensure reproductive choice for all Californians.

 Los Angeles Times, September 4, 2021.

 https://www.latimes.com/opinion/story/2021-09-04/california-contraception-abortion-coverage-bills-legislature.
- 55. Grossman D. Texas' abortion crisis proves the abortion pill needs to be in every drug store. NBC News, September 9, 2021. https://www.nbcnews.com/think/opinion/texas-abortion-crisis-proves-abortion-pill-needs-be-every-drug-ncna1278829.
- 56. Bracey Sherman R, Grossman D. The FDA Didn't Liberate Abortion—but We Still Can. The Nation, December 17, 2021. https://www.thenation.com/article/society/fda-abortion-pill/.
- 57. Grossman D. Abortion pills by mail are safe. The FDA finally acknowledged it. Washington Post, December 20, 2021. https://www.washingtonpost.com/outlook/2021/12/20/telemedicine-abortion-fda-safe/.
- 58. Ralph L, Baba F, Biggs MA, Barar R, Serrano S, Gurazada T, Grossman D. Effectiveness and safety of medication abortion by telemedicine and mail-order pharmacy provision: Study protocol for a prospective, observational, non-inferiority cohort study. April 28, 2022. Available at https://osf.io/s7698/.
- 59. Becker A, Grossman D. The Anti-Abortion Myth Haunting the Pro-Choice Movement. The Nation, December 21, 2022. https://www.thenation.com/article/society/anti-abortion-myth-haunting-pro-choice-movement/.
- 60. Bracey Sherman R, Grossman D, Weitz T. The FDA's Abortion Announcement Is Not What You Think. The Nation, January 6, 2023. https://www.thenation.com/article/society/fda-medication-abortion-pharmacies/.
- 61. Grossman D. Over-the-counter birth control pills would be life-changing for millions. Los Angeles Times, April 29, 2023. https://www.latimes.com/opinion/story/2023-04-29/birth-control-pills-over-the-counter-fda-approval.
- 62. Grossman D, Joffe C, Kaller S, Kimport K, Kinsey E, Lerma K, Morris N, White K. Care Post-Roe: Documenting cases of poor-quality care since the Dobbs decision. Advancing New Standards in Reproductive Health (ANSIRH), University of California, San Francisco, 2023. Available at https://www.ansirh.org/sites/default/files/2023-05/Care%20Post-Roe%20Preliminary%20Findings.pdf.
- 63. Grossman D. The Victory for Over-the-Counter Birth Control Pills Is Just the Beginning. New York Times, July 19, 2023. https://www.nytimes.com/2023/07/19/opinion/birth-control-pills-opill-over-the-counter.html.

LANGUAGES

Fluent in Spanish, conversant in French.

Exhibit 2

doc**v**erify



TMAB Haskell affidavit.docx.pdf

DocVerify ID:

77625F35-33B2-4A99-B275-6D489B85B127

Created:

May 08, 2024 12:26:05 -5:00

Pages:

8

Remote Notary:

Yes / State: OH

This document is a DocVerify VeriVaulted protected version of the document named above. It was created by a notary or on the behalf of a notary, and it is also a DocVerify E-Sign document, which means this document was created for the purposes of Electronic Signatures and/or Electronic Notary. Tampered or altered documents can be easily verified and validated with the DocVerify veriCheck system. This remote online notarization involved the use of communication technology.

Go to www.docverify.com at any time to verify or validate the authenticity and integrity of this or any other DocVerify VeriVaulted document.

E-Signature Summary

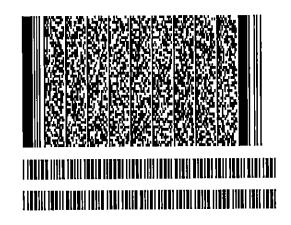
E-Signature 1: Martin Haskell (mh)

May 08, 2024 13:34:10 -5:00 [3972ĆC744B74] [66.161.150.106] martyh@fortemgt.com (Principal) (Personally Known)

E-Signature Notary: Theresa M Sabo (TMS)

May 08, 2024 13:34:10 -5:00 [74AD86188238] [65.60.211.87] tess.sabo@gmail.com

I, Theresa M Sabo, did witness the participants named above electronically sign this document.



DocVerify documents cannot be altered or tampered with in any way once they are protected by the DocVerify VeriVault System. Best viewed with Adobe Reader or Adobe Acrobat.

All visible electronic signatures contained in this document are symbolic representations of the persons signature, and not intended to be an accurate depiction of the persons actual signature as defined by various Acts and/or Laws.



IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Plaintiffs,

Case No. A 2101148

Judge Alison Hatheway

V.

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

AFFIDAVIT OF W.M. MARTIN HASKELL, M.D., IN SUPPORT OF PLAINTIFFS' SECOND MOTION FOR PRELIMINARY INJUNCTION

I, W.M. Martin Haskell, M.D., having been duly sworn and cautioned according to law, hereby state that I am over the age of eighteen years and am competent to testify as to the facts set forth below based on my personal knowledge:

- 1. I am the sole shareholder and Medical Director of Women's Med Group Professional Corporation ("WMGPC"), which has owned and operated Women's Med Dayton ("WMD") in Kettering, Ohio since 1983. WMGPC was formerly Women's Medical Professional Corporation. WMGPC and its predecessor organizations have provided safe and compassionate reproductive health care in Ohio since 1973.
- I am a physician with nearly 50 years' experience in women's health. I have been a 2. licensed physician in the state of Ohio since 1974.
- I earned a B.A. from Ohio Wesleyan University in 1968 and a Doctorate of 3. Medicine from the University of Alabama in 1972. I completed five and one-half years of postgraduate residency training in anesthesia, general surgery, and family practice. I passed my Board exam in family medicine in 1978. I also personally provided abortion care in an outpatient setting from 1978 until 2019.

- 4. As owner of WMGPC, I supervise and manage the provision of all abortion care at WMGPC facilities and am responsible for developing and approving WMGPC's policies and procedures. I have also served as the Medical Director of WMD since 1983. As Medical Director of WMD, I supervise physicians and clinicians and oversee the clinic's daily operations, business matters, and compliance with all applicable laws and regulations.
- Injunction to block the enforcement of the following abortion restrictions: (1) the Advanced Practice Clinician ("APC") Ban [R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), and 4730.42(A)(1), and Ohio Admin. Code 4723-9-10(K) and 4730-2-07(E)], and (2) the Evidence-Based Use Ban [R.C. 2919.123]. I am familiar with these laws because I have complied with them in my practice and ensure that the physicians, clinicians, and other staff that I supervise at WMD comply with them as well.
- 6. I understand that these laws interfere with the ability of Plaintiffs to provide and patients to access medication abortion in Ohio by: (1) restricting qualified and skilled advanced practice clinicians from providing abortion care, including medication abortions,, regardless of their education, training, and experience (the APC Ban) and (2) prohibiting abortion providers from prescribing mifepristone for abortion in any way that differs from the express terms of the FDA's mifepristone approval letter and mifepristone's final printed labeling ("FPL"), a practice commonly known as "off-label" use (the Evidenced-Based Use Ban). I understand that violation of these requirements may carry criminal, civil, and/or disciplinary penalties.
- 7. It is my opinion that these laws, separately and together, restrict access to medication abortion care, are not medically justified, and do not advance patients' health. To the contrary, these laws impede and delay timely access to abortion, impose medical, logistical,

77625F35-3382-4A99-B275-6D489B85B127 --- 2024/05/08 12:26:05 -5:00 --- Remote Notary

financial, emotional and other burdens on abortion patients, and restrict the ability of health care providers to assist patients in exercising their right to abortion, thereby risking harm to patient health and well-being.

8. The facts I state here are based on my experience, information obtained in the course of my duties at WMD, review of WMD business records, and personal knowledge that I have acquired through my service at WMD and my familiarity with medical practice in general and the relevant medical literature and research. If called and sworn as a witness, I could and would testify competently thereto.

Abortion Care at WMD

- WMD provides an array of reproductive health care, including pregnancy testing, 9. birth control, and abortion care. WMD is an ambulatory surgical facility ("ASF") under Ohio law. WMD is the only abortion provider in the Dayton, Ohio area, and one of only 9 clinics providing abortion care in the state.
- WMD currently contracts with two physicians who staff the clinic during the 5 10. days a week it is open, with at least one physician in the facility every day we are open and serving patients. WMD currently does not employ any advanced practice clinicians.
- WMD provides medication abortion up to 70 days (10 weeks) LMP, the current 11. legal limit for medication abortion under the Evidence-Based Use Ban.
- WMD serves a diverse patient population. Approximately 50% of our patients are 12. poor or low income and receive some sort of private funding assistance to pay for abortion care at WMD.
- Our patients seek abortion for a wide variety of deeply personal reasons. For 13. example, some patients seek abortion because they have concluded that they are unable to become

36D489B85B127

a parent for the first time or add another child to their family due to their age, education or work responsibilities, existing caretaking obligations, or a lack of financial resources or emotional support. Some patients do not want to become parents at all. Some patients make the decision to terminate their wanted pregnancy because of pregnancy complications that endanger their health or life or because of a diagnosis of a fetal anomaly. Other patients decide to have an abortion because they are experiencing intimate partner violence and feel that they do not want to be bound to their abusive partner or bring a child into an unsafe environment. There are also patients who seek abortion care because their pregnancy is the result of rape or incest.

The Ban on Advanced Practice Clinicians and Its Impact on WMD and Its Patients

- It is my understanding that Ohio law prohibits anyone who is not a physician from 14. providing abortion care, including medication abortion care, in the state.
- What this means is that, despite their experience, training and capabilities, APCs 15. are unable to provide medication abortion to patients in Ohio. This is so even though, as I understand it, APCs have a broad scope of practice that encompasses the provision of near identical care, including the prescription of the same drugs used in medication abortion for miscarriage management.
- From a qualification and safety perspective there is no reason why APCs should 16. be unable to provide the informed consent discussion or provision of care in regards to medication abortion.
- But for the APC Ban, WMD would seek to hire and train APCs-including nurse 17. practitioners ("NPs"), certified nurse midwives ("CNMs"), and/or physician assistants ("PAs")—to provide medication abortions. Doing so would enable WMD to increase the number of available abortion appointments and the number of locations from which medication abortion

is available. Indeed, if WMD were able to hire and train APCs to provide medication abortion, I would seek to open up a new, second health center located in the greater Cincinnati area, and would hire and train APCs to provide medication abortion there, in order to increase access to medication abortion for patients in a region of the state that is facing an ever growing influx of out-of-state patients seeking care.

- The APC Ban interferes with and burdens our patients' access to abortion because 18. it subjects medication abortion patients to unnecessary delays in accessing care that increase risks to their health, and it adds to the financial and logistical barriers already associated with obtaining an abortion. As a result of the APC Ban, the number of available abortion providers in the state is unnecessarily limited, meaning that patients have to wait longer and potentially travel farther distances in order to obtain abortion care. If APCs were instead permitted to provide medication abortion in accordance with their training and scope of practice, the pool of available providers could be increased, and, with it, the number of appointments available to patients, as well as the number of geographic locations from which patients could obtain medication abortion. APC provision of medication abortion would also serve to free up physician providers to accommodate more patients seeking procedural abortions sooner. All of this would minimize delays in accessing abortion care, which only harm patient health and well-being,1 and reduce the financial and logistical obstacles patients face when needing to travel to access care.
- The APC Ban also interferes with and obstructs WMD's provision of assistance to 19. Ohioans seeking to access abortion. As noted above, there are currently only two physicians who contract with WMD and must provide for the increasing number of patients seeking both medication and procedural abortion care at our health center. But for the APC Ban, we would seek to hire and train APCs to provide medication abortion care, which (as also noted above)

56D489B85B127

¹ While abortion is always very safe, the risks associated with it increase as pregnancy progresses.

would increase our capacity to provide timely, accessible abortion care for all our patients. This would enable both our medication abortion patients and our procedural abortion patients to be seen sooner, reducing delay and its associated harms to patient health and well-being,

The Evidence-Based Use Ban and Its Impact on WMD and Its Patients

- 20. It is my understanding that the Evidence-Based Use Ban prohibits WMD abortion care providers from prescribing mifepristone for abortion care in any way that departs from the FPL for mifepristone; in other words, it prohibits evidenced-based, "off-label" prescription of mifepristone for abortion.
- 21. Off-label use of medications pursuant to evidence-based protocols is an essential part of medical practice. In fact, it is common for new uses or dosing regimens to be widespread and well-accepted long before they are reflected in the labeling. Off-label protocols are supported by evidence-based medical practices and providers' exercise of their professional judgment in caring for their patients.
- 22. Indeed, even mifepristone is routinely prescribed off-label in Ohio outside of the abortion context. Health care providers in Ohio, including those at WMD, are legally permitted to prescribe mifepristone for other non-abortion purposes, including miscarriage management, according to evidence-based, off-label protocols. It is only when it comes to the use of mifepristone for abortion care that providers in Ohio are restricted to prescribing based on an out-dated label that does not comport with the most current, evidenced-based practices.
- 23. Indeed, research shows that a regimen of mifepristone and misoprostol is safe and effective beyond 70 days LMP, through at least 77 days LMP.² Nevertheless the Evidence-Based

² See, e.g., Ilana G. Dzuba et al., A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review, 102 Contraception 104, 104, 106 (2020); Nathalie Kapp et al., Medical Abortion in the Late First Trimester: A Systematic Review, 99 Contraception 77, 77–86 (2019).

Use Ban precludes providers from prescribing mifepristone for abortion care to patients who are beyond 70 days LMP, even when they are still at a point in pregnancy where extensive medical evidence and widespread practice shows they can safely and effectively undergo a medication abortion. This unnecessarily restricts our patients' ability to obtain their preferred or medically indicated method of abortion.

- There are patients for whom an evidence-based, off-label mifepristone regimen-24. including a regimen that allows for use of mifepristone and misoprostol to end a pregnancy after 70 days LMP—is the safest and most effective way to end a pregnancy. This includes patients who are survivors of partner or sexual violence, for whom inserting objects into the vagina may be painful or traumatizing, as well as patients for whom procedural abortion may be contraindicated, such as those with uterine fibroids that significantly distort the cervical canal.³
- 25. If these patients are unable to obtain a medication abortion as a result of the Evidence-Based Use Ban's unnecessary 70 day LMP limit, they will be forced to either undergo an undesired procedural abortion, which may be medically contraindicated; travel out of state to attempt to access medication abortion (and incur related physical and financial costs associated with delayed care and travel); seek medication abortion outside the medical system, at potential risk to their health; or carry to term and give birth.
- The Evidence-Based Use Ban does not advance patient health, and, in fact, harms 26. patients by unnecessarily restricting their access to medication abortion, potentially delaying their receipt of care, and limiting providers' discretion to use the most appropriate, evidenced-based and safest medical treatments for their patients.

³ ACOG, Medication Abortion Up to 70 Days Gestation, Practice Bulletin, N 225, October 2020. https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-day s-of-gestation

77625F35-33B2-4A99-B275-6D489B85B127 — 2024/05/08 12:28:05 -5:00 --- Remate Notary

27. But for the Evidence-Based Use Ban, WMD's providers would prescribe mifepristone for the termination of pregnancies consistent with the best available medical evidence, including through at least 77 days LMP.

FURTHER AFFIANT SAYETH NAUGHT.

W.M. Martin Haskell, M.D.
o5/08/2024 e in Franklin County, Ohio, this [] day of [], 2024.
TERSU

Notarial act performed by audio-visual communication

State of Ohio

Theresa M Sabo

Commission # 2016-RE-619622 Electronic Notary Public

My Comm Exp. Nov 28, 2026

Exhibit 3

IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

v.

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

AFFIDAVIT OF DR. ADARSH E. KRISHEN IN SUPPORT OF PLAINTIFFS' SECOND MOTION FOR A PRELIMINARY INJUNCTION

I, Dr. Adarsh E. Krishen, having been duly sworn and cautioned according to law, hereby state that I am over the age of eighteen years and am competent to testify as to the facts set forth below based on my personal knowledge:

- I have submitted two affidavits in this case: (1) an affidavit dated March 29, 2021, in support of Plaintiffs' Motion for a Temporary Restraining Order Followed by a Preliminary Injunction [hereinafter "Aff."]; and (2) a reply affidavit dated April 16, 2021, in support of Plaintiff's Motion for a Preliminary Injunction [hereinafter "Reply Aff."].
- I have reviewed both documents in preparing this affidavit. Except as noted 2. below, the facts outlined in my prior affidavits have not changed.
- My March 29, 2021, affidavit outlined my qualifications. A copy of my 3. curriculum vitae (CV) is attached to this affidavit as Exhibit A.
- The facts I state here are based on my experience, my review of Planned 4. Parenthood of Greater Ohio's ("PPGOH's") business records, information obtained in the course of my duties at PPGOH, and personal knowledge that I have acquired through my service at PPGOH. If called and sworn as a witness, I could and would testify competently thereto.

- 5. As PPGOH's Chief Medical Officer, I supervise physicians and other clinicians, including advanced practice clinicians ("APCs"); manage the provision of all medical services at PPGOH; and am responsible for developing PPGOH's policies and procedures and ensuring compliance with applicable laws and regulations. I am also familiar with the impact that R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1) and Ohio Adm.Code 4723-9-10(K), and 4730-2-07(E) (collectively, the "APC Ban") and R.C. 2919.123 (the "Evidence-Based Use Ban") have on our operations, our staff, and our patients.
- 6. I understand that the APC Ban precludes APCs, including nurse practitioners ("NPs"), from providing abortion, including medication abortion, in Ohio, even if that care would otherwise be within the APC's scope of practice.
- 7. I understand that the Evidence-Based Use Ban prohibits practitioners in Ohio from prescribing mifepristone in an evidence-based, "off-label" manner for abortions. I understand this restriction to require those prescribing mifepristone for abortion care in Ohio to do so in accordance with all of the components of the United States Food and Drug Administration's ("FDA's") final printed label for mifepristone. The label approves the use of mifepristone for abortion through 70-days, as measured from a patient's last menstrual period ("LMP"). This means that the Evidence-Based Use Ban effectively precludes providers from prescribing mifepristone to patients who are beyond 70 days LMP, even though research demonstrates that it is safe and effective through at least 77 days LMP. I also understand that the Evidence-Based Use Ban may be read to restrict the use of misoprostol to the dosage, timing, and route of administration set forth in the FDA label when it is used as part of the two-drug regimen with mifepristone to induce an abortion. This would also preclude providers from using

evidence-based dosages, timing, and route of administration for misoprostol (when used in conjunction with mifepristone for abortion) that research shows is most effective for some patients.

8. I understand that violating the APC Ban or the Evidence-Based Use Ban may carry criminal, civil, and/or disciplinary penalties.

I. PPGOH's Telemedicine Medication Abortion Protocol

- 9. In my March 29, 2021, affidavit, I described the telemedicine medication abortion ("TMAB") protocol we had in place at the time. Aff. ¶¶13-14. We subsequently discontinued that TMAB protocol because staffing shortages made it no longer feasible.
- 10. Recently, PPGOH began piloting a new protocol for eligible medication abortion patients who want to have their Day 2 appointment via telehealth. The Day 1 intake, assessment, and informed consent process for these patients has not changed. Aff. ¶ 13. Rather than needing to have their Day 2 telemedicine appointment at one of our health centers, however, eligible TMAB patients are now given a combination-coded lockbox containing mifepristone and misoprostol, along with nausea and pain medications, at their first appointment. The patient then has their Day 2 appointment at least 24 hours later via a secure video conferencing platform from a location they choose.
- 11. During the Day 2 appointment, the physician confirms the patient's identity and location, confirms that the patient is certain in their decision to have an abortion, and discusses the patient's symptoms to ensure they do not have changed symptoms that would make them ineligible for medication abortion since their Day 1 visit. The physician also answers any questions the patient has during this appointment. After these discussions, the physician gives the

patient the lockbox's combination and watches the patient remove and ingest the mifepristone.

The patient then takes the misoprostol 24 to 48 hours later.

12. PPGOH has provided the TMAB lockbox pilot protocol to a small group of initial patients and is working toward offering it more broadly to eligible patients. Anecdotal patient feedback has been overwhelmingly positive. Patients have expressed being grateful that they do not have to physically travel to a clinic twice to receive care and how much they like being able to have their abortion in a comfortable, familiar location. Provider feedback has also been incredibly positive. Providers are glad to be able to offer more patient-centered care rather than having to force patients who are eligible for TMAB to nevertheless make a second, potentially very onerous, trip to a clinic.

II. The APC Ban Harms PPGOH's Patients & Staff

A. PPGOH's Provision of Abortion Care

- 13. PPGOH operates two facilities licensed as ambulatory surgical facilities ("ASFs") under Ohio law. They are located in Columbus and Bedford Heights (near Cleveland) and both medication and procedural abortions are offered at both sites. PPGOH provides medication abortions through 70 days LMP and procedural abortions through 19 weeks, 6 days LMP at both of its ASFs.¹
- 14. Both ASFs have a physician on site each day they are open. While we aim to have both locations open as many days as possible each week,² physician staffing challenges can limit our ability to do so. Our ASFs are generally open 5 or 6 days per week, but we are not always

¹ When I submitted my March 29, 2021, affidavit, PPGOH's East Columbus ASF provided procedural abortion through 17 weeks, 6 days LMP. Aff. ¶ 9.

² Ideally, at least one of our ASFs would be open seven days per week. This simply is not presently feasible because we do not have enough physicians to staff a full seven-day schedule.

able to maintain this schedule. Physician staffing is particularly challenging at our Bedford Heights ASF, and there are some weeks when we cannot even staff a full 5-day schedule.

- 15. Due to Ohio's APC Ban, all of the abortions at PPGOH must be provided by the physicians. Since all of our physicians are needed in the ASFs and only physicians are allowed to provide medication abortion, appointments for medication abortion patients are limited to our two ASF locations in Bedford Heights and Columbus. This burdens our medication abortion patients who do not live near those locations and limits our overall number of available abortion appointments for both medication and procedural abortion. Far more patients need to access abortion than PPGOH has capacity to serve with our current physician staffing.
- 16. In addition to the two ASFs, PPGOH has 13 health centers³ that are not ASFs located throughout Ohio.⁴ PPGOH's health centers provide a wide range of care, including wellness and preventive care, birth control, pregnancy testing, testing and treatment for sexually transmitted infections, cancer screening, and gender affirming care, among others.
- 17. PPGOH employs APCs who staff our health centers. At least one NP is on site at each of our non-ASF health centers every day. NPs are highly-skilled medical professionals who are trained and qualified to handle the wide array of care we provide to patients at our health centers. In addition to the education and training necessary to obtain and maintain their licenses, PPGOH has strong internal standards and assesses providers' readiness before they are approved to provide care to our patients. All of our providers also participate in ongoing training and education.

³ PPGOH has closed two health centers since my March 29, 2021, affidavit. At that time, PPGOH operated 15 non-ASF health centers. Aff. ¶ 9. PPGOH also provides care to patients via telehealth through our Virtual Health Center, which is staffed by nurse practitioners.

⁴ PPGOH's health centers are located in: Akron, Athens, Bedford Heights (separate from the Bedford Heights ASF), Canton, Columbus (two locations), Cleveland (two locations), Kent, Mansfield, Rocky River, Toledo, and Youngstown.

- 18. All APCs, including NPs, learn as part of their education and training how to assess patients, when to consult with a physician, and when to refer patients for a higher level of care. All of our NPs have at least one physician available to them for consultation at all times. Each of the physicians with whom PPGOH contracts to provide care in our ASFs participates in PPGOH's Standard Care Arrangement ("SCA") for physician supervision of NPs we employ. Additionally, each of the physicians and NPs is encouraged to contact me whenever they need input on patient care.
- 19. Some of the care that is within our NPs' scope of practice is far more technically complex, and carries more medical risk, than providing medication abortion. For example, NPs in our health centers routinely perform intrauterine device ("IUD") insertion and removal, Nexplanon⁵ insertion and removal, and colposcopies. Our NPs are also trained to perform lidocaine cervical blocks as part of their training as Women's Health Nurse Practitioners. Each of these procedures is more complicated and carries more potential risks than the provision of medication abortion, which is incredibly safe.
- 20. Our NPs have prescriptive authority and routinely prescribe medications to patients as part of the wide array of care they provide in our health centers, including gender affirming care, pre-exposure HIV prophylaxis (commonly called "PrEP"), and the provision of misoprostol for non-abortion care.
- 21. One example of non-abortion care where PPGOH's NPs might use misoprostol is when caring for a patient who has had an incomplete abortion—where their pregnancy has ended but some of the pregnancy tissue has not passed naturally. In such cases, our NPs may prescribe misoprostol to prompt the uterus to contract and expel its remaining contents. Using misoprostol

⁵ Nexplanon is a long-acting birth control implant that is inserted under the skin in a patient's upper arm via a small incision.

to help soften the cervix to help with difficult IUD insertions is also within our NPs' scope of practice and care that they provide at PPGOH's health centers.

B. The APC Ban Delays Care and Forces Patients to Travel Unnecessarily

- 22. The APC Ban harms patients by forcing them to travel to one of our two ASFs to receive care from a physician even though that care can be safely and effectively provided by non-physician clinicians like APCs.⁶ Without the APC Ban, PPGOH could begin the process of training APCs to provide medication abortion. This would allow us to potentially expand our services to provide medication abortion at our non-ASF health centers, shortening the distance many patients have to travel to access care. In addition to benefiting our medication abortion patients, this would free up appointments for our procedural abortion patients in our ASFs.
- 23. PPGOH's patients come from Ohio and other states. Due to the APC Ban and the challenges PPGOH faces recruiting physicians, all of PPGOH's abortion patients have to travel to one of our ASFs for care. Even our Ohio patients may struggle to arrange travel to Columbus or Bedford Heights for care if they do not have a car and live in a neighborhood with poor public transportation, or if they do not live in either city where PPGOH has an ASF. Patients without a car themselves may need to rely on others to borrow one or give them a ride, or somehow cobble together the trip without a car (i.e., using a mix of public transportation and paid fares). In addition to posing logistical challenges, this can result in patients having to disclose to several people that they need assistance getting to their abortion appointment. For example, traveling from either the Mansfield or Norwalk areas to one of our ASFs requires driving over 60 miles

⁶ I am aware of, and have submitted an affidavit in, *Preterm-Cleveland*, et al. v. Yost, Franklin C.P. No. 24 CV 002634, in which PPGOH and other plaintiffs challenge Ohio laws mandating an in-person Day 1 appointment followed by a 24-hour waiting period before the patient can receive an abortion. The travel burdens of those requirements and the APC Ban compound to delay care.

⁷ Aff. ¶ 24; Reply Aff. ¶¶ 4–8.

each way. For out-of-state patients, the time and expense required to travel to Ohio for an abortion can increase exponentially.

- 24. The majority of PPGOH's abortion patients already have children and therefore often must arrange and pay for childcare in order to attend their appointments. This means that some of our patients who are single parents may need to tell two or more people that they need to travel for their appointment either to have someone care for their children near home or to travel with them to care for their children during their appointment. This can compromise the confidentiality of their pregnancy and abortion decision. Other parent-patients must bring their children to their appointments because they have no childcare options. This increases travel-related costs (e.g., an extra bus ticket, needing a larger hotel room, higher food costs to feed more people, etc.) and requires a reliable support person to agree to take time out of their day to accompany the patient to their appointment and serve dual roles of escort and childcare provider while the patient is receiving care. Not every patient has such support available. Reducing travel times can benefit patients by reducing how much time they need childcare and, in some cases, making it possible for them to avoid needing to pay for childcare altogether (such as being able to attend an appointment while their child is in school).
- 25. The burdens associated with the APC Ban are especially difficult for patients who have less stability in their daily lives. For example, patients who are experiencing intimate partner violence may have immense difficulty getting to medical appointments without being detected by the person who is abusing them—this includes not only finding a way to explain their physical absence, but also obtaining transportation and the funds needed to pay for travel and the abortion care itself. This can endanger the patient, who may experience physical, sexual, or emotional violence if detected, and who might thereafter be subjected to heightened physical

and/or emotional control by the person who is abusing them. The farther the patient needs to travel, the longer they need to be away and the more difficult these challenges become.

- 26. Needing to travel a long distance for care is especially burdensome for our patients who are experiencing homelessness. Needing to travel is tremendously difficult for people who do not have a safe, private place to live, or who do not have a secure place to store belongings that they cannot bring with them. In my experience, patients experiencing homelessness sometimes struggle more than other patients to come to an appointment at a scheduled time and may not be able to use online scheduling systems to make or reschedule appointments. The difficulty can be especially acute for patients experiencing homelessness who work and have children. These patients face all the same difficulties that other working and parenting patients face related to needing to take time off work and find childcare, but with added risk and fear that comes with navigating those dynamics with little to no safety net.
- 27. The financial burdens described above are especially onerous for our patients living on low incomes or experiencing poverty who have to travel long distances to one of our two ASFs, or who need more scheduling flexibility than our ASFs can accommodate given the volume of need. For such patients, attending an appointment for care can mean forgoing basic needs, like having food to eat or hygiene products to use.
- 28. Young adults—especially students, who have limited financial and transportation resources and often live away from their support system or are traveling for summer internships—also have a particularly challenging time traveling to obtain the care they need.
- 29. Both of our ASFs have more patients seeking care than we can serve given physician staffing challenges. If we were able to have APCs provide medication abortion, we would be able to increase the number of providers, thereby increasing not only the number of

available appointments but also the number of health centers from which we could provide abortion care. This would help mitigate geographic barriers to access. The APC Ban precludes us from doing this and forces patients to wait until an appointment is available with a physician at one of our ASFs and to travel longer distances than otherwise necessary to that ASF for care, thereby delaying their access to care. Being forced to remain pregnant against their will harms patients' health and well-being. We have had patients who had previous high-risk pregnancies, or patients with chronic illness, who cannot physically or emotionally endure another pregnancy and suffer needlessly due to a delay in obtaining abortion care. Moreover, while abortion is very safe, its risks increase as pregnancy progresses.

- 30. Furthermore, delay may impact some patients' ability to have their desired or medically indicated abortion method by pushing them past the point when medication abortion is an option. As discussed below, the Evidence-Based Use Ban compounds this harm.
- 31. The APC Ban also harms PPGOH's staff. Requiring all abortions to be provided by physicians, and therefore in ASFs, reduces the number of patients we can serve and forces some of our patients to travel much farther than would be necessary if we could offer care in additional locations. This is distressing to providers given how great the need for care is in Ohio and our providers' deep commitment to providing each patient the care they need in a patient-centered, compassionate way. Knowing that the APC Ban prevents us from meeting an acute health care need and forces our patients to jump through unnecessary, onerous hoops is frustrating and demoralizing for providers.

III. The Evidence-Based Use Ban Harms PPGOH's Patients & Staff

32. The current FDA label for mifepristone, which was approved in 2016, contemplates its use through 70 days LMP. The 2016 label also provides the following regimen:

the patient first takes 200 mg of mifepristone orally after receiving it in person from a clinician in a clinic setting; then, 24 to 48 hours later, the patient takes 800 mcg of misoprostol by placing it in their cheek pouch (buccal administration). The patient then follows up with a health care provider 7 to 14 days later to confirm pregnancy termination. The FDA later changed the Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone in 2021 and 2023 to remove the in-person dispensing requirement for mifepristone, which allowed for its mailing and for pharmacists to dispense it.⁸

- 33. Since 2016, research has demonstrated that mifepristone can be safely and effectively used to terminate pregnancy through at least 77 days LMP. Nevertheless, Ohio's Evidence-Based Use Ban prevents abortion providers from caring for patients according to the best medical evidence-instead restricting use to the strict confines of the outdated FDA label.
- 34. Without the Evidence-Based Use Ban, PPGOH would provide medication abortion to qualified patients beyond 70 days LMP, which would allow PPGOH to provide medication abortion patients with more patient-centered care suited to their individual needs and preferences.
- 35. Some patients strongly prefer medication to procedural abortion. Losing the option to have a medication abortion can be incredibly distressing for these patients. For example, patients who are pregnant as the result of rape or incest may find the prospect of having medical instruments inserted into their vagina traumatizing and emotionally intolerable. Other patients may need to have a medication abortion based on medical contraindications for

⁸ FDA, Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (Mar. 23, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-pregnancy-through-ten-weeks-gestation (last accessed May 3, 2024).

procedural abortion, such as an allergy to sedation medications, seizure disorder, or anatomic structural variations, and thus may be unable to access abortion altogether in Ohio.

- 36. Patients may be unable to access medication abortion before 70 days LMP for many reasons. Some patients may not realize that they are pregnant until they are close to, or beyond, 70 days LMP. Others may be pushed past the legal limit for medication abortion in Ohio due to the challenges I discussed above in scheduling an appointment based on clinic and patient availability and arranging travel to a clinic.
- 37. The Evidence-Based Use Ban may also be read to prevent us from providing individualized, patient-centered care in prescribing misoprostol for use as part of the two-drug regimen for medication abortion, along with mifepristone. For example, while the regimen set forth in the outdated FDA label indicates that misoprostol should be administered buccally, other routes of administration (e.g., vaginal and oral) are safe and effective, and may in fact be preferred by patients for individual reasons. Nevertheless, the Evidence-Based Use Ban could be read to preclude us from providing misoprostol to our patients in accordance with a protocol that allows for vaginal or oral administration when used alongside mifepristone for abortion.
- 38. The Evidence-Based Use Ban also harms PPGOH's staff. Having to tell patients who want a medication abortion and are at a point in pregnancy where research demonstrates they can safely and effectively have one that they cannot because they are beyond 70 days LMP is emotionally painful for PPGOH's providers. PPGOH's providers are committed to providing individualized, evidence-based, compassionate care to each patient. Having to deny a patient safe, evidence-based care that the patient wants, and not being able to provide the highest evidence-based standard of care to each patient simply because of the Evidence-Based Use Ban, is therefore deeply distressing. The Challenged Requirements force PPGOH's staff to be

complicit in inflicting the laws' harms. Knowing this, and seeing the pain it causes patients, harms our staff.

FURTHER AFFIANT SAYETH NAUGHT.

Adarsh E. Krishen, M.D.

Planned Parenthood of Greater Ohio

Sworn to and subscribed before me this _____ day of May, 2024.

Notary Public

13

Exhibit 4





TMAB Lewis affidavit.docx.pdf

DocVerify ID:

4F60B6A3-795D-4908-B881-B06D5B781E10

Created:

May 08, 2024 12:28:31 -5:00

Pages:

7

Remote Notary:

Yes / State: OH

This document is a DocVerify VeriVaulted protected version of the document named above. It was created by a notary or on the behalf of a notary, and it is also a DocVerify E-Sign document, which means this document was created for the purposes of Electronic Signatures and/or Electronic Notary. Tampered or altered documents can be easily verified and validated with the DocVerify veriCheck system. This remote online notarization involved the use of communication technology.

Go to www.docverify.com at any time to verify or validate the authenticity and integrity of this or any other DocVerify VeriVaulted document.

E-Signature Summary

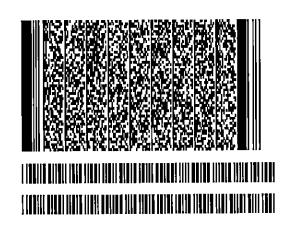
E-Signature 1: Bethany Lewis (BL)

May 08, 2024 13:47:06 -5:00 [6A21490C03ED] [98.103.72.50] blewis@preterm.org (Principal) (ID Verified)

E-Signature Notary: Theresa M Sabo (TMS)

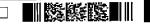
May 08, 2024 13:47:06 -5:00 [4120F2982E55] [65.60.211.87] tess.sabo@gmail.com

I, Theresa M Sabo, did witness the participants named above electronically sign this document.



DocVerify documents cannot be altered or tampered with in any way once they are protected by the DocVerify VeriVault System. Best viewed with Adobe Reader or Adobe Acrobat.

All visible electronic signatures contained in this document are symbolic representations of the persons signature, and not intended to be an accurate depiction of the persons actual signature as defined by various Acts and/or Laws.



IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Plaintiffs,

Case No. A 2101148

Judge Alison Hatheway

V.

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

AFFIDAVIT OF BETHANY LEWIS, LISW-S, IN SUPPORT OF PLAINTIFFS' SECOND MOTION FOR PRELIMINARY INJUNCTION

I, Bethany Lewis, LISW-S, having been duly sworn and cautioned according to law, hereby state that I am over the age of eighteen years and am competent to testify as to the facts set forth below based on my personal knowledge:

- I am the Executive Director of Preterm-Cleveland ("Preterm"), a plaintiff in this case. 1. Preterm is a nonprofit clinic in Cleveland that offers sexual health services and reproductive health care, including abortion. Preterm has been serving the greater Cleveland area since 1974.
- I have held this position since December 2023. As Executive Director, I am responsible 2. for overall administration and management of Preterm, as well as our physicians, clinicians, and administrative staff. I am responsible for developing and approving all of Preterm's policies and procedures, including ensuring compliance with all applicable laws and regulations.
- I earned a B.A. from Ohio State University in Psychology and Sexuality Studies, and a 3. Masters in Social Work from the University of Michigan with a focus on Community Organizing with children and youth in families and communities. I am a Licensed Independent Social Worker.
- I submit this affidavit in support of Plaintiffs' Second Motion for a Preliminary Injunction 4. to block the enforcement of the following abortion restrictions: (1) the Advanced Practice



Clinician ("APC") Ban [R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), and 4730.42(A)(1), and Ohio Admin. Code 4723-9-10(K) and 4730-2-07(E)], and (2) the Evidence-Based Use Ban [R.C. 2919.123]. I am familiar with these laws because I ensure that the physicians, clinicians, and other staff that I supervise at Preterm comply with them.

- It is my understanding that the APC Ban prohibits qualified and skilled advanced practice 5. clinicians (i.e., nurse practitioners, certified nurse midwives, and physician assistants) from providing abortion, including medication abortion, regardless of their education, training, and experience.
- It is also my understanding that the Evidence-Based Use Ban prohibits the prescription of 6. mifepristone for abortion in any way that differs from the express terms of the FDA's mifepristone approval letter and mifepristone's final printed labeling ("FPL"), a practice commonly known as "off-label" use. I understand that, in effect, the Evidence-Based Use Ban imposes a prohibition on providing mifepristone for abortion after 70 days, as dated from the first day of a patient's last menstrual period ("LMP").
- I understand that violation of these requirements may carry criminal, civil, and/or 7. disciplinary penalties. It is my opinion that, both individually and collectively, these laws impede patients' access to time-sensitive care, risking harm to their health and well-being; interfere with patients' ability to make and carry out their own reproductive decisions; single out patients seeking abortion and their health care providers for discriminatory treatment; and obstruct our staff's ability to exercise their best medical judgment in tailoring care to the needs of each patient.
- The facts I state here are based on my experience, information obtained in the course of 8. my duties at Preterm, my review of Preterm's business records, and personal knowledge that I

2B06D5B781E10

4F60B6A3-795D-4908-B881-B06D5B781E10 --- 2024/05/08 12:28:31 -5:00 --- Remate Natary

have acquired through my service at Preterm. If called and sworn as a witness, I could and would testify competently thereto.

Care at Preterm

- Preterm provides an array of sexual and reproductive health care, including pregnancy 9. testing, birth control, STI testing and treatment, yearly gynecological exams, miscarriage management, ultrasounds, as well as both procedural and medication abortion care. Over 90% of our patients come to us for abortion care. Preterm is an ambulatory surgical facility ("ASF") under Ohio law. Preterm is one of only nine clinics providing abortion care in the state.
- Preterm currently contracts with four physicians who divide among them the four days a 10. week the clinic schedules patients, with at least one physician in the facility every day we are serving patients. Preterm currently does not employ any advanced practice clinicians.
- Preterm provides medication abortion up to 70 days (10 weeks) LMP, the current legal 11. limit for medication abortion under Ohio law.
- 12. Most of our patients live in northeast Ohio, but we also see many patients from across the state as well as from other states, including Georgia, Pennsylvania, Tennessee, Florida, and Texas. The majority of our patients are economically disadvantaged. The majority also qualify for Medicaid. Additionally, approximately 65% of our patients already have children.
- Our patients seek abortion for many reasons. For example, some patients seek abortion 13. because they are unable or unwilling to add another child to their family, pre-existing education, or work responsibilities, existing family or childcare obligations, or a lack of financial resources or emotional support. Some patients simply do not want to be parents at all. Other patients seek an abortion because they are hoping to leave an abusive partner and do not want to risk being tied to

3B06D5B781E10

4F60B6A3:795D-4908-B881-B06D5B781E10 -- 2024/05/08 12:28:31 -5:00 -- Remote Notary

them because of their pregnancy. There are also patients who seek abortion care because their pregnancy is the result of sexual assault.

At Preterm we have seen an increase in the demand for appointments since the U.S. 14. Supreme Court's ruling in Dobbs v. Jackson Women's Health Organization. As states across the South and Midwest limit or ban abortion, more patients are forced to travel to states such as Ohio, where care remains legal. This influx of patients has only exacerbated the existing strains on Preterm's capacity and scheduling flexibility attributable to the limited number of physicians willing to provide abortion in the state, which in turn delays and burdens patients' access to time-sensitive care.

The Ban on Advanced Practice Clinicians and Its Impact on Preterm and Its Patients

- I understand that, under current Ohio law, only physicians are allowed to provide 15. abortion care, including medication abortion.
- In other words, it's my understanding that, despite their qualifications, Ohio law prevents 16. APCs from providing medication abortion, even though (as I understand it) their scope of practice includes nearly identical functions in other contexts, including prescription of the medications used in medication abortion for miscarriage management.
- If not for the APC Ban, Preterm would hire and train APCs to provide medication 17. abortions, expanding the availability and accessibility of services and appointments. Currently, the caseload of non-abortion services at Preterm is not sufficiently high to support hiring an APC but, absent the APC Ban, Preterm would hire APCs to provide both medication abortion and non-abortion services. This would not only create additional appointment availability for medication abortion patients, but would also free up Preterm's physicians to provide more

4F60B6A3-795D-4908-B881-B06D5B781E10 — 2024/05/08 12:28:31-5:00 — Remote Notary

procedural abortions, thereby increasing access to and availability of time-sensitive abortion care for all of Preterm's abortion patients.

- 18. By unnecessarily limiting the pool of available medication abortion providers in Ohio to physicians only, the APC Ban interferes with our patients' exercise of their decision to obtain time-sensitive abortion care. The Ban subjects medication abortion patients to unnecessary delays in accessing abortion care and imposes significant financial and logistical burdens on patients by, among other things, delaying their ability to access care until later in pregnancy and/or forcing them to travel further distances to other clinics in order to obtain timely care, thereby harming (rather than advancing) patient health, safety and well-being.
- The APC Ban also interferes with Preterm's ability to professionally assist Ohioans 19. seeking to obtain abortions by precluding Preterm from hiring and training APCs to provide medication abortion, which would enable the clinic to expand appointment availability and see more patients sooner, thereby mitigating delays in accessing time-sensitive care.
- Currently there are only four physicians at Preterm who provide for the increasing 20. number of patients seeking care at our health center. Very often patients struggle to find available appointments that match their needs. Many patients have work schedules that leave them free only on Saturdays. Likewise, many patients are only able to get childcare on certain days which, when combined with the clinic's capacity and scheduling limitations based on our limited number of providers, only further constraints their ability to secure a timely appointment for care, pushing them further into their pregnancy.
- If not for the APC Ban, we could expand the pool of qualified professionals able to 21. provide medication abortion care by hiring and training APCs to handle the increased patient load. This would mean our patients would have a larger pool of providers and availability of

5B06D5B781E10

appointments from which to choose to obtain medication abortion care, lowering one of the most pervasive barriers to timely access to care for our patients.

The Evidence-Based Use Ban and Its Impact of Preterm and Its Patients

- It is my understanding that the Evidence-Based Use Ban prohibits providers from 22. prescribing mifepristone in an evidence-based, "off-label" manner for abortion care.
- I understand that research shows that a regimen of mifepristone and misoprostol to 23. terminate a pregnancy is safe and effective beyond 70 days LMP. However, I also understand that the Evidence-Based Use Ban effectively imposes a 70 day LMP limit on medication abortion care in Ohio by forcing providers to prescribe mifepristone only in accordance with the drug's FPL. In practice, this means that Ohio patients who are pushed past the 70 day LMP limit due to delays in accessing care, or other factors, are precluded from obtaining medication abortion in Ohio, despite the fact that (as I understand it) medication abortion is still safe and effective through at least 77 days LMP.
- 24. As I understand it. Ohio law does not impose similar restrictions on the use of mifepristone for other purposes, including miscarriage management.
- By preventing Preterm from offering medication abortion to patients whose pregnancies 25. have passed 70 days LMP and limiting Preterm's physicians' discretion to provide the most appropriate and evidenced-based care, the Evidenced-Based Use Ban interferes with our patients' exercise of their decision to obtain an abortion. The Ban subjects patients to harms associated with being denied a desired medication abortion, which can be particularly distressing for patients who have health conditions that make medication abortion the medically advisable

¹ The risk that a patient may be delayed past the 70 day LMP limit for medication abortion is only heightened by Ohio's mandated 24-hour waiting period and in-person counseling requirement for abortion patients, which, in practice, together often delay patients' access to care for much longer than 24 hours. Preterm is also a plaintiff in a lawsuit challenging the constitutionality of these laws.

4F60B6A3-795D-4908-B881-B06D5B781E10 --- 2024/05/08 12:28:31 -5:00 --- Remote Notary

option, and for those who are pregnant as a result of rape or incest, and for whom a procedural abortion may be re-traumatizing due to the insertion of instruments into the vagina. Depriving patients of the ability to obtain a medication abortion after 70 days LMP that could still be safely and effectively provided based on the best available medical evidence forces them to undergo an undesired and potentially medically contraindicated procedural abortion, or to travel out of state for medication abortion, seek care outside the medical system, or carry a pregnancy to term and give birth, all with attendant risks of harm to their health, safety, and well-being.

26. But for the Evidence-Based Use Ban, Preterm would prescribe mifepristone for the termination of pregnancies beyond 70 days LMP, consistent with the best available medical evidence, including through at least 77 days LMP.

FURTHER AFFIANT SAYETH NAUGHT.

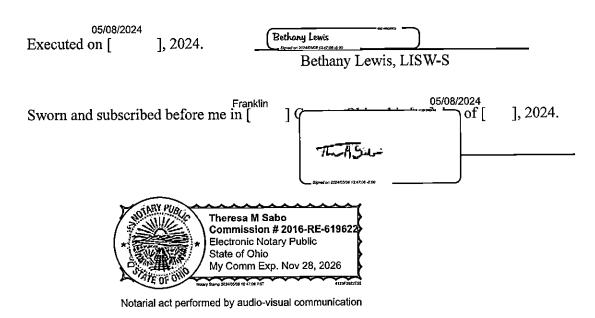


Exhibit 5

IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

v.

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

AFFIDAVIT OF SHARON LINER, M.D., IN SUPPORT OF PLAINTIFFS' SECOND MOTION FOR A PRELIMINARY INJUNCTION

I, Sharon Liner, M.D., being duly sworn on oath, do depose and state as follows:

- 1. I previously submitted an affidavit on March 30, 2021, in support of Plaintiffs' Motion for a Temporary Restraining Order Followed by Preliminary Injunction [hereinafter "Aff."]. I also prepared an expert report pursuant to Ohio Rule of Civil Procedure 26, dated April 28, 2022, which I understand has been disclosed to the then-defendants in this case.
- 2. I have reviewed both documents in preparing this expert affidavit. Except as noted below, the facts outlined in my prior affidavit and my expert report have not changed. I continue to rely upon the unchanged facts as supplemented by the additional facts discussed below.
- 3. The facts I state here and the opinions I offer are based on my education, years of medical practice, my expertise as a doctor and specifically as an abortion provider, my personal knowledge, my review of Planned Parenthood Southwest Ohio Region ("PPSWO") business records, information obtained through the course of my duties at PPSWO, and my familiarity with relevant medical literature and statistical data recognized as reliable in the medical profession.

- 4. As the Medical Director, I supervise all PPSWO clinicians, including physicians and advanced practice clinicians ("APCs"). PPSWO currently employs nurse practitioners ("NPs") and certified nurse midwives ("CNMs"), two types of APCs. I understand that R.C. 2317.56(B), 2919.123, 4723.44(B)(6), 4723.50(B)(1), 4723.151(C), 4730.02(E), 4730.03(F), 4730.39(B)(2), 4730.42(A)(1) and Ohio Adm.Code 4723-9-10(K) and 4730-2-07(E) (collectively, the "APC Ban") make it unlawful for advanced practice clinicians to provide abortion, including medication abortion, regardless of their education, training, and experience.
- By prohibiting qualified and competent APCs from providing abortion care, including medication abortion, the APC Ban unnecessarily limits the number of abortion providers at PPSWO, and thus the number of locations where abortion can be provided and the number of available appointments. As a result, the APC Ban reduces access to important, time-sensitive abortion care, thereby undermining patient wellbeing and public health. It also exposes patients to financial, logistical, psychological, and medical burdens. The APC Ban has these detrimental effects without advancing patient safety because the medical evidence and extensive experience show that APCs can provide medication abortion just as safely and effectively as physicians.
- 6. I understand that R.C. 2919.123 (the "Evidence-Based Use Ban") requires that mifepristone, one of the two drugs used in the most common medication abortion regimen, be prescribed only in accordance with the United States Food and Drug Administration's ("FDA's") final printed label for the drug. Practically, this means that mifepristone is available only to patients seen in Ohio within a limited gestational window—through 70 days (10 weeks) of pregnancy, as counted from the first day of a patient's last menstrual period ("LMP")—even though research has demonstrated the efficacy and safety of off-label use of mifepristone through at least 77 days (11 weeks) LMP. I also understand that the law may restrict the dosing and route

of administration of the second drug in the most common medication abortion regimen (misoprostol) when it is used alongside mifepristone as part of the two drug regimen to terminate a pregnancy, and there is a risk that a hostile prosecutor could attempt to use the law to restrict other applications of mifepristone for abortion-related purposes (e.g., for cervical ripening prior to a procedural abortion).

7. The Evidence-Based Use Ban restricts the evidence-based use of mifepristone without medical justification. Off-label use of medication is common throughout the field of medicine and allows providers to update their practice according to the best medical evidence. The Evidence-Based Use Ban reduces access to medication abortion by limiting mifepristone prescription to 70 days LMP, despite the fact that research shows that mifepristone is a safe and effective method of terminating a pregnancy through at least 77 days LMP. This means that patients who are more than 70 days LMP pregnant, but still within a window when mifepristone is safe and effective, cannot access medication abortion in Ohio. As a result, their only options are to seek a procedural abortion (potentially against their preference or medical indication), travel out of state to receive a medication abortion, seek medication abortion outside of a medical setting, or carry their pregnancy to term.

I. Telemedicine at PPSWO

8. In my previous affidavit, I detailed the evolution of telemedicine services at PPSWO, including for medication abortion. Aff. ¶¶ 16–20, 36–47. We currently offer telemedicine for non-abortion services via the direct-to-patient model, whereby a patient with internet access and a video device can connect with one of our highly qualified health care professionals in the comfort of their own home or at another location of their choosing.

- 9. While it is possible to have a medication abortion via telemedicine in Ohio due to the preliminary injunction in this case, Ohio law still requires that abortion patients travel to a clinic or health center to receive certain state-mandated information in person from a physician at least 24 hours prior to obtaining an abortion.¹ Thus, all abortion patients, including medication abortion patients, must still have two separate appointments.
- 10. PPSWO previously offered telemedicine medication abortion via the in-office model but stopped doing so for administrative reasons.
- 11. Recently, PPSWO began to have some patients complete their second visit for a medication abortion via direct-to-patient telemedicine at least 24 hours following their in-person visit to the clinic. Under our new telemedicine medication abortion protocol, at their first in-person appointment, the patient receives a combination-coded secure container containing their doses of mifepristone and misoprostol as well as nausea medication and ibuprofen (a "lockbox"), which they take home with them from the appointment. At least 24 hours later, the patient can do their second visit via telemedicine from their home or another location of their choosing. During that second appointment, the physician confirms the patient's decision to seek an abortion, confirms that they have not had a change in their symptoms or other medical concerns, and answers any questions the patient may have. The physician then gives the patient the combination code to the lockbox, from which the patient removes the mifepristone and shows it to the physician. The physician then observes the patient ingesting the mifepristone. The patient then takes the misoprostol 24 to 48 hours later.

¹ R.C. 2317.56(B)(l), 2919.193–194. PPSWO, together with other abortion providers, recently filed a lawsuit challenging the constitutionality of these requirements. *See generally Preterm-Cleveland v. Yost*, Franklin C.P. No. 24 CV 002634. I submitted an affidavit in support of Plaintiffs' Motion for Preliminary Injunction in that case.

12. The medical eligibility requirements and Day 1 visit for this new telemedicine medication abortion protocol are the same as I described in my prior affidavit. Aff. ¶ 36. However, we also ensure that patients have an internet connection, a video device, and a safe and comfortable place from which to conduct the appointment.

II. Effects of the Evidence-Based Use Ban

- 13. Off-label prescription is common throughout the field of medicine and allows providers to update their practice according to the best medical evidence. For example, misoprostol was originally approved by the FDA as an ulcer medication, but I prescribe it for several gynecological applications, including for medication abortion.
- 14. The FDA first approved mifepristone in 2000 for use up to 49 days LMP. Even at that time, evidence already showed that an updated regimen (dosage, timing, and route of administration) of mifepristone and misoprostol was safe and effective for abortion through 63 days LMP.²
- 15. Subsequent research showed that other regimens of mifepristone and misoprostol were even safer and more effective and could be used later in pregnancy. In 2016, the FDA approved an updated label for Mifeprex (the brand name for mifepristone) with the following regimen through 70 days LMP: on the first day, the patient takes 200 mg of mifepristone orally; 24 to 48 hours later, the patient takes 800 mcg of misoprostol buccally (in the cheek pouch); and 7 to 14 days later, the patient follows up with a healthcare provider to confirm that the pregnancy has been terminated.³ Subsequent changes to the Risk Evaluation and Mitigation Strategy ("REMS")

² Schaff et al., Low-Dose Mifepristone Followed by Vaginal Misoprostol at 48 Hours for Abortion Up to 63 Days, 61 Contraception 41 (2000).

³ FDA, MIFEPREX: Highlights of Prescribing Information (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (last accessed May 3, 2024).

for mifepristone in 2021 and 2023 lifted the requirement that the drug be dispensed in-person, thereby allowing for its mailing, and allowed pharmacists to dispense mifepristone.⁴

- 16. Since 2016, new research has shown that mifepristone is a safe and effective way to terminate a pregnancy through at least 77 days LMP.⁵
- 17. Despite this, Ohio law continues to prohibit mifepristone's use to terminate a pregnancy after 70 days LMP. Thus, PPSWO only provides medication abortion through 70 days LMP. Absent the Evidence-Based Use Ban, PPSWO would provide medication abortion consistent with the best available medical evidence, including through at least 77 days LMP. The gestational limit imposed by the Evidence-Based Use Ban thus limits patients' ability to access medication abortion in Ohio.⁶
- 18. Many patients seeking to access medication abortion in Ohio may be pushed past the current legal limit for medication abortion (70 days) even though they would otherwise be able to access medication abortion before 77 days LMP. These patients will be forced to travel out of state to obtain medication abortion care if they are able, get a procedural abortion, attempt to manage their own abortion outside the medical system, or remain pregnant against their will.
- 19. Some patients may not realize they are pregnant until after 70 days LMP and thus are unable to access medication abortion in Ohio.

⁴ FDA, Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (Mar. 23, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation (last accessed May 3, 2024).

⁵ Dzuba et al., A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review, 102 Contraception 104 (2020); Dzuba et al., A Non-Inferiority Study of Outpatient Mifepristone-Misoprostol Medical Abortion at 64–70 Days and 71–77 Days of Gestation, 101 Contraception 302 (2020).

⁶ The barriers to abortion access described below are compounded by other Ohio laws including the APC Ban and the 24-hour waiting period requirement, which forces most patients to make two trips to the clinic in order to receive an abortion. R.C. 2317.56(B).

- As I explained in my prior affidavit, Aff. ¶¶ 34–36, and also described below, infra ¶¶ 43, 20. 47, PPSWO conducts all Day 1 visits at our Cincinnati ambulatory surgical center, and we also provide all medication abortions, other than those we provide via telemedicine, at that clinic. Traveling to the clinic is very burdensome for some patients. Even patients who live close to the clinic may have to take unreliable public transportation, cobble together rides from friends or family members, or figure out how to pay for a rideshare service. Others travel to our clinic from distant parts of Ohio or other states. Because we are the nearest abortion provider for people from some parts of Indiana, Kentucky, and West Virginia—all of which ban abortion entirely—we see many out-of-state patients. In the past year, we have seen patients from 16 states, including farther away states such as Florida and Georgia. The in-person visit requirement forces most patients to make two trips to the clinic at least 24 hours⁷ apart in order to receive an abortion and thus means that many patients must arrange overnight accommodations. Having to travel to the clinic imposes logistical and financial barriers to many patients and may make them unable to get to the clinic before 70 days LMP. These patients are thus unable to access medication abortion in Ohio.
- 21. Because many of our patients are already parents, they may need to arrange for childcare to obtain an abortion, which may be an additional cost and a further barrier to getting to our Cincinnati clinic before 70 days LMP. Many patients also lose wages because they have to miss work and do not work in jobs that provide paid time off. These costs are substantial for patients living paycheck to paycheck and can mean the difference between buying groceries for their families that week or not. These logistical barriers and additional costs also prevent some

⁷ In practice, the 24-hour delay is often drawn out further. Patients can easily be delayed by more than a week between their first and second appointments.

patients from getting to the clinic before 70 days LMP. These patients are thus unable to access medication abortion in Ohio.

- 22. Patients who are able to travel out of state to obtain a medication abortion may incur additional costs associated with traveling further from home such as gas, bus tickets, and even somewhere to stay overnight. They may also need to arrange additional childcare or take additional time off work, also at a greater cost.
- 23. Patients who are unable to obtain a medication abortion in Ohio may be forced to remain pregnant for longer, imposing medical burdens on them. When some patients come to our clinic seeking abortions, they are very ill and need an abortion as soon as possible. For example, some patients experiencing hyperemesis gravidarum (severe nausea and vomiting) are not able to go about their daily lives as long as they are pregnant because they are too ill. Patients may have other medical conditions necessitating an abortion, such as needing to start cancer treatment. Furthermore, while abortion is incredibly safe, its risks increase with gestational age.
- 24. Remaining pregnant also imposes both psychological and emotional burdens on patients. Most abortion patients—once they have decided to have an abortion—strongly prefer to end their pregnancy as soon as possible. These burdens may be especially heavy for patients who have become pregnant as a result of rape or incest. For patients experiencing intimate partner violence, remaining pregnant for longer means that their abusive partner is more likely to discover their pregnancy, putting them at risk of violence and retaliation.
- 25. Some patients who are unable to access medication abortion in Ohio due to the Evidence-Based Use Ban will have to have procedural abortions to terminate their pregnancies, against their preference or medical indication. As I explained in my prior affidavit, some patients have a strong preference for medication rather than procedural abortion, including because of a

history of sexual assault. Aff. ¶ 29. For these patients, procedural abortion may feel like a violation of their bodily autonomy and/or traumatic. Yet the Evidence-Based Use Ban may mean some of these patients must have a procedural rather than medication abortion. Some PPSWO patients with a strong preference for medication abortion who are between 71 and 77 days LMP have gone out of state to get a medication abortion rather than have a procedural abortion in Ohio.

- 26. As I said in my prior affidavit, medication abortion may also be safer than procedural abortion for some patients. Aff. ¶ 29. Some patients between 71 and 77 days LMP may have to undergo an abortion procedure that poses greater medical risk for them as a result of the Evidence-Based Use Ban. For other patients, medication abortion may be the only medically safe option. For example, this may be true for patients with anomalies of the reproductive and genital tract, such as significant uterine fibroids or didelphys, which can make it difficult to perform an abortion by procedure. These patients are forced to travel out of state (if they are able) to get a medication abortion or remain pregnant against their will.
- 27. Other patients may seek medication abortion outside the medical system, which can carry greater risks than if supervised by a qualified clinician.
- 28. The Evidence-Based Use Ban also intrudes on the patient-provider relationship. I obtain informed consent from patients for any form of medical care I provide. The purpose of informed consent is to notify a patient of the intended procedure or treatment and advise them of the treatment's or procedure's nature, risks, benefits, and alternatives. Once a patient understands their options, they should be able to choose the treatment that best meets their needs. The Evidence-Based Use Ban takes away the choice of medication abortion for patients seeking to

terminate their pregnancies between 71 and 77 days LMP without medical justification and in contravention of best medical practices.

- The Evidence-Based Use Ban may also impact patients other than those seeking to 29. terminate their pregnancies via medication abortion between 71 and 77 days LMP. It also affects misoprostol use in medication abortion. The FDA label contemplates that patients will take four 200 mcg tablets of misoprostol 24 to 48 hours after mifepristone buccally. Buccal administration of medication means that the patient places the tablets between their cheek and gums for 30 minutes and then swallows any remnants with water or another liquid.8 However, newer research indicates that for patients who are between 9 and 11 weeks LMP, it is most effective to take a second dose of misoprostol (also four 200 mcg tablets) 4 hours after the first dose.9 But because the Evidence-Based Use Ban restricts the use of misoprostol to the what is outlined in the FDA label for mifepristone when the drug is used in combination with mifepristone to induce an abortion, we do not provide patients with this evidence-based treatment. Instead, we tell patients to monitor their bleeding (one of the normal effects of medication abortion), and if they do not have the expected bleeding, on an individual basis after assessment, we may instruct them to take an additional dose of misoprostol. However, this is usually at least 24 hours after the first misoprostol dose, rather than 4 hours.
- Furthermore, some patients may prefer to take misoprostol orally or vaginally, rather than 30. buccally, but we do not instruct them to do so because the Evidence-Based Use Ban precludes those alternative routes of administration. Buccal and vaginal administration have been shown to have similar efficacy and safety; oral administration is slightly less effective and may cause more

<sup>FDA, supra note 3.
Dzuba et al., A Repeat Dose, supra note 5.</sup>

nausea, but is nonetheless preferable for some patients.¹⁰ For some patients with extreme nausea, putting anything in their mouth can be difficult. Others may be sensitive to the taste or feel of buccal administration. The standard of care indicates that patients should be able to make this choice for themselves after an informed consent process, but the Evidence-Based Use Ban precludes them from making this choice.

31. There is also a risk that a hostile prosecutor could view the Evidence-Based Use Ban as precluding the use of mifepristone as a dilator for cervical preparation prior to a second trimester procedural abortion. While research indicates this is effective and safe, ¹¹ if we use mifepristone in this manner, we run the risk that those tasked with enforcement will view this as violating the Evidence-Based Use Ban.

III. Effects of the APC Ban

32. Throughout my tenure at PPSWO, I have worked closely with APCs. With the exception of our ambulatory surgical facility ("ASF") in Cincinnati, our clinics¹² are headed and primarily staffed by advanced practice clinicians. PPSWO currently employs 11 nurse practitioners, 2

¹⁰ Young et al., Comparison of Vaginal and Buccal Misoprostol after Mifepristone for Medication Abortion through 70 days of Gestation: A Retrospective Chart Review, 115 Contraception 62 (2022); Winikoff et al, Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion: A Randomized Controlled Trial, 115 Journal of Obstetrics & Gynecology 1303 (2008); Am. Coll. of Obstetricians & Gynecologists, Medication Abortion Up to 70 Days of Gestation, Practice Bulletin No. 225 (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation (last accessed May 3, 2024).

¹¹ Diedrich et al., Society of Family Planning Clinical Recommendations: Cervical Preparation for Dilation and Evacuation at 20–24 Weeks' Gestation, 101 Contraception 286 (2020); Lambert et al., Adjuvant Misoprostol or Mifepristone for Cervical Preparation with Osmotic Dilators before Dilation and Evacuation, 132 Contraception (Apr. 2024); Uhm et al., Mifepristone Prior to Osmotic Dilators for Dilation and Evacuation Cervical Preparation: A Randomized, Double-Blind, Placebo-Controlled Pilot Study, 107 Contraception 23 (Mar. 2022).

¹² We operate one other health center in Cincinnati as well as one each in Dayton, Hamilton, and Springfield.

certified nurse midwives, and one APC who is both an NP and CNM. We would also consider employing physician assistants for future open clinician positions.

- 33. Like other Ohio APCs, PPSWO's APCs provide a broad range of health care services, have broad prescriptive authority, and regularly provide care that is comparable to or higher risk and/or complexity than medication abortion.
- 34. PPSWO APCs provide gender affirming care, pre-exposure HIV prophylaxis (commonly called "PrEP"), screening and treatment of sexually transmitted infections, intrauterine device insertion and removal, insertion and removal of contraceptive implants, lidocaine cervical blocks, colposcopy, endometrial and vulvar biopsies, loop electrosurgical excision procedures ("LEEPs"), and bartholin cyst treatment, among other forms of care.
- 35. As part of their education and training, APCs are taught when to refer patients for a higher level of care. I work closely with our APCs and frequently consult with them on complex cases.
- 36. Because of the APC Ban, however, physicians provide all abortions at PPSWO. I am one of two staff physicians at PPSWO, and three additional per diem physicians also provide abortion care at PPSWO.
- 37. Because Ohio law requires that procedural abortions be performed at an ASF, we only perform procedural abortions at our Cincinnati ASF. Furthermore, because Ohio law requires that a physician obtain informed consent in-person at least 24 hours prior to obtaining abortion, and our only health center that routinely has physicians present is the Cincinnati ASF, all medication abortion patients must travel to that clinic for their Day 1 appointment. Furthermore, because medication abortion must be provided by a physician in Ohio, all medication abortions

provided by PPSWO, other than those provided via telemedicine, take place at the Cincinnati ASF.

- 38. Our model of staffing our non-ASF facilities with APCs and the Cincinnati ASF with physicians means that most preparation and follow-up care for medication abortion is provided by either physicians or registered nurses. However, one NP, Plaintiff Julia Quinn, currently works at the Cincinnati ASF and is involved in pre- and post-medication abortion care.
- 39. Absent the APC Ban, it is within the scope of practice of properly trained APCs to provide medication abortion. Research shows that APCs can provide medication abortion as safely and effectively as physicians.¹³ Furthermore, I am aware that APCs in other states regularly provide medication abortion care. There is no medical reason why APCs should not be allowed to provide medication abortion.
- 40. Indeed, it is within the scope of practice of properly trained APCs to provide care throughout the entire medication abortion process. Pre-medication abortion care, including reviewing medical history, screening for contraindications, and if indicated, ultrasound, is within their scope. APCs are also capable of obtaining informed consent from medication abortion patients. I am aware that APCs in other states regularly provide pre-medication abortion care.
- 41. It is also within the scope of practice of properly trained APCs to provide post-medication abortion care, including ultrasound and addressing rare complications, and I am aware that APCs in other states regularly provide post-medication abortion care. For example, one complication of medication abortion is incomplete abortion, meaning that the pregnancy has ended but there are retained products of conception in the patient's uterus. The most common

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

intervention for incomplete abortion is an additional dose of misoprostol, which APCs are more than capable of administering.

- 42. The APC Ban seriously constrains the availability of medication abortion in Ohio to the detriment of patients' health and wellbeing. Absent the APC Ban, PPSWO would train its current APCs to provide medication abortion (including via telemedicine and beyond 70 days LMP if the Evidence-Based Use Ban were also enjoined), and hire additional APCs as needed to provide this care, and, as a result, could expand medication abortion services.
- 43. PPSWO currently provides medication abortion 4 to 5 days a week. We currently offer medication abortion appointments Tuesday through Friday and one Saturday per month. All Day 1 medication abortion appointments take place at our Cincinnati ASF, and with the exception of telemedicine appointments, all Day 2 medication abortion appointments also take place at our Cincinnati ASF.
- 44. Absent the APC Ban, we could offer both Day 1 and Day 2 medication abortion appointments at all five of our health centers, including those sites headed by NPs. We could also likely offer medication abortion appointments additional days of the week and at more times. At our Cincinnati ASF, we might also be able to offer more medication abortion appointments because we would have a greater number of providers.
- 45. Lifting the APC Ban would mean that all PPSWO clinicians, including physicians and APCs, could practice at the top of their license. Physicians would be able to focus on providing procedural abortions.
- 46. I anticipate that a greater number of medication abortion appointments will offer additional flexibility to patients and thus increase abortion access in Ohio. As I explained above, supra ¶ 21–22, many of our patients face logistical barriers to accessing abortion. Being able to

offer medication abortion at all of our health centers would reduce travel burdens for patients. For example, our Cincinnati ASF is currently the closest abortion provider for a patient living in Hamilton, Ohio. Instead of having to travel approximately 20 miles in each direction twice to obtain a medication abortion, the patient might be able to obtain a medication abortion closer to their home at our health center in Hamilton.

- 47. Similarly, patients struggling to take time off of work or school to access medication abortion might have more appointment options. For example, if a patient regularly worked Tuesday through Saturday, they would not be able to access medication abortion on the days we currently offer it without taking time off work—potentially unpaid. However, all of our health centers are open on Mondays, and we might be able to offer medication abortion on Mondays absent the APC Ban, meaning this patient would not lose wages or potentially have to disclose to their employer the reason for their absence from work.
- 48. Additional medication abortion appointments may mean that patients are able to terminate their pregnancies sooner, reducing the medical and psychological burdens I described supra ¶¶ 26–27.

* * *

49. For all of these reasons, I believe that the Evidence-Based Use Ban and the APC Ban deprive PPSWO's patients of access to critical health care and will threaten their health, safety, and lives without creating any health or safety benefit whatsoever for our patients.

//

//

//

FURTHER AFFIANT SAYETH NAUGHT.

Sharon Liner, M.D.

Planned Parenthood Southwest Ohio

Sworn to and subscribed before me this _____ day of May, 2024.

Notary)Public

SHANDELL EVERSOLE NOTARY PUBLIC STATE OF OHIO Comm. Expires April 7, 2027

Exhibit 6

IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

v.

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

AFFIDAVIT OF JULIA QUINN, MSN, WHNP-BC, IN SUPPORT OF PLAINTIFFS' SECOND MOTION FOR A PRELIMINARY INJUNCTION

I, Julia Quinn, MSN, WHNP-BC, having been duly sworn and cautioned according to law, hereby state that I am over the age of eighteen years and am competent to testify as to the facts set forth below based on my personal knowledge:

I. MY QUALIFICATIONS

1. I am an advanced practice registered nurse ("APRN"), a type of advanced practice clinician ("APC"), in the Surgery and Family Planning Departments of Planned Parenthood Southwest Ohio Region ("PPSWO"). Prior to taking my current position, I was a registered nurse ("RN") in the Surgery Department of PPSWO from April 2022 until March 2023. I provide a range of sexual and reproductive health care, well-person care, and gender affirming care to PPSWO's patients in our health centers and I assist physicians who provide abortion care in our surgical center. I also train RNs, NPs, medical students, and residents at PPSWO.

¹ As described below, I am a board-certified nurse practitioner, which is one type of APRN.

- 2. Prior to starting at PPSWO, I worked in various roles supporting abortion providers. For example, from May 2019 to February 2022, I was a nurse practitioner ("NP") at Planned Parenthood Southeast where I provided reproductive health care, including medication abortion education and complication management. I also served as a part time RN with two other abortion providers, where I provided pre- and post-procedural abortion care from October 2017 to February 2022.
- 3. I hold a Bachelors of Science in Nursing and a Masters of Science in Nursing from Emory School of Nursing. I also hold a Bachelors of Arts in Ecology, Evolution, and Organismal Biology from Vanderbilt University.
- 4. I have been an RN since 2017 and an NP since 2019. I am licensed as an NP and as an RN in Ohio. I am also board certified as a Women's Health Nurse Practitioner ("WHNP"). I also hold a Drug Enforcement Administrative license to prescribe controlled substances as an NP in Ohio.
- 5. The facts I state here are based on my education, training, and experience; information obtained in the course of my duties at PPSWO; and personal knowledge that I have acquired through my service at PPSWO.
- 6. I submit this affidavit in support of Plaintiffs' Second Motion for a Preliminary Injunction. I understand that Plaintiffs are challenging Ohio laws that prevent advanced practice clinicians from providing medication abortion in Ohio (collectively, the "APC Ban"), even if they are trained and qualified to do so within their scope of practice. I understand that the challenged laws preclude anyone other than a physician from providing both medication and procedural abortions in Ohio.

//

II. ADVANCED PRACTICE CLINICIANS

- 7. The term APC includes NPs, certified nurse midwives, and physician assistants. APCs have at least masters-level training in medicine and health care. APC training places significant emphasis on recognizing when a patient needs to be referred to another provider, which can include referral to a specialist or to a physician for care beyond an APC's scope of practice. NPs also typically have an educational focus on health promotion and education that emphasizes preventive care and helping patients avoid illness and disease.
- 8. In Ohio, APCs collaborate with physicians under Standard Care Agreements ("SCAs"), which provide for physician supervision and availability to consult with the APC as needed. The physician does not need to be physically present when the APC provides care. APCs are trained and qualified to safely and effectively treat patients with a high degree of independence. We routinely obtain informed consent from patients for diagnosis and treatment, take patient histories, assess patients physically, diagnose conditions, perform certain procedures, prescribe medication, and provide treatments.
- 9. In general, as an NP, my scope of practice is determined by my training, education, and experience in practice. Other than the APC Ban, I do not know of any Ohio law that expressly says I cannot provide a certain treatment or procedure to a patient when doing so would otherwise be within my scope of practice.

III. ABSENT THE APC BAN, PROVIDING MEDICATION ABORTION IS WITHIN APCS' SCOPE OF PRACTICE.

10. "Medication abortion" generally refers to the use of two medications, mifepristone and misoprostol, in combination to end a continuing pregnancy. It is available in Ohio for the first 70 days of pregnancy, as measured from the first day of a patient's last

menstrual period ("LMP").² Patients first take mifepristone, which blocks the hormone progesterone, thereby stopping the pregnancy from further developing. Then, within the next 48 hours, the patient takes the second medication, misoprostol, which causes the uterus to contract and expel its contents in a manner similar to a miscarriage.

- 11. Absent the APC Ban, providing medication abortion would be within the scope of practice of APCs. Absent the APC Ban, I would train and begin to provide medication abortion to patients in Ohio. Once trained, I would provide medication abortion to PPSWO patients, including providing medication abortion beyond 70 days LMP if the Evidence-Based Use Ban is enjoined. In light of the previously-entered injunction against the Telemedicine Ban, I could provide medication abortion both in person and via telemedicine.
- 12. APCs are trained to screen patients for medical contraindications before prescribing medications and counsel patients on the risks and benefits of, and alternatives to, different forms of treatment.
- 13. Medication abortion is extremely safe, and treating the rare complications from medication abortion is generally within APCs' scope of practice. APCs are also trained to recognize when to refer patients to a higher level of care.
- 14. Further, APCs in Ohio can prescribe mifepristone and misoprostol for non-abortion care. For example, APCs in Ohio can prescribe these medications for miscarriage care and for cervical ripening for Intrauterine Device ("IUD") insertion. Use of these medications for miscarriage care typically involves the same medication regimens, patient assessment, counseling, and risk as use of these medications for induced abortion.

² Although research has demonstrated that mifepristone can be safely and effectively used to end a pregnancy at least through 77 days LMP, I understand that Ohio law currently only allows it to be used for abortion according to its Food and Drug Administration ("FDA") label, which allows its use through 70 days LMP.

- 15. At PPSWO, my Ohio APC colleagues and I provide other health care, including prescribing medication, that is at least comparable to providing medication abortion in terms of the complexity of screening for contraindications or risk factors, counseling patients, and monitoring for and managing complications. For example, APCs prescribe gender affirming hormone care, which involves screening for risk factors and contraindications, extensive counseling, and frequent follow up, as well as selecting medication routes and doses based on patient goals and risk factors, titrating doses, and managing complications. Another example of comparably complex care provided by APCs in Ohio would be the prescription of pre-exposure HIV prophylaxis (commonly called "PrEP") and post-exposure HIV prophylaxis (commonly called "PrEP"), which both involve screening for contraindications and risk factors and monitoring kidney function while patients are taking the medication, as well as extensive counseling regarding risks, alternatives, and use.
- eligibility; counsel them regarding their options, including risks and benefits of different options; and either prescribe or place (with IUDs and Nexplanon) their chosen contraception. Assessing a patient for contraception eligibility can be more complicated than providing medication abortion because some birth control pills that contain estradiol, as well as contraceptive patches and rings, increase a patient's risk for blood clots, and these medications are often taken long term. A patient's risk for blood clots is often multifactorial and nuanced, and APCs routinely navigate assessing this risk compared to risk of pregnancy and counseling patients about weighing risks and alternative methods. In some cases, a patient's risk is high enough to preclude prescribing them an estradiol-containing medication. APCs can, and do, routinely provide patients this care safely and effectively.

17. Beyond this medication-based care, myself and other Ohio APCs perform various procedures that are more technically complex and/or carry higher risk of complications than medication abortion. This includes inserting IUDs, which can involve using mifepristone or misoprostol for pre-insertion cervical ripening and carries risk of uterine perforation and infection; and removing IUDs, which can require use of instruments in the uterus (when removing an IUD without strings). I also insert and remove Nexplanon contraceptive implants under the upper-arm skin via an incision.

IV. THE APC BAN HARMS PATIENTS IN OHIO

- 18. The APC Ban is detrimental to patients. Medication abortion is a critical need for many of my patients, and it is frustrating not to be able to help them. In my experience, most patients who seek an abortion want to proceed with treatment as soon as possible after they have made their decision to terminate their pregnancy. At present, I am unable to help them, which delays their care. For example, if I am seeing a patient to insert an IUD, but the patient and I learn at that appointment that they are pregnant and the patient decides they want to have an abortion, I would not be able to conduct their informed consent (or "Day 1" visit) at that same appointment. Instead, the patient would have to make two visits to our ASF in Cincinnati to obtain medication abortion from a physician.
- 19. If I could provide medication abortion, including providing the state-mandated pre-abortion information and obtaining informed consent, it would increase PPSWO's ability to serve our patients. PPSWO has greater patient volume and need relative to our capacity. PPSWO has a limited number of physicians who currently have to provide all medication and procedural abortions. Having APC capacity to provide medication abortion would free up physician time to

serve more patients who need procedural abortions or other forms of complex gynecological care. It could also enable PPSWO to see medication abortion patients more quickly.

- 20. Absent the APC Ban, PPSWO would also be able to ensure greater continuity of care for our patients. Patients should be able to receive care from a provider of their choosing who is qualified to safely and effectively provide that care. PPSWO's APCs provide a wide range of patient care every day in our health centers. Over time, some patients develop relationships with APCs in our health centers and/or increased comfort with a familiar clinic even if they see different providers at different times. Sexual and reproductive health care is typically extremely intimate and personal, and patients are often more comfortable receiving that sensitive care from a trusted provider and clinic with whom they have established relationships.
- 21. PPSWO does not have enough physicians to staff both our ambulatory surgical facilities ("ASFs") and health centers with physicians. Thus, all medication abortions are provided at our Cincinnati ASF.³ This means that, in practice, the APC Ban requires many of PPSWO's patients to have their abortion at a clinic and with a clinician who is new to them, rather than at a clinic and with a clinician they might otherwise choose due to familiarity. It can be difficult for patients to understand and accept that they have to go to a different clinic for care and work with a new person for that care after having already developed a relationship of trust with myself or another APC colleague at one of our health centers. This is particularly true with patients who distrust medical providers.
- 22. Some patients do not realize that they are pregnant until they come to one of PPSWO's health centers for other care, such as contraception care. The APC Ban can be

³ The exception to this is telemedicine abortions. Still, all telemedicine abortion patients have to go to the Cincinnati ASF for their Day 1 visit since, under the current law, the state-mandated pre-abortion information must be provided in person and by a physician. See R.C. 2317.56, 2919.192–94.

particularly distressing for these patients, who often expect that they might be able to have an abortion or at least begin the informed consent process required by Ohio law that same day. Instead, we have to send patients to our Cincinnati ASF or another abortion provider to essentially start the process over again with a physician. This can be especially problematic for patients who ultimately decide they want medication abortion care and have a short window to do so, since medication abortion is currently only available in Ohio through 70 days LMP. These patients may not be able to access a medication abortion within 70 days LMP, which then forces them to travel out of state for a medication abortion, attempt to manage their abortion outside of the medical system, have a procedural abortion, or remain pregnant against their will.

23. The need for abortion care in Ohio is great, and I would like to be able to help meet that need. I chose to provide the type of care in the setting that I do because I strongly believe that people should be able to have high quality care—regardless of the type of care they need. Patients want and expect this when seeking medical care. Not being able to provide this type of care because of Ohio's APC Ban prevents me from following principles that I believe are central to compassionate, patient-centered, evidence-based care, such as deeply respecting patient dignity and autonomy. This is distressing. It is especially hard to be unable to take care of patients in the way they want and need because I see colleagues in other states with the same training and qualifications as myself who are able to provide medication abortions, while I am subject to arbitrary, medically unnecessary Ohio laws that prevent me from doing the same.

//

//

//

FURTHER AFFIANT SAYETH NAUGHT.

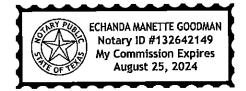
Julia Dring ARA

State of Texas County of Jefferson Julia Quinn, MSN, APRN, WHNP-BC
Planned Parenthood Southwest Ohio Region
Julia Quinn who produced Ohio
Drivers License as identification

Sworn to and subscribed before me this 8th day of May, 2024.

E'Chanda Manette Gordman Notary Public

E'Chanda Manette Goodman
Remote Online Notary Public
State of Texas, Jefferson County



This notarial act was an online notarization along with multi-factor authentication and using audio/video recording.

Exhibit 7

doc**v**erify



Spetz Affidavit.pdf

DocVerify ID:

E37232A3-BF64-4364-A2DC-921E99C6387F

Created:

April 12, 2024 16:59:50 -5:00

Pages:

40

Remote Notary:

Yes / State: OH

This document is a DocVerify VeriVaulted protected version of the document named above. It was created by a notary or on the behalf of a notary, and it is also a DocVerify E-Sign document, which means this document was created for the purposes of Electronic Signatures and/or Electronic Notary. Tampered or altered documents can be easily verified and validated with the DocVerify veriCheck system. This remote online notarization involved the use of communication technology.

Go to www.docverify.com at any time to verify or validate the authenticity and integrity of this or any other DocVerify VeriVaulted document.

E-Signature Summary

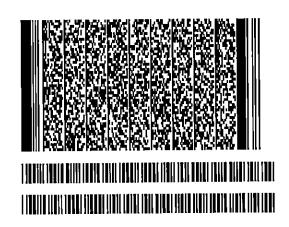
E-Signature 1: Joanne Spetz (JS)

April 12, 2024 17:11:03 -5:00 [76797ACA0868] [128.218.42.81]
joanne.spetz@gmail.com (Principal)

E-Signature Notary: Theresa M Sabo (TMS)

April 12, 2024 17:11:03 -5:00 [271CAB412722] [65.60.211.87] tess.sabo@gmail.com

I, Theresa M Sabo, did witness the participants named above electronically sign this document.



DocVerify documents cannot be altered or tampered with in any way once they are protected by the DocVerify VeriVault System. Best viewed with Adobe Reader or Adobe Acrobat.

All visible electronic signatures contained in this document are symbolic representations of the persons signature, and not intended to be an accurate depiction of the persons actual signature as defined by various Acts and/or Laws.



IN THE COURT OF COMMON PLEAS HAMILTON COUNTY, OHIO

PLANNED PARENTHOOD SOUTHWEST OHIO REGION, et al.,

Case No. A 2101148

Plaintiffs,

Judge Alison Hatheway

v.

OHIO DEPARTMENT OF HEALTH, et al.,

Defendants.

EXPERT AFFIDAVIT OF JOANNE SPETZ, Ph.D., IN SUPPORT OF PLAINTIFFS' SECOND MOTION FOR PRELIMINARY INJUNCTION

I, Joanne Spetz, Ph.D., am over the age of eighteen and competent to testify. I make this affidavit based on personal knowledge and, being duly sworn on oath, do depose and state as follows:

I. BACKGROUND AND QUALIFICATIONS

1. I am the Brenda and Jeffrey L. Kang Presidential Chair in Health Care Financing and Director of the Philip R. Lee Institute for Health Policy Studies, University of California, San Francisco ("UCSF"). I am also a Professor in the Department of Family and Community Medicine and in the School of Nursing at UCSF. In these and previous positions, I have extensively researched nurse practitioners and nurse midwives, the impact of laws and regulatory policies on health behaviors and health workforce labor markets, and the quality of care provided by nurses. I have a particular interest in how the organization and regulation of our health care system affects the provision of, and access to, care.

E37232A3-BF64-4364-A2DC-921E99C6387F --- 2024/04/12 16:59:50 -5:00 --- Remote Notary

- I hold an M.A. and Ph.D. in Economics from Stanford University, which I received 2. in 1993 and 1996, respectively. I also received a Bachelor of Science in Economics from the Massachusetts Institute of Technology in 1990.
- I have authored or supervised numerous studies and systematic reviews evaluating 3. how restrictions on nurse practitioners' ("NPs"") and nurse midwives' ("NMs"") scope of practice—that is, rules defining which services NPs and NMs can provide and under what circumstances—affect health care delivery and access to care. I have also led and contributed to research on the roles of physician assistants ("PAs"), including on how insurance payment policies affect their employment and demand for their services in long-term care. I am currently the principal investigator of the National Dementia Workforce Study, which is an \$81 million project funded by the National Institutes of Health to examine the characteristics of the workforce that serves people with dementia and their impact on health outcomes, including the roles of NPs and PAs.
- I recently completed a study funded by the National Institutes of Health on how 4. state-level scope of practice regulations of NPs, NMs, clinical nurse specialists, and PAs affect their ability to offer medication treatment for opioid use disorder and previously completed a smaller study on the same topic funded by the National Council of State Boards of Nursing ("NCSBN"). I was also co-investigator for a study funded by NCSBN on state scope of practice regulations and NP prescribing of opioids. I am currently principal investigator for two interrelated studies funded by the California Health Care Foundation for which I surveyed 4,000 Californiaresident NPs, NMs, and licensed midwives to learn how changes in California's scope-of-practice regulations have affected their employment and the care they provide. I recently completed research as a co-investigator evaluating how state NP scope of practice regulations impact access

E37232A3-BF64 4364-A2DC-921E99C6387F --- 2024/04/12 16:59:50 -5:00 --- Remote Notary

to health care services among those living in underserved areas. I have been a principal investigator on multiple grants from the Robert Wood Johnson Foundation measuring progress toward nationwide implementation of recommendations by the Institute of Medicine's Committee on the Future of Nursing, which I discuss in greater detail below. I have also completed reviews of the literature on the effect of NP, NM, and PA scope of practice regulations on access, cost, and quality of health care for the California Health Care Foundation.

- 5. I am a member of multiple professional societies, such as AcademyHealth, the American Society of Health Economists, the Gerontological Society of America, and the International Health Economics Association; these are the premier professional organizations for the fields in which I conduct research, and their annual conferences draw thousands of attendees. I actively serve as a committee member, abstract review, and presenter for all of these organizations. I currently serve on the editorial board and as a reviewer for several academic journals, including *Medical Care Research and Review*, *Health Affairs*, and *JAMA Network* journals. I have served on two National Academies of Sciences, Engineering, and Medicine ("Natl. Academies") Committees: one focused on research on the impact of nurse credentials on quality of care, and the other focused on the managerial implications of generational differences in the workplace.
- 6. A full list of my employment history, publications, presentations, professional memberships, and honors and awards is included in my *curriculum vitae*, which is attached as Exhibit A.

II. FACTUAL BASIS FOR EXPERT TESTIMONY

7. The facts I state here and opinions I offer are based on my education and training, my own research, and my regular review of other research in the field. All opinions stated herein are to a reasonable degree of professional certainty.

8. I understand that various state laws prohibit NPs, NMs, and PAs (collectively, "advanced practice clinicians" or "APCs") in Ohio from providing abortion, including medication abortion, regardless of whether such care is within an APC's competency and regardless of patient need, and instead permit only physicians to provide abortion (collectively, the "APC Ban"). I further understand that Plaintiffs in this case are seeking a preliminary injunction of the APC Ban as applied to APCs' provision of medication abortion.

III. OPINIONS

- 9. As a health care economist, I specialize in assessing how systemic structures affect access to and quality of health care. I am deeply familiar with, and have contributed to, the research and literature relating to the role and regulation of APCs in the U.S. health care system.
- 10. APCs are vital participants in the U.S. health care system. As states and accreditation bodies have heightened educational standards for APCs, a large and growing body of research has confirmed the safety and efficacy of their provision of care, and as the nation's physician shortage crisis has worsened, APCs' practice authority has expanded significantly. APCs are safely providing a broader range of services, with fewer conditions and limitations, than ever before.

¹ Natl. Academies et al., The Future of Nursing 2020–2030: Charting a Path to Achieve Health Equity, at 87 (2021), https://doi.org/10.17226/25982 (accessed Apr. 10, 2024).

E37232A3-BF64-4364-A2DC-921E99C6387F — 2024/04/12 16:59:50 -5:00 — Remote Notary

- 11. Today, APCs hold prescriptive authority in every state, including for controlled substances,² and they are key providers of primary, gynecological, maternity, acute, and chronic care across the country. They are particularly likely to serve low-income patients and those living in rural and medically underserved areas. Citing the robust evidence confirming the safety of APC provision of care within their scope of practice and the nation's urgent health care needs, leading authorities—such as the National Academy of Medicine, the Federal Trade Commission, and the National Governors Association—recommend that APCs take on an even greater role in the health care system, practicing to the fullest extent of their education and training.
- 12. Ohio's APC Ban undermines APCs' ability to care for their patients and is out-of-step with APCs' essential role in the health care systems of Ohio and the nation.

A. Regulation of APCs

13. NPs and NMs are two of the four recognized categories of advanced practice registered nurses ("APRNs") in Ohio and in the United States. Both NPs and NMs in Ohio hold national certification and are thus called certified nurse practitioners ("CNPs") and certified nurse midwives ("CNMs"), respectively, in that state as well as some other states.³

² Am. Academy of Physician Assocs., *PA Prescribing* (Apr. 2019), https://www.aapa.org/wp-content/uploads/2017/03/f-833-4-8256527_dk6DMjRR_Prescribing_

IB 2017 FINAL.pdf (accessed Apr. 10, 2024); Am. Assn. of Nurse Practitioners, State Practice Environment, https://www.aanp.org/advocacy/state/state-practice-environment (accessed Apr. 10, 2024); U.S. Dept. of Justice Drug Enforcement Administration, Diversion Control Div., Mid-Level Practitioners Authorization by State, https://www.deadiversion.usdoj.gov/drugreg/practioners/index.html (accessed Apr. 10, 2024).

³ R.C. 4723.41(A); Ohio Adm.Code 4723-8-01(A); Ohio Bd. of Nursing, APRN Licensure and Practice in Ohio, https://nursing.ohio.gov/resources-for-practice-and-prescribing/resources/04-aprn-licensure-and-practice (accessed Apr. 10, 2024). Nurse anesthetists, who administer anesthesia and provide related care, and clinical nurse specialists, who provide advanced nursing care and acute and chronic care management, are also types of APRNs. See APRN Licensure and Practice in Ohio.

- taking health histories and performing physical examinations, providing health education and counseling, diagnosing and treating acute and chronic illnesses, providing immunizations, performing procedures, ordering and interpreting lab tests and x-rays, coordinating patient care across multiple providers, and prescribing and managing medications and other therapies (including at least Schedule III controlled substances in every state and the District of Columbia 4). The Veterans Health Administration reports that the roles of NPs are similar to those of physicians. Nationwide, NPs accounted for at least 25% of rural and 23% of nonrural primary care providers in 2016. Furthermore, NPs are a key source of care in community health centers and nurse-managed health centers, which serve about 20 million patients a year. NP education covers a common range of medical topics including physiology, body systems, and diagnosing and treating illnesses and conditions. Their initial education also includes an area of focus, such as family practice, pediatrics, women's health, adult-gerontology, psychiatry, or acute care.
- 15. Nationally, NMs provide primary and specialized care to patients who need gynecological care, including family planning services; preconception care; care throughout the course of pregnancy, including childbirth and postpartum care; and neonatal care. NMs "provide initial and ongoing comprehensive assessment, diagnosis and treatment. They conduct physical

⁴ U.S. Dept. of Justice Drug Enforcement Administration, *supra* note 2.

⁵ Alexandra Hobson & Alexa Curtis, *Improving the Care of Veterans: The Role of Nurse Practitioners in Team-Based Population Health Management*, 29 Journal of the Am. Assn. of Nurse Practitioners 644, 645 (2017) ("NPs function in a similar capacity to physicians within the VHA primary care system including serving as primary care providers.").

⁶ Hilary Barnes et al., Rural and Nonrural Primary Care Physician Practices Increasingly Rely on Nurse Practitioners, 37 Health Affairs 908, 909–10 (2018).

⁷ Kaiser Family Found., Kaiser Comm. on Medicaid & the Uninsured, *Improving Access to Adult Primary Care in Medicaid: Exploring the Potential Role of Nurse Practitioners and Physician Assistants*, at 3 (Mar. 2011), https://www.kff.org/wp-content/uploads/2013/01/8167.pdf (accessed Apr. 10, 2024).

examinations; prescribe medications including controlled substances and contraceptive methods; admit, manage and discharge patients; order and interpret laboratory and diagnostic tests and order the use of medical devices."8 NMs can prescribe controlled substances in every state and the District of Columbia. 9 Many NMs also hold certification as NPs; for instance, this is true for approximately half of California's NMs. 10

- PAs, like NPs and NMs, play a vital role in expanding access to medical care. 16. especially in underserved communities and areas. PAs are licensed health care professionals who practice medicine in collaboration with physicians and other providers. Their responsibilities include diagnosing illness, creating treatment plans, performing procedures, and prescribing medications, including controlled substances. They are recognized and licensed in every U.S. state.11
- APCs' competencies also include recognizing cases when a patient has complex 17. needs requiring evaluation or treatment beyond the clinician's education, training, or skills—just as a physician would refer patients to a specialty provider if the patients' needs are outside of that physician's area of expertise.

⁸ Am. College of Nurse-Midwives, Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives, (Dec. 2011). http://www.midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/00000000266 /Definition%20of%20Midwifery%20and%20Scope%20of%20Practice%20of%20CNMs%20and %20CMs%20Dec%202011.pdf (accessed Apr. 10, 2024).

⁹ Kathryn Osborne, Regulation of Controlled Substance Prescribing: An Overview for Certified Nurse-Midwives and Certified Midwives, 62 Journal Midwifery & Women's Health 341 (2017).

¹⁰ Joanne Spetz et al., 2017 Survey of Nurse Practitioners and Certified Nurse-Midwives 15, Cal. Bd. of Registered Nursing (Apr. 11, 2018), https://www.rn.ca.gov/pdfs/forms/survey2017npcnmfinal.pdf (accessed Apr. 10, 2024).

¹¹ Am. Academy of Physician Assocs., List of Licensing Boards, https://www.aapa.org/advocacycentral/state-advocacy/state-licensing/list-of-licensing-boards/ (accessed Apr. 10, 2024).

Throughout the country, APCs are subject to two principal layers of regulation: 18. licensure and scope of practice.

APC Licensure 1.

- 19. First, as with many occupations, licensure is "a process that establishes the conditions for entry into an occupation. . . . Generally, an applicant for licensure must demonstrate a minimum degree of competence, based on education and training, to obtain the government's permission to provide professional services in a given jurisdiction."¹²
- Today, all states, including Ohio, as well as the District of Columbia, require 20. prospective NPs to hold a registered nurse license and prove their competency as an NP through additional certification and/or educational requirements. Ohio, like all states and the District of Columbia, requires completion of a master's, postgraduate, or doctorate degree from an accredited NP program, and 47 states, including Ohio, and the District of Columbia require that the candidate obtain certification from a nationally recognized certifying body such as the American Academy of Nurse Practitioners or the American Nurses Credentialing Center. 13 The certification "tests the applicant's knowledge and skill in diagnosing, determining treatments, and prescribing for their

¹² Daniel J. Gilman & Tara Isa Koslov, Fed. Trade Comm., Policy Perspectives: Competition and Regulation Nurses, (Mar. Advanced Practice at https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulationadvanced-practice-nurses/140307aprnpolicypaper.pdf (accessed Apr. 10, 2024) [hereinafter "FTC Report"].

https://www.ncsbn.org/nursing-regulation/practice/aprn/ NCSBN, Certification Map. aprn-consensus-implementation-status/certification-map.page (accessed Apr. 10, 2024). The three states that do not require such national certification for NP licensure (California, Indiana, and New York) instead require either certification or completion of a board-approved master's degree with similar course requirements to those accepted by the national certifying bodies. Natl. Governors Assn., The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care, at 8 (Dec. 20, 2012), https://www.nga.org/center/issues/health-issues/the-role-of-nurse-practitionersin-meeting-increasing-demand-for-primary-care (accessed Apr. 10, 2024).

patient population of focus."¹⁴ In Ohio, NPs are licensed as certified nurse practitioners and receive approval to practice as CNPs by the Board of Nursing, which oversees their practice.¹⁵

21. NMs are educated in both midwifery and nursing. As with NPs, today all states and the District of Columbia require NM applicants to hold a registered nurse license and prove their competency through additional certification and/or educational requirements. The District of Columbia and all but one state (Pennsylvania) require completion of a master's, postgraduate, or doctorate degree from an accredited NM program, and all but two states (New York and Pennsylvania) require certification by the American Midwifery Certification Board. In Ohio, NMs are licensed as certified nurse midwives and receive approval to practice as CNMs by the Board of Nursing, which oversees their practice. In

22. PAs are generally licensed and regulated by Boards of Medicine, including in Ohio.¹⁸ In all states, an applicant seeking PA licensure must have passed the national certification examination offered by the National Commission on Certification of Physician Assistants.¹⁹ Applicants are eligible to take this exam after completing a nationally-accredited education program; as of January 1, 2021, all accredited PA education programs across the U.S. must confer a graduate degree.²⁰

¹⁴ Natl. Governors Assn., *supra* note 13.

¹⁵ R.C. 4723.41–42.

¹⁶ NCSBN, APRN Consensus Model by State, https://www.ncsbn.org/public-files/aprn consensus model by state.pdf (accessed Apr. 10, 2024).

¹⁷ R.C. 4723.41–42.

¹⁸ R.C. 4730.01 et seq.

N.C. 4750.01 et seq.

19 Natl. Comm. on Certification for Physician Assistants, Become Certified, https://www.nccpa.net/become-certified/ (accessed Apr. 10, 2024).

²⁰ ARC-PA, *Accredited Programs*, http://www.arc-pa.org/accreditation/accredited-programs/ (accessed Apr. 10, 2024).

2. APC Scope of Practice

- 23. The second layer of APC regulation relates to "scope of practice," which defines which professional services an APC is authorized to provide. These rules dictate which patients an APC may treat, what services they may deliver, and the extent to which they are permitted to practice independently (that is, without formal physician oversight or supervision). Scope of practice rules may bar APCs from performing certain services or treating certain categories of patients unless they first complete additional training, obtain a particular certification, obtain and document a specific form of supervision (e.g., from a physician or a more experienced APRN), or meet other regulatory requirements.
- 24. APCs' scope of practice is governed by state law under the state's nurse practice act, physician practice act, or other similar practice regulations and is administered and regulated by each state's licensing boards. State legislatures may set the broad outlines of scope of practice but delegate to the state's licensing boards to flesh out the specific details and enforce the rules under penalty of professional discipline. As a general matter, however, these licensing boards do not have detailed lists of procedures, tests, or treatments that APCs are categorically precluded from performing. This is because whether a specific treatment is within a provider's scope of practice is typically linked to the APCs' education and the licensing examinations they take.
- 25. Thirty-three U.S. states have implemented scope of practice laws that allow NPs full practice independence without any physician oversight, even when prescribing controlled substances.²¹ In some of these states, NPs must complete up to five years of practice in formal

²¹ Benjamin J. McMichael & Sara Markowitz, *Toward a Uniform Classification of Nurse Practitioner Scope of Practice Laws*, 80 Med. Care Research & Review 1 (2023); Bruce Jaspen, Forbes, *Kansas Lifts Hurdles to Nurse Practitioners, Becomes 26th State to Do So* (Apr. 15, 2022), https://www.forbes.com/sites/brucejapsen/2022/04/15/kansas-lifts-hurdle-to-nurse-practitioners-becomes-26th-state-to-do-so/?sh=33927160793f (accessed Apr. 10, 2024). In addition, California

collaboration or supervision with a physician or experienced NP before the NP can practice without formal oversight. More than half of all states allow NMs to practice independently without physician oversight.²²

In every state except New Mexico, physician assistants are required to have a 26. formal collaboration or supervision agreement with a physician.²³ However, in most states, this does not require that the physician be on-site with the PA, and regulations allow PAs substantial autonomy in clinical decisionmaking.²⁴

Expanded Role of APCs in the United States Health Care System В.

APCs have taken on an increasingly significant role in the United States health care 27. system over the past several decades, and particularly since the turn of the 21st century. This is a product of four interwoven trends: (1) enhanced educational requirements for APC licensure; (2)

passed legislation in September 2020 that allows NPs to practice without formal physician 890, 2019-20 Leg., Reg. Sess. (Ca. 2020), available at oversight. See A.B. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200AB890 (accessed Apr. 10, 2024); Sophia Bollag, The Bee, New California Law Aims for More Medical Providers Practitioners More Authority (Sept. 29, 2020), Giving Nurse bvhttps://www.sacbee.com/news/politics-government/capitol-alert/article246035050.html (accessed Apr. 10, 2024) (California).

²² Joanne Spetz, Cal. Health Care Found., California's Nurse Practitioners: How Scope of Practice Laws Impact Care, at 5-6 (May 2, 2019), https://www.chcf.org/publication/californias-nursepractitioners/ (accessed Apr. 10, 2024); Connie Kwong et al., Cal. Health Care Found., California's Midwives: How Scope of Practice Laws Impact Care, at 11 tbl.7 (Oct. 2019), https://www.chcf.org/wp-content/uploads/2019/10/California'sMidwivesScopePracticeLaws ImpactCare.pdf (accessed Apr. 10, 2024). The exact number of states with full practice independence may vary slightly depending on which professional organization is interpreting the regulations.

²³ Am. Med. Assn., Physician Assistant Scope of Practice (2018), https://www.amaassn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/state-law-physicianassistant-scope-practice.pdf (accessed Apr. 10, 2024).

²⁴ Id.; Joanne Spetz et al., Transformation of the Nonphysician Health Professions, in The Healthcare Professional Workforce: New Directions in Theory and Practice 51, 57 (2016).

E37232A3-BF64-4364-A2DC-921E99C6387F --- 2024/04/12 16:59:50 -5:00 --- Remote Notary

growing numbers of APC graduates; (3) steadily expanding APC scope of practice; and (4) greater utilization of APCs' services, particularly in the context of pregnancy care.

1. Enhanced Educational Requirements

- 28. Today, all NP programs in the United States are offered at the graduate level and are required to be accredited by a nationally recognized nursing and/or education accreditation body.²⁵
- 29. However, this has not always been the case. When the first educational programs for NPs were established in the 1960s and 1970s, they conferred certificates rather than diplomas. Furthermore, many of the initial graduates of NP programs had received their registered nurse education in diploma programs based in hospitals rather than universities.
- 30. Indeed, it is only in recent years that certification bodies and state legislatures have uniformly required a graduate degree for new NPs. For example, the National Certification Corporation—the premiere certification body for NPs in the obstetric, gynecologic, and neonatal nursing specialties—only began requiring a master's degree for nurses seeking certification as women's health nurse practitioners in 2007.²⁶
- 31. Although midwifery has a long history—women have likely been assisting one another in childbirth for millennia—nurse midwifery was not established as a distinct field until 1925, and national certifications in nurse midwifery were first offered in 1970 by the American

²⁵ Westat for the Office of the Assistant Secy. for Planning & Evaluation, *Impact of State Scope of Practice Laws and Other Factors on the Practice and Supply of Primary Care Nurse Practitioners: Final Report*, at 27 (2015), https://aspe.hhs.gov/system/files/pdf/167396/NP SOP.pdf (accessed Apr. 11, 2024) [hereinafter "ASPE Report"].

²⁶ Jane H. Kass-Wolff & Nancy K. Lowe, A Historical Perspective of the Women's Health Nurse Practitioner, 44 Nursing Clinics of N. Am. 271, 277 (2009).

E37232A3-BF64-4364-A2DC-921E99C6387F.— 2024/04/12 16:59:50 .-5:00 ... Remote Notary

College of Nurse Midwives. A graduate degree has been required for new applicants for certification by the American Midwifery Certification Board only since 2010.²⁷

- 32. For both NPs and NMs, there is a growing trend toward curriculum standardization across institutions.²⁸ In 2008, after five years of study and debate, a group of nursing accreditation, certification, and licensing organizations, along with several APRN groups, developed a consensus model for the accreditation, education, training, certification and licensure of APRNs.²⁹ State boards of nursing in every state have signed onto the APRN consensus model, although changes to rules and regulations are generally required to be approved by the state legislatures. To date, 17 states have fully enacted the consensus model for all APRN roles.³⁰ Ohio's education and certification requirements are aligned with the consensus model.³¹
- 33. Similar to NPs and NMs, PA education began with a variety of certificate and degree programs. The first program at Duke University was a two-year program based on a traditional medical education.³² Today, all PA education is at the master's degree level, and students must matriculate at an accredited education program in order to take the national licensing examination.³³ The accreditation requirement has promulgated consistent standards for PA

Am. College of Nurse-Midwives, Essential Facts about Midwives, http://www.midwife.org/Essential-Facts-about-Midwives (accessed Apr. 11, 2024).

²⁸ ASPE Report, *supra* note 25, at 27.

²⁹ Inst. of Med. of the Natl. Academies, *The Future of Nursing: Leading Change, Advancing Health*, at 106 (2011), https://www.nap.edu/read/12956 (accessed Apr. 11, 2024) [hereinafter "IOM Report"].

³⁰ NCSBN, *supra* note 16. Those states are Alaska, Connecticut, Delaware, Hawaii, Idaho, Kansas, Kentucky, Minnesota, Montana, New Mexico, North Dakota, Oregon, Rhode Island, Utah, Vermont, West Virginia, and Wyoming.

³¹ *Id.* at 3.

³² See James F. Cawley et al., Origins of the Physician Assistant Movement in the United States, 25 Journal of the Am. Academy of Physician Assistants 36, 38 (2012).

³³ See Am. Academy of Physician Assocs., Become a PA, https://www.aapa.org/career-central/become-a-pa/ (accessed Apr. 11, 2024).

education nationwide. After completion of a PA education program, all states require applicants to take and pass the Physician Assistant National Certifying Examination to qualify for licensure.³⁴

2. Growing Numbers of APC Graduates

- 34. Individuals are entering into and graduating from APC post-graduate programs at unprecedented rates. The number of students enrolled in APRN master's programs increased 68.6% between 2006 and 2011, from 56,028 to 94,480 persons.³⁵ More than 39,000 people completed NP education programs in the 2021–22 year,³⁶ which is nearly six times the 6,611 graduates in 2003.³⁷ From 2007 to 2022, the number of newly certified NMs increased from 285 to 799.³⁸ Similarly, the number of PA graduates has increased markedly over the decades: there were 767 graduates in 1984–85,³⁹ approximately 4,554 in 2003,⁴⁰ and 9,446 in 2018–19.⁴¹
- 35. According to the American Association of Nurse Practitioners, there were more than 385,000 NPs certified to practice in the United States in 2022.⁴²

Am. Academy of Physician Assocs., *PA Scope of Practice* (Sept. 2019), https://www.aapa.org/download/61319/ (accessed Apr. 11, 2024); Spetz, *supra* note 24.

³⁵ John K. Iglehart, Expanding the Role of Advanced Nurse Practitioners—Risks and Rewards, 368 New England Journal of Med. 1935, 1937 (2013).

³⁶ Am. Assoc. of Nurse Practitioners, *NP Fact Sheet*, https://www.aanp.org/about/all-about-nps/np-fact-sheet (accessed Apr. 11, 2024) [hereinafter "NP Fact Sheet"].

³⁷ U.S. Health Resources & Servs. Admin., *Projecting the Supply and Demand for Primary Care Practitioners Through 2020*, at 16 (2013), https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/projecting-primary-care.pdf (accessed Apr. 11, 2024).

³⁸ See Am. Midwifery Certification Bd., 2022 Annual Report, at 3 (2019), https://www.amcbmidwife.org/docs/default-source/annual-reports/2022-amcb-annual-report.pdf?sfvrsn=7e6deb8b_2 (accessed Apr. 11, 2024).

³⁹ See Physician Assistant Educ. Assn., *Program Report 35: Data from the 2019 Program Survey*, at 33 (2020), https://paeaonline.org/wp-content/uploads/2020/11/program-report35-20201014.pdf (accessed Apr. 11, 2024).

⁴⁰ See Physician Assistant Edn. Assn., Twentieth Annual Report on Physician Assistant Educational Programs in the United States, 2003–2004, at 56 (Aug. 2004), https://paeaonline.org/wp-content/uploads/imported-files/20th-Annual-Report-on-Physician-Assistant-Educational-Programs-in-the-United-States-2003-2004.pdf (accessed Apr. 11, 2024).

⁴¹ See Physician Assistant Educ. Assn., supra note 39, at 33.

⁴² NP Fact Sheet, *supra* note 36.

E37232A3-BF64 4364-A2DC-921E99C6387F -- 2024/04/12 16:59:50 -5:00 -- Remote Notary

- 36. According to the American Midwifery Certification Board, as of May 2022, there were 13,640 NMs in the United States.⁴³
- 37. The National Commission on Certification of Physician Assistants reported that there were 168,318 certified PAs in the United States in 2022.⁴⁴

3. Expanded Legal Authority for APC Practice

- 38. Perhaps the most significant change over the past two decades is in the broadening of APC practice authority, with particularly notable expansions for APRNs. According to the Institute of Medicine's ("IOM's") 2010 Future of Nursing report, "[f]or several decades, the trend in the United States has been toward expansion of scope-of-practice regulations for APRNs, but this shift has been incremental and variable. Most recently, the move to expand the legal authority of all APRNs to provide health care that accords with their education, training, and competencies appears to be gathering momentum."
- 39. In 1997 alone, 37 states enacted 83 laws expanding scope of practice for APRNs. 46
 Between 2004 and 2012, eight additional states liberalized their scope of practice rules for APRNs. 47 Since 2007, 32 states have enacted regulatory changes that have provided NPs with a greater degree of practice authority, including 16 states that now allow NPs to practice without

⁴³ See Am. Midwifery Certification Bd., Certified Nurse-Midwives/Certified Midwives by State (May 2022), https://www.amcbmidwife.org/docs/default-source/reports/number-of-cnm-cm-by-state---may-2021.pdf?sfvrsn=d11af62c_6 (accessed Apr. 11, 2024).

⁴⁴ See Natl. Comm. on Certification of Physician Assistants, 2022 Statistical Profile of Certified PAs: Annual Report, at 10 (2023), https://www.nccpa.net/wp-content/uploads/2023/04/2022-Statistical-Profile-of-Board-Certified-PAs.pdf (accessed Apr. 11, 2024).

⁴⁵ IOM Report, *supra* note 29, at 106; *see also* ASPE Report, *supra* note 25, at 5 ("There has been a general trend over time toward allowing NPs greater practice authority" (citation omitted)).

⁴⁶ Benjamin G. Druss et al., *Trends in Care by Nonphysician Clinicians in the United States*, 348 New England Journal of Med. 130, 131 (2003).

⁴⁷ ASPE Report, *supra* note 25, at 18; *see also* Iglehart, *supra* note 35, at 1939.

physician oversight.⁴⁸ In total, 32 states allow NPs to practice and prescribe medications without physician oversight either immediately upon licensure or after a transitional period with oversight by a physician or experienced NP.⁴⁹

40. In 2006, Georgia became the last state to grant NPs prescriptive authority, ⁵⁰ and in 2016, Florida became the last state to authorize NPs and NMs to prescribe controlled substances. ⁵¹ Today, NPs, NMs, and PAs hold prescriptive authority, including for controlled substances, in all 50 states and the District of Columbia. ⁵² NPs may prescribe controlled substances, including Schedule III substances, such as products containing less than 90 milligrams of codeine, ketamine, and anabolic steroids, in every state and Schedule II substances, such as oxycodone, methadone, and fentanyl, in all but four states. ⁵³ As of 2022, 96.2% of NPs prescribed medications, and those in full-time practice wrote an average of 21 prescriptions per day. ⁵⁴ (My understanding is that

⁵⁴ NP Fact Sheet, *supra* note 36.

⁴⁸ Campaign for Action, *Our Dashboard* (Mar. 6, 2024), https://campaignforaction.org/resource/our-dashboard/ (accessed Apr. 11, 2024).

⁴⁹ *Id.*

⁵⁰ Briana Ralston et al., *The NP: Celebrating 50 Years*, 115 Am. Journal of Nursing 54, 57 (2015). ⁵¹ Fla. Bd. of Nursing, *Important Legislative Update Regarding HB 423* (Apr. 15, 2016), http://floridasnursing.gov/latest-news/new-legislation-impacting-your-profession/ (accessed Apr. 11, 2024) (describing new legislation that allows PAs and "ARNPs" to prescribe controlled substances listed in Schedules II—IV as of January 1, 2017); Fla. Bd. of Nursing, *Updated Standards for Protocols: Physicians and ARNPs* (Jan. 12, 2016), http://floridasnursing.gov/latest-news/standards-for-protocols-physicians-and-arnps/ (accessed Apr. 11, 2024) (defining "ARNPs" to include NPs, CNMs, and certified registered nurse anesthetists); Kathryn Osborne, *Regulation of Prescriptive Authority for Certified Nurse-Midwives and Certified Midwives: 2015 National Overview*, 60 Journal of Midwifery & Women's Health 519, 530 (2015) (noting *before* the change in Florida's laws that "one of the 2 states that previously denied CNMs the ability to prescribe controlled substances as of 2011 (Alabama) now allows CNMs to prescribe Schedule III to V controlled substances...").

⁵² NP Fact Sheet, *supra* note 36; Am. College of Nurse-Midwives, *supra* note 27; Osborne, *supra* note 51, at 530; Am. Academy of Physician Assocs., *supra* note 2.

⁵³ U.S. Dept., of Justice Drug Enforcement Administration, *supra* note 2.

E37232A3-BF64 4364-A2DC-921E99C6387F — 2024/04/12 16:59:50 -5:00 — Remote Notary

mifepristone and misoprostol, used in medication abortion, are relatively lower risk medications that are not controlled substances.)

- 41. Notably, the United States Drug Enforcement Administration (the "DEA") does not place any unique restrictions on APC prescription of controlled substances. APCs may register with the DEA just as physicians do and prescribe controlled substances consistent with any state-specific requirements (such as additional educational or supervision requirements). 55
- 42. A similar trend toward expanded practice authority for APCs is visible at the federal level. For example, in 2016, the U.S. Department of Veterans Affairs announced new regulations permitting full practice authority for the nearly 6,000 APRNs in its workforce, allowing them "to practice to the full extent of their education, training, and certification, regardless of state restrictions that limit such full practice authority, except for applicable state restrictions on the authority to prescribe and administer controlled substances, when such APRNs are acting within the scope of their VA employment."⁵⁶
- 43. This expansion of APC practice has included their authorization to provide abortion, including both medication and aspiration abortion. In 2013, 16 states allowed APCs to provide medication abortion, and only four of these allowed them to perform abortion

⁵⁵ See U.S. Dept. of Justice Drug Enforcement Administration, supra note 2; 21 C.F.R. § 1301.11 et seq.

⁵⁶ U.S. Dept. of Veterans Affairs, *VA Grants Full Practice Authority to Advance Practice Registered Nurses* (Dec. 14, 2016), https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2847 (accessed Apr. 11, 2024). The final regulations did not apply to Certified Registered Nurse Anesthetists.

procedures.⁵⁷ Now, 21 states and the District of Columbia allow APCs to provide medication abortion, and 19 of these and the District of Columbia allow them to provide procedural abortion.⁵⁸

4. Increased Utilization of APC Services

- 44. Unsurprisingly, as the numbers of APCs have increased and their practice authority has expanded, a growing number of Americans are relying on them for care.
- 45. According to the Kaiser Family Foundation, "NPs are . . . by far, the fastest growing segment of the primary care professional workforce; between the mid-1990s and the mid-2000s, their numbers (per capita) grew an average of more than 9% annually, compared with . . . just 1% for primary care physicians." Between 1998 and 2010, the number of Medicare patients receiving care from NPs increased 15-fold. These trends have continued over the past decade, with the number of people working as NPs nearly tripling from 91,000 in 2010 to 266,012 in 2022. The United States Bureau of Labor Statistics projects that NP employment will grow 45% by 2032.

⁵⁷ 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. Journal of Pub. Health 454, 455 fig. 1 (2013).

AP Toolkit, State Abortion Laws and Their Relationship to Scope of Practice, https://aptoolkit.org/advancing-scope-of-practice-to-include-abortion-care/state-abortion-laws-and-their-relationship-to-scope-of-practice/ (accessed Apr. 11, 2024).

⁵⁹ Kaiser Family Found., supra note 7, at 3; David I. Auerbach et al., Growing Ranks of Advanced Practice Clinicians—Implications for the Physician Workforce, 378 N. England J. of Med. 2358, 2359 (2018).

⁶⁰ Yong-Fang Kuo et al., States with the Least Restrictive Regulations Experienced the Largest Increase in Patients Seen by Nurse Practitioners, 32 Health Affairs 1236, 1236 (2013).

⁶¹ David I. Auerbach et al., Growing Ranks of Advanced Practice Clinicians—Implications for the Physician Workforce, 39 Health Affairs 273, 274 (2020); Health Resources & Service Administration, NCHWA Nursing Workforce Dashboard, https://data.hrsa.gov/topics/health-workforce/nursing-workforce-dashboards (accessed Apr. 11, 2024).

⁶² U.S. Bureau of Labor Statistics, *Occupational Outlook Handbook: Nurse Anesthetists, Nurse Midwives, and Nurse Practitioners*, https://www.bls.gov/ooh/healthcare/nurse-anesthetists-nurse-midwives-and-nurse-practitioners.htm#tab-6 (accessed Apr. 11, 2024).

- 46. The United States Bureau of Labor Statistics also reported PA employment at 148,000 as of May 2022 and estimates further growth by 27% by 2032.⁶³
- 47. Similarly, the proportion of singleton births (i.e., a birth of a single child) for which an NM was the primary clinician managing the birth, as recorded on the birth certificate, increased nationwide from 5.3% in 1994 to 8.4% in 2013 and further rose to 10.9% in 2022.⁶⁴ The rate of midwife-attended birth in Ohio is slightly lower than the national average, at 9.9% in 2022.⁶⁵
- 48. An earlier study evaluating the results of two nationally representative surveys found that the proportion of patients who saw a non-physician clinician (broadly defined) for care rose from 30.6% to 36.1% between 1987 and 1997.⁶⁶ Between 2013 and 2019, the percentage of health care evaluation and management visits provided by NPs and PAs to Medicare fee-forservice enrollees increased from 14% to 25.6%, with the likelihood of receiving care from an NP or PA highest among rural residents.⁶⁷ Between 2013 and 2021, the percentage of NPs and PAs among clinicians prescribing medications for Medicare enrollees rose from approximately 32% to more than 50%.⁶⁸ The proportion of beneficiaries having an NP as their primary provider nearly doubled between 2012 and 2017, and patients cared for by NPs were more likely to have multiple

⁶³ U.S. Bureau of Labor Statistics, *Occupational Outlook Handbook: Physician Assistants*, https://www.bls.gov/ooh/healthcare/physician-assistants.htm#tab-6 (accessed Apr. 11, 2024).

⁶⁴ Sara Markowitz et al., Competitive Effects of Scope of Practice Restrictions: Public Health or Public Harm, 55 Journal of Health Economics 201, 217 (2017); Ctrs. for Disease Control & Prevention, About Natality, 2016–2022 expanded, http://wonder.cdc.gov/natality-expanded-current.html (accessed Apr, 11, 2024).

⁶⁵ Ctrs. for Disease Control & Prevention supra note 64.

⁶⁶ Druss et al., *supra* note 46, at 133–34.

⁶⁷ Sadiq Y. Patel et al., Provision of Evaluation and Management Visits by Nurse Practitioners and Physician Assistants in the USA from 2013 to 2019: Cross-Sectional Time Series Study, 382 BMJ 1 (2023).

⁶⁸ Roderick S. Hooker & John M. Zobitz, Prescribing by Physician Associates and Nurse Practitioners in Older Adults Is Outpacing Traditional Prescribers: Implications for Practice in American Medicine, 81 Sage Journals 156 (2023).

chronic conditions than patients cared for by physicians.⁶⁹ Interestingly, while these trends generally reflect "an increase in the proportion of patients treated by *both* physicians and non-physician clinicians, and a corresponding decrease in the proportions treated by only one of the two types of providers," this has not held true in the context of pregnancy care.⁷⁰ Surveys have shown a decrease in the proportion of women receiving pregnancy-related care from physicians and an increase in the proportion receiving such care only from non-physicians.⁷¹

- 49. More recently, NPs have been serving as the primary care providers in thousands of retail clinics (walk-in clinics located in retail stores and pharmacies) nationwide, where they treat common conditions such as ear infections and bronchitis at lower cost and greater convenience. The 2021, APCs accounted for 18% of all community health center medical services staff, while physicians accounted for only 17%. The National Association of Community Health Centers reports that these providers are hiring APCs at higher rates than physicians.
- 50. APCs are also playing greater roles in health care specialties, such as surgical care and oncology. More than 20,800 PAs worked in surgical specialties in 2021, an increase of 37.7% from 2015;⁷⁵ in 2021, nearly 3,200 PAs worked in cardiology, an increase of 40.7% from 2015;

⁶⁹ Taressa K. Fraze et al., Role of Nurse Practitioners in Caring for Patients with Complex Health Needs, 58 Med. Care 853, 857 (2020).

⁷⁰ *Id.* at 134–35 (emphasis added).

⁷¹ *Id.* at 135.

Rand Corp., The Evolving Role of Retail Clinics (Nov. 10, 2016), https://www.rand.org/pubs/research briefs/RB9491-2.html (accessed Apr. 11, 2024).

⁷³ Natl. Assn. of Community Health Ctrs., *Community Health Center Chartbook*, at fig.5-5 (2023), https://www.nachc.org/wp-content/uploads/2023/07/Community-Health-Center-Chartbook-2023-2021UDS.pdf (accessed Apr. 11, 2024).

⁷⁴ *Id.* at fig.5-6.

⁷⁵ Natl. Comm. on Certification of Physician Assistants, Annual Report: 2021 Statistical Profile of Certified PAs by Specialty, at 8 (2022), https://prodcmsstoragesa.blob.core.windows.net/uploads/files/2019%20Specialty%20Report%20Final%20(v7)_compressed%20(1).pdf (accessed Apr. 12, 2024); Natl. Comm. on Certification of Physician Assistants, Annual Report: 2019 Statistical Profile of Certified PAs by Specialty, at 14, 19, 89 (2020),

E37232A3-BF64-4364-A2DC-921E99C6387F — 2024/04/12 16:59:50 -5:00 — Remote Notary

and almost 1,750 worked in oncology, an increase of 90.1% from 2015. For oncology patients enrolled in Medicare, NPs accounted for 31.5% of the clinicians providing care in 2013.76

Furthermore, a growing number of NPs and PAs work in hospitals, providing acute 51. and emergency care side-by-side with hospitalist physicians.⁷⁷ Indeed, health care institutions are increasingly incorporating NPs and PAs into inpatient care as lead providers, with strong results. For instance, data from two intensive care units ("ICUs") at Columbia Presbyterian Medical Center in New York—where one unit was staffed by medical residents and the other unit was staffed by NPs and PAs—demonstrated equivalent outcomes in hospital mortality, length of hospital stay, length of ICU stay, and discharge destination. 78 According to the American Association of Nurse Practitioners' 2020 national sample survey, more than 45% of NPs employed full-time in the U.S. hold hospital privileges.⁷⁹

APCs Play an Outsized Role in Caring for Patients in Rural and C. Underserved Areas.

The United States faces a crisis of physician shortages, particularly in the area of 52. primary care. In a 2024 report, the Association of American Medical Colleges (the "AAMC") projected a shortage of up to 86,000 physicians by 2036, with the shortage for primary care

https://prodemsstoragesa.blob.core.windows.net/uploads/files/2019%20Specialty%20Report%20 Final%20(v7) compressed%20(1).pdf (Apr. 12, 2024).

⁷⁶ Lorinda A. Coombs et al., Nurse Practitioners and Physician Assistants: An Underestimated Workforce for Older Adults with Cancer, 67 Journal of Am. Geriatrics Soc. 1489 (2019).

⁷⁷ Natl. Comm. on Certification of Physician Assistants, Annual Report 2021, supra note 75, at 36; Fred Wu & Michael A. Darracq, Physician Assistant Utilization in U.S. Emergency Departments: 2010 to 2017, 42 Am. Journal of Emergency Med. 132 (2021); Louise Kaplan & Tracy A. Klein, Characteristics and Perceptions of the US Nurse Practitioner Hospitalist Workforce, 33 Journal of Am. Assn. of Nurse Practitioners 1173 (2021); Tracy A. Klein et al., Hiring and Credentialing of Nurse Practitioners as Hospitalists: A National Workforce Analysis, 11 Journal of Nursing Reg. 33 (2020).

⁷⁸ Hayley B. Gershengorn et al., Impact of Nonphysician Staffing on Outcomes in a Medical ICU, 139 Chest 1347 (2011).

⁷⁹ NP Fact Sheet, *supra* note 36.

=37232A3-BF64-4364-A2DC-921E99C6387F --.2024/04/12 16:59:50 -5:00 --- Remote Notary

physicians estimated as large as 40,400.80 The severity of projected shortages depends in part on the availability of APCs to ease demand for physicians; the AAMC projection model included estimates of the percentage of new demand that could be filled by APCs, ranging from 25% to 50% for primary care and from 20% to 40% for women's health.81

- Fortunately, with growing numbers and expanded practice authority, APCs are 53. stepping up to meet the United States' pressing health care needs. The U.S. Federal Trade Commission (the "FTC") observes that "the United States suffers from widespread distributional problems in the supply of health care professionals [, which] has the greatest impact on America's poorest citizens . . . [and] [r]ural communities, too, are particularly vulnerable to provider shortages and access problems."82 But, the FTC notes, "[a]s primary care provider shortages have worsened, APRNs have played an even greater role in alleviating the effects of shortages and mitigating access problems. For example, APRNs make up a greater share of the primary care workforce in less densely populated areas, less urban areas, and lower income areas, as well as in [health professional shortage areas]."83
- The Office of the Assistant Secretary for Planning Evaluation in the U.S. 54. Department of Health and Human Services (the "ASPE") has similarly noted that "NPs are extending access to care in rural and underserved areas and are key providers in health centers."84 Indeed, 84% of NPs in isolated rural towns are predicted to have their own patient panel (i.e.,

⁸⁰ AAMC, The Complexities of Physician Supply and Demand: Projections From 2021 to 2036, at vi (Mar. 2024), https://www.aamc.org/media/75236/download?attachment (accessed Apr. 10, 2024).

⁸¹ *Id.* at 35.

⁸² FTC Report, supra note 12, at 21 (citations omitted).

⁸³ *Id.* at 25.

⁸⁴ ASPE Report, supra note 25, at 10.

patients primarily under their care), compared with 57% in urban areas.85 Furthermore, research has demonstrated that NMs provided care to more women on Medicaid in rural areas of California and Washington than did obstetricians. 86 As of 2021, NP, CNM, and PA employment in federallyqualified health centers, which serve low-income populations, exceeds physician employment, having increased over 150% from 2010 to 2021.87 These findings are consistent with the original intention of NP education: independent practice, particularly in rural communities where physicians were not working.

The Future of Nursing report observes that the health care system's increased 55. reliance on APCs "has helped ease access bottlenecks, reduce waiting times, increase patient satisfaction, and free physicians to handle more complex cases."88

Leading Authorities Recommend Allowing APCs to Practice to the Fullest D. Extent of Their Education and Training.

- Leading national authorities agree on the need to eliminate scope of practice 56. restrictions that prevent APCs from practicing to their full capacity, including physician oversight requirements and unjustified restrictions on the patients whom APCs may serve or the types of care they may provide.
- The Institute of Medicine's Future of Nursing report's number one 57. recommendation for the future of nursing is: "Remove scope-of-practice barriers. Advanced practice registered nurses should be able to practice to the full extent of their education and

⁸⁵ Id. at 36.

Am. College of Nurse-Midwives, Midwifery: Evidence-Based Practice (2012), http://www.midwife.org/acnm/files/ccLibraryFiles/Filename/000000004184/Midwiferyevidence-Based-Practice-March-2013.pdf (citing Kevin Grumbach et al., Who is Caring for the Underserved? A Comparison of Primary Care Physicians and Non-Physician Clinicians in California and Washington, 31 Ann. Fam. Med. 97 (2003)).

⁸⁷ Natl. Assn. of Community Health Ctrs., *supra* note 73, at figs.5-1, 5-5.

⁸⁸ IOM Report, supra note 29, at 98.

E37232A3-BF64-4364;A2DC-921E99C6387F --- 2024/04/12 16:59:50 -5:00 --- Remote Notary

training."⁸⁹ Among the examples the report provides of restrictions that "could greatly limit the ability of APRNs to fully utilize their education and training" are laws prohibiting an APRN from performing aspiration abortions.⁹⁰

- 58. In 2021, the National Academy of Medicine (formerly the IOM) released a new report, *The Future of Nursing 2020–2030*. This report reiterated the recommendation of the original *Future of Nursing* committee that "[a]ll organizations, including state and federal entities and employing organizations, should enable nurses to practice to the full extent of their education and training by removing barriers "91
- 59. To achieve its goal of removing barriers that impede APRNs from practicing to the full extent of their education and training, the first IOM report recommended (among other things) that the FTC and the Antitrust Division of the Department of Justice "urge[]" states with "unduly restrictive regulations . . . to amend them to allow [APRNs] to provide care to patients in all circumstances in which they are qualified to do so."
- entitled Competition and the Regulation of Advanced Practice Nurses. Based on "the findings of the IOM and other expert bodies—analyses based on decades of research and experience—on issues of APRN safety, effectiveness, and efficiency," as well as the Commission's "own reviews of pertinent literature and stakeholder views," the FTC advised policymakers that "APRN scope of practice limitations should be narrowly tailored to address well founded health and safety concerns, and should not be more restrictive than patient protection requires." Specifically,

⁸⁹ Id. at 9.

⁹⁰ Id. at 3-14, H-4, 100-01.

⁹¹ Natl. Academies, supra note 1, at 363.

^{.92} *Id.* at 10–11.

⁹³ FTC Report, supra note 12, at 3-4.

"APRN certification and state licensure requirements should reflect the types of services that APRNs can safely and effectively provide, based on their education, training, and experience." 94

- 61. The FTC urges policymakers to consider, for instance:
 - Will the regulation significantly impede competition by . . . reducing the [] availability [of health care services]?
 - Are there any significant and non-speculative consumer health and safety needs that particular regulatory restrictions . . . are supposed to meet?
 - Do those particular regulations actually provide the intended benefits—such as improvements in health care outcomes . . . ?
 - When consumer benefits are slight, insubstantial, or highly speculative, a regulation that imposes non-trivial impediments to competition is not justified.
 - Are the regulations narrowly tailored to serve the state's policy priorities?⁹⁵

Through letters, legislative testimony, and amicus briefs, ⁹⁶ the FTC has "consistently urged state legislators to avoid imposing restrictions on APRN scope of practice unless those restrictions are necessary to address well-founded patient safety concerns." ⁹⁷

62. Similarly, in 2012, the National Governors Association (the "NGA") released a report entitled *The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care*, which concluded that, "[i]n light of the research evidence, states might consider changing scope of practice restrictions and assuring adequate reimbursement for their services as a way of encouraging and incentivizing greater NP involvement in the provision of primary health care."

⁹⁴ Id.

⁹⁵ *Id.* at 16–17.

⁹⁶ Id. at A1–A3. For example, in 2020, the FTC urged Ohio to expand APRN practice authority. Fed. Trade Comm., Letter to Representative Thomas E. Brinkman, Jr. (Jan. 9, 2020), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-ohio-house-representatives-concerning-ohio-house-bill-177/v200005ohiohb177aprnscomment.pdf (accessed Apr. 12, 2024).

⁹⁷ FTC Report, supra note 12, at 2.

⁹⁸ Natl. Governors Assn., supra note 13, at 11.

- 63. Furthermore, while the American Association of Retired People ("AARP") is not a governmental institution, its policy shift in 2010 to support expanding APRNs' scope of practice illustrates the growing consensus over the past decade. AARP advised: "Current state nurse practice acts and accompanying rules should be interpreted and/or amended where necessary to allow APRNs to fully and independently practice as defined by their education and certification."99
- 64. Similarly, national organizations such as the National Rural Health Association recommend that PA laws be modernized to expand the PA role in meeting health care needs. 100 The American Academy of Physician Assistants has established Six Key Elements of a Modern PA Practice Act, which supports the greatest possible contribution of PAs within their collaborative relationships with physicians. 101
- 65. The U.S. Departments of Health and Human Services, Treasury, and Labor issued a report in 2018, observing that scope of practice restrictions may limit clinicians' ability to practice in ways that do not address demonstrable or substantial risks to consumer health and safety. The agencies recommended that states consider changes to their regulations to allow all health care providers to utilize their full skill set.¹⁰²
- 66. The rationale underlying these recommendations is consistent: scope of practice barriers needlessly prevent clinicians from fully utilizing their education and training while

⁹⁹ IOM Report, *supra* note 29, at 106 (citation omitted).

¹⁰⁰ See Roger Wells et al., Natl. Rural Health Assn., National Rural Health Association Policy Brief (July 2017), https://www.ruralhealthweb.org/NRHA/media/EmergeNRHA/Advocacy/Policy%20documents/04-09-18-NRHA-Policy-Physician-Assistants-Modernize-Laws-to-Improve-Rural-Access.pdf (accessed Apr. 12, 2024).

¹⁰¹ See Am. Academy of Physician Assocs., The Six Key Elements of a Modern PA Practice Act (2017), https://www.aapa.org/wp-content/uploads/2017/05/6_KE_Chart_5-5-17.pdf (accessed Apr. 11, 2024).

¹⁰² U.S. Dept. of Health & Human Servs. et al., *Reforming America's Healthcare System Through Choice and Competition*, at 31, 36 (2018), https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf (accessed Apr. 12, 2024).

diminishing APCs' ability to meet patients' pressing health care needs. For instance, the FTC explains: "Potential competitive effects can be especially striking where there are primary care shortages, as in medically underserved areas or with medically underserved populations. When APRNs are free from undue supervision requirements and other undue practice restrictions, they can more efficiently fulfill unmet health care needs." ASPE similarly notes

Full NP practice authority is associated with a larger share of NPs providing primary care, and this impact is greater in rural areas. This suggests that the effect of SOP [scope of practice] regulations may be greatest in rural areas where there has historically been a documented need for primary care services. ¹⁰⁴

- 67. Peer-reviewed research supports this conclusion. For instance, the ASPE report notes that, based on 1996–2010 data, "states relaxing restrictions on SOP experienced growth in the number of routine checkups, improvements in quality of care measures, and decreases in emergency room use by patients with ambulatory-care sensitive conditions." ¹⁰⁵
- 68. And in a 2016 systematic review of the impact of state NP scope of practice regulations on health care delivery, my colleagues and I determined that "[s]tates granting NPs greater SOP authority tend to exhibit (a) an increase in the number and growth of NPs through higher APRN educational enrollment and migration and (b) greater provision of primary care by NPs and expanded health care utilization, especially among rural and vulnerable populations." 106
- 69. Newer studies have confirmed that there is a greater supply of NPs, particularly in federally designated health professional shortage areas and rural communities, when there are fewer restrictions on NPs' practice. 107

¹⁰³ FTC Report, supra note 12, at 4.

¹⁰⁴ ASPE Report, *supra* note 25, at 50.

¹⁰⁵ *Id.* at A-7 (citation omitted).

¹⁰⁶ Ying Xue et al., Impact of State Nurse Practitioner Scope-of-Practice Regulation on Health Care Delivery: Systematic Review, 64 Nursing Outlook 71, 82 (2016).

¹⁰⁷ Ryan Kandrack et al., Nurse Practitioner Scope of Practice Regulations and Nurse Practitioner Supple, 78 Med. Care Research & Rev. 208 (2021); Bo Kyum Yang et al., State Nurse Practitioner

- Similarly, recent research has documented that the supply of midwives is greater 70. when they are afforded greater practice authority, particularly in rural communities. 108
- Research on the role of PAs in expanding access to care has also shown the 71. importance of scope of practice regulations. 109 PAs are more likely than physicians to provide care in rural areas and to low-income and underserved populations. 110
 - Clinicians' Professional Organizations Formally Endorse Advanced Practice Ε. Clinicians' Provision of Abortion Care.
- The American College of Obstetricians and Gynecologists ("ACOG") published a 72. December 2020 opinion calling for the repeal of requirements that only physicians or obstetriciangynecologists may provide abortion care. 111 In explaining this position, ACOG stated, "[R]esearch from several countries indicates that outcomes [for first trimester abortion provided by APCs] are similar to those when the service is provided by physicians." ACOG also stated, "[S]everal reports show no differences in outcomes in first-trimester medication and aspiration abortion by health

Practice Regulations and U.S. Health Care Delivery Outcomes: A Systematic Review, 78 Med. Care Research & Rev. 183 (2021); Tianyuan Luo et al., Labor Market Outcomes of Granting Full Professional Independence to Nurse Practitioners, 60 Journal of Regulatory Economics 22 (Aug. 2021); Ying Xue et al., Full Scope-of-Practice Regulation Is Associated with Higher Supply of Nurse Practitioners in Rural and Primary Care Health Professional Shortage Counties, 8 Journal of Nursing Reg. 5 (Jan. 2018).

¹⁰⁸ Brittany L. Ranchoff & Eugene R. Declercq, The Scope of Midwifery Practice Regulations and the Availability of the Certified Nurse-Midwifery and Certified Midwifery Workforce, 2012–2016, 65 Journal of Midwifery & Women's Health 3 (2019).

¹⁰⁹ See, e.g., Michelle Proser et al., Community Health Centers at the Crossroads: Growth and Staffing Needs, 28 Journal of Am. Academy Physician Assistants 49 (2015).

¹¹⁰ See Grumbach, supra note 86, at 97; Christine M. Everett et al., Physician Assistants and Nurse Practitioners as a Usual Source of Care, 25 Journal of Rural Health 407, 407 (2009); Wells et al., supra note 100; Ying Xue et al., Trends in Primary Care Provision to Medicare Beneficiaries by Physicians, Nurse Practitioners, or Physician Assistants: 2008-2014, 8 Journal of Primary Care & Community Health 256, 256 (2017).

¹¹¹ (Dec. No. 815 2020), ACOG. **ACOG** Committee Opinion https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasingaccess-to-abortion (accessed Apr. 11, 2024) (replacing Committee Opinion No. 613 (Nov. 2014)).

E37232A3-BF64-4364-A2DC-921E99C6387F — 2024/04/12 16:59:50 -5:00 --- Remote Notary

care practitioner type and indicate that trained advanced practice clinicians can safely provide abortion services," providing multiple citations from the scholarly literature to support these statements.

- 73. ACOG also recommended in its Committee Opinion on Abortion Training and Education, published in 2014 and reaffirmed in 2019 and 2022, that the pool of non-obstetrician-gynecologist providers, including family physicians and APCs, be expanded by opposing restrictions that limit abortion provision to physicians only. ACOG observed that such restrictions limit both patient access to care and the education and training received by APCs.
- 74. Physicians for Reproductive Health has also urged policymakers to eliminate burdensome restrictions on the provision of abortion care by APCs. 113
- 75. The American Public Health Association has similarly stated: "There is evidence that with appropriate education and training, NPs, NMs, and PAs can competently provide all components of medication abortion care (pregnancy testing counseling, estimating gestational age by exam and ultrasound, medical screening, administering medications, and postabortion follow-up care)" They further recommended that APCs be engaged in the provision of medication and aspiration abortion, and that scope-of-practice regulations should align with this recommendation. 114

ACOG, ACOG Committee Opinion No. 612 (Nov. 2014), https://www.acog.org/clinical/clinical-guidance/committeeopinion/articles/2014/11/abortion-training-and-education (accessed Apr. 11, 2024).

Press Release, Physicians for Reproductive Health, Reproductive Health Care Providers: Abortion Is Essential (Apr. 1, 2020), https://prh.org/press-releases/reproductive-health-care-providers-abortion-is-essential/ (accessed Apr. 11, 2024).

¹¹⁴ Am. Pub. Health Assn., Policy Number 20112, Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants (Nov. 1, 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 (accessed Apr. 11, 2024).

E37232A3-BF64-4364-A2DC-921E99C6387F --- 2024/04/12 16:59:50 --5:00 --- Remote Notary

- In their comprehensive guidelines for abortion care, the World Health Organization 76. recommends that medication abortion be provided by traditional and complementary medicine professionals such as nurses, midwives, associate/advanced associate clinicians, generalist medical practitioners, specialist medical practitioners, community health workers, and pharmacy workers. 115
- The primary international organization for midwifery, the International 77. Confederation of Midwives, agrees that people seeking abortion care should be able to receive such care from midwives. 116 Likewise, the primary national association for nurse-midwives, the American College of Nurse-Midwives, published its own position statement explicitly aligning with the aforementioned statements by the American Public Health Association and International Confederation of Midwives in support of all APCs as abortion providers. 117
- The American Academy of Physician Assistants published a position statement in 78. 2021 that also recognizes the role of PAs in providing abortion care. They wrote that PAs "are

¹¹⁵ 69 - 70(2022),Abortion Care Guideline, at World Health Org., 2024). https://apps.who.int/iris/rest/bitstreams/1394380/retrieve (accessed Apr. 11, "Complementary medicine" or "alternative medicine" refers "to a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health-care system." World Health Org., Traditional, Complementary https://who.int/health-topics/traditional-complementary-and-Integrative Medicine, integrative-medicine#tab=tab 1 (accessed Apr. 12, 2024).

¹¹⁶ Int'l Confederation of Midwives, Position Statement: Midwives Provision of Abortion-Related https://www.internationalmidwives.org/assets/ Services (last affirmed 2014), files/statement-files/2018/04/midwivesprovision-of-abortion-related-services-eng.pdf (accessed Apr. 12, 2024).

¹¹⁷ Am. College of Nurse-Midwives, Position Statement: Midwives as Abortion Providers (Mar. 2018), https://www.midwife.org/acnm/files/acnmlibrarydata/uploadfilename/00000000314/psmidwives-as-abortion-providers-final-19-mar-18.pdf (accessed Apr. 12, 2024).

safe, qualified providers of first trimester abortion care, including surgical aspiration and medication-induced terminations."118

- Research Confirms the Safety of, and Patient Satisfaction with, Health Care F. by APCs.
- There is a large body of literature confirming the safety of, and patient satisfaction 79. with, APCs' providing health services within their education and training.
- For instance, the ASPE report notes, "Patient satisfaction with and consumer 80. acceptance of NPs are high, and clinical outcomes have repeatedly been found equivalent with those of physicians."119 According to the NGA, "None of the studies in [its] literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures. Moreover, the studies suggest that NPs may provide improved access to care."120 The FTC wrote in its 2014 report that "FTC staff are not aware of any contrary empirical evidence to support the contention that there are patient harm or risks associated with APRN prescribing of non-controlled substances."121
- Indeed, multiple systematic reviews have found consistent evidence that NPs 81. provide comparable or better care within their scope of practice than do physicians, with comparable or better outcomes. 122 Studies have found safety, accuracy, and satisfaction

¹¹⁸ Am. Academy of Physician Assocs., PAs in Obstetrics and Gynecology, at 2 (Jan. 2021), https://www.aapa.org/download/19515 (accessed Apr. 12, 2024).

¹¹⁹ ASPE Report, supra note 25, at 10 & A-2.

¹²⁰ Natl. Governors Assn., supra note 13, at 7-8.

¹²¹ FTC Report, supra note 12, at 37-38.

¹²² See, e.g., Julie Stanik-Hutt et al., The Quality and Effectiveness of Care Provided by Nurse Practitioners, 9 Journal of Nurse Practitioners 492, 492, 498 (2013); Mary D. Naylor & Ellen T. Kurtzman, The Role of Nurse Practitioners in Reinventing Primary Care, 29 Health Affairs 893, 894-95 (2010); Robin P. Newhouse et al., Advanced Practice Nurse Outcomes 1990-2008: A Systematic Review, 29 Nursing Economic 1, 18 (2011).

equivalency between APC and physician care, even for complex, invasive procedures like colonoscopies, 123 which have a complication rate of approximately 2.8% 124 which is higher than the approximately 2% complication rate for abortion. 125

These findings hold true in states that grant NPs and NMs full practice and 82. prescriptive authority without physician oversight requirements. For instance, a 2017 analysis of the impact of state NP scope of practice regulations on the quality of primary care provided to Medicare beneficiaries concluded: "Our analyses failed to find support for the outcomes-related arguments of those advocating for restricting the [scope of practice] of NPs on the basis of patient safety and offer support for those who claim that NP [scope of practice] restrictions have real consequences for health of populations in areas where access to primary care is low."126

¹²⁴ Am. Soc. for Gastrointestinal Endoscopy, Guideline: Complications of Colonoscopy 74 Gastrointestinal Endoscopy 745, 745 (2011).

32921E99C6387F

¹²³ Michele Limoges-Gonzalez et al., Comparisons of Screening Colonoscopy Performed by a Nurse Practitioner and Gastroenterologists, 34 Gastroenterology Nursing 210, 212-13, 215 (2011) (no immediate complications reported for either physician or NP groups; no statistically significant differences between physician and NP groups in terms of reported pain, duration of procedure, withdrawal time, sedative and analgesic use, or cecal intubation rates; greater neoplasia detection rates in NP group; greater satisfaction among patients seen by NPs); M. Phillip Fejleh et al., Quality Metrics of Screening Colonoscopies Performed by PAs, 33 Journal of Am. Academy of PAs 43 (2020); Lukejohn W. Day et al., Non-Physicians Performing Lower and Upper Endoscopy: A Systematic Review and Meta-Analysis, 46 Endoscopy 401 (2014); Monica Riegert et al., Experience of Nurse Practitioners Performing Colonoscopy After Endoscopic Training in More Than 1,000 Patients, 8 Endoscopy Internatl. Open E1423 (2020).

¹²⁵ Karima R. Sajadi-Ernazarova & Christopher L. Martinez, Abortion Complications, StatPearls (last updated May 24, 2020), https://www.ncbi.nlm.nih.gov/books/NBK430793/ (accessed Apr. 12, 2024).

¹²⁶ Jennifer Perloff et al., Association of State-Level Restrictions in Nurse Practitioner Scope of Practice with the Quality of Primary Care Provided to Medicare Beneficiaries, 76 Med. Care Research & Rev. 18 (2019); see also, e.g., Ellen T. Kurtzman et al., Does the Regulatory Environment Affect Nurse Practitioners' Patterns of Practice or Quality of Care in Health Centers?, 52 Health Servs. Research 437, 445 (2017) ("[T]here was little evidence to reject the null hypothesis—that is, that state-granted NP independence has no effect on NPs' . . . quality of care—across the outcomes studied.").

- 83. Similarly, a 2017 review of the impact of changes in state NM scope of practice regulations between 1994 and 2013 found that "states that allow for CNMs fully enabled practice, have on average, little or no differences in maternal health behaviors or infant health outcomes as compared to states with more restrictive SOP." Indeed, the principal exception to this "little or no differences" conclusion is that states that allow NMs broader practice authority reap the benefits of lower rates of labor inductions and C-sections. The authors concluded: "The results point to the conclusion that restrictions on CNM [scope of practice] primarily serve as barriers to practice and removing these restrictions has the potential to improve the efficiency of the health care system for delivery and infant care." 129
- 84. Multiple studies have established the safety of abortion care provided by APCs, and medical organizations such as the American College of Obstetricians and Gynecologists, the American Public Health Association, and the World Health Organization support this practice. The first study demonstrating the safety of APCs' abortion care, conducted in Vermont and published in 1986, found that complication rates for PAs performing abortion procedures were not statistically different from the complication rates of physicians. ¹³⁰ Subsequent studies documented

¹³⁰ See, e.g., Mary Anne Freedman et al., Comparison of Complication Rates in First Trimester Abortions Performed by Physician Assistants and Physicians, 76 Am. Journal of Pub. Health 550, 550 (1986).

¹²⁷ Markowitz, *supra* note 64, at 202.

¹²⁸ IA

¹²⁹ Id.; see also Meg Johantgen et al., Comparison of Labor and Delivery Care Provided by Certified Nurse-Midwives and Physicians: A Systematic Review, 1990 to 2008, 22 Women's Health Issues e73, e78 (2012) ("Based on this systematic review, there is moderate to high evidence that CNMs rely less on technology during labor and delivery than do physicians and achieve similar or better outcomes."); Lauren Hoehn-Velasco et al., Health Outcomes and Provider Choice under Full Practice Authority for Certified Nurse-Midwives, 92 Journal of Health Economics, (Dec. 2023) (finding "full practice authority leads to a clear increase in reported CNM/CM-attended deliveries without a noticeable impact on obstetric outcomes (cesarean, induction, adverse neonatal events) or mortality (maternal or neonatal)"); Benjamin McMichael, Healthcare Licensing and Liability, 95 Ind. L.J. 821 (2020).

similar levels of safety of abortion procedures provided by PAs.¹³¹ Rigorous research has documented similar outcomes for aspiration abortion provided by NPs, NMs, and PAs as compared with physicians.¹³² Indeed, reviews of the international literature have reported similar results regarding the safety of abortion care provided by APCs, sometimes called "mid-level providers," in other countries.¹³³

85. It is also worth noting that only 1.1% of NPs have been named as a primary defendant in a malpractice case for all types of diagnoses and procedures nationwide. ¹³⁴ The overall rate of malpractice reports against NPs registered in the Healthcare Integrity and Protection Data Bank is 1.2 per 1,000 NPs and 2.1 per 1,000 PAs in the nation, compared with a significantly higher rate for physicians: 11.2 per 1,000. ¹³⁵

G. APCs in Ohio

86. I have reviewed Ohio's licensing and practice requirements, and they are consistent with the national landscape I have described. It is my opinion that Ohio restrictions banning APCs from providing medication abortion are out of step with how these clinicians are otherwise regulated.

¹³¹ See Marlene B. Goldman et al., Physician Assistants as Providers of Surgically Induced Abortion Services, 94 Am. Journal of Pub. Health 1352, 1355–56 (2004).

¹³² See Tracy A. Weitz et al., Safety of Aspiration Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver, 103 Am. Journal of Pub. Health 454 (2013); Tracy A Weitz et al., Research Informs Abortion Care Policy Change in California, 104 Am. Journal of Pub. Health e3, e3 (2014); Eva Patil et al., Aspiration Abortion with Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians, 61 Journal of Midwifery & Women's Health 325 (2016); Amy Levi et al., Training in Aspiration Abortion Care: An Observational Cohort Study of Achieving Procedural Competence, 88 Internatl. Journal of Nursing Studies 53 (2018).

¹³³ Sharmani Barnard et al., *Doctors or Mid-Level Providers for Abortion*, Cochrane Database of Systematic Revs. (July 27, 2015).

¹³⁴ NP Fact Sheet, supra note 36.

¹³⁵ Douglas M. Brock et al., *Physician Assistant and Nurse Practitioner Malpractice Trends*, 74 Med. Care Research & Rev. 613, 613 (2017).

E37232A3-BF64-4364-A2DC-921E99C6387F — 2024/04/12 16:59:50 -5:00 --- Remote Notary

87. In general, Ohio CNPs and CNMs "may provide to individuals and groups nursing care that requires knowledge and skill obtained from advanced formal education and clinical experience" 136 and based on demonstrated knowledge, skills, and abilities. 137 Specifically, Ohio allows CNPs to "provide preventive and primary care services, provide services for acute illnesses, and evaluate and promote patient wellness within the nurse's nursing specialty, consistent with the nurse's education and certification, and in accordance with rules adopted by the board" under a collaborative practice agreement with a Ohio-licensed physician. 138 Also under a collaborative practice agreement with a Ohio-licensed physician, Ohio CNMs "may provide the management of preventive services and those primary care services necessary to provide health care to women antepartally, intrapartally, postpartally, and gynecologically, consistent with the nurse's education and certification, and in accordance with rules adopted by the board of nursing." 139

88. Ohio PAs may perform "services authorized by the supervising physician" that are within the "physician's normal course of practice and expertise." These services include "[o]rdering diagnostic, therapeutic, and other medical services," "[a]ssisting in surgery," and "[a]ny other services that are part of the supervising physician's normal course of practice and expertise." Ohio's regulation of PAs is aligned with five of six "essential elements" defined by the American Academy of Physician Assistants. 141

35921E99C6387F

¹³⁶ R.C. 4723.43.

¹³⁷ Ohio Adm.Code 4723-4-05(D).

¹³⁸ R.C. 4723.43(C).

¹³⁹ R.C. 4723.43(A).

¹⁴⁰ R.C. 4730.20(A).

Timothy Bates et al., Healthforce Center at UCSF, California's Physician Assistants: How Scope of Practice Laws Impact Care, at 10 (Sept. 25, 2018), https://www.chcf.org/publication/californias-physician-assistants/ (accessed Apr. 11, 2024); Am. Academy of Physician Assistants, Number of Key Elements in State PA Law (Feb. 2020), https://www.aapa.org/wp-content/uploads/2017/01/Six_Key_Elements_Map_5-8-17.pdf

E37232A3-BF64-4364-A2DC-921E99C6387F --- 2024/04/12 16:59:50 - 5:00 -- Remote Notary

- 89. In Ohio, a physician may not collaborate with more than five APRNs and five PAs in the prescribing component of their practice. 142 The CNP or CNM and physician develop the agreement, which specifies drugs, devices, medical treatments, tests, and procedures that may be prescribed, ordered, and performed by the CNP or CNM. 143
- 90. As elsewhere, APCs in Ohio are subject to state and national educational requirements, accreditation requirements, certification requirements, licensing requirements, and continuing education responsibilities.¹⁴⁴
- 91. Specifically, an applicant for Ohio CNP or CNM practice must hold a current, active license as a registered nurse in Ohio; a graduate degree in nursing (or in a related field that qualifies the applicant to sit for the certification examination); and professional certification following examination by a national certification board (such as the American Midwifery Certification Board, the American Nurses Credentialing Center, the National Certification Corporation, or the American Academy of Nurse Practitioners). 145
- 92. Similarly, Ohio PAs must hold a graduate degree from an accredited program "in a course of study with clinical relevance to the practice of physician assistants" and professional certification from a national certification board. 146

⁽accessed Apr. 11, 2024). Ohio sets statutory limits to the number of PAs a physician can supervise rather than allowing this determination to be made at the practice level. See infra ¶ 89.

¹⁴² R.C. 4723.431(A)(1) (APRNs); R.C. 4730.21(B) (PAs).

¹⁴³ R.C. 4723.431 (APRNs); Ohio Adm.Code 4723-8-04 (APRNs); R.C. 4730.19 (PAs).

¹⁴⁴ As to PAs: R.C. 4730.11 (qualifications and requirements for license); R.C. 4730.14 (renewal); R.C. 4730.49 (continuing medical education). As to NPs and NMs: R.C. 4723.41 (application); R.C. 4723.24(C)(2); Ohio Adm.Code 4723-8-08 (renewal).

¹⁴⁵ R.C. 4723.41(A); Ohio Bd. of Nursing, *Approved APRN National Certifying Boards*, https://nursing.ohio.gov/licensing-and-certification/training-programs/01-board-approved-certifying-orgs (accessed Apr. 11, 2024).

¹⁴⁶ R.C. 4730.11.

- 93. Ohio APCs must renew their license to practice biannually.¹⁴⁷ To renew approval to practice in Ohio, an APC must complete continuing education and maintain national certification.¹⁴⁸
- 94. As part of a patient care team, CNPs and CNMs have broad practice authority in Ohio, including the authority to prescribe medications. Ohio CNPs and CNMs are allowed to prescribe Schedule II through Schedule VI drugs (including drugs with a high potential for abuse and severe psychiatric or physical dependence, like opioids and amphetamines) provided they have appropriate DEA registration.
- 95. Ohio similarly allows PAs to prescribe and dispense medications (including controlled substances) and perform minor procedures, provided they practice with physician collaboration. The primary supervising physician must ensure that the PA's scope of practice is clearly identified and that the delegation of the medical task is appropriate to the skills and competencies of both the supervising physician and the PA. 152
- 96. APCs in Ohio are permitted to provide health care services other than early abortion that I understand entail comparable—and sometimes far greater—medical risks, such as delivering babies. 153

¹⁴⁷ R.C. 4723.24(A)(1)(c) (APRNs); R.C. 4730.14(A) (PAs).

¹⁴⁸ R.C. 4723.24(C)(2) (APRNs); Ohio Adm.Code 4723-8-08 (APRNs); R.C. 4730.14(B) (PAs); R.C. 4730.49 (PAs).

¹⁴⁹ R.C. 4723.43.

¹⁵⁰ R.C. 4723.481; Ohio Adm.Code 4723-9-10.

¹⁵¹ R.C. 4730.15 (prescriptive authority); R.C. 4730.20 (services that may be performed by a PA, including prescriptive authority); R.C. 4730.21 (physician supervision); R.C. 4730.41 (prescriptive authority); 4730.411 (prescription of Schedule II controlled substances).

¹⁵² R.C. 4730.19; R.C. 4730.21.

¹⁵³ R.C. 4723.43; Elizabeth Raymond & David Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215 (Feb. 2012).

As elsewhere, APC practice improves access to care in Ohio, particularly in 97. primary care and in rural areas where there are fewer physicians. In 2021, it was estimated that there were 35,333 physicians in Ohio-302.3 per 100,000 population. 154 The distribution of physicians varied widely between urban and rural areas, with 355.9 per 100,000 population in metropolitan counties, 93.0 per 100,000 in micropolitan counties, and only 38.8 per 100,000 in rural counties. In 2021, there were 4,515 PAs (38.3 per 100,000 population), 14,971 NPs (127.1 per 100,000 population) and 306 CNMs (2.6 per 100,000 population). Moreover, CNPs, CNMs, and PAs were more likely than physicians to practice in rural counties in 2021; 1.6% of CNPs, 1.6% of CNMs, 0.9% of PAs, and 0.5% of physicians were located in a rural county. In rural counties of Ohio in 2021, there were only 172 physicians, compared with 232 CNPs, 5 CNMs, and 42 PAs. These data are consistent with national analyses that report that NPs, NMs, and PAs nationwide are significantly more likely than physicians to practice in rural areas, and they serve a higher proportion of uninsured patients and other vulnerable populations. 155 These data also demonstrate that APCs play an important role in delivering essential health care services in Ohio.

IV. CONCLUSION

In sum, Ohio's ban on APC provision of medication abortion, regardless of the 98. APC's qualifications or the patient's needs, is inconsistent with the nationwide and Ohio-specific trajectory—particularly over the past two decades—toward allowing APCs to perform all services within their education and training, especially in medically underserved areas where the need is greatest.

Human Servs., https://data.hrsa.gov/data/download?data=AHRF#AHRF (accessed Apr. 12, 2024).

38921E99C6387F

¹⁵⁴ (2021),Profile Ohio Physician Workforce AAMC. https://www.aamc.org/media/58291/download (accessed Apr. 11, 2024). 155 Data Downloads, Health Resources & Servs. Administration, United States Dept. of Health &

E37232A3-BF64-4364-A2DC-921E99C6387F -- 2024/04/12 16:59:50 -5:00 -- Remote Notary

99. My opinions are based on my education, training, research, and attendance at and participation in conferences relating to health care economics, APC scope of practice, and health care services, as well as on my ongoing review of relevant literature. The literature that informs my opinions includes, but is not limited to, the studies cited in my declaration.

E37232A3-BF64-4364-A2DC-921E99C6387F --- 2024/04/12 16:59:50 --- Remote Notary

Joanne Spetz		
JOANNI	E SPETZ, Ph.D.	

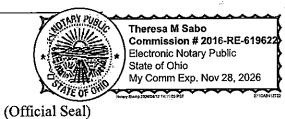
Franklin County, Ohio State

The 15 w

Signed and sworn to before me this day by

Date:

Notary Public



Notarial act performed by audio-visual communication



University of California San Francisco

CURRICULUM VITAE

Name:

Joanne Spetz

Position:

Director

Brenda and Jeffrey L. Kang Presidential Chair in Healthcare Finance

Philip R. Lee Institute for Health Policy Studies

Address:

3333 California Street, Suite 265

University of California, San Francisco

San Francisco, CA 94143-0936

Voice: (415) 502-4443

email: joanne.spetz@ucsf.edu

EDUCATION:

1986-90	Massachusetts Institute of Technology	S.B.	Economics
1990-93	Stanford University	M.A.	Economics
1993-96	Stanford University	Ph.D.	Economics

PRINCIPAL POSITIONS HELD:

1991-1992	Stanford University	Research Assistant, Economics
1993-1995	Palo Alto VA Health Care System	Health Research Specialist
1995-2001	Public Policy Institute of California	Research Fellow
1999-2004	University of California, San Francisco	Assistant Adjunct Professor, Department of
	•	Community Health Systems, School of Nursing
2004-2009	University of California, San Francisco	Associate Adjunct Professor, Department of
	·	Community Health Systems, School of Nursing
2009-2011	University of California, San Francisco	Adjunct Professor, Department of Community
	•	Health Systems, School of Nursing
2011-2020	University of California, San Francisco	Professor in Residence, Philip R. Lee Institute
	•	for Health Policy Studies & Department of
		Family and Community Medicine
2013-2021	University of California, San I	Francisco Associate Director for Research,
Healthforce	•	
		Center at

UCSF

2020-present

University of California, San FranciscoBrenda and Jeffrey L. Kang Presidential

Chair

in

Healthcare Finance

2020

University of California, San FranciscoAssociate Director for Research, Philip

R. Lee

Institute

for Health Policy Studies

2020-present University of California, San Francisco

Professor (tenured), Philip R. Lee Institute for Health Policy Studies & Department of Family

page 1 of 77

Spetz, revised 3/27/2024

and Community Medicine

2020-present

University of California, San Francisco Director, Philip R. Lee Institute for

Health

Policy

Studies

2020-present

University of California, San Francisco Claire D. and Ralph G. Brindis Endowed

Professorship in Health Policy Studies

2020-present

University of California, San Francisco Caldwell B. Esselstyn Chair in Health

Policy

OTHER POSITIONS HELD CONCURRENTLY:

1992-1993 Stanford University Lecturer,

Economics

1993 Stanford University Teaching

Assistant, Economics

1997 University of California, Santa Cruz

Visiting Professor, Economics

2001 University of California, Berkeley

Visiting Professor, Public Health

2001-2002 Public Policy Institute of California

Adjunct Fellow
2001-2007

Center for California Health Workforce

2001-2007 Center for California Hea
Studies Associate Director

2006-2009 Department of Social and Behavioral

Sciences,

Associate Adjunct Professor
School of Nursing, UCSF

2006-2014 Palo Alto VA Health Care System

Research Scientist (without compensation)

2009-present Department of Social and Behavioral Sciences, Adjunct Professor/Professor-in-School of Nursing, UCSF Residence

2009-present

Health Services and Policy Analysis

Doctoral Faculty Affiliate

Program, UC Berkeley
2011-2016

Nursing Management Policy and

Leadership Clinical Professor

Specialty, School of Nursing, Yale

University
2011-present Department of Community Health

Systems Professor-in-Residence School of Nursing, UCSF

2019 School of Nursing and Midwifery, Edith

Cowan Visiting Professor
University, Australia

2020-present Bakar Computational Health Sciences
Affiliated Faculty

Institute, UCSF

2021-present

Center

2021-present

Research Scientist (without compensation)

UCSF Pain and Addiction Research

Member

San Francisco VA Health Care System

HONORS AND AWARDS:

1990	Phi Beta Kappa
1990	Society of Sigma Xi
1990-1995	National Science Foundation Fellowship
1993	Teaching Assistant Award, Stanford University
1993-1994	Bradley Foundation Fellowship
1994-1995	Performance Awards, Department of Veterans Affairs
2005	Best Abstract Award, Workforce Sessions, AcademyHealth
2006	Top 25 Downloaded Papers, Nursing Outlook, summer quarter
2011	Honorary Fellow, American Academy of Nursing
2013	Best Abstract Award, Interdisciplinary Research Group on Nursing Issues, AcademyHealth
2016	Mentorship Award, Interdisciplinary Research Group on Nursing Issues, AcademyHealth
2016	Nursing Outlook Excellence in Education Writing Award (as co-author)
2017	Best of Annual Research Meeting Abstract, AcademyHealth
2020	Outstanding Journal Reviewer for 2019, Health Services Research
2020	Excellence in Nursing Education Award, Nursing Outlook
2021	Outstanding Journal Reviewer for 2020, Health Services Research

CONTINUING EDUCATION AND TRAINING:

2011	Strategic communications, Robert Wood Johnson Foundation/Spittire Strategies
2013	Confidential Information Protection and Statistical Efficiency Act (CIPSEA) training
2019	Special Sworn Status, U.S. Census Bureau
2021	Diversity, Equity, and Inclusion Champion

KEYWORDS/AREAS OF INTEREST:

Economics, health care workforce, nursing workforce, long-term care, hospital industry, quality of care, drug policy, cost-effectiveness analysis, econometrics.

PROFESSIONAL ACTIVITIES

PROFESSIONAL ORGANIZATIONS

Memberships

1991-present 1993-present 1993-2004 1993-2007 1995-2002 1995-2002 1995-present	Economics Graduate Student Association, Stanford University American Economic Association AcademyHealth (formerly Association for Health Services Research) American Public Health Association Association for Public Policy Analysis and Management Western Economic Association Health Economics Research Organization International Health Economics Association Bay Area Labor Economists
1996-2002	Bay Area Labor Economists

1997-2001 Western Regional Science Association 2004-present American Society of Health Economists 2017-present Gerontological Society of America

Service to Professional Organizations

Academy	Head	lth
---------	------	-----

2002-2003	Program Committee for Workforce sessions at Annual Research Meeting
2006-2007	Program Committee for Workforce sessions at Annual Research Meeting
2007-2008	Theme Leader for Workforce sessions at Annual Research Meeting
2008-2009	Program Committee for Workforce sessions at Annual Research Meeting
2009	Invited participant at Summit on Health Services Research Data & Methods
2009, 2010	Resume reviewer/mentor at Annual Research Meeting
2009-2010	Theme Leader for Workforce sessions at Annual Research Meeting
2010-2011	Program Committee for Annual Research Meeting
2012-2013	Program Committee for Workforce sessions at Annual Research Meeting
2014	Poster Walk Leader
2015-2016	Program Committee for Workforce sessions at Annual Research Meeting;
	Program Committee for Late-Breaking Abstracts
2019-2021	Membership Committee, Member
2019	Program Committee for Workforce sessions at Annual Research Meeting

Interdisciplinary Research Group on Nursing Issues (special interest group of AcademyHealth)

	····· J ===============================
2005-2007	Treasurer
2007-2008	Nominating Committee
2008-2009	Chair-Elect
2009-2010	Chair
2010-2011	Program Committee
2012-2013	Program Committee

International Health Economics Association

2002-2003 Program Committee for Convention

2003	Poster Award Committee
2003	Session chair for biennial meeting (2 sessions)
2004-2005	Scientific Committee member
2010-present	Scientific Committee member
	Planning Committee for pre-conference Teaching Day
	Lead Organizer, Economics of Health Workforce Pre-Congress Session
2018-present	Lead Organizer, Health Workforce Special Interest Group

American Society of Health Economists

2007-2008	Scientific Committee member
2011-2018	Scientific Committee member

Association for Public Policy Analysis and Management

110000000000000000000000000000000000000	3. ×
1999	Session chair for annual conference
2000-2003	Policy Council member
2001-2002	Nominations Committee
2002-2003	Session chair for annual conference
2002-2003	Conference program committee member

anizations

1991-1992	Stanford Economics Graduate Student Ass	
1996	Western Economic Association	Session chair for annual conference
1996-2003	Bay Area Labor Economists	Co-chairperson
1999	Health Economics Research Organization	Session chair for annual conference
2002	Health Economics Research Organization	Session organizer for annual conference
2010	Workshop on Health IT and Economics	Program Committee for annual conference
2012-2013	International Health Workforce Collaborat	
2013	Economics of the Health Workforce	Program Committee
	Conference	
2014-present	International Health Workforce Collaborat	ive Program Committee for U.S. delegation
2015-2016	International Health Workforce Collaborat	ive Host Program Committee

SERVICE TO PROFESSIONAL PUBLICATIONS:

2005-2007	Medical Care Research and Review	Guest Editor for special issue
2005-2016	BioMed Central	Statistical Review Panel
2008-present	Medical Care Research and Review	Editorial Board
2009-2013	BMC Health Services Research	Associate Editor
2011-2016	Nursing Economics	Columnist: Economic\$ of Health Care and
	-	Nursing
2013-2016	BMC Health Service Research	Editorial Advisor
2018-2019	Health Affairs	Consulting Editor for Theme Issue
2018-2021	HSR: Health Services Research	Editorial Board
2018-2019	Journal of the American Geriatrics Society	
2019-2020	Medical Care Research and Review	Co-Editor of special issue
2022-present	Health Affairs Scholar	Editorial Advisory Board

Ad-hoc referee for:

1997-2009	International Journal of the Economics of Business
1998-2008	Southern Economic Journal
1998-2012	Economics of Education Review
1999	Journal of Regional Science
1999-present	Inquiry
2000-2015	Journal of Human Resources
2000-present	Health Affairs
2000-present	Health Services Research
2000-present	Journal of Health Economics
2002-present	Medical Care
2003	Journal of Health Policy, Practice, and Law
2004	Policy Studies Journal
2004-present	Journal of Policy Analysis and Management
2004-2013	BMC Health Services Research
2004-2018	Industrial and Labor Relations Review
2005-2006	Eastern Economics Journal
2006	BMC Family Practice
2006-2015	Health Care Management Review
2007	BMC Public Health

2007	Western Journal of Nursing Research
2007-present	Journal of General Internal Medicine
2008	Forum for Health Economics and Policy
2008-present	Medical Care Research and Review
2009-2010	BMC Nursing
2009-2010	Health Economics, Policy, and Law
2009-2010	Journal of Clinical Nursing
2010-2011	American Journal of Managed Care
2010-2011	International Journal of Nursing Scholarship
2010-present	Health Economics
2011	International Journal of Health Care Finance and Economics
2012	Policy Politics and Nursing Practice
2012	International Nursing Review
2012-2017	Nursing Economics
2013	Human Resources for Health
2013-2014	HealthCare: Journal of Delivery Science
2014-present	Nursing Outlook
2014-present	American Journal of Health Economics
2016	Canadian Journal of Economics
2017	American Journal of Preventive Medicine
2019	JAMA
2020	Social Science and Medicine
2021	American Economic Journal: Economic Policy
2022	JAMA Network Open

INVITED PRESENTATIONS

International

1996

	≛
2003	San Francisco: session organizer, session chair, research presentation
2005	Barcelona: research presentation, poster presentation
2007	Copenhagen: 2 research presentations
2009	Beijing: research presentation

2011 Toronto: research presentation

Sydney, 2 research presentations 2013

International Health Economics Association Vancouver: Canada: poster

Milan, session organizer, 1 research presentation, session chair 2015

Boston, session organizer, 1 research presentation, session chair, discussant 2017 Basel, pre-Congress session organizer, 1 research presentation in pre-Congress session

2019

Virtual, 1 research presentation 2021

Cape Town, 1 research presentation, session chair, poster 2023

Conference on the Global Health Workforce, Berkeley, California (poster) 2008

International Seminar on Nursing Workforce and Labour Market Research, sponsored by 2009 Dohisha University, Honolulu, Hawaii, (invited research presentation and paper)

Global Health Leadership Forum, "Mixing It Up: How Non-Physicians Can Deliver Care," 2010 Berkeley, CA (presenter and discussion leader)

Economics of the Health Workforce, Sydney Australia (presenter) 2013

International Health Workforce Collaborative, London, UK (poster) 2015

- 2016 International Health Workforce Collaborative, Washington DC (poster)
- 2018 International Health Workforce Collaborative, Queenstown, New Zealand (poster)
- 2019 Edith Cowan University, Joondalup, Australia (public lecture)
- 2019 Sir Charles Gairdner Hospital, Nedlands, Australia (public lecture)-
- 2019 MyVista Aged Care, Mt. Lawley, Australia (panel presentation)
- 2019 Joondalup Private Hospital, Joondalup, Australia (public lecture)
- 2019 Hollywood Private Hospital, Nedlands, Australia (public lecture)
- 2019 University of Western Australia School of Public Health, Perth, Australia (public lecture)
- 2019 International Health Workforce Collaborative, Ottawa, Canada (2 posters, podium)
- 2020 International Health Economics Association, Health Workforce Special Interest Group (webinar organizer and presenter)
- 2020 Instituto de Estudos para Políticas de Saúde (IEPS), Brazil (panel presentation)

National

AcademyHealth

- 1994 poster presentation
- 1996 poster presentation
- 1997 research presentation
- 1998 poster presentation
- 1999 poster presentation
- 2000 1 research presentation and 1 poster
- 2001 poster presentation
- 2002 1 research presentation and 1 poster
- 2003 poster presentation
- 2004 poster presentation
- 2005 2 research presentations, 2 posters, 1 presentation for special interest group
- 2006 poster presentation
- 2007 1 research presentation, 1 panel presentation, 1 poster, and session chair
- 2008 2 research presentations, 2 posters, 1 presentation for special interest group, and session chair
- 2009 1 research presentation, Chair of program for special interest group
- 2010 1 research presentation, 1 poster, session chair, and Chair of special interest group meeting
- 2011 3 research presentations, 1 poster
- 2012 2 research presentations, 1 poster
- 2013 2 research presentations, 1 presentation for special interest group
- 2014 2 research presentations, 1 poster, organized 1 invited session & served as chair
- 2015 1 research presentation, 1 poster
- 2016 2 presentations for special interest group, 1 poster
- 2017 3 research presentations, 1 "Best of ARM" presentation, 2 presentations for special interest groups
- 2018 1 research presentation, 1 presentation for special interest group, 1 poster
- 2019 1 presentation for special interest group
- 2021 1 research presentation
- 2022 poster presentation

American Society of Health Economists

- 2006 research presentation, discussant
- 2008 2 research presentations, poster
- 2012 2 research presentations, session chair
- 2014 2 session chairs, 1 research presentation, organized 4 sessions

2016	2 presentations, discussant, session organizer, pre-conference session presenter
2018	2 presentations, discussant (2), session organizer (2), session chair (2)
2020	1 presentation
2021	discussant, session chair
2022	2 presentations, discussant, session chair
Other 1	Professional Association Conferences
1994	Association for Public Policy Analysis and Management (research presentation)
1996	American Public Health Association (poster)
1996	Association for Public Policy Analysis and Management (roundtable speaker)
1997	Association for Public Policy Analysis and Management (research presentation)
1997	Allied Social Sciences Associations (2 research presentations)
1998	American Public Health Association (research presentation)
1998	Allied Social Sciences Associations (research presentation)
1998	Association for Public Policy Analysis and Management (research presentation)
1999	Association for Public Policy Analysis and Management (session chair, research presentation)
1999	American Public Health Association (research presentation)
1999	Allied Social Sciences Associations (research presentation)
2001	Association for Public Policy Analysis and Management (2 research presentations)
2002	Association for Public Policy Analysis and Management (session chair, research presentation)
2002	Allied Social Sciences Associations (session chair and research presentation)
2003	American Public Health Association (research presentation)
2003	Association for Public Policy Analysis and Management (research presentation)
2004	Association for Public Policy Analysis and Management (2 research presentations)
2005	Association for Public Policy Analysis and Management (research presentation)
2007	Forum of State Nursing Workforce Centers annual meeting (invited presentation)
2010	Workshop in Health Information Technology Economics (research presentation)
2012	Allied Social Sciences Associations (research presentation)
2012	Forum of State Nursing Workforce Centers annual meeting (research presentation)
2012	Workshop in Health Information Technology Economics (research presentation)
2014	American Association of Medical Colleges Health Workforce Conference (1 research
2015	Forum of State Nursing Workforce Centers annual meeting (4 research presentations)
2015	American Association of Medical Colleges Health Workforce Conference (1 research presentation, 1 panel moderator, 1 poster)
2016	Allied Social Sciences Associations (discussant) presentation, 1 poster)
2016	American Association of Medical Colleges Health Workforce Conference (2 research presentations)
2017	Forum of State Nursing Workforce Centers annual meeting (3 research presentations)
2022	Gerontological Society of America (poster)
2023	American Geriatrics Society (2 posters)
	l National Meetings and Presentations
1993	The University-Industry Interface in Medical Technology, Institute of Medicine (research presentation)
1994	National Bureau of Economic Research, Summer Workshop (research presentation)
1996	National Conference of State Legislatures, Immigrant and Multicultural Health Conference

page 8 of 77

Spetz, revised 3/27/2024

(panel presentation and moderator)

1996 NurseWeek Editorial Advisory Board (keynote)

- 2001 Third Annual Evidence-Based Practice Nurse Executive Conference, University of Pennsylvania (panel presentation)
- 2001 Health Resources and Services Administration, U.S. Department of Health and Human Services (research presentation)
- 2003 Association of Health Care Journalists, Fourth National Conference (panel presentation)
- 2003 National Conference of State Legislatures, Nursing Education and State Policy Conference (panel presentation)
- 2004 Petris Center Conference on Antitrust and Health Care, UC Berkeley (research presentation)
- 2004 The Intersection of Nursing and Health Services Research, invitational conference, University of North Carolina at Chapel Hill (research presentation)
- 2004 Critical Linkages: Patient Safety, Nurse Staffing, and Leadership Solutions, Joint Commission on Accreditation of Healthcare Organizations (presentation)
- 2005 National Nursing Quality Databases Conference: Building Bridges from Research to Practice, San Francisco, CA (presentation)
- 2005 National Conference of State Legislatures, session sponsored by Service Employees International Union, "Who Will Care? Strategies to Solve NursingWorkforce Shortages"
- 2008 VA eHealth University, Tampa, FL (training seminar)
- 2008 Institute of Medicine, Promoting Team Care Symposium, Los Angeles, CA (presentation)
- 2008 VA Information Resource Center, Web seminar on evaluating the VA's health IT systems (live web seminar)
- 2009 Impact of Patient Safety Initiatives on Nursing Workflow and Productivity (funded by AHRQ), Millbrae, California (methodologic expert participant)
- The Future of Health Services Research in 2020: Data and Methods (organized by AcademyHealth, funded by Robert Wood Johnson & Commonwealth Foundations), Washington, DC (invited participant)
- 2010 Association of Women's Health, Obstetric & Neonatal Nurses (AWHONN) Convention, Las Vegas, NV (invited presentation)
- Nursing Economics 4th Annual Nurse Faculty/Nurse Executive Summit, Scottsdale, AZ (invited presentation)
- 2011 Kaiser Permanente National Workforce Planning & Development Conference, Oakland, CA (invited panel)
- 2012 American Association of Colleges of Nursing, Doctoral Education Conference, Naples, FL (keynote)
- 2012 Pacific Institute of Nursing, Annual Conference, Honolulu, HI (invited presentation)
- 2012 Robert Wood Johnson Foundation, Future of Nursing Campaign for Action, "How Do You Measure Your Progress? Dashboard Data and Measuring Nurse Education" (webinar)
- 2012 American Academy of Nursing, Washington, DC (poster presentation)
- 2012 Robert Wood Johnson Foundation, Future of Nursing Campaign for Action, "Data: An Overview of What is Collected, Where to Access It and How to Use It"
- American College of Nurse Midwives, Briefing on Women's Health Workforce, Washington, DC (speaker)
- 2013 Collaborative Alliance for Nursing Outcomes, Annual Conference, Seattle WA (podium presentation)
- Joint Center for Political and Economic Studies, Report Release Roundtable, Washington DC (presenter)
- 2014 Health Workforce Technical Assistance Center, "Using Employer Surveys to Assess Health Workforce Demand" (webinar)

- 2014 American National Standard Institute, Invitational meeting on "Building a Quality, Flexible and Mobile Health Care Workforce for the Future," Washington DC (panelist)
- 2014 Federal Trade Commission, Workshop on Competition in Health Care, Washington DC (panelist)
- 2015 Health Workforce Technical Assistance Center, "Entry and Exit of Workers in Long-Term Care" (webinar)
- 2015 Institute of Medicine Committee for the Evaluation of the Impact of the Institute of Medicine Report: The Future of Nursing: Leading Change, Advancing Health. (presentation)
- 2015 Sigma Theta Tau International Convention, pre-conference workshop (workshop presentation & management)
- 2016 RAND Corporation, Webinar, "Best Practices Using Peer Providers in Mental Health and Substance Use Disorders" (invited presentation)
- 2016 Texas Medical Center, National Convening, Health Workforce Innovations to Support Delivery System Transformation (invited presentation)
- 2016 Montana State University, Forecasting the RN Workforce Invitational Convening (invited presentation and participation)
- 2016 SAMHSA Region IX and X Workforce Development retreat, San Francisco, CA
- American Organization of Nurse Executives / Robert Wood Johnson Foundation, Invitational Meetings on Advancing Progression in Nursing Program Transition (invited presentation and participation, 2 meetings)
- 2017 Health Workforce Technical Assistance Center, "Data Collection to Advance Nursing Workforce Planning in California" (webinar)
- 2017 American Association of Colleges of Nursing, Spring Annual Meeting (invited presentation)
- 2017 Montana State University, Team-Based Long-Term Care Invitational Meeting (invited presentation and participation)
- 2018 Health Workforce Research Center Symposium: Workforce Strategies to Improve Health Outcomes, Washington, DC (invited presentation and participation)
- 2019 Serious Illness Quality Alignment Hub (webinar presenter)
- 2019 Health Workforce Technical Assistance Center webinar series (presenter)
- 2020 Emergency Health Workforce Policies to Address COVID-19: Expanding Scope of Practice, George Washington University (webinar presenter)
- 2020 All About Nursing podcast (interview)
- 2020 National Institute on Aging, Dementia Care and Services Summit (presenter)
- 2021 AARP Future of Nursing Health Equity Action Forum: Nursing as a Career to Achieve Financial Security & Promote Health Equity (panelist)
- 2021 Inline Sessions: How NPs Affect Quality, Access to Care, & Costs (featured panelist)
- Healthcare Value Hub: Expanded Scope of Practice Laws During the Pandemic A Trend That's Here to Stay? (Presentation)
- 2021 The Handoff Podcast (Interview)
- 2021 AcademyHealth Health Economics Interest Group Webinar: Navigating a Soft Money Environment (Panelist)
- 2021 Health Workforce Technical Assistance Center Webinar: RN Research Using the NSSRN (presentation)
- National Academies of Science Engineering and Medicine, Board on Health Care Services Spring Meeting (presentation)
- 2022 AcademyHealth and Robert Wood Johnson Foundation Future of Nursing Research Webinar (presentation)
- 2022 National Academy for State Health Policy, Annual Conference (plenary panelist)
- 2023 America's Physician Groups Annual Conference (plenary panelist)

- National Research Summit on Care, Services, and Supports for Persons with Dementia and their Caregivers/Care Partners (presentation, session moderator)
- 2024 Health Equity Action Network, Investigator Skills Development Network webinar (presentation)
- 2024 Center to Accelerate Population Research in Alzheimer's, Mind Memory podcast (interviewee)
- 2024 American Medical Directors Association, More of a Good Thing Roundtable (presentation)
- 2024 Hopkins Economics of Alzheimer's Disease and Services (HEADS) Center Monthly Seminar (presentation)

Regional and Other Invited Presentations

- 1996 Bay Area Labor Economists, Semi-Annual Meeting (research presentation)
- 1996 Western Economic Association (research presentation, discussant)
- 1997 University of California, Davis (research paper)
- 1997 University of California, Santa Cruz (research paper)
- 1998 University of California, Davis (research paper)
- 1998 Bay Area Labor Economists, Semi-Annual Meeting (research presentation)
- 1998 Western Economic Association (discussant)
- 1998 Western Regional Science Association (discussant)
- 1999 Bay Area Labor Economists, Semi-Annual Meeting (research presentation)
- 2000 California's Minimum Nurse Staffing Legislation Stakeholder Meeting, California HealthCare Foundation (research presentation)
- 2000 Democrats of Rossmoor (keynote)
- 2000 Western Regional Science Association (research presentation)
- 2001 California Organization of Associate Degree Nursing Directors and California Association of Colleges of Nursing Deans and Directors Annual Meeting (keynote)
- 2001 The Petris Center for Health Care Markets and Consumer Welfare, Charity Care Conference (group discussion leader)
- 2001 California Office of Statewide Health Planning and Development (research paper)
- 2001 Catalyst Corporation, Advisory Committee (keynote)
- 2002 College of Marin Nursing School Graduation (keynote)
- 2002 Union College, Schenectady, New York (research presentation)
- 2004 Causes and Consequences of the Nurse Shortage: Developing a Solution in Illinois, University of Illinois at Chicago (research presentation)
- Nurse-to-Patient Ratios: Research and Reality. Sponsored by the Massachusetts Health Policy Forum and Boston Federal Reserve Bank New England Public Policy Center, Boston, MA (presentation)
- 2006 Increasing Diversity in the Health Care Professions. Sponsored by the Discrimination Research Center and California State University, Sacramento (presentation)
- 2006 SEIU Nurse Alliance Legislative Leadership Meeting, Sacramento, CA (presentation)
- 2006 University of Minnesota, School of Business (research seminar)
- 2007 Increasing Career Opportunities in Nursing and Allied Health in the Los Angeles Area.

 Sponsored by the LA Health Collaborative, Los Angeles, CA (presentation)
- 2008 ADVANCE for Nurses, Forum for Healthcare Recruitment, Sacramento, CA (roundtable panel speaker)
- 2008 MIT Club of Northern California Healthcare Forum, "National Health Reform: Single Payer vs. Managed Competition," Palo Alto, CA (presenter)
- 2009 Connecticut Nursing Leadership Forum, "Minimum Staffing Ratios: Research and Strategies," Wallingford, CT (presenter)
- 2010 SEIU Nurse Alliance Legislative Leadership Meeting, Sacramento, CA (presentation)

- 2010 George Washington University, School of Nursing & Department of Health Policy, School of Public Health and Health Services, "Nurses and Unionization" (invited seminar)
- 2010 University of Toronto, School of Nursing, "Nursing Shortage: Myth or Reality" (expert panel with Christine Kovner, Cheryl Jones, and Carol Brewer)
- 2010 Medical Industry Leadership Institute, Carlson School of Business, University of Minnesota, "Nurses and Unionization" (invited seminar)
- 2010 University of Indiana / Purdue University at Indianapolis, Department of Economics, "Nurses and Unionization" (invited seminar)
- 2010 University of Washington, School of Public Health, "Nurses and Unionization" (invited seminar)
- 2010 Western Institutes of Nursing (2 podium presentations)
- 2011 Collaborative Alliance for Nursing Outcomes, Annual Conference (2 presentations)
- University of California San Francisco, "The Present and Future of California's Registered Nurse Labor Market: Shortages, Surpluses, and Surprising Trends." (webinar)
- 2011 Princeton University, Department of Economics, Industrial Relations Section, "The Impact of Nursing Unions on Wages, Staffing, and Patient Outcomes" (invited seminar)
- 2012 San Francisco General Hospital, Nursing Practice Council, Journal Club presentation
- 2012 California Organization of Associate Degree in Nursing Program Directors, "How Do We Measure Success? Data Needs for the Changing Health Workforce" (invited keynote)
- 2012 University of North Carolina, Globalization of the Nursing Workforce invitational meeting (invited presentation)
- 2012 University of California San Francisco, "The Present & Future of California's Registered Nurse Labor Market: Shortages, Surpluses, and New Trends." (webinar)
- Association of California Nurse Leaders, San Francisco Chapter, "The Impact of Nurse Unions on Wages, Staffing, and Patient Outcomes" (invited keynote at monthly meeting)
- 2012 University of California Berkeley Health Services Research Colloquium
- 2012 Minnesota Nurse Leadership Summit (invited keynote)
- 2013 University of North Carolina, Cecil Sheps Center (research seminar)
- 2013 University of California San Francisco, "The Nursing Labor Market in California: Still in Surplus?" (webinar)
- 2013 Association of California Nurse Leaders, East Bay Chapter, "New Developments in California's RN Labor Market" (invited keynote at monthly meeting)
- 2013 UCSF Global Health Economics Consortium Colloquium, San Francisco (speaker and workshop leader)
- 2014 Service Employees International Union-United Health Workers Education Fund, "Impact of the
- 2010 Affordable Care Act on the CA Labor Force" (webinar)
- 2014 Northwest Organization of Nurse Executives, annual Fall Conference (invited panel presentation)
- 2015 Pennsylvania State University, Health Services Research Colloquium, "What Predicts a Nurse Practitioner Working in Primary Care?" (invited colloquium presentation)
- 2015 University of Hawaii Manoa School of Nursing, Dean's Invited Lecture (3 presentations)
- 2015 California Institute for Nursing and Health Care, Seismic Shift in Nursing Roles event (Panel presentation)
- 2015 Tobacco-Related Disease Research Program, Marijuana Regulation: Lessons from Tobacco-Related Disease Research and Tobacco Control (presentation)
- 2015 California Hospital Association Workforce Committee (presentation)
- 2015 California Health Workforce Initiative Meeting (presentation)
- 2016 University of Minnesota, Division of Health Policy and Management (invited presentation)
- 2016 California Organization of Associate Degree of Nursing Program Directors and California Association of Colleges of Nursing Joint Conference (keynote presentation)
- 2016 Bay Area Black Nurses Association, Flo Stroud Pre-Conference (invited presentation)

2017	JVS Health Workforce Advisory Board (invited presentation)
2017	Greater Bay Area Mental Health & Education Workforce Collaborative, Oakland, CA (invited
	presentation)
2017	Holy Names University, 3 rd Annual Nursing Symposium: The Power of Nursing: Agents for
	Change (invited presentation)
2017	West Virginia Future of Nursing Coalition, Statewide Convening, Charleston, West Virginia
	(invited presentation)

- 2017 California Health Workforce Initiative Meeting (presentation)
- 2018 Riverside Registered Nursing Regional Summit, Riverside, California (presentation)
- 2018 Orange County Registered Nursing Regional Summit, Irvine, California (presentation)
- 2018 Central Valley Registered Nursing Regional Summit, Fresno, California (presentation)
- 2018 Sacramento Registered Nursing Regional Summit, Sacramento, California (presentation)
- 2018 Los Angeles Registered Nursing Regional Summit, Los Angeles, California (presentation)
- 2018 San Diego Registered Nursing Regional Summit, San Diego, California (presentation)
- 2018 Bay Area Registered Nursing Regional Summit, Oakland, California (presentation)
- 2019 California State University Los Angeles Evidence-Based Nursing Summit (keynote)
- 2019 Highland Hospital, Oakland, California (grand rounds presentation)
- 2019 Leonard Davis Institute, University of Pennsylvania (seminar speaker)
- 2019 Govern For California 3rd Annual Policy Retreat (panel presentation)
- 2020 Insure the Uninsured Project 24th Annual Conference (panel presentation)
- 2020 KOED Forum (panelist, two sessions)
- 2020 UCSF Alumni Week Policy Issues Panel (panelist)
- 2020 Advancing New Standards in Reproductive Health (seminar speaker)
- 2020 California Office of Statewide Health Planning and Development, Health Professions Education Foundation meeting (presentation)
- 2020 Health Career Connection (panel presentation)
- 2021 UCSF Health Services Research Symposium: The Future of Health and Pandemic Policy in the Biden Administration (organizer & moderator)
- 2022 University of Indiana School of Public Affairs (research seminar)
- 2022 University of North Carolina, Chapel Hill, School of Nursing Hillman Scholars (seminar)
- 2022 UCSF Osher Center Mini Medical School (presenter)
- 2022 State Net Capitol Journal Hot Issues Webinar (panelist)
- 2022 California Endowment Health Workforce Diversity webinar (moderator)
- 2022 California Legislative Staff Education Institute, Health Policy Education Institute (presenter)
- 2022 California Organization of Associate Degree Nursing & California Association of Colleges of Nursing Fall Conference (presenter & panelist)
- 2023 Philip R. Lee Institute for Health Policy Studies Sacramento Symposium (moderator & presenter)
- 2024 University of California Health Systemwide Grand Rounds (panelist)
- 2024 Philip R. Lee Institute for Health Policy Studies Sacramento Symposium (moderator)

GOVERNMENT AND OTHER PROFESSIONAL SERVICE:

Testimony and Briefings

- 1999 U.S. House of Representatives Committee on Education and the Workforce, Testimony, "Examining the Impact of Minimum Wages on Welfare to Work"
- 2001 Illinois Governor's Task Force on Patient Safety, Testimony, "Patient Safety and Staffing"
- 2001 California Assembly Health Committee, Testimony, "Nursing in California: A Workforce Crisis"

- 2002 California Postsecondary Education Commission, Research briefing, "Admission Policies and Attrition Rates in Community College Nursing Programs"
- 2003 California Assembly Health Committee, Testimony, "Hospital Systems in California: An Overview of Bargaining Power"
- 2003 California Policy Research Center Legislative Briefing, "Admission Policies and Attrition Rates in Community College Nursing Programs"
- 2004 Nevada Legislative Committee on Health Care Subcommittee to Study Staffing of the System for Delivery of Health Care in Nevada Advisory Committee, Testimony, "Patient Safety and Nurse Staffing"
- 2004 California Program on Access to Care and Center for California Health Workforce Studies
 Briefing Moderator, "The Impact of Medi-Cal Cuts of Medical Providers: Doctors, Hospitals, and Clinics"
- 2004 Massachusetts State Legislature, briefings to the Chair of the House Committee on Health Care,
 Director of Policy of the Speaker of the House, Deputy General Counsel of House Committee
 on Ways and Means, and Legislative Director for Chair of Senate Health Committee on
 minimum nurse-to-patient ratios in California hospitals
- 2005 California Board of Registered Nursing, report to the Board, "Forecasting the Future Nursing Workforce"
- 2005 State of California Agency Officials Briefing, "Forecasting the Future Nursing Workforce"
- 2005 California Program on Access to Care and Center for California Health Workforce Studies
 Briefing Moderator and Presenter, "California Nurse Shortage: Impact of Nurse Education
 and Training Initiatives"
- 2006 California Health Workforce Policy Commission, Presentation on "Regional Nursing Shortages"
- 2007 California Board of Registered Nursing, Board Meeting, Presentation on "The 2006 Survey of Registered Nurses in California"
- 2007 California Board of Registered Nursing, Board Meeting, Presentation on "2007 Forecasts of the Supply and Demand for Nurses"
- 2007 California Governor's Task Force on the Nursing Shortage, Presentation on "Forecasts of Statewide and Regional RN Shortages"
- 2008 California Community Colleges Economics Development Program Advisory Committee, Strategic Review & Advance Subcommittee, Presentation on "Health Workforce Needs in California and the Role of Community Colleges"
- 2008 California Board of Registered Nursing, Board Meeting, Presentation on "Endorsement of Nurses into and out of California"
- 2009 California Board of Registered Nursing, Board Meeting, Presentation on "California's Nursing Workforce in 2008"
- 2009 California Board of Registered Nursing, Board Meeting, Presentation on "Forecasts of the Supply and Demand of RNs in California"
- 2009 Institute of Medicine Committee on the Future of Nursing, Presentation on "Scope of Practice of Advanced Practice Nurses in the United States"
- 2010 California Office of Statewide Health Planning and Development, Healthcare Workforce Policy Commission, Presentation on "The Current State of California's Nursing Workforce"
- 2010 California Office of Statewide Health Planning and Development and California Workforce Investment Board, Facilitated Panel Discussion on Preparing for Healthcare Reform and Healthcare Workforce Development
- California Senate Business, Professions, and Economic Development Committee, testimony on "Status of Nursing Shortages, Education, Workforce Development and Diversity in California"

- 2011 California Board of Registered Nursing, Board Meeting, Presentations on "Outcomes of Nurses Placed on Probation" and "California's Nursing Workforce in 2010"
- 2011 California Board of Registered Nursing, Board Meeting, Presentations on "California's Advanced Practice Nursing Workforce" and "Forecasts of the Supply and Demand of RNs in California"
- 2012 California Office of Statewide Health Planning and Development, Healthcare Workforce Policy Commission, Presentation on "The Current State of California's Nursing Workforce"
- 2013 California Board of Registered Nursing, Board Meeting, Presentation on "California's Nursing Workforce in 2012"
- 2013 California Board of Registered Nursing, Board Meeting, Presentation on "Forecasts of the Supply and Demand of RNs in California"
- 2014 California Public Employees Retirement System Board Meeting, Presentation on "Challenges in Hospital Management"
- 2015 California Board of Registered Nursing, Board Meeting, Presentation on "California's Nursing Workforce in 2014"
- 2015 California Board of Registered Nursing, Board Meeting, Presentations on "Forecasts of RN Supply and Demand through 2035" and "Simulation Education and RN Readiness for Practice"
- 2015 City and County of San Francisco Workforce Investment Board Healthcare Subcommittee (presentation)
- 2015 California Workforce Development Board Meeting (presentation)
- 2015 HRSA and SAMSA online briefing on the Peer Provider Workforce
- 2017 California Board of Registered Nursing, Board Meeting, Presentation on "California's Nursing Workforce in 2016" and "Forecasts of RN Supply and Demand through 2035"
- 2018 California Healthcare Workforce Policy Commission, Presentation on "Supply and Demand of Registered Nurses in California"
- 2018 Massachusetts Health Policy Commission, Market Oversight and Transparency Committee,
 Presentation on "Analysis of Potential Cost Impact of Mandated Nurse-to-Patient Staffing
 Ratios"
- 2018 Massachusetts Health Policy Commission, Health Cost Trends Hearing, Presentation on "Analysis of Potential Cost Impact of Mandated Nurse-to-Patient Staffing Ratios"
- 2019 California Future Health Workforce Commission: Meeting the Demand for Health Care, briefing, Sacramento, CA
- 2019 California Future Health Workforce Commission: Meeting the Demand for Health Care, briefing, Los Angeles, CA
- United States District Court Eastern District of Virginia, Expert witness, Case No.
 3:18-CV-428-HEH. Falls Church Medical Center LLC, et al., vs. M. Normal Oliver, et al.
- 2022 California Labor & Workforce Development Agency, presentation
- 2022 California Health Workforce Education and Training Council Quarterly Meeting, presentation
- 2022 California Department on Aging, Webinar on California GROWS Initiative, panelist
- 2022 Oregon Health Workforce Committee, special meeting, presentation
- 2022 Oregon Health Policy Board, Educational Webinar, presentation
- 2023 California Board of Registered Nursing, Board Meeting (presentation)

Boards, Commissions, and Committees

California Strategic Planning Committee for NursingAdvisory Committee

1996-2000 California Strategic Planning Committee for Nursing, Modeling Member

Research, and Development Workgroup

The Scope of Practice of Nurse Practitioners, Physician Member

Assistants, and Certified Nurse Midwives (study funded by

	U.S. Health Resources and Services Administration, conducted	
2002-2006	by SUNY – Albany), Advisory Committee California Board of Registered Nursing, Nursing Workforce Advisory Committee	Member
2002-2005	Central Valley Nursing Diversity Project, Steering Committee	Member
2002-2003	National Commission for VA Nursing	Member
2003	Johnson & Johnson Faculty Grants Advisory Committee, Northern California	Member
2003-2004	Creating a National Nurse Practitioner Database (study funded by U.S. Health Resources and Services Administration, conducted by SUNY – Albany),	Member
	Advisory Committee	
2004-2009	California Institute on Nursing and Health Care, Statewide Master Plan Project, Data Focus Area, Advisory Committee	Member
2005-2016	California Board of Registered Nursing, Education Issues Workgroup	Member
2006	California Institute on Nursing and Health Care, Diversity Project, Advisory Committee	Member
2006-2007	Robert Wood Johnson Foundation and Rutgers Center for State Health Policy, Invitational Conference on The Economics of	Member
	Nursing: Paying for Quality Nursing Care, Advisory Committee	
2009-2011	111011111111111111111111111111111111111	Consultant
2011-2011	Collaborative Alliance for Nursing Outcomes (CALNOC)Oper	
2011-2012	Bipartisan Policy Center Health Professional Workforce Initiative,	Member
2011-2012	Advisory Committee New Mexico Robert Wood Johnson Foundation Nursing and	Member
2011-2012	Health Policy Collaborative, Mark	
in	Tibular 1 only Condition 19, 12-11-1	
	New Mexico Study, National Adv	isory Committee
2011-2016	UCSF US Centre for Evidence-based Patient Care Quality	Founding
	Improvement A Joanna Briggs Institute Affiliated Centre	Faculty
2011-preser		
2012-2013	Emergency Department Quality Indicators Project, Stanford	Internal Expert Group
	Center for Primary Care and Outcomes Research, funded by	
0040 0045	U.S. Agency for Healthcare Research and Quality	Member
2012-2015	Institute of Medicine, Standing Committee on Credentialing Research in Nursing	
2013-2016	Process Redesign Advisory Group, National Center for Inter- Professional Education	Member
2013-2017	Association of Women's Health Obstetric and Neonatal Nurses, Science Team for Perinatal Nurse Staffing Research Project	Member
2014	Institute of Medicine, Planning Committee for Workshop on Credentialing Research in Nursing	Member
2014	National Governor's Association Policy Academy, Building a Ex Transformed Health Care Workforce	
2014-2023	UnitedHealth Group External Clinician Advisory Board	Member
2016	National Academies of Science Engineering and Medicine, Planning Committee for Workshop on Future Financing of Health Professions Education, IPHE Global Forum	Member

2017	Health Teams for Frail Elders Conference, Planning Committee	Member	
2017-2018	California Future Health Workforce Commission, Technical	Member	
	Advisory Committee		
2017-2019	HealthImpact & California Action Coalition, Advisory Committee	Member	
	ntCalifornia Board of Registered Nursing, Nursing Education and	Member	
1	Workforce Advisory Committee		
2018	California Future Health Workforce Commission, Aging	Member	
	Subcommittee		
2018	National Academies of Science Engineering and Medicine,	Member	
	Planning Committee for Strengthening the Connection between		
	Health Professions Education and Practice: A Joint Workshop		
2019-2020	National Academies of Science Engineering and Medicine,	Member	
	Committee on Consideration of Generational Issues in Workforce		
	Management and Employment Practices		
2022-2023	LeadingAge California Stakeholder Advisory Group for The	Member	
	Gateway-In Project		
2022-2025	Futuro Health, Board of Directors		Member
2022-2023	National Institute on Aging Steering Committee for the National	Member	
	Research Summit on Care, Services, and Supports for Persons		
	with Dementia and their Caregivers/Care Partners		
2024	International Council of Nurses, Involving Nurses in HumanAdv	isory Group	
	Resources in Health Planning Project		

Technical Assistance and Consultation

- 2010 Colorado Health Institute, Alternative Primary Care Clinicians: A Workshop on Best Practices for Surveying the NP and PA Workforce. Expert meeting for consultation and guidance. Denver, Colorado.
- 2010 American Nurses Association. Expert Roundtable on economic issues facing nursing, in preparation for 2011 Policy Conference. Silver Spring, Maryland.
- 2011 National Longitudinal Survey of New Graduate Nurses, New York University. Technical review meeting.
- 2012 Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Technical Expert Panel, Effective Strategies to Increase the Supply of Primary Care Providers and Services. Washington, DC.
- Bureau of Health Professions, U.S. Department of Health and Human Services, Expert Panel,
 Data and Methods for Tracking the Supply, Demand, Distribution and Adequacy of the
 Primary Care Workforce. Washington, DC.
- Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Technical Expert Panel, Analysis of Physician Time Use Patterns under the Medicare Fee Schedule. Washington, DC.
- 2012 Robert Wood Johnson Foundation, Academic Progression in Nursing (APIN) Applicant Information Session, webinar presenter
- Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Technical Expert Panel, Health Practitioner Bonuses and Their Impact on the Availability and Utilization of Primary Care Services. Washington, DC.
- 2018 External Expert Meeting on Background Factors and Service Innovations Affecting the Behavioral Health Workforce and Implications for Workforce Modeling and Projections. Health Resources and Services Administration. Washington, DC.

Research and Proposal Reviews

California HealthCare Foundation, manuscript reviewer 2001 Robert Wood Johnson Foundation, proposal reviewer 2003 Institute for Social and Economic Research and Policy (ISERP), Columbia University, proposal 2005 Hospital Ownership and Performance, Research Project Funded by Robert Wood Johnson 2005 Foundation, expert panel for meta-analysis 2005-2006 The Social and Economic Consequences of Tobacco Control Policy, book chapter reviews at proposal and completion stages. Book commissioned by the American Legacy Institute, edited by Peter Bearman, Kathryn Neckerman, and Leslie Wright Blackwell Publishing, Book proposal review 2007 National Science Foundation, Research proposal review 2008 Department of Veterans Affairs, Pilot Project Grant reviews 2009 Department of Veterans Affairs, Nursing Research Initiative Merit Review Panel 2010 Health Research Board of Ireland, Collaborative Applied Research Grants review 2012 Research Foundation - Flanders, Post-Doctoral Fellowship review 2015 Review Panel for RFA-DA-18-005: Expanding Medication Assisted Treatment for Opioid Use 2017 Disorders in the Context of the SAMHSA Opioid STR Grants, National Institute on Drug Abuse Chair for ZDA1 HXO-H (06) S, Multisite Clinical Trials (2 RFAs), National Institute on Drug 2018 Abuse 2018-2019 Agency for Healthcare Research and Quality, Healthcare Effectiveness and Outcomes Research Study Section ad-hoc Member 2019-2023 Agency for Healthcare Research and Quality, Healthcare Effectiveness and Outcomes Research Study Section regular member John A. Hartford Foundation, Program Reviewer 2020 Review Panel for PAR-21-169: Support for Research Excellence (SuRE) Award, National 2023

UNIVERSITY AND PUBLIC SERVICE

Institutes for Health

UNIVERSITY SERVICE

University of California System-Wide

2017 UCOP Nursing School Budget Advisory Group (Member)

2023-present University of California Public Policy Leaders (UC-PPL) (Member)

UCSF Campus-Wide

2010	Inter-Professional Education Day Curriculum Ambassador Mentor
2012	Inter-Professional Health Education Day Group Facilitator
2012	Asian Health Institute Roundtable Speaker
2014-present	Office of Sponsored Research Advisory Board Member
2017	Consultation on Risk Assessment Methodology for UCSF Audit and Advisory Services
2020-present	Population Health Data Initiative Steering Committee Co-Lead
	National Clinician Scholars Program Leadership Council Member
2021-present	UCSF Data Guild Steering Committee Member

2024-present UCSF Learning Health Systems Embedded Scientist Training and Research Center Advisory Committee Member

School of Medicine

2006	Ad hoc review for business proposal for Asian Cardiovascular Center at UCSF
	Search committee for Director of Health and Society Pathway at UCSF
2010	
2012	Center for Health Care Value Training Initiative Committee
2020-present	School of Medicine Directors in Population Health and Health Equity (Member)
2020-present	Center for Health Care Value Steering Committee (Member)
2021-present	School of Medicine Space Committee (Member)
2021-2022	Chair of Department of Family and Community Medicine Search Committee (Member)
2022-2023	Chair of Department of Epidemiology and Biostatistics Search Committee (Member)
2022-2023	Endowed Professorship in Health Policy and Primary Care Search Committee (Chair)
2022-2023	School of Medicine Annual Retreat Planning Committee (Member)
2022-present	Chairs and Directors Council on Diversity (CD2), Department Accountability
-	Subcommittee (Member)
2023	Vice-Dean for Population Health and Health Equity Search Committee (Member)

School of Nursing

2004	Research proposal reviewer, Sigma Theta Tau, Alpha Eta Chapter (UCSF)
2006	Lunch Discussion with Clinical Faculty on compensation issues
2009	Task Force on Data for Doctoral Program Committee (Member)
2021-202	23Director of Institute on Health and Aging Search Committee (co-Chair)

Departmental Service

Philip R. Lee Institute for Health Policy Studies 2008-2013 Health Policy Seminar Planning Committee (Member)

2008-2013	Health Policy Seminar Planning Committee (Member)
2011-2012Ad-h	oc Planning Committee for Advisory Board Meeting (Member)
2012	Ad-hoc Committee for Faculty Appointments (Member)
2013-2020	Faculty Appointment Committee (Chair)
2015	Faculty Search Committee (Chair)
2022-present	Faculty Search Committee (Chair)

Healthforce Center at UCSF

2001-2011	Project Directors/Managers Committee (Member)
2004-2007	Research Working Group (Organizer)
2006-2011	Research Team Task Force (Member)
2011-2012	Transition Team (Co-Chair)
2012-2021	Executive Committee (Member)
2013-2021	Research Faculty Group (Chair)
2021-present	Research Faculty Group (Member)

Other Departments

	· · · · · · · · · · · · · · · · · · ·
	1 Community Health Systems, Merit Review Committees (Member)
2004-200	7Community Health Systems, Administration Program Strategy Committee (Member)
2005-200	9 Community Health Systems, Comprehensive Exam Grader
2014	Social & Behavioral Sciences, Faculty Search Committee (Member)
2014	Dept. of Emergency Medicine, Faculty Search Committee (Member)
	-

2016Dept. of Family & Community Medicine, Faculty Search Committee (Member)

2017Dept. of Preventive & Restorative Dentistry, Faculty Search Committee (Member)

2017 Department of Clinical Pharmacy, Faculty Search Committee (Member)

2022 Department of Family Health Care Nursing, Faculty Peer Review

Committee (Member)

Service to Other Universities

1992-1993 Economics Graduate Policy Committee, Stanford University (Member)

1993 Stanford in Government Health Policy Internship, Selection Committee (Member)

2002, 2004UC Berkeley, School of Public Health, Summer Internship Program (Intern Sponsor)

2002-2013Massachusetts Institute of Technology Externship Program, Extern Sponsor at UCSF

International Visitors

Nov 2001	Justine Curnow, Australian Medical Workforce Advisory and the Australian Health
	Workforce Advisory Committee. Participated in meeting of four UCSF faculty and
	staff.

- May 2002 Division of Health Policy Research, National Health Research Institutes, Taiwan.

 Organized meeting with Dr. Ivy Tsai regarding Taiwan's Future Requirement for Physicians and WTO's Influence Upon It.
- Sept 2003 Dr. James Buchan, Faculty of Social Sciences and Health Care, Queen Margaret University College, Edinburgh, Scotland. Meetings and consultation regarding minimum nurse staffing ratios in California and Australia, as part of project for British National Health Service.
- March 2004 Research Institute for National Health, Japan. Organized meeting of five UCSF faculty with group of physicians interested in the study of medicine and social science.
- April 2004 Dr. Annette J Lankshear, Department of Health Sciences, University of York, England.

 Day-long meeting held at UCSF.
- May 2006 United Kingdom House of Commons Committee on Health, Inquiry into Workforce Needs and Planning for the Health Service. Organized meeting of three UCSF faculty with 11-person Committee.
- June 2006 Dr. Alvisa Palese, Professor, Udine University, Italy. One-hour meeting held at UCSF.
- Nov 2006 Dr. Toon Keng Wong, Principal Assistant Secretary at the Ministry of Health of Malaysia Training Division in Kuala Lumpur. One-month sponsorship of WHO Fellow in Health Workforce Planning and Development.
- Mar 2014 Lisa Smith, RN, Director, Nursing Education and Workforce, Whittington Health, National Health Service, London, England. One-week visitor via a Florence Nightingale Fellowship.
- Mar-Sep 2014 Jia Guo, Assistant Professor, Central South University, School of Nursing. Six-month visiting fellowship through a faculty development award from the China Medical Board.
- Aug 2018 Korean Ministry of Health and Welfare and Korea Institute for Health and Social Affairs, visiting delegation to support development of a national health workforce policy plan.

PUBLIC SERVICE:

MIT Club of Northern California and other MIT Alumni Activity

1991-1998 Education Counselor, MIT Admissions Office

1992-1994 Vice President of Young Alumni Events, MIT Club of Northern California

1995-1997 Vice President of Communications, MIT Club of Northern California

1997-2020	Board of Directors, MIT Club of Northern California
2001-2002	Nominating Committee, MIT Club of Northern California
2004-2005	Nominating Committee, MIT Club of Northern California
2006-2008	Executive Committee, MIT Club of Northern California Board of Directors
2008-2010	Healthcare Forum planning team member, MIT Club of Northern California
2012-2019	Executive Committee, MIT Club of Northern California
2016-2018	Chair, Nominating Committee, MIT Club of Northern California
2020-2023	Honorary Director, MIT Club of Northern California
	•

Alpha Phi International Fraternity

1991-1993	Chapter Advisor, Alpha Phi International Fraternity, Stanford University
1995-1997	Co-chair, Alpha Phi Ivy Connection, Peninsula/South Bay
1998-2000	Technology Task Force, Alpha Phi International Fraternity
2008	Alumnae Strategy Summit, Alpha Phi International Fraternity

Pied Piper Players Community Theater

Set Construction Committee (3 shows)			
2007	Concessions Chairperson		
2008, 2010	Props Team (3 shows)		
2009	Cast: Mrs. Blewett, Anne of Green Gables; Mr. Salt, Willy Wonka		
2009-2010	Program Development Committee		
2009-2013	Board of Directors		
2011	Property Master		

American Youth Soccer Organization

2004-2007	Referee, under 6 and under 8 girls
2008-2009	Team Parent, under 8 girls (2008), under 10 girls (2009)

Baywood Elementary School

2003-2010	Library volunteer, classroom volunteer
2007-2010	Library volunteer coordinator

Borel Middle School

2010, 2011 Property Master, Borel Drama

Hillsdale High School

2012-2016	Music Boosters, Member
2013-2015	Music Boosters, Secretary

Homeless Cat Network

2017-present Volunteer, Kitten Kamp

FIRST (For Inspiration and Recognition of Science and Technology)

2010-2014	Coach, First Lego League, Team M
2014-present	Coach, First Technology Challenge, Team M (8381)

SUMMARY OF SERVICE ACTIVITIES

My service activities have spanned the university, federal and state government agencies, national and regional organizations, and professional organizations. For the University of California System, I served on the Nursing School Budget Advisory Group, which examined the funding models of the four UC nursing schools and made recommendations to the President. I have been a member of the Office of Sponsored Research Advisory Board since 2014, providing review and guidance to OSR in its work to support the research endeavors of UCSF.

My departmental service is centered at the Philip R. Lee Institute for Health Policy Studies, where I was appointed Director in November 2020, and Healthforce Center, where I was Associate Director for Research from 2013 to 2021. Prior to becoming Director at the Institute, I was Chair of the Faculty Appointments Committee and Associate Director for Research. These roles enabled me to expand the network of faculty engaged in policy and health services research across UCSF and join the Steering Committee of the Population Health Data Initiative. At Healthforce Center, I worked with the Director to develop a transition plan for the Center when its founding director announced his retirement. This involved interviewing key stakeholders within and outside UCSF to identify the Center's strengths, weaknesses, opportunities, and threats, and developing a proposal to the Dean for the next director.

I am actively involved in several professional organizations. I regularly serve on the scientific committees and abstract review committees of AcademyHealth, the American Society of Health Economists, and the International Health Economics Association. I am now completing my term on the Membership Committee of AcademyHealth. In 2019, I collaborated with a team of international scholars to develop a Health Workforce Special Interest Group for the International Health Economics Association. We sponsored a full day session preceding the main Congress of the Association in July, which exceeded anticipated attendance. We are now planning activities for the year and will sponsor another pre-Congress session in 2021. I also serve on the US Planning Committee for the International Health Workforce Collaborative, which meets every 1-2 years to share research, policy, and program ideas on meeting the health care needs of the U.S., Canada, U.K., Australia, and New Zealand.

At the national level, I was a member of the National Academies of Science Engineering and Medicine Committee on Consideration of Generational Issues in Workforce Management and Employment Practices and a member of the Institute of Medicine Standing Committee on Credentialing Research in Nursing. I have served on the Planning Committees for two workshops of the National Academies' Inter-Professional Health Education Global Forum. I am a member of the External Clinician Advisory Board of UnitedHealth Group and was a member of the Process Redesign Advisory Group of the National Center for Inter-Professional Education from 2013 through 2016.

My service within California includes frequent consultation and presentation to California governmental agencies and task forces, including the Board of Registered Nursing and the Office of Statewide Health Planning and Development. I was a member of the management team of the California Future Health Workforce Commission and served on the Aging Subcommittee and Technical Assistance Committee.

I have served as an ad-hoc member of scientific review committees for the National Institute on Drug Abuse and the Agency for Healthcare Research and Quality and am a new member to the Healthcare Effectiveness and Outcomes Research section for AHRQ. I am on the Editorial Boards of *Medical Care Research and Review*, and regularly complete peer reviews for other journals.

CONTRIBUTIONS TO DIVERSITY

My dedication to expanding opportunities for underrepresented minorities and women throughout the economy and society was sparked in my high school years and has deepened through myriad experiences. During my undergraduate studies, I spent my summers as a math and computer science tutor at the Urban Scholars Program at the University of Massachusetts, Boston. This program provided advanced educational opportunities to gifted inner-city public high school students, with the aim of sending them to

college. The students were predominantly Black, Latinx, and Southeast Asian immigrants who were highly gifted, and they faced language, cultural, financial, and resource barriers that might have been persistent were it not for this program. I had the opportunity to observe the specific needs of young people adopting a new self-identity of high academic potential, navigating conflicting social mores of parents versus peers, living in insecure neighborhoods, and discussing the racism they faced on a daily basis. And, I saw how well-aimed and consistent support enabled these young people to find their voice, develop their confidence, organize busy academic and activity schedules, and create academic and professional goals that they almost always achieved. Graduates of the program went to Harvard, MIT, University of Michigan, and elsewhere, and frequently returned to visit us during breaks for informal mentoring.

This experience cemented my interest in teaching and also opened my eyes to the importance of recognizing the diverse backgrounds from which students come. In the three programs in which I have developed at taught courses at UCSF, I have worked with students who are the first in their generation to attend college, who have undocumented immigrant parents, need accommodations for disabilities, and/or who are juggling school, parenthood, and full-time jobs. Identifying the stresses they are facing has been essential to my supporting them when they are struggling with meeting deadlines or understanding course material. By focusing on their individual needs and strengths, and expressing confidence in their ability to be successful, I aim to assure students that their challenges are normal and that they can achieve their goals regardless of their background.

Over the past few years, I have had the opportunity to develop a deeper understanding of strategies to support first-generation-to-college students by mentoring a faculty member who has developed a first-generation-to-nursing support program at UCSF (FirstGenRN). By mentoring this faculty member, I am not only furthering the career of a talented woman in academia but also am learning a great deal about how to better support first-generation students and faculty members, who are also often from under-represented racial/ethnic groups and immigrants. This will surely be an area for my development throughout my career.

Mentoring early-stage faculty members is also connected to my long-standing interest in expanding the roles of women and underrepresented minorities in science and academia. Women were the minority in my undergraduate class at the Massachusetts Institute of Technology and my PhD program in economics at Stanford. Economics, like most other science disciplines, has a well-documented high rate of attrition of women and minorities from college to graduate school, from graduate school to academia, and through the academic ranks. My personal experience and the research literature suggest that the difficulty of balancing an academic career with family life is one of the most important causes of the loss of women in science and academia. Academic systems are rarely well-designed to support family life. As a mentor of many women faculty at UCSF and from other universities, I offer empathetic guidance in navigating competing demands. I encourage the women I mentor to focus on a long-term career trajectory in which they may not be the first to attain promotions or receive awards, but that those promotions and awards can be attained. While this approach can apply to both men and women, I have found it to be particularly empowering for women who feel pressured to be professionally successful while often having high levels of stress associated with dual-career households and young children.

My research has been informed by my interactions with healthcare workers, starting in my pre-college years. As a high school student, I worked in the dining room of an assisted living facility, which exposed me to the wide range of highly-skilled – but often poorly paid – staff who are essential to providing high-quality support to people with long-term care needs. Healthcare workers who are from under-represented racial, ethnic, gender, and sexual identity groups are often marginalized in health care. My research has sought to uncover these issues and includes studies of discrimination in the promotion of registered nurses, wage differences faced by long-term care nurses, disparities in the well-being of long-term care workers, and earnings differentials for women serving in academic medicine leadership positions. I am for this research to create a heightened awareness of the perpetuation of wage discrimination so that it can be actively dismantled.

TEACHING and MENTORING

FORMAL SCHEDULED CLASSES FOR UCSF STUDENTS

Academic Yr	Course No. & Title	Teaching Contribution	Uni ts	Class Size
Full Charge				
2001-2004	N287E: Advanced Financial Management	Full charge	4	6-7
2002	N226: Clinical Implications of Managed Care	Full charge	1	40
2006	N287E: Advanced Financial Management	Full charge	3	15
2006	N289A: Advanced Quantitative Research Methods	Co-FOR	4	22
2007	S222: Health Economics and Policy	Full charge	2	150
2013	BioE297: Health Care Finance and Economics	Full charge	2	18
2013-2022	BioE285: Health Care Finance and Economics	Full charge	2	24-42
2014	MHA200B: Introduction to Health Systems Management	Full charge; two quarters	3	21-25
2014-2020	MHA204: Healthcare Finance, Technology, and Business	Full charge; two quarters per year	3	21-31
2016-2019	Health Economics (Health Policy & Law Master's)	Shared charge	3	17
2017	Cost Analysis and Value-Based Care (Health Policy & Law Master's)	Shared charge	3	8
2019	Health Economics 2 (Health Policy & Law Master's)	Shared charge	3	10
Guest Lectu	ires			_
1999	N287E: Advanced Financial Management	3 3-hour lectures	4	6
2001, 2009	SOC222: Health Economics and Policy	1 3-hour lecture	3	80
2002-2003	N150: Community Health Nursing	1 1-hour lecture	3	40
2004	CP133: Health Economics and Pharmacoeconomics	1 1-hour lecture	2	120
2004-2022	S284: Health Care Economics	1 1.5-hour lecture	4_	8
2004-2005	S210: Proseminar in Health Policy	1 1-hour lecture	1	12
2005	N262.06: Research Utilization in Health Policy	1 2-hour lecture	2	2-8
2006	N248: Patient Safety Seminar	1 30-minute discussion	1-6	8
2007	CP123: Health Policy	1 1-hour lecture	3	120
2007	N262.06: Research Utilization in Health Policy	1 2-hour lecture	2	2
2008	CP123: Health Policy	1 1-hour lecture	3	120
2012	N241: Dimensions of Leadership	1 2-hour lecture	2	120

2014-2021	GHS 209: Comparative Health Systems	1 2-hour workshop	3	60
2014	CP133: Health Policy for Pharmacists	1 1.5-hour lecture	3	120
2020	N245B: Clinical Prevention and Population Health	1 2-hour guest lecture	1	15
2021	N200.01 Master of Science In Nursing Epilogue	1 30-minute lecture	1	154
Independen	t Study and Research Practica			
2005	N4710: Independent Study, Olga Ivanco	Full charge	2	1
2006	N276: Research Rotation, Michelle Tellez	Full charge	6	1
2006	N249: Independent Study, Michelle Tellez	Full charge	2	1
2006-2007	N276: Research Rotation, Barbara Burgel	Full charge	3	1
2008	N276: Research Rotation, Shin Hye Park	Full charge	3	1
2008	N276: Research Rotation, Hyang Yuol Lee	Full charge	3	1
2008	N276: Research Rotation, Shin Hye Park	Full charge	2	1
2010-2011	Mentor to Curriculum Ambassador Program, Inter-Professional Health Education program	Shared charge with Renee Courey	n/a	6
2010	N471: Practicum in Health Policy, Katherine Chadwick	Full charge	2	1
2013	N471: Practicum in Health Policy, Emma Moore	Full charge	2	1
2013	N276: Research Rotation, Lorinda Coombs	Full charge	2	1
2015	N276: Research Rotation, Renee Smith	Full charge	2	1
2016	N276: Research Rotation: Zoey Stafford	Full charge	2	1
2021	HPL 249: Independent Study: Harold Collard	Full Charge	4	1

POSTGRADUATE AND OTHER COURSES

2003	Robert Wood Johnson Foundation Schol	lars in Health Policy Research	2-hour lecture
	Postdoctoral Program		
2008	Institute for Health Policy Studies Postd	octoral Seminar 1.5-hour sem	inar
2008	Robert Wood Johnson Foundation Scho	lars in Health Policy Research	30-minute presentation
	Postdoctoral Program		
2009	Institute for Health Policy Studies P	ostdoctoral Seminar 1.5-h	our seminar
2012	Pathway to Health and Society	3-hour seminar/session	
2013, 2	2014 Pathway to Health and Society	2-hour seminar/session	
	016 Decision and Cost Effectiveness An	alvsis (master's level) Stude	ent mentor

POSTDOCTORAL STUDENTS SUPERVISED OR MENTORED:

Dates	Name	Program or School	Role	Current Position
2012-2016	Michelle Ko	UCSF, Department of General Internal Medicine & Institute for Health Policy Studies	Mentor	Associate Professor, UC-Davis
2015-2017	Kristine Himmerick	UCSF, Healthforce Center	Post-doctoral sponsor & advisor	Practicing physician assistant
2016-2020	Nancy Dudley	UCSF School of Nursing pre-doctoral student; San Francisco VA postdoctoral scholar	Dissertation mentor; Post-doc research collaborator & mentor	Associate Professor, San Jose State University
2023-prese	Juliana Friend	UCSF, Philip R. Lee Postdoctoral Fellow	Mentor	444444
2023-prese	Sophie Morse	UCSF, Philip R. Lee Postdoctoral Fellow	Mentor	
2023-prese nt	Lei Chen	UCSF, Institute for Health Policy Studies post-doctoral fellow	Mentor & collaborator	
2023-prese nt	Taylor B. Rogers	UCSF, Institute for Health Policy Studies & Healthforce Center post-doctoral fellow	Mentor & collaborator	
2023-prese nt	Michael Mensah	National Clinician Scholar, Yale University	Mentor	Fellow, Yale University

PREDOCTORAL STUDENTS SUPERVISED OR MENTORED:

Dates	Name	Program or School	Role	Current Position
1996-1999	Michael Ash	UC Berkeley, Economics	Mentor	Professor & Chair of Economics, University of Massachusetts, Amherst
1997-1999	Mark Smith	Yale University, Economics	Summer internship sponsor, mentor	Research Director, Behavioral Health and Quality Research, Truven Healthcare
1997-2000	Shannon Mitchell	UC Berkeley School of Public Health	Dissertation committee	Independent researcher and instructor
2000-2002	Alison Kris	UCSF, Community Health Systems, School of Nursing	Dissertation committee	Professor, Fairfield University

2003-2004	Amalia Miller	Stanford University,	Research advisor	Professor, University of Virginia
2003-2006	Sukyong Seo	UC Berkeley School of Public Health	Dissertation committee	Professor, Eul-Ji University, Seoul, Korea
2004-2007	Michelle Tellez	UCSF, Community Health Systems, School of Nursing	Dissertation committee, independent study instructor	Associate Professor (retired), California State University East Bay
2006-2007	Lisa Black Thomas	UCSF, Social and Behavioral Sciences	Dissertation committee	Associate Professor, University of Nevada, Reno
2006-2007	Barbara Burgel	UCSF, Community Health Systems, School of Nursing	Mentor, independent study instructor	Clinical Professor (retired), UCSF
2007-2009	Teresa Serratt	UCSF, Social and Behavioral Sciences	Qualifying committee, dissertation committee	Associate Professor, Boise State University
2008	Hyang-Yuol Lee	UCSF, Social and Behavioral Sciences	Independent study instructor	Assistant Professor, Catholic University, South Korea
2008-2012	Alan Benson	MIT, Sloan School of Management	Research mentor	Associate Professor, University of Minnesota
2008-2011	Shin Hye Park	UCSF, Community Health Systems, School of Nursing	Independent study instructor, qualifying exam committee, dissertation committee	Associate Professor, University of Kansas
2009-2010	Nickie Gallaher	UCSF, School of Pharmacy	Research project advisor	Marketing Director, Genentech
2011-2012	Debra Wallace	Western University of Health Science	Dissertation mentoring and guidance	Nurse Educator and Nurse Practitioner, Western University of Health Sciences
2011-2013	Jose Dy Bunpin	UCSF, School of Nursing	Dissertation committee	Professional Development Director, Kaiser Permanente Antioch Medical Center
2014-2015	Bahar Navab	UC Berkeley, School of Public Health	Qualifying committee	Assistant Vice Chancellor, Student Affairs, UC-Berkeley
2014-2016	Satu Larson	UCSF, School of Nursing	Qualifying committee, Dissertation committee	Pediatric Complex Care Manager, Santa Cruz Women's Health Center

2014-2016	Bronwyn Fields	UC-Davis, School of Nursing	Dissertation committee	Associate Professor, Sacramento State University
2015-2017	Debby Rogers	UCSF, School of Nursing	Qualifying committee	VP, Clinical Performance & Transformation, California Hospital Association
2017-2019	Kirsten Wisner	UCSF, School of Nursing	Qualifying committee, Dissertation committee	Director of Nursing Research, Salinas Valley Memorial Healthcare
2017-2019	Shira Winter	UCSF, School of Nursing	Qualifying committee, Dissertation committee	Researcher, Center for Nursing Research and Innovation at Mount Sinai Medical Center
2021	Lady Bolongaita	University of Toronto, Institute of Health Policy, Management, & Evaluation	Dissertation appraisal and defense examiner	Analyst, Statistics Canada
2020-2021	Rory Watts	University of Western Australia, School of Population and Global Health	Professional mentor, Viva Voce examiner	Consulting Scientist, World Health Organization
2022-prese nt	Jennifer Dunn	UCSF, School of Nursing	Dissertation Committee	Assistant Professor, School of Nursing, UCSF
2021-prese	Rosalind de Lisser	Vanderbilt University	Dissertation research mentor	Associate Clinical Professor
2023-prese	Nayeon Lee	University of North Carolina, Chapel Hill	Dissertation Committee	

OTHER FORMAL TEACHING

1992	Stanford University	lecturer, mathematics review for doctoral stud	ents)
------	---------------------	--	-------

- 1993 Stanford University (lecturer, introductory economics)
- 1993 Stanford University (teaching assistant, health economics and economic policy)
- 1993 Stanford University (lecturer, health economics)
- 1997 University of California, Santa Cruz (visiting professor, health economics)
- 1997 San Francisco State University (guest lecture teaching)
- 1999 San Jose State University (guest lecture teaching)
- 2000 Mills College, Oakland (guest lecture teaching)
- 2001 University of California, Berkeley (visiting professor, School of Public Health, health economics)
- 2008 University of California, Berkeley (guest lecture, School of Public Health, health economics)
- 2009 University of California, Berkeley (guest lecture, School of Public Health, health economics)
- 2009 University of California, Berkeley (guest lecture, School of Public Health, health workforce)
- 2010 University of California, Berkeley (guest lecture, School of Public Health, health economics)
- 2010 University of Indiana / Purdue University at Indianapolis (guest lecture, Department of

Economics, doctoral-level health economics)

- 2011 University of California, Berkeley (guest lecture, School of Public Health, health workforce)
- 2011 University of California, Berkeley (guest lecture, School of Public Health, health economics)
- 2012 University of California, Berkeley (guest lecture, School of Public Health, health workforce)
- 2012 University of California, San Francisco (presenter, Stories from the Bedside Grand Rounds)
- 2015 University of California, Berkeley (guest lecture, School of Public Health, health workforce)
- 2017 University of California, Berkeley (guest lecture, School of Public Health, health workforce)
- 2021 University of California Hastings (guest lecture, Health Equity Advocacy & Leadership Lab)

SPECIAL COURSES

- 2010 Berkeley Global Health Workforce Economics Network, weeklong course on International Human Resources for Health, Berkeley, California (course faculty)
- World Health Organization/Global Health Workforce Economics Network, weeklong course on International Human Resources for Health, Rio de Janeiro, Brazil (course faculty)
- 2012 Master's student preceptorship, Yale University, School of Nursing
- 2019 Edith Cowan University School of Nursing and Midwifery, 2-hour course on health economic analysis, Joondalup, Australia (course faculty)

FACULTY MENTORING

Dates	Name	Position While Mentored	Mentoring Role	Current Position
2003-200	Surrey Walton	Associate Professor, University of Illinois at Chicago, School of Pharmacy	Research advice, reviewed research proposals	Professor, University of Illinois at Chicago, School of Pharmacy
2005-200 6	Teresa Scherzer	Assistant Adjunct Professor, UCSF School of Nursing	Career guidance	Academic Programs Evaluator, UCSF School of Nursing
2007-201	Michelle Tellez	Assistant Professor, Cal State U – East Bay	Professional advice, research collaboration	Associate Professor (retired), California State University – East Bay
2007-201	Lisa Black Thomas	Assistant Professor, U Nevada - Reno	Professional advice, research collaboration	Associate Professor, University of Nevada, Reno
2009-201	Renee Hsia	Assistant Professor, UCSF	Mentor for KL2 award	Professor, UCSF
2009-201	Kara Odom Walker	Assistant Professor, UCSF	Mentor for grant development	Chief Population Health Officer, Nemours Children's Health
2009-201	Teresa Serratt	Assistant Professor, U Nevada - Reno	Professional advice, research collaboration	Associate Professor, Boise State University

2010-pre sent	Elizabeth Mertz	Assistant Professor, UCSF	Mentor and research collaborator	Professor, UCSF
2011-pre sent	Henry Michtalik	Assistant Professor, Internal Medicine, Johns Hopkins University	Mentor for K award, career mentor	Assistant Professor, Internal Medicine, Johns Hopkins University
2012-pre sent	Laura Wagner	Assistant Professor, Community Health Systems, UCSF	Mentor and collaborator	Professor, Community Health Systems, UCSF
2012-pre sent	Bianca Frogner	Assistant Professor, George Washington University	Mentor and research collaborator	Professor, University of Washington
2014-pre sent	Ulrike Muench	Assistant Professor, UCSF	Mentor and collaborator	Associate Professor, Social and Behavioral Sciences, UCSF
2017-201 9	Jason Flatt	Assistant Professor, UCSF & University of Nevada, Las Vegas	Mentor and collaborator	Assistant Professor, University of Nevada, Las Vegas
2020-202 1	Sunny Hallowell	Assistant Professor, Villanova University	Mentor and collaborator	Associate Professor, Villanova University
2020-pre sent	Xiaochu Hu	Lead Research Analyst, AAMC	Mentor, ASHEcon mentoring program	Lead Research Analyst, AAMC
2020-pre sent	Molly Candon	Assistant Professor, University of Pennsylvania	Mentor and collaborator	Assistant Professor, University of Pennsylvania
2020-pre sent	Samira Soleimanpour	Research Scientist, UCSF	Mentor	Professor, UCSF
2021 - 202 2	Amy Witkoski Stimpfel	Assistant Professor, New York University	Mid-career review panel	Assistant Professor, New York University
2021-pre sent	Mark Unruh	Associate Professor, Cornell University	Mentor	Associate Professor, Cornell University
2021-202	Emmanuel Drabo	Assistant Professor, Johns Hopkins University	Mentor, AcademyHealth/ ASHEcon Diversity Mentoring Program	Assistant Professor, Johns Hopkins University
2022-pre sent	Renee Mehra	Assistant Professor, UCSF	Mentor	Assistant Professor, UCSF

2023-pre sent	Katherine J. Wen	Assistant Professor, Vanderbilt University	Mentor, AcademyHealth/ ASHEcon Diversity Mentoring Program	Assistant Professor, Vanderbilt University
2023-pre sent	Jennifer Yarger	Assistant Professor, UCSF	Mentor	Assistant Professor, UCSF

TEACHING AIDS

2012 Kaiser Family Foundation, KaiserEDU.org, online tutorial on Nursing Labor Markets

OTHER MENTORING AND CAREER DEVELOPMENT

2004	One promotion/appointment review letter
2008	Two promotion/appointment review letters
2009	One promotion/appointment review letter
2010	One promotion/appointment review letter
2011	Three promotion/appointment review letters
2012	One promotion/appointment review letter
2013	Four promotion/appointment review letters
2014	Six promotion/appointment review letters
2015	Seven promotion/appointment review letters
2016	Nine promotion/appointment review letters
2017	Nine promotion/appointment review letters
2018	Five promotion/appointment review letters
2019	Seven promotion/appointment review letters
2020	Five promotion/appointment review letters
2021	Eleven promotion/appointment review letters
2022	Two promotion/appointment review letters

TEACHING AWARDS AND NOMINATIONS

1993 Teaching Assistant Award, Stanford University

TEACHING NARRATIVE

I have developed five courses in master's degree programs at UCSF, four of which were for online programs. I have been the Faculty on Record for BioE 285: Health Care Finance and Economics since 2013 (the course was BioE 297 in its first year). BioE 285 is part of the UCSF/UC-Berkeley Master's in Translational Medicine program and provides an overview of how the health care systems of the United States and other countries are organized and financed, and the implications of organization and finance for technology development and translation. The course receives very positive reviews from learners and provides an essential body of knowledge that is leveraged throughout the program.

I served Faculty on Record for MHA 204 through Summer 2020, which is part of the online Master's of Science in Health Administration and Interprofessional Leadership. I co-taught the course in Summer 2020 to ensure a successful handoff to a new faculty member. For this course, and previously for MHA 200B: Introduction to Health Systems Management, I developed all online content and also served and the real-time instructor to guide online discussions, grade assignments, and provide mentorship.

In 2016, I co-developed two courses for the Health Policy and Law Master's degree program, which is a joint program of UCSF and UC Hastings College of Law. This program is entirely delivered online, and my role included developing competencies and content plans, developing and recording course materials for at least 50% of the courses, and co-teaching the courses. This program is now converting courses to a semester-based academic calendar and I will support the new faculty who will reorganize the coursework to align with the new calendar.

I am a regular guest lecturer for numerous courses at UCSF and UC-Berkeley, including annual lectures for S284 Health Care Economics (since 2004) and GHS 209 Comparative Health Systems (since 2014). I recently served on two dissertation committees for School of Nursing PhD students.

I actively participate in the International Health Economics Association's Teaching Health Economics Special Interest Group. I also mentored early-stage scholars in coauthoring and revising three book chapters over the past two years.

MENTORING SUMMARY

I mentor many early-stage scholars, both at UCSF and other universities. In 2021 I served on two dissertation defense committees for international doctoral candidates at University of Toronto and University of Western Australia. I also have commenced work with two doctoral candidates: I am on the dissertation committee of Jennifer Dunn, a doctoral student at UCSF, and am a dissertation mentor for Rosalind de Lisser, a doctoral candidate at Vanderbilt University.

I continue to formally mentor several UCSF faculty, including Dr. Elizabeth Mertz (School of Dentistry), Laura Wagner (School of Nursing), and Ulrike Muench (School of Nursing). In my role as Director of IHPS, I informally mentor all of our early-stage faculty to support their career development and advancement. I also formally mentor several early-stage researchers at other universities. I serve as a mentor through the AcademyHealth/American Society of Health Economists Diversity Mentoring Program for Emmanuel Drabo, an Assistant Professor at Johns Hopkins University. I also formally mentor Mark Unruh at Cornell University, Amy Witkoski Stimpfel at New York University, and Xiaochu Hu at the American Academy of Medical Colleges Health Workforce Center. I informally mentor and collaborate with Molly Candon at the University of Pennsylvania. In 2016 received the Interdisciplinary Research Group on Nursing Issues Mentorship Award.

RESEARCH AND CREATIVE ACTIVITIES

RESEARCH AWARDS AND GRANTS

Current

1. 1 U81HP26494 (Principal Investigator)

U.S. Bureau of Health Workforce, Health Resources and Services Admin.

9/1/2013 - 8/31/2027

\$533,932 total/year 10

2. 2018-HPC-004 (Principal Investigator)

Massachusetts Health Policy Commission

Health Care Workforce Support

8/13/2018 - 6/30/2024
\$125,000

3. 1R01AG074227 (Co-Investigator) 07/01/2021 - 06/30/2026
National Institute on Aging (NIH) \$2,492,398 total/years 1-5

Relationships of dementia care workforce experiences, training, & work environment to resident outcomes in skilled nursing facilities

Principal Investigator: Laura Wagner, UCSF

4. G-31678 (Principal Investigator) California Health Care Foundation Understanding the Impact of AB890: Setting the Baseline	08/02/2021 - 03/31/2024 \$265,250 total
5. G-31691 (Principal Investigator) California Health Care Foundation Examining California's Midwifery Workforce and the Potential Impact of Reg	08/23/2021 - 03/31/2024 \$134,490 direct gulatory Changes
6. U24 MD017250 (Co-Investigator) National Institute on Minority Health Disparities (NIH) Research Coordinating Center to Reduce Disparities in Multiple Chronic Dise Principal Investigators: E. Charlebois, S. Gansky, & K. Rhoads, UCSF	09/01/2021 - 08/31/2026 \$22,499,999 eases
7. 3 T32 HS022241 (Principal Investigator of subaward) University of California Berkeley (AHRQ primary) UC Berkeley – UCSF Health Services Research Training Program Principal Investigator: H. Rodriguez (UC Berkeley)	12/09/2021-6/30/2028 \$139,512 direct year 5
8. R24AG077014 (Principal Investigator) National Institute on Aging (NIH) Advancing Workforce Analysis and Research for Dementia (AWARD) Netwo	07/01/2022 – 05/31/2027 \$247,994 direct / year 1 ork
9. CT-2223-31 (Principal Investigator) California Department of Aging Evaluation of California GROWS Innovation Fund Investments	12/01/2022-08/31/2024 \$767,940 direct total
10. MST0001652 (Principal Investigator) AARP Measuring the success of recommendations implemented to advance the initial Nursing, 2022-2025	02/01/2023 - 06/30/2025 \$228,000 total ative on the Future of
11. 22-23117 (Principal Investigator) California Department of Health Care Access and Information Office of Health Care Affordability Program Planning and Support Services	06/01/2023 – 08/31/2024 \$209,582 direct total
12. 20232381 (Co-Investigator) The California Endowment California Health Workforce Policy Center	07/01/2023 – 12/31/2028 \$823,325 direct / year 1 \$6,086,956 direct / total
13. 92323 (Principal Investigator) California Board of Registered Nursing RN Workforce Surveys and Analyses	07/01/2023 – 06/30/2025 \$209,374 direct/year I \$465,637 total
14. G-33085 (Principal Investigator)California Health Care FoundationAllied, Behavioral Health, and Nursing Health Workforce Almanac	09/01/2023 – 08/31/2024 \$136,996 total
15. 1U54AG084520 (Principal Investigator of subaward)	09/30/2023 - 08/31/2028

Spetz, revised 3/27/2024

page 33 of 77

University of Michigan (National Institute on Aging primary) National Dementia Workforce Study Principal Investigator: D. Maust (University of Michigan) \$576,584 direct / year 1 \$2,706,379 direct / years 1-5

Pending

P	a	S	t

1. 5 U76 MB 10001-02 (Co-Investigator)	9/30/97 - 9/29/01
Bureau of Health Professions, HRSA, US DHHS	\$172,500 total/yr 1
Center for California Health Workforce Studies	\$690,000 total/yrs 1-4
Principal Investigator: Kevin Grumbach, UCSF	
•	

2. 99-1039 (Co-Investigator)	1/1/00 - 1/30/01
California HealthCare Foundation	\$266,000 total
Meeting California's Nursing Workforce Needs in the 21st Century	
Principal Investigator: Edward O'Neil, UCSF	

3. 99-1039 (Co-Investigator)	6/1/00 - 12/31/00
California HealthCare Foundation	\$44,700 total/yr 1
Minimum Nurse Staffing Legislation in California	
Principal Investigator: Edward O'Neil, UCSF	

4. R01 CA-81130-01 (Consultant)	10/1/00 - 9/30/03
National Cancer Institute (NIH)	\$250,000 direct/yr 1
Use of Cancer Screening in a Managed Care Environment	\$750,000 direct/yrs 1-3
Principal Investigator: Kathryn Phillips, UCSF	

5. 53-5701-3060 (PI on subcontract)	9/1/01 - 8/31/03
California HealthCare Foundation	\$125,000 total/yr 1
Hospital Systems in California	\$250,000 total/yrs 1-2
Principal Investigator: Glenn Melnick, University of Southern California	

6. 1 U79 HP 00004-01 (Associate Director) Bureau of Health Professions, HRSA, US DHHS	9/30/01 – 2/28/07 \$250,000 total/yr 1
Center for California Health Workforce Studies Principal investigator: Kevin Grumbach, UCSF	\$1,250,000 total/yrs 1-5

7. (Co-investigator)	2/1/02 - 1/31/03
California Policy Research Center	\$25,000 total/yr 1
Admissions and Attritions in California Community College Nursing Programs	
Principal Investigator: Jean Ann Seago, UCSF	

8. (Co-investigator)	2/1/02 - 1/31/03
California HealthCare Foundation	\$25,000 total/yr 1
Admissions and Attritions in California Community College Nursing Programs	

Admissions and Attritions in California Community College Nursing Program Principal Investigator: Jean Ann Seago, UCSF

9. (Co-investigator) The California Endowment Admissions and Attritions in California Community College Nursing Programs Principal Investigator: Jean Ann Seago, UCSF	2/1/02 – 1/31/03 \$25,000 total/yr 1
10. 20012298 (Co-Investigator) The California Endowment Central Valley Nursing Workforce Diversity Initiative Evaluation Principal investigator: Kevin Grumbach, UCSF	2/15/02 – 2/14/07 \$300,000 total/yr 1 \$1,500,000 total/yrs 1-5
11. 01-1729 (Principal Investigator on subcontract) California HealthCare Foundation Closures of Hospital Services: Effects on California Communities Principal Investigator: Richard Scheffler, UC - Berkeley	9/1/02 – 1/31/05 \$150,000 total/yr 1 \$300,000 total/yrs 1-2
12. 1 U79 HP 00032-01 (Co-PI) Bureau of Health Professions, HRSA, US DHHS Supply, Demand, and Use of Licensed Practical Nurses Principal investigator: Jean Ann Seago, UCSF	9/30/02 – 9/29/04 \$183,261 direct/total
13. ER02-03 (PI) Public Policy Institute of California The Effect of Changes in Hospital Control on Patient Care, and the Effect of Minimum Wages on Welfare Caseloads	10/1/02 – 6/30/03 \$19,000 total
14. M382848 (Principal Investigator) California Employment Development Department Nurse Workforce Initiative Evaluation	10/1/02 – 10/31/06 \$73,991 total/yr1 \$999,750 total/yrs 1-4
15. 617291 (PI on subcontract) The Brookings Institution The Impact of Federal Health Spending on Cities Principal Investigator: Dan Gitterman, University of North Carolina	4/1/03 – 3/31/04 \$44,175 total
16. U01AI51315-01A1 (Co-Investigator) National Institute of Allergy and Infectious Disease Clinical Trial of Short Course vs. INH for LTBI in Jail Principal Investigator: Mary White, UCSF	9/30/03 – 3/31/2009 \$231,732 direct/yr 1 \$2,485,961 direct/yrs 1-4
17. Principal Investigator Robert Wood Johnson Foundation Nurses' Valuation of Fringe Employment Benefits	3/1/04 – 9/30/04 \$51,000 total
18. Principal Investigator of Subcontract Brookings Institution Data Brief: Measuring Federal Health Spending in Urban Economies Principal Investigator: Daniel Gitterman, University of North Carolina	4/30/04 – 9/30/04 \$15,000 total/yr I \$15,000 total/yr I
19. CI-07-01 (Co-Investigator)	5/1/04 - 12/31/07

Spetz, revised 3/27/2024

page 35 of 77

Clinical Research Investigator Program, UCSF Cancer Center	\$75,000 total/yr 1 \$150,000 total/yrs 1-2
Estradiol and Breast Cancer Prevention: Cost-Effectiveness Principal Investigator: Mary Beattie, UCSF	\$130,000 total/y1s 1-2
20. Co-Investigator Gordon and Betty Moore Foundation Betty Moore CalNOC Nurse-Related Outcomes Principal Investigator: Nancy Donaldson, UCSF	9/1/04 – 2/28/05 \$1,427,817 total/yrs1-3
21. UC1 HS15096 (Principal Investigator of Subcontract) Agency for Healthcare Research and Quality Implementation and Evaluation of IT in a Rural Hospital Principal Investigator: Paul Galloway, HMS Incorporated	9/30/04 – 9/29/08 \$500,000 total/yr 1 \$1,500,000 total/yrs 1-4
22. RWJF #051136 and Moore #637 (Principal Investigator) Robert Wood Johnson Foundation, the Gordon & Betty Moore Foundation The Effect of Information Technology on Nurses and Patients in the Veterans Health Administration	11/1/04 – 3/31/08 \$141,617 total/yr 1 \$300,000 total/yrs 1-2
23. California Dept. of Consumer Affairs #078-2473-4 (Principal Investigator) California Board of Registered Nursing California BRN Registered Nurse Workforce Forecasting Analysis	12/1/04 – 6/30/05 \$13,292.00 total
24. Co-Investigator Gordon and Betty Moore Foundation Betty Moore CalNOC Nurse-Related Outcomes Principal Investigator: Nancy Donaldson, UCSF	6/1/05 – 3/31/06 \$1,427,817 total/yrs1-3
25. 078-2948-5 (Principal Investigator) California Board of Registered Nursing RN Workforce Surveys and Analysis	11/17/05 – 6/30/07 \$245,875 direct/yrs 1-2
26. 055702 (Co-Investigator) Robert Wood Johnson Foundation Rapid Response Team Initiative Principal Investigator: Nancy Donaldson, UCSF	12/15/05-12/31/07 \$110,313 direct/yr 2
27. 05-1372 (Principal Investigator) California HealthCare Foundation Distributional Effects of Minimum Nurse-to-Patient Ratios	3/1/06 – 9/30/08 \$99,495 direct/yr 1 \$150,449 direct/yrs 1-2
28. 924 (Principal Investigator)Gordon and Betty Moore FoundationEvaluation of the Shared Services Project of the Betty Irene MooreNursing Initiative	4/1/06 – 2/28/10 \$78,716 direct/yr 1 \$245,648 direct/yrs 1-3
29. 1132 (Principal Investigator) Gordon and Betty Moore Foundation Analysis of Changes in RN Satisfaction Between 2004 and 2006	6/1/06 – 5/31/07 \$35,466 total

Spetz, revised 3/27/2024

page 36 of 77

30. 58296 (Co-Investigator) Robert Wood Johnson Foundation Interdisciplinary Nursing Quality Research Initiative Principal Investigator: Mary Blegen, UCSF	7/15/06 – 7/14/08 \$175,606 total/yr 1 \$346,083 total/yrs 1-2
31. 2R01HS10153 (Principal Investigator of Consortium Agreement) Agency for Healthcare Research and Quality Nurse Staffing, Financial Performance, Quality of Care Principal Investigator: Barbara Mark, University of North Carolina – Chapel Hi	9/1/06 – 8/31/11 \$300,000 total/yr 1 \$1,200,000 total/yrs 1-4 II
32. 1R01HS014207-01A2 (Principal Investigator) Agency for Healthcare Research and Quality The Effect of Hospital Unions on Staffing and Patient Care	7/1/07 – 6/30/11 \$207,090 direct/yr 1 \$603,598 direct/yrs 1-4
33. 078-3874-7 (Principal Investigator) California Board of Registered Nursing RN Workforce Surveys and Analysis	9/7/07 – 6/30/09 \$414,000 total/yrs 1-2
34. HHSH230200732009C (Principal Investigator) Bureau of Health Professions, U.S. Department of Health and Human Services 2008 National Sample Survey of Registered Nurses Collaborating organization & primary contractor: Westat, Inc. Project Director	9/21/07 - 11/30/11 \$2,920,000 total :: Vasudha Narayanan
35. 1767 (Principal Investigator) Gordon and Betty Moore Foundation Analysis of Changes in RN Satisfaction Between 2004 and 2008	3/1/08 – 11/1/09 \$57,872 total
36. 1899 (Principal Investigator) Gordon and Betty Moore Foundation Evaluation of Impact of Programs to Expand the Supply of Faculty in the San Francisco Region on Educational Expansion	9/1/08 – 8/31/10 \$95,632 total/yr 1 \$200,970 total/yrs 1-2
37. 65993 (Principal Investigator) Robert Wood Johnson Foundation Research on the Future of Nursing	5/1/09 – 7/31/11 \$100,000 total/yrs 1-2
38. 2561 (Principal Investigator) California Board of Registered Nursing RN Workforce Surveys and Analysis	9/17/09 – 6/30/11 \$414,000 total/yrs 1-2
39. (Principal Investigator of Subaward) University of Wisconsin (Primary funder: Robert Wood Johnson Foundation) Evaluation of the ACCEL Nurse Education Program	1/1/10 – 12/31/11 \$40,988 total
40. (Principal Investigator) Gordon and Betty Moore Foundation Analysis of Changes in RN Satisfaction Between 2004 and 2010	2/15/10 – 4/30/11 \$65,000 total

8/1/10 - 7/31/1341. 2537 (Principal Investigator) Gordon and Betty Moore Foundation \$245,475 total New RN Graduate Hiring Survey 4/1/11 - 9/30/1342. 68806 (Principal Investigator) \$175,000 total Robert Wood Johnson Foundation Indicators Tracking Work and Summative Evaluation of the Initiative for the Future of Nursing 7/1/11 - 6/30/1343. 1111-002-0702 (Principal Investigator) \$414,000 total/yrs 1-2 California Board of Registered Nursing RN Workforce Surveys and Analysis 8/1/11 - 6/30/1244. (Principal Investigator of Project under Master Contract) \$130,000 total California Department of Public Health Survey of Nurse Practitioner and Nurse Midwife Use of Health Information Technology PI of Master Contract: Andrew Bindman, MD, UCSF 9/1/11 - 6/30/1345. (Principal Investigator) \$68,056 total Gordon and Betty Moore Foundation Analysis of Changes in RN Satisfaction Between 2004 and 2012 4/1/2012-9/30/2012 46. (Co-Investigator) California Dental Association \$97,900 Reducing the Barriers to Oral Health in California PI: Peter Rechmann, DDS, PhD, UCSF. 4/15/2012 - 4/14/2013 47. 69986 (Principal Investigator) \$100,000 total Robert Wood Johnson Foundation Research Management for the Campaign For Action 6/1/2012 - 11/30/201248. (Co-Investigator) \$50,000 total California Office of Statewide Health Planning and Development Research Support for the OSHPD Data Clearinghouse PI: Janet Coffman, UCSF. 9/15/2012 - 5/31/2019 49. R01 DA034091 (Principal Investigator - Multiple PI) \$1,577,389 total National Institute on Drug Abuse, National Institutes of Health Testing Medical Marijuana's Unintended Consequences for Youth and Young Adults MPI: Laura Schmidt & Joanne Spetz.

50. UD7HP25048 (Co-Investigator)

9/30/2012 - 9/29/2015

U.S. Bureau of Health Professions, Health Resources and Services Administration Interprofessional Collaborative Practice for Nurse Education, Practice, Quality, and Retention PI: Carmen Portillo (UCSF)

51. 70872 (Principal Investigator) Robert Wood Johnson Foundation Research Management for the Campaign For Action 4/15/2013 - 4/14/2014\$100,000 total

52. 17692 (Principal Investigator) California HealthCare Foundation	5/15/2013 - 1/14/2014 \$87,256
Allied and Nursing Health Workforce Almanac	
53. REQ0010424 (Principal Investigator) California Board of Registered Nursing RN Workforce Surveys and Analysis	7/1/2013 - 6/30/2015 \$414,000 total
54. 2537 (Principal Investigator) Gordon and Betty Moore Foundation RN Supply and Demand: Local Forecasting and National Dissemination	8/1/2013 - 7/31/2015 \$250,000 total
55. (Principal Investigator of Subaward) U.S. Bureau of Health Professions, Health Resources and Services Administra University of Washington (primary awardee) Rural Nurse Practitioners and Physician Assistants	9/1/2013 – 8/31/2015 ation
56. 71320 (Principal Investigator) Robert Wood Johnson Foundation Measuring the Success of the Initiative on the Future of Nursing	10/1/2013 – 9/30/2016 \$102,803 total
57. (Co-Investigator) Gordon and Betty Moore Foundation Disseminating the Emerging HealthCare Leaders Program PI: Sunita Mutha, UCSF	12/1/2013 — 11/30/2015
58. (Co-Investigator) The California Endowment Evaluation of ACA Workforce Investments PI: Sunita Mutha, UCSF	3/1/2014 — 12/31/2014
59. 71844 (Principal Investigator) Robert Wood Johnson Foundation Research Management for the Campaign For Action	5/15/2014 – 5/14/2015 \$100,000 total
	6/1/2014 – 2/28/2015
60. (Co-Investigator) American College of Rheumatology Demonstrating Value and Assessing Emerging Models of Payment in Rheum PI: Janet Coffman, UCSF	
61. 72123 (Principal Investigator) Robert Wood Johnson Foundation Multi-Site Evaluation of Innovative Oral Health Workforce Interventions Co-PI: Dana Hughes, UCSF	10/15/2014 – 7/31/2019 \$1,020,000 total
62. (Co-Investigator) California HealthCare Foundation #18630 Medi-Cal Waiver Development: Technical Assistance on Workforce PI: Sunita Mutha, UCSF	11/24/2014 - 2/28/2015

Spetz, revised 3/27/2024

page 39 of 77

1/1/2015 - 12/31/201663. (Co-Investigator) \$300,000 total National Council of State Boards of Nursing Impact of State Scope-of-Practice Regulation on the Availability of Nurse Practitioners in Caring for Vulnerable Populations PI: Ying Xue, University of Rochester 2/1/2015 - 12/31/201564. (Principal Investigator) \$60,000 total California Workforce Investment Board Effect of the Affordable Care Act on the California Health Workforce 2/1/2015 - 1/31/2016 65. (Co-Investigator) \$149,134 total Health Care Cost Institute The Effect of State Scope of Practice Laws on Pharmaceutical Utilization PI: Ulrike Muench, UCSF 2/1/2015 - 6/30/201666. (Principal Investigator) \$95,000 total St. Luke's Health Initiatives Arizona Health Workforce Demand Study 3/1/2015 - 12/31/201667. (Principal Investigator) \$175,000 total California Respiratory Care Board California Respiratory Care Workforce Study 7/1/2015 - 6/30/201768. REQ0014653 (Principal Investigator) \$414,000 total California Board of Registered Nursing RN Workforce Surveys and Analysis 7/1/2015 - 6/30/202069. U01 DE025507 (Co-Investigator) \$2,199,999 total National Institute for Dental and Craniofacial Research Coordinating Center to Help Eliminate/Reduce Oral health Inequalities in Children PI: Stuart Gansky, UCSF 8/1/2015 - 1/31/201770. 72889 (Principal Investigator) \$75,000 total Robert Wood Johnson Foundation Research Management for the Campaign For Action 9/1/2015 - 8/31/201771. R21082330 (Co-Investigator) \$466,412 total National Institute for Child Health and Development Juvenile Court Approaches to Reduce Reproductive Health Disparities PI: Marina Tolou-Shams, UCSF 5/1/2016 - 7/31/201772. CRN 5374-8948 (Co-Investigator) \$172,174 direct Kaiser Foundation Health Plan Current and Future Trends in the Primary Care Workforce PI: Janet Coffman, UCSF 6/1/2016 - 6/30/201773. 54827 (Principal Investigator) \$65,954 California HealthCare Foundation

Spetz, revised 3/27/2024

page 40 of 77

Allied and Nursing Health Workforce Almanac

74. 25IR-0025 (Co-Investigator)

7/1/2016 - 6/30/2019

California Tobacco Related Disease Research Program

Measuring combined tobacco, e-cigarette, and marijuana use in California

PI: Dorie Apollonio, UCSF

75. 174982 (Co-Investigator) California HealthCare Foundation 10/1/2016 - 10/31/2017

\$196,041 total

Enhancing the Utilization of Peer Providers in California

PI: Susan Chapman, UCSF

76. 74076 (Principal Investigator) Robert Wood Johnson Foundation 10/1/2016 - 9/30/2019

\$102,803 total

Measuring the Success of the Initiative on the Future of Nursing

77. 19841 (Co-Investigator)

10/15/2016 - 10/31/2017

\$82,812 direct

California HealthCare Foundation Assessing the Adequacy of the Behavioral Health Workforce in California

PI: Janet Coffman, UCSF

78. 4600009546 (Mertz)

6/5/2017-4/30/2020

\$224,495

William K. Kellogg Foundation

WKKF Dental Therapy Pilot Project Evaluation

PI: Elizabeth Mertz, UCSF

79. (Co-Investigator)

7/1/2017 - 6/30/2019

\$300,000 total

California Tobacco Related Disease Research Program Effects of California's 2016 tobacco policies on initiation, use & quitting

PI: Dorie Apollonio, UCSF

80. 0.5342 (Principal Investigator) California Board of Registered Nursing 7/13/2017 - 6/30/2019

\$414,000 total

RN Workforce Surveys and Analysis

81. (Co-Investigator)

7/1/2017 - 6/30/2019

National Council of State Boards of Nursing

State Nurse Practitioner Scope-of-Practice Regulation and Access to Health Care in Rural and Primary Care Health Professional Shortage Areas

PI: Ying Xue, University of Rochester

82. A130763 (Principal Investigator)

9/01/2017 - 6/30/2020

\$400,000 total

San Francisco Human Services Agency Evaluation of Support At Home Pilot Program

83. R01 HS025715-01 (Co-Investigator)

9/01/2017 - 6/30/2021

\$722,705 total direct

Agency for Healthcare Research and Quality Looking at birth outcomes and their relationship to registered nurse staffing

PI: Audrey Lyndon, New York University

Spetz, revised 3/27/2024

page 41 of 77

84. 6939 (Principal Investigator)

11/01/2017 - 6/30/2019

Gordon and Betty Moore Foundation

\$600,000 total

Developing recommendations for the workforce for care of people with complex health issues

85. (Principal Investigator)

12/01/2017 - 11/30/2018

Public Health Institute (primary funding: Gordon & Betty Moore Foundation)

\$79,930 total

California Future Health Workforce Commission

86. (Principal Investigator)

6/1/2018 - 8/31/2019

California HealthCare Foundation

\$62,114 total

Scope of Practice Expansions to Improve Access to Quality Care

87. (Principal Investigator)

7/1/2018 - 11/30/2019

George Washington University (subaward)

\$95,772

Hematology Workforce Survey

88. R101026 (Principal Investigator)

8/1/2018 - 7/31/2020

National Council of State Boards of Nursing

\$299,947 total/years 1-2

Nurse Practitioner Roles in Addressing the Opioid Crisis: Impact of State Scope of Practice Regulations on Provision of Medication-Assisted Treatment

89. R101036 (Co-Investigator)

8/1/2018 - 12/31/2020

National Council of State Boards of Nursing

\$300,000 total/years 1-2

Prescriptive Authority and Nurse Practitioner Opioid Prescribing Practices

PI: Ulrike Muench, UCSF

90. R21 DA046051-01A1 (Co-Investigator)

2/1/2019 - 1/31/2021

National Institute on Drug Abuse (NIH)

\$441,792 total

Linking local variation in marijuana and opioid policies to health outcomes

PI: Dorie Apollonio, UCSF

91. G-30280 (Principal Investigator) California Health Care Foundation 4/01/2019 - 6/30/2019

\$24,500 total

Nurse Practitioners: Briefing Support

92. 76389 (Principal Investigator)

4/01/2019 - 12/31/2020

Robert Wood Johnson Foundation

\$75,000 total

Research Manager to Support the National Academy of Medicine Committee on the Future of Nursing 2030

93. 41057 (Principal Investigator)

7/1/2019 - 6/30/2021

California Board of Registered Nursing

\$410,908 total

RN Workforce Surveys and Analysis

94. A133606 (Spetz)/1K23AI146268-01 (Kelly)

9/1/2019-8/31/2020

Emory University/ Agency for Healthcare Research and Quality

\$35,479 direct

Annual Health Economics Conference