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**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON**

STATE OF WASHINGTON; STATE OF OREGON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF ILLINOIS; ATTORNEY GENERAL OF MICHIGAN; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF RHODE ISLAND; STATE OF VERMONT; DISTRICT OF COLUMBIA; STATE OF HAWAII; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; and COMMONWEALTH OF PENNSYLVANIA,

Plaintiffs,

v.

NO. 1:23-cv-03026

DECLARATION OF KAREN NELSON

1 UNITED STATES FOOD AND
DRUG ADMINISTRATION, et al.,
2
Defendants.
3
4

5 I, Karen Nelson, declare as follows:

6 1. I am over the age of 18, am competent to testify as to the matters
7 herein, and make this declaration based on my personal knowledge.

8 2. I am the President and CEO of Planned Parenthood of Maryland,
9 Inc. (PPM). I have been President and CEO of PPM since March 2016. I have
10 worked for Planned Parenthood organizations since 1994, including serving as
11 President and CEO from 2008-2016 for Planned Parenthood of Central and
12 Western New York and its predecessor organization, Planned Parenthood of
13 Western New York.

14 3. This declaration is based on my personal knowledge, professional
15 knowledge, my review of PPM's records, and the knowledge that I have acquired
16 in the 29 years of service with affiliates of Planned Parenthood. If called and
17 sworn as a witness, I could and would testify competently to the information
18 contained in this declaration.

19 4. There are two Planned Parenthood affiliates that operate health
20 centers in Maryland: PPM and Planned Parenthood of Metropolitan Washington,
21 DC, Inc. (PPMW). PPM and PPMW are separately incorporated entities. PPMW
22 is responsible for services in Montgomery and Prince George's counties, and

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1 PPM has responsibility for the rest of the state. Planned Parenthood's mission in
2 Maryland includes providing a wide range of high quality, affordable
3 reproductive health care services; education to empower individuals to make
4 informed reproductive choices; and advocacy to protect the right to make those
5 choices.

6 **Access to Abortion in Maryland**

7 5. Collectively, PPM and PPMW currently operate nine health centers
8 providing 8,700 abortion visits a year in Maryland. A map of the locations of
9 Planned Parenthood health centers in Maryland is attached as Exhibit A. Each
10 clinic offers medication abortions. Procedural abortions are available only at
11 PPM's sites in Baltimore City and Annapolis.

12 6. Access to abortions in Maryland, particularly in the rural areas, is
13 limited. According to the Guttmacher's Institute's last survey of providers in
14 Maryland in 2020, 63% of Maryland counties had no clinics providing abortion
15 care, and 23% of women lived in those
16 counties. https://onlinelibrary.wiley.com/doi/epdf/10.1363/psrh.12215

17 7. PPM and PPMW's clinics are located in medically underserved
18 communities. Forty-four percent of PPM and PPMW's abortion patients are
19 enrolled in the Maryland Medical Assistance Program.

20 8. Maryland has a long history of protecting abortion rights. In 1991,
21 the Maryland General Assembly passed legislation to repeal pre-*Roe* abortion
22

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1 restrictions and to codify the right to abortion. This legislation was ratified by the
2 voters of Maryland in 1992 in a referendum known as Question 6. In anticipation
3 of the *Dobbs* decision, in 2022, the Maryland General Assembly enacted the
4 Abortion Care Access Act to, among other things, increase the number and
5 diversity of abortion providers, provide for abortion care coverage without cost-
6 sharing and deductible requirements in state-regulated private plans, and require
7 the Maryland Medical Assistance Program to provide abortion care coverage
8 without restrictions that would be inconsistent with the rights protected by
9 Maryland statutes. The Maryland Medical Assistance Program had provided
10 abortion care coverage under certain circumstances prior to the Abortion Care
11 Access Act, but the Act removed the Program's previous restriction that limited
12 coverage to individuals who were the survivors of rape or incest, had fetuses with
13 severe abnormalities, or faced serious somatic or mental health issues.
14 9. Despite Maryland's long history of protecting abortion rights,
15 Maryland has twice as many pregnancy centers as abortion clinics.
16 https://cnsmaryland.org/2021/10/29/anti-abortion-crisis-pregnancy-centers-
17 outnumber-abortion-providers-in-maryland-2-to-1/. Crisis pregnancy centers are
18 organizations that provide services such as pregnancy testing and referrals to
19 adoption centers but withhold accurate information about or referrals for abortion
20 services. Pregnant individuals have greater access to crisis pregnancy centers
21 than abortion providers in Maryland, particularly on the Eastern Shore and in
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Southern Maryland. Crisis pregnancy centers, which do not provide medication abortion, face no regulatory restrictions such as the REMS provider agreements. Meanwhile, abortion clinics and private providers must comply with the FDA's REMS requirements, including the provider agreement, for Mifepristone. Such restrictions have contributed to the shortage of abortion providers.

The Impacts of *Dobbs*

10. Maryland is the southernmost state on the East Coast where the legality of abortion is not under threat. As a result, Maryland plays an important role in providing access to abortion in the Mid-Atlantic and Southern Region. Following the *Dobbs* decision, our neighboring state of West Virginia banned abortion. As a result, Western Maryland has become the closest option for many people in West Virginia seeking abortion care. People from Pennsylvania also travel to Maryland for abortion services because Pennsylvania imposes restrictions such as 24-hour waiting periods. Despite the increased need for access to abortion services in the three counties of Western Maryland since the *Dobbs* decision, abortion access remains very limited. There are no abortion providers in Garrett and Allegany Counties. While there is a provider of medication and procedural abortion care in Washington County in Western Maryland, we understand that the clinic has limited hours and frequent protests may intimidate or deter some people in seeking care at that location. While the recent change in the REMS permitting certified pharmacies to dispense

1 Mifepristone could improve access in Maryland through telehealth, we are
2 concerned that the number and location of certified pharmacies may be too
3 limited. Research shows that the number of counties across the country without
4 a pharmacy has grown by 630 between 2003 and 2018, with an additional 302
5 counties being left with a single pharmacy. https://rupri.org/wp-
6 content/uploads/2018-Pharmacy-Closures.pdf. As more states ban abortion, we
7 are expecting out-of-state patients to increasingly rely on Maryland providers in
8 all regions. However, most providers of procedural care are concentrated in the
9 Baltimore-Washington metropolitan area.

10 **Mifepristone**

11 11. All of PPM and PPMW's clinics provide medication abortions using
12 mifepristone, an essential medicine for patients and providers. Seventy-six
13 percent of abortions performed at PPM and PPMW's clinics are medication
14 abortions involving the use of mifepristone.

15 12. If patients cannot access mifepristone, negative consequences will
16 occur. When patients are not able to access mifepristone, their options are
17 misoprostol-only abortions or procedural abortions.

18 13. For patients who do not have access to mifepristone or are unable to
19 obtain a medication abortion within the first ten weeks of pregnancy, procedural
20 abortion may be their only option. Patients should be able to choose which option
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1 is best for them, in consultation with their providers, and our data shows that most
2 patients prefer medication abortion.

3 14. Procedural abortions are also more difficult to access. Unlike
4 mifepristone, which is available at each of PPM and PPMW's clinics, including
5 telehealth appointments, and can be mailed to patients in Maryland, procedural
6 abortions can be obtained only at PPM's sites in Baltimore and Annapolis. In
7 Western Maryland, we know of only one procedural care provider who offers a
8 limited number of hours, and we understand there are no providers of procedural
9 abortions in Southern Maryland and on the Eastern Shore.

10 15. Procedural abortion can also be more expensive. While PPM
11 charges the same rate for first trimester procedural abortions and medication
12 abortions, we understand other providers may charge more for procedural care.
13 PPM and other providers also generally charge more for procedural care for
14 individuals whose pregnancy has further progressed. Some abortion providers,
15 who provide services in either a hospital or ambulatory surgery center setting,
16 require the Maryland Medicaid Assistance Program to pay a facility fee. If the
17 Maryland Medicaid Assistance Program must pay for more procedural care,
18 particularly for procedures later in pregnancy, the Program will likely see an
19 increase in claims for facility fees.

20 16. PPM and other providers will be forced to adopt misoprostol-only
21 regimens if mifepristone is not available. The misoprostol-only regimen is a less
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effective regimen compared to mifepristone and misoprostol combination. Relying on misoprostol only increases rates of failed medication abortion with ongoing pregnancy, increases rates of incomplete abortions requiring additional visits and procedures, and results in more complications such as retained pregnancy tissue and excessive bleeding. A misoprostol-only regimen is a longer process for patients to manage. The average time of heavy bleeding and cramping with mifepristone and misoprostol is 4 to 6 hours. With misoprostol-only, this period is between 12-18 hours. As a result, patients will need to take more leave from work or school and face additional challenges in managing family obligations. For out-of-state patients, patients may require longer stays, increasing their expenses because of higher travel and lodging costs as well as more time off work.

17. Mifepristone is also used in second trimester procedural abortion and induction of labor abortion. Without mifepristone, these procedures will require a longer time to complete and possibly increase risk of complications as providers must start using a regimen that is less effective or less familiar to complete these procedures. Patient discomfort may also increase during pre-abortion procedures as osmotic dilators will be needed to prepare the cervix, which may have been avoided by using a protocol that includes mifepristone.

18. If access to medication abortion is reduced, more patients will need procedural care. As there are fewer providers that offer procedural care, patients

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1 will likely experience delays in accessing procedural care. As a result, patients
2 may be later in pregnancy when obtaining procedural care, which can increase
3 the risk of complications, the cost for the procedure and travel, and the need for
4 additional comfort measures and sedation. There is also risk of overwhelming a
5 network of abortion providers who are already stretched in responding to the need
6 to provide more services to out-of-state patients following the *Dobbs* decision.
7 19. If mifepristone is not available for medication abortion, providers
8 will face the challenge of meeting the needs for more procedural care. There is
9 already a shortage of providers offering procedural care, made more severe by
10 the general shortage of health care professionals. Just as in other states, Maryland
11 is facing a health care professional shortage that spans across all health
12 occupations, including physicians, advanced practice clinicians, and nurses.
13 Providers will also have to expand capacity to address the higher rate of
14 complications from the misoprostol-only regimen. Providers will also face
15 additional costs and time for clinical administrative staff to create training
16 materials to train staff on misoprostol-only regimen, patient counseling, and
17 patient education materials. In addition, providers will need to work with private
18 insurers, the Maryland Medical Assistance Program, and other payors to change
19 reimbursement policies which are all based on a mifepristone-misoprostol
20 combination for care. Providers also anticipate that many patients may think
21 that medication abortion is no longer available if mifepristone is no longer
22

available. Patients are already confused about whether abortion is legal because of the constantly changing legal landscape, and providers will need to invest additional resources about educating patients about the continued availability of misoprostol for medication abortion.

The 2023 Mifepristone REMS

20. As part of the Maryland's Abortion Care Access Act of 2022, the Maryland General Assembly established the Abortion Care Clinical Training Program with a required annual appropriation of $3.5 million in state funding. The goal of this state-funded program is to increase the number and diversity of abortion providers as well as support the integration of abortion care into a full range of health care settings, including private practice settings. https://mgaleg.maryland.gov/cmte_testimony/2022/hgo/1x16G_PH6b5hEmXDQmybkZEtaYAOn8uUy.pdf However, the promise of this state investment will not be realized if the REMS remains in place, as it creates a barrier for practitioners, particularly those in private practices with fewer administrative resources to navigate the required provider and patient agreements.

I declare under penalty of perjury under the laws of the State of Maryland and the United States of America that the foregoing is true and correct.

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1 DATED this 23 day of March, 2023, at Baltimore,
2 Maryland 21201.
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4 KAREN NELSON
5 President and CEO
Planned Parenthood of Maryland
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11 ***Exhibit A***
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HEALTH CENTERS

1 Annapolis
929 West St.
Suite 200
Annapolis, MD 21401

2 Baltimore
330 N. Howard Street
Baltimore, MD 21201

3 Easton
8579 Commerce Drive
Suite 102
Easton, MD 21601

4 Frederick
170 Thomas Johnson Drive
Suite 100
Frederick, MD 21702

5 Owings Mills
1866 Reisterstown Road
Suite D
Pikesville, MD 21208

6 Towson
8501 LaSalle Rd
Suite 309
Towson, MD 21286

7 Waldorf
Gateway Plaza
3975 St. Charles Parkway
Waldorf, MD 20602

8 Suitland
5001 Silver Hill Road
Suite 103
Suitland, MD 20746

9 Gaithersburg
19650 Clubhouse Road
Suite 101
Gaithersburg, MD 20886