Physicians for Reproductive Health

June 8, 2023

Senator Elizabeth Warren
309 Hart Senate Office Building
Washington, DC 20510

Senator Tammy Duckworth
524 Hart Senate Office Building
Washington, DC 20510

Senator Mazie Hirono
109 Hart Senate Office Building
Washington, DC 20510

Senator Tina Smith
720 Hart Senate Office Building
Washington, DC 20510

Dear Senators Warren, Hirono, Duckworth, and Smith:

As a board-certified OB/GYN and abortion provider in Washington DC, as well as the President and CEO of Physicians for Reproductive Health (PRH), I appreciate your commitment to ensuring our communities have access to the comprehensive sexual and reproductive health care they need, including access to abortion care. As you know, PRH is a national network of physician advocates that includes doctors of many specialties from across the country. We work to mobilize the medical community by educating and organizing providers while using medicine and science to advance access to care for all people. We are grounded in the belief that we, as physicians, have an opportunity and an obligation to leverage the privilege that our white coats provide to center those we care for in our work and our advocacy. This work is necessary to ensure all people can live freely with dignity, safety, and security. I am proud to be in this work with you.

As I described to you in my previous letters, the devastation following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* has been far reaching for those seeking as well as those providing abortions. In the aftermath of the Court's decision, we have watched an already devastating abortion access crisis become far worse. As of today's date, nineteen states have severely restricted or banned abortion care entirely. Already, data is beginning to show the consequences of this decision and subsequent state bans on abortion with tens of thousands of people having been denied care and forced to remain pregnant against their will. Our network of providers has been reeling as we have continued to grapple with this new and constantly shifting legal landscape and the devastation it is causing to the people we care for.

As you rightly note, the attacks on abortion access, including attacks on access to medication abortions using mifepristone, have continued to escalate. These attacks, although frightening, are not surprising as we have long known the ultimate goal and intention of anti-abortion groups and policy makers has been to ban all methods of abortion care and to punish and criminalize those that provide and access this essential care.

We also know that regardless of the Supreme Court's decision, the continued onslaught of state abortion bans, or the outcome of baseless lawsuits attempting to undermine the FDA's approval of mifepristone, that people will continue needing care. Our movement – providers, abortion and mutual aid funds, advocates, practical support organizations – is collectively doing everything it

can right now to ensure people have both the resources they need, as well as accurate information to make informed decisions about their options for accessing abortions, including self-managing their abortion care when needed or desired. People have been self-managing their abortions, either in whole or in part, outside of the formal medical system for generations. As a community of health care providers, we are committed to correcting misinformation and ensuring people have the support and resources they need in a way that is best for them. We know that changes to the legality of abortion do not change the safety of abortion care. The real threat to people who self-manage their care in this moment is not a medical one; it is a legal one as people who self-manage and those that support them are continuing to be targeted, surveilled, and criminalized.

This is not how health care should work, and it does not have to be this way. Everyone should be able to get care in their own community, in a manner that is best for them, with people they trust. Whether that is in-clinic care, accessing medication abortion through telehealth services, or self-managing their abortion with pills on their own terms. I'm glad to be working with you towards this better world.

Please find responses to your questions below. I hope it is helpful to you as you continue championing the importance of access to comprehensive reproductive health care, including abortion care. Should you need additional information please do not hesitate to reach out.

Sincerely,

Dr. Jamila Perritt, MD, MPH, FACOG
President & CEO
Physicians for Reproductive Health

1. **How has access to medication abortion changed since the Supreme Court issued its decision in *Dobbs v. Jackson Women's Health Organization* and since the District Court's ruling in *Alliance for Hippocratic Medicine v. FDA*?**

In order to fully respond to your questions, I believe it is essential to provide additional information both on mifepristone and misoprostol as these are the two medications that can be used in medication abortion care.

In a medication abortion that uses both mifepristone and misoprostol: the first medication mifepristone, stops hormones from going to the pregnancy. The second medication, misoprostol, causes cramping and bleeding, which causes the pregnancy to pass and expel. Both of these essential medications are safe and effective and have undergone extensive scientific and medical research.

Mifepristone was approved for use by the FDA in 2000 following a rigorous 54-month review period. Nothing about mifepristone's approval was accelerated, and the FDA's analysis included

the review of three complete phases of clinical trials that involved thousands of participants and whose data showed the drug was safe and effective. Since mifepristone's initial approval in the U.S., it has been used by millions of people to end their pregnancies. In fact, in 2021 over half of abortions in the U.S. were medication abortions using the mifepristone/misoprostol regimen. This real-world experience coupled by more than 100 research publications in peer-reviewed journals supports mifepristone's well-documented safety record. In addition, leading medical and scientific organizations, including the World Health Organization, the American Medical Association, the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians, have continued to recognize the safety and efficacy of mifepristone and recommend its use in obstetric and abortion care.

Not only is the use of mifepristone in medication abortion care highly safe and effective, misoprostol can also safely and effectively be used to end a pregnancy with or without the addition of mifepristone. Misoprostol alone is likely the most common method of medication abortion used worldwide due to its availability in many places over the counter without a prescription and at low cost. Access to misoprostol is essential for the full range of pregnancy-related care as it has been used widely to support abortion, childbirth, labor, miscarriage management, and to treat serious postpartum bleeding.

It is critical to state explicitly that medication abortion using mifepristone and misoprostol is still available in states where abortion remains legal and the District Court's ruling in *Alliance for Hippocratic Medicine v. FDA* has been stayed while the case continues to work its way through the lower courts. With that said, it is undeniable that access to medication abortion care using mifepristone and misoprostol has drastically changed since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* and the District Court's ruling in *Alliance for Hippocratic Medicine v. FDA* raises deep concerns about the future of access to mifepristone. PRH described how critical access to mifepristone is for abortion and miscarriage care in our amicus briefs to the Fifth Circuit Court of Appeals and the Supreme Court.

Following the *Dobbs* decision, thirteen states have banned abortion entirely and six states have enacted severe restrictions, all but pushing abortion care out of reach for many people except those in the earliest stages of pregnancy. In these states, access to medication abortion care has been severely curtailed, forcing people to travel outside of their communities and often their states of residence to access medication abortion. For many seeking care, this limits their options to only procedural abortion care, particularly for those who are unable to gather the resources necessary to obtain the procedure until later in pregnancy. For thousands of people, the costs and hurdles imposed by abortion restrictions have been insurmountable and many have been forced to remain pregnant. This is an unconscionable public health and human rights crisis.

In places where abortion remains legal in at least some circumstances, fifteen states have restricted access to medication abortion care by imposing medically unnecessary requirements including that medication be provided by a physician, mandating in person visits to obtain the medications, arbitrary gestational limits, a requirement that mifepristone be taken in the presence of a physician, and banning the mailing of pills for medication abortion to a patient seeking care. These barriers imposed on medication abortion care are compounding on top of an unpredictable

and shifting legal landscape making it extremely difficult for people to get the care they need in their communities. During the 2023 state legislative sessions we saw an uptick in the number of bills that were introduced that targeted access to medication abortion care, showing clearly that access to mifepristone, and likely in the future misoprostol, will continue to be a target of anti-abortion policy makers.

While the District Court's decision in *Alliance for Hippocratic Medicine v. FDA* is not in effect, there is no doubt that should Judge Kacsmaryk's order be allowed to stand, in whole or in part, and mifepristone were to be removed even temporarily from the market, that it would have devastating consequences and would impact every state across the country. This impact would be felt regardless of whether the state has protective abortion laws on the books. While there is another safe and effective medicine that is used in medication abortion care and can be used alone, misoprostol, not every provider or clinic is currently in a position to offer the misoprostol only protocol, and most importantly, many patients may prefer the protocol that includes both medications, allowing them to more closely time the passage of the pregnancy and duration of bleeding and cramping that occurs during the process. Furthermore, for those seeking clinic-based care, limiting the options for abortion care to only procedural abortions would lengthen already long wait times for appointments. If mifepristone is unavailable, far fewer people can be cared for on any given day. The reality is this will mean many more people will be forced to carry pregnancies to term. All of these outcomes are intentional – the cruelty is the point. This is a bleak picture to paint, particularly since there is clear evidence showing that when an individual is denied an abortion their physical, mental, emotional, and financial health all suffer. These impacts are felt for generations to come, thrusting many deeper into poverty and eliminating their ability to exercise agency and autonomy over their own bodies and their own lives.

2. **Have your providers seen an increase in confusion from patients and/or providers regarding the safety, efficacy, and legality of medication abortion? Please describe how this relates to both mifepristone and misoprostol.**

Yes. The whiplash and uncertainty stemming from both the Supreme Court's decision in *Dobbs* and the District Court's decision in *Alliance for Hippocratic Medicine* have many people seeking medication abortion confused about whether they are legally able to do so. Our providers have had patients cancel or not show for appointments because they think the medications are illegal or are banned. Many people, as with many facets of health care, are unaware of the multiple regimens or options for obtaining a medication abortion using mifepristone/misoprostol or the misoprostol only protocol. The confusion extends to the availability and legality of both medications. This lived experience is supported by recent data from the Kaiser Family Foundation which found nearly half of adults in the United States are unsure whether medication abortion is legal where they live. When there are multiple conflicting orders from different courts in different parts of the country and cases are moving rapidly, patients are fearful about who they can trust and where they can get the care they need. This is not how health care should work. All people should be able to choose the care that is best for them in the community where they live with people they trust.

3. How have state-imposed restrictions on medication abortion affected patients?

State-imposed restrictions and bans on medication abortion have had a profound and detrimental effect on access to medication abortion. Thirteen states have banned abortion entirely and six states have enacted severe restrictions all but pushing abortion care out of reach for many people except those in the earliest stages of pregnancy. On top of those bans and severe restrictions fifteen additional states restrict access to medication abortion care by imposing medically unnecessary requirements including that medication be provided by a physician, mandating in person visits to obtain the medications, arbitrary gestational limits, a requirement that mifepristone be taken in the presence of a physician, and banning the mailing of pills for medication abortion to a patient. These medically unnecessary barriers severely curtail people's ability to access necessary care.

Restrictions on abortion care are devastating to the health and well-being of individuals and their families. They have far-reaching consequences that deepen existing inequities and worsen health outcomes for pregnant people and people giving birth. For example, research shows that women who have been denied an abortion are more likely to experience high blood pressure and other serious medical conditions during the end of pregnancy; more likely to remain in relationships where interpersonal violence is present; and more likely to experience poverty. Research also shows that the states with higher numbers of abortion restrictions are the same states with the poorest maternal and infant health outcomes. This is because while most people will have healthy pregnancies, some will experience illnesses or conditions where pregnancy can cause serious problems. Efforts to push both medication and procedural abortion out of reach in large geographic swaths of this country will continue to exacerbate this country's maternal health crises.

It is undeniable that state-imposed restrictions on abortion impact everyone. Nevertheless, Black, Indigenous, people of color, immigrant communities, young people, LGBTQ+ people, people with disabilities, people with low incomes, as well as those living in geographically isolated areas, will be impacted the most. It is critical to understand that restrictions and bans on abortion, across all methods of care, do not exist in a vacuum. They are shaped by systemic and structural conditions. Factors including entrenched institutional racism and discrimination, barriers to health coverage for care, systemic and intentional income inequality, and inadequate workplace supports including lack of paid leave from work, all contribute to the disproportionate impact of abortion restrictions on those who experience oppression across numerous domains of their identities.

The reality is, when medication abortion care is pushed out of reach in one's own community it forces people to travel sometimes thousands of miles to obtain care they should be able to get right at home. Clinics in more protective states are continuing to grapple with the influx of patients travelling and wait times are long, increasing the costs and barriers to care. For those who are not able to pull together the resources to travel to get care, many will be forced to remain pregnant at the expense of their autonomy, well-being, and health.

4. **Are your members experiencing challenges related to pharmacist refusals of prescriptions for misoprostol? Please describe.**

Yes. We have heard from multiple individuals in our network across different states that they continue to see pharmacists refuse prescriptions for both mifepristone and misoprostol. In regards to misoprostol specifically, one patient in North Carolina at her nine-week ultrasound found out her fetus had no heartbeat and she was experiencing a missed miscarriage. She was prescribed misoprostol to pick up at a local Walgreens; however, while trying to pick up the prescription at the pharmacy she was berated with questions from the pharmacists. She was asked if she knew the risks "of bleeding out and potentially death of this medicine:" both scientifically and medically unfounded warnings, as misoprostol is a safe and effective medication. The pharmacist continued to intimidate the patient, warning her of the risks of extreme bleeding that can lead to complications or death. Our provider's patient was upset by the intensity of the pharmacists' warnings but still wanted the medication. The pharmacist continued to ask if the patient's doctor had given proper instructions on how to take the medications and insisted on looking at the patient's secure medical portal and messages between herself and her providers. Finally, before providing the medication the pharmacist asked explicitly if she could call her doctor to confirm that this was for a missed miscarriage. Her doctor confirmed and she was able to receive the medication but the barrage of questions and unfounded warnings left the patient feeling intimidated, shamed, and as if her privacy had been violated.

In Tennessee, one of our providers shared that following the *Dobbs* decision and Tennessee's trigger ban going into effect, multiple pharmacists refused to fill a prescription for misoprostol for missed abortions because the diagnosis code had the word abortion in it (the medical terminology for miscarriage is "spontaneous abortion"). This created significant and harmful delays for medically necessary care for countless patients.

In Ohio, another provider shared that pharmacists have called her to confirm the prescription for misoprostol was not for an abortion and had one pharmacist say it was the grocery store chain policy that they needed to ask. These instances have become more frequent since the Supreme Court's decision in *Dobbs.*

Another one of our providers is conducting research on this precise topic and has given PRH permission to share some preliminary findings. In this study, researchers contacted all local pharmacies in the state of Arizona with trained research assistants using a standardized script, posing as a 22 year-old patient with no insurance who has been diagnosed with an early pregnancy failure (miscarriage) on ultrasound who is trying to fill a prescription for misoprostol. Of the pharmacies contacted, 25% could not fill the misoprostol the same day (238/941), and of those 11% (25/238) either have policies prohibiting the dispensing of misoprostol or require documentation of the diagnosis before dispensing misoprostol. The national chain pharmacies more frequently had these policies. The most disturbing quote from the over 900 calls was this: *"The pharmacist would need to first speak with the prescribing physician to confirm a diagnosis.*

They would then need to first consult with their legal department to be sure all three parties were in agreement that it is reasonable to fill the prescription."[1]

It is evident from these stories that two things are happening simultaneously – there is immense fear in this moment from providers across practice settings that they will be caught in the crosshairs and criminalized if they provide this necessary care and in some cases a provider's religious or moral belief is being used as a weapon to deny people the care they need. In either circumstance, this is not how health care should work and under no circumstances should a provider's religious or moral beliefs determine the care a patient is able to receive.

5. **What guidance have you provided to your members, if any, about how to administer medication abortion in light of increased misinformation and the ongoing litigation in *Alliance for Hippocratic Medicine v. FDA* and *Washington v. FDA*?**

Although many providers in our network conduct research and have been leaders in crafting clinical care protocols, Physicians for Reproductive Health does not provide specific guidance on how to provide medication abortion. We do not set medical or clinical policy guidelines for abortion providers. However, we have continued to keep our network apprised of the rapidly developing court cases and we stand in strong support of the physicians in our network who are fighting to provide compassionate, lifesaving, essential care to their communities. We partner with organizations like the Society of Family Planning, Planned Parenthood Federation of American, and the National Abortion Federation that provide information about evidence-based standards and protocols.

6. **What effect would a stay of the FDA's approval of mifepristone have on patients and providers?**

A stay on the FDA's approval of mifepristone would be devastating on the health and well-being of patients across the country and would disrupt access to a range of reproductive health care. The bottom line is that any restriction, barrier, ban, or bar on access to essential medications, will be devastating and will result in people not being able to get the care they need in the time or way that they need it. When abortion is more challenging to access many people are pushed later into pregnancy as people try to navigate the immense logistical hurdles associated with forced travel and the health and wellbeing of individuals, families, and communities suffer. If mifepristone's approval were stayed and no longer accessible, in states where abortion is not banned some people may still be able to access medication abortions using a misoprostol only protocol. Misoprostol can be used to safety and effectively end a pregnancy, and studies of self-

[1] Forthcoming publication, Access to Misoprostol study, a collaboration between the OBGYN departments at the University of Arizona College of Medicine-Tucson and University of Hawaii John A. Burns School of Medicine.

managed use of misoprostol alone regimens have found high levels of effectiveness, with 93-99% of participants reporting complete abortions without the need for procedural care.

For those who are not able to access misoprostol, procedural abortion care will continue to be an option in places where abortion care remains legal; however, a stay of mifepristone's approval will cause significant hurdles as procedural abortion care must be provided in-clinic where there are already significant wait times and a shortage of providers who are able to provide procedural care. In short, removing the approval of mifepristone could have devastating consequences and once again upend the abortion access landscape only a short time after the Supreme Court's decision in *Dobbs*.

7. **How would a stay of the FDA's approval of mifepristone affect providers' ability to treat miscarriages?**

A stay of mifepristone's approval would affect providers' ability to treat spontaneous abortions, commonly termed "miscarriages." Use of mifepristone and misoprostol in combination to treat miscarriages can shorten the length of time someone is miscarrying and is an effective way to treat early pregnancy loss. This means that using mifepristone in miscarriage care can decrease the risk of hemorrhage or infection as well as the likelihood of a procedural intervention. Taking mifepristone off of the market for abortion care would mean it is also unavailable for miscarriage management.

However, it is not the only medication available as misoprostol can be used alone and is a safe and effective way to support patients who are experiencing a miscarriage. However, the bottom line is that this is a medical decision that should be made and managed by individuals in consultation with their trusted providers and support networks. Courts should not be inserting themselves unnecessarily into the patient-provider relationship and undermining decades of medical and scientific evidence that demonstrates that mifepristone is a safe and effective medication. Each patient is different and every pregnancy is unique, which is why patients should be able to get a full spectrum of individualized care responsive to their needs.

8. **Is there additional information you would like to share regarding women's health care including access to abortion and medication abortion, the impacts of the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization* and the District Court's ruling in *Alliance for Hippocratic Medicine v. FDA*, and how providers are navigating the criminalization of abortion and increased surveillance in a number of states?**

Yes, in your letter you reference severe misinformation about medication abortion care being peddled by anti-abortion extremists, including so-called medication abortion reversal. We appreciate this acknowledgment and would like to provide you with information that may be helpful as you continue to push back on these harmful and medically inaccurate narratives.

Abortion "reversal" is a non-medical term used by those whose desire is to eliminate access to abortion to describe a medically unproven protocol in which a high dose of progesterone is given after mifepristone is administered for a medication abortion. This regimen relies on experimental

treatment that does not follow standard research protocol. Proponents of so-called abortion reversal rely on case series, the lowest level of evidence, which cannot prove cause and effect.

In December of 2019, the results from the first randomized control study (the highest level of scientific study) on abortion "reversal" were published. This study had to be stopped because of significant safety concerns about the regimen, namely heavy bleeding that in some cases required blood transfusion and even emergency surgery. The study concluded that the efficacy of progesterone for nullifying the effects of mifepristone could not be estimated due to these significant safety concerns. Notably, the American College of Obstetrics and Gynecology (ACOG) does not recommend the practice, stating that "claims of medication abortion reversal are not supported by the body of scientific evidence, and this approach is not recommended in ACOG's clinical guidance on medication abortion." As shown by the incomplete study, this approach is not safe, effective, or based on medical evidence.

Given the misinformation that is being circulated about medication abortion care, we need champions like you to continue sharing scientifically and medically accurate information about medication abortion care and the safety and effectiveness of mifepristone and misoprostol.