Exhibit A

Declaration of
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

HEIDI PURCELL, M.D., FACOG, *et al.*

Plaintiffs,

v.

DORIS FINK, J.D., *in her official capacity as* ACTING SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIVIL ACTION
Case No. 1:17-cv-00493-JAO-RT

DECLARATION OF HONOR MACNAUGHTON, M.D.

Judge: Hon. Jill A. Otake
Hearing Date: Vacated per ECF 107
Trial Date: Vacated per ECF 82

DECLARATION OF HONOR MACNAUGHTON, M.D.

Honor MacNaughton, M.D., declares and states as follows:

1. I make this declaration based on my own personal knowledge. If called to testify, I could and would do so competently as follows.

2. I am a board-certified family medicine physician and an Associate Professor of Family Medicine at Tufts University School of Medicine. I serve patients and train family medicine residents in a hospital safety net system in the metropolitan-Boston area, where I provide primary care and reproductive health services.

3. I earned my Bachelor of Arts from Harvard University in 1998 and my medical degree from University of Massachusetts School of Medicine in 2004. I completed my residency in family medicine at Tufts University Family Medicine Residency in 2007.

4. I am a member of Plaintiff Society of Family Planning ("SFP"), which is a medical society for providers and advocates focused on family planning and just and equitable access to abortion and contraception. I am also a member of the American Academy of Family Physicians and the Massachusetts Academy of Family Physicians.

5. I submit this declaration in support of Plaintiffs' motion for summary judgment and in opposition to Defendants' motion for summary judgment in

Plaintiffs' challenge to the U.S. Food and Drug Administration's ("FDA") Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex and its generic (collectively "mifepristone"). I submit this declaration in my individual capacity and as a member of SFP, and not on behalf of any institution with which I am affiliated.

6. I use "Mifepristone REMS" as a shorthand in this declaration to refer to both the REMS and the three Elements to Assure Safe Use ("ETASU") it includes for mifepristone.

7. The safety net hospital system in which I work includes two hospitals and twenty outpatient clinics providing care to predominantly low-income patients throughout the greater Boston area. I provide primary care, including reproductive health care, in outpatient clinic settings. I am also part of a team overseeing the three reproductive health clinics within the system, and I have administrative responsibilities with respect to implementing our system's compliance with the REMS across all of the outpatient clinics.

8. I am a certified prescriber under the REMS and regularly prescribe mifepristone to patients for both abortion and miscarriage care, both through in-person appointments at one of our clinic locations and via telehealth.

9. Through my administrative role overseeing our system's compliance with the REMS, I have direct knowledge that more than eighty of my colleagues in

primary care and obstetrics and gynecology ("OB/GYN") regularly prescribe mifepristone to their patients at fifteen of our twenty outpatient clinics.

10. The Mifepristone REMS directly imposes multiple, ongoing burdens on me and my colleagues by forcing us to comply with requirements that take considerable time and energy to navigate and that compromise our clinician-patient relationships and ability to practice our profession. These ongoing burdens include the time, labor, and health system resources necessary to navigate and fulfill the prescriber certification, pharmacy certification, and patient agreement requirements—burdens that would not exist but for the REMS. The REMS also routinely complicates and interferes with the counseling process for my medication abortion and miscarriage patients, by (1) creating administrative complexities that I'm forced to spend considerable time and effort navigating with my patients during each appointment, and (2) mandating the provision of duplicative and, for some patients, inaccurate counseling information. The REMS burdens my and my colleagues' patients as well. As detailed further below, the REMS undermines patients' access to mifepristone, creates delays in their care, and causes some of our patients confusion and distress.

11. When my colleagues and I prescribe mifepristone to our patients (whether for abortion or miscarriage care), we offer them different options for receiving the medication so they can fill their prescription in the way that best meets

their needs. Patients who come to an in-person appointment at one of the clinic sites that stocks mifepristone onsite can pick it up directly from the provider at the appointment. Telehealth patients and patients attending appointments at a clinic site that does not stock mifepristone (or that is out of stock) can opt either to have their prescription filled at one of four retail pharmacies affiliated with our health system, all of which are certified pharmacies under the REMS, or to receive the medication through a courier delivery service.

12. But the REMS compromises our ability to provide this care. Because of the administrative burdens created by the REMS's prescriber and pharmacy certification requirements, my colleagues and I are not able to prescribe mifepristone through any pharmacies other than the four pharmacies affiliated with our system that have completed the REMS certification process. When the REMS changed in January 2023 to permit retail pharmacy dispensing, I spent approximately twelve hours trying to develop a process that would allow us to send prescriptions to external certified pharmacies, including retail chains like Walgreens and CVS. However, the REMS requires every individual clinician who prescribes mifepristone within our health system—of which there are more than eighty—to complete a prescriber certification form and fax it to every individual certified pharmacy where a patient fills their prescription for mifepristone. Given the geographic distribution of our patients, there are potentially hundreds of pharmacy locations across

Massachusetts that they may use. The administrative burden on me and my colleagues to (1) identify which pharmacy locations are REMS-certified and willing to fill prescriptions for mifepristone, and then (2) send an individual prescriber agreement to every single one, was insurmountable.

13. Moreover, it was virtually impossible for me to get firm information from these external pharmacies about the details and processes necessary to work with them, such as which of their locations were certified and able to receive and fill mifepristone prescriptions. For example, despite hours of effort, I was unable to even get a clear answer from one large pharmacy chain about who the right person was to talk to about their process; in another case, my multiple calls simply went unreturned. It simply is not feasible for me and my colleagues to do this kind of leg work—for each mifepristone prescription—to attempt to confirm whether the patient's preferred pharmacy is certified and each send our certification form over if so, or if not, to identify an alternative certified pharmacy that would be convenient for the patient.

14. If not for the pharmacy certification requirement, my colleagues and I could simply write a prescription for mifepristone and send it to a patient's preferred pharmacy. Then, the pharmacy would either dispense it if they had it in stock; promptly order the medication into stock; or transfer the prescription to a pharmacy that already has it in stock. This is how pharmacy dispensing virtually always works,

including for other time-sensitive medications I prescribe (such as antibiotics, pain medications, or emergency contraception).

15. Instead, my colleagues and I are only able to send prescriptions for mifepristone through the four pharmacies associated with our health system, or to arrange for delivery to the patient by courier. As detailed below, each of these options can impose burdens on patients and delay care.

16. My patients, the majority of whom are low-income, face substantial barriers to accessing health care. Many of my patients are struggling financially; they have told me that even finding and paying for transportation to a medical appointment or to pick up a prescription can present a hardship. They have also told me that they struggle to find childcare or to arrange time off work, which can further complicate their ability to travel to our clinics or pharmacies. Public transportation options to reach many of our clinic locations and pharmacies are limited. My patients without reliable access to a car often need to either pay for a rideshare, which can present a financial barrier, or find someone to drive them, which can cause delays and jeopardize their privacy. As a result, it can be difficult for patients to travel to an appointment at one of our clinic locations, let alone one that stocks and dispenses mifepristone onsite. While I am currently able to offer telehealth appointments to these patients, I will then need to work with them to figure out how they will access their mifepristone prescription, a task that the REMS complicates considerably.

17. Our four pharmacy locations are not always convenient or easily accessible for the patients we serve, who come from a large geographic area. I have had patients tell me that they would not be able to access transportation or arrange childcare to enable them to make an in-person trip to one of these pharmacy locations. Moreover, some of these pharmacies have limited hours during evenings and weekends, and some of my patients have told me that they are not able to come during those hours because of inflexible work schedules or family responsibilities.

18. We also offer a courier delivery option, but this is not an option for all patients either. To receive the medication through the courier system (which requires a signature), the patient must be available for a four-hour window to receive the delivery. Courier delivery also has limited evening and weekend delivery options, which makes it even more difficult for some patients to receive their medication this way. Some patients have told me that their work or family responsibilities make it difficult to find a four-hour window when courier delivery is available and when they can be present to receive the package. While I am aware of mail-order pharmacies that could present an alternative option for delivery of mifepristone, exploring this option (which our health system does not use for any other medication) would require additional administrative work, including setting up entirely new internal systems, that I do not currently have the capacity to take on, in light of all the other REMS-specific administrative work already taking up my and

my colleagues' time and resources. For the moment, therefore, we are only able to offer our patients delivery by courier, which we began using for mifepristone delivery during the COVID pandemic.

19. Other patients have told me that they cannot receive their prescription by courier delivery at all because of privacy concerns if others in their household were to find out about their prescription or because they do not have a permanent mailing address. It is especially important for patients in these fraught situations to be able to pick up their medication at a nearby pharmacy—but the burdens of pharmacy certification and prescriber certification make it extremely difficult for us to offer a wider range of pharmacy options to our patients.

20. The difficulty of navigating where and how a patient can access their medication can lead to delays. For example, I recently had a patient to whom I prescribed mifepristone who was not able to come in person to a pharmacy location or to be home to receive courier delivery until her next day off work, which was the following weekend, several days after her appointment. Without the REMS, I would have been able to send the prescription to her local pharmacy, and she would have been able to access and use the medication days earlier—likely the same day as her appointment.

21. The REMS also imposed significant administrative burdens on me and my colleagues as we attempted to set up prescribing through the four pharmacies. In

order for me and my colleagues to be able to send prescriptions to these pharmacies—all of which are retail pharmacies that can also fill prescriptions from providers outside of our health care system—the pharmacies first had to complete the REMS pharmacy certification process and set up systems internally to ensure their ability to comply with the REMS requirements, such as ensuring four-day delivery to patients and storing, tracking, and ensuring confidentiality of provider certification forms. After that, each of our providers who intended to fill prescriptions through the pharmacies had to complete their certified prescriber form and send it to the pharmacies. This necessitated extensive coordination with the chairs of multiple departments in our health system to reach alignment on the process, ensure consistent communication with individual prescribers about the process and their responsibilities relating to the REMS, and confirm the collection and storing of their certification forms. I was responsible for coordinating this process with the pharmacies, and the various departments. It has taken me hours and hours of work across more than six months to get all of these pieces in place. The process of getting individual prescribers certified is still ongoing.

22. In addition, I will next need to update our onboarding materials for new hires to integrate the new REMS-required certification process into their training. In order to do so, I will need to coordinate with our Information Technology ("IT") department and other departments involved in internal prescriber education to access

the REMS-related training materials, make the necessary updates to them, and work with IT to get the updated forms uploaded to our internal intranet system. Making this update is not a simple task in a large health system like the one where I work and could take weeks or more of back and forth with colleagues. If not for the REMS, I would not need to undertake this lengthy administrative process.

23. There is no other medication that I prescribe that requires me to sign a form attesting that I have the necessary qualifications to prescribe it. As part of my ethical obligations, professional responsibilities, and standard of care, for every prescription I write, I cannot and do not prescribe medication unless I have the qualifications to assess patient eligibility for the medication, screen for contraindications, counsel my patients about risks and alternatives, and ensure a plan for follow-up care.

24. In order to ensure system-wide compliance with the REMS, my health system imposes an additional credentialing requirement for anyone who wants to prescribe mifepristone to our patients, which requires completing a unique training and going before the credentialing committee. Although not expressly required by the REMS, my health system does this to ensure compliance in light of the complexities created by the REMS, given the size of the health system. This credentialing imposes another layer of burden for providers like me who provide medication abortion and early miscarriage care in our practices, and it limits the

number of providers who provide this care. Through my work coordinating our system's procedures to comply with the REMS, I have had colleagues tell me that they want to provide this care but have not been able to take the time out of their busy practices to complete the credentialing process. This process, which would not exist if not for the REMS, does not exist for any other medication within our health system.

25. The REMS also imposes burdens on me and my patients as a result of the requirement to sign a specified Patient Agreement form.

26. This form does not add anything of value to the patient counseling process. It is part of my ethical obligations to my patients to ensure informed consent, including by discussing the risks and benefits of treatment, alternatives to treatment, and making sure my patients know when to contact me or another health care provider in the event of side effects or complications. I do this for all of my patients, whenever providing care. There is no other medication I provide for which FDA requires me to review and sign a special counseling form with my patients.

27. Not only does the REMS-mandated form not in any way benefit my interactions with my patients, it presents an administrative burden. For every mifepristone prescription, I must ensure the patient signs (manually, or via docusign for telehealth appointments) the Patient Agreement Form, sign it myself, and ensure a copy is placed in the patient's medical records. For patients who sign the form

manually in paper copy, this requires me to ensure that administrative staff at the clinic where the appointment takes place scan the paper form into the patient's electronic medical record, since we store all patient records electronically. If I am working at one of the several clinic sites that does not have access to onsite scanning, I have to ensure that the form gets to another location where it can be scanned. All of this takes time and effort that I do not need to expend for other medications and that I would not need to expend when prescribing mifepristone, if not for the REMS.

28. Moreover, far from benefiting the counseling process, the REMS-mandated form actually conflicts with evidence-based counseling for some of my patients. For example, when appropriate for the patient, I sometimes prescribe mifepristone to my patients according to a different evidence-based protocol than what is stated on the patient agreement form, such as using a shorter interval between taking the mifepristone and misoprostol or a different, evidence-based route of administering the misoprostol. The discrepancy between the patient's individualized treatment plan and the form has created confusion for patients and required extra time to address and explain.

29. The REMS-mandated form also burdens the counseling process with patients to whom I prescribe mifepristone and misoprostol as part of the gold-standard two-drug regimen for miscarriage management. The REMS-mandated form states that "I have decided to … end my pregnancy," which is inaccurate for

patients who are experiencing early pregnancy loss and is confusing and emotionally upsetting for many of these patients. Because of this, I worked with my colleagues to create a second consent form appropriate for their clinical circumstances. When going through informed consent with these patients, after providing the accurate counseling information, I then must explain to them that they are also required to sign a form (the REMS-mandated form) that says things that are not applicable to their individual circumstances. This is confusing for patients and unnecessarily complicates the counseling process. If not for the REMS mandating use of the inaccurate patient agreement form for these patients, these patients would not have to sign either of these two forms on top of the otherwise standard informed consent process. But, because of the REMS, there are two layers of paperwork I must complete with each of them. It is also burdensome and distressing for me professionally to have to go through a REMS-mandated process that I know can be confusing, clinically inaccurate, and emotionally upsetting to my patients, given my ethical obligations to provide individualized care and act in my patients' best interests.

30. In addition, as part of my administrative responsibilities for overseeing the REMS program, I am responsible for ensuring that the REMS-mandated form is made accessible across our system to all our providers for use with their patients. This means that, when the REMS was updated in January 2023, I had to work with

IT to replace the old form with the new one, work with other staff within our health system to get the updated form translated into three additional languages so that it would be usable within our patient population (many of whom have limited or no English proficiency), and then work with IT to upload all of those additional translated versions to our system's intranet as well. This work was essentially doubled in order to be able to provide mifepristone to miscarriage patients, because, when we created the second, miscarriage-specific form, I also had to ensure that it was translated and uploaded to the system.

31. Between the patient agreement form and the need to figure out with each patient how they will receive their medication given that we cannot simply issue the prescription to their preferred local pharmacy, a significant chunk of each appointment is dedicated to working through non-clinical, administrative tasks that do not add anything to the safety or benefits for patients, and that would not exist but for the REMS. In order to account for the added time necessary to comply with these REMS-specific administrative requirements, appointments involving a mifepristone prescription are *double* the length of a standard primary care appointment in our system, even though the care itself is not more complicated. This creates intense pressure on our health care system and limits the number of patients we can serve because each mifepristone patient requires twice as much time as patients seeking other kinds of routine care, solely because of the REMS. As a result,

our health system has had to limit the number of mifepristone appointments that can be scheduled each day to avoid creating an overly burdensome ripple effect on our other patients. That means there are fewer appointments available for patients seeking abortion and miscarriage care, creating scheduling delays that burden patients.

32. I believe that providing mifepristone for abortion and miscarriage care is an essential health service for my patients. In order to ensure I can continue providing this care, I am forced to navigate all of the added administrative burdens detailed above and to experience concrete, negative impacts on my interactions with patients, solely as a result of the REMS. Because these administrative burdens decrease the number of mifepristone prescribers and available appointments, the REMS also burdens my patients by delaying and complicating their access to this essential care. I understand that if I failed to comply with the mifepristone REMS, I could lose my status as a REMS-certified prescriber and thus be prevented from continuing to provide this care at all. It would be devastating to me, personally and professionally, to be prevented from providing my patients with this essential health care that I am trained to provide and that I have invested considerable time and energy in ensuring remains accessible to my and my colleagues' patients.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 30, 2025, in Malden, MA.

Honor MacNaughton, M.D.