# Exhibit I

Declaration of Jared Garrison-Jakel, M.D.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GRAHAM T. CHELIUS, M.D., *et al.*,

Plaintiffs,

vs.

XAVIER BECERRA, J.D., *in his official capacity as* SECRETARY, U.S. D.H.H.S., *et al.*,

Defendants.

CIV. NO. 1:17-cv-00493-JAO-RT

[CIVIL RIGHTS ACTION]

**DECLARATION OF JARED GARRISON-JAKEL, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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

Jared Garrison-Jakel, 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 and addiction medicine doctor in Guerneville, California, and a member of the California Academy of Family Physicians ("CAFP"). I understand that CAFP is a plaintiff in this litigation challenging the U.S. Food and Drug Administration's imposition of a Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex, and write in support of that litigation. The Mifeprex REMS causes injury to me and my patients. But for the REMS, I could and would provide Mifeprex to my patients.

3. I received my undergraduate degree from Pomona College in 2005, a Master's in Public Health from the University of California Berkeley in 2009, and my medical degree from the University of California Irvine School of Medicine in 2010. I subsequently completed an internship and residency in family medicine at Sutter Medical Center of Santa Rosa in California.

4. I am trained in both medication and surgical abortion and provided those services while in my residency at Sutter Medical Center of Santa Rosa.

5. Since 2013, I have practiced at Russian River Health Center in Guerneville, California ("Russian River"). I submit this declaration in my individual capacity and— besides CAFP—not on behalf of any institution with

which I am associated, including the health center.

6. Russian River is a federally qualified health center ("FQHC"). FQHCs offer primary health care services to low-income populations in medically underserved areas. Guerneville, where Russian River is located, is an economically depressed city with virtually no other health care facilities. Our health center is located about 30 minutes away from any other doctor's office.

7. Many of my patients have little access to transportation outside of the community where Russian River is located. This lack of transportation makes it difficult to access even urgent health care services. For example, I treated one patient who had a terrible cut in her hand—the laceration reached the tendon. I told this patient that she needed to see a hand surgeon due to the severity of the laceration, but the patient explained that such travel would be impossible for her. She told me, "Doc, either you fix it now or no one's fixing it."

8. As explained below, because of the REMS, medication abortion is not available in the health center where I work. As a result, I have had to turn away patients who need abortion care. The closest clinic that offers abortion services is a one-hour round-trip from our health center. Traveling such a distance is a significant impediment for the populations I serve, who generally struggle to afford and arrange for things like transportation and child care. And, making this journey may very well also require my patients to miss work, and therefore lose wages—

that is, if they can get time off work at all; at the low-wage jobs where my patients typically work, there is often no paid leave. The reality is that it can be difficult or impossible for my patients to overcome all of these barriers.

9. I am medically qualified to provide Mifeprex to my patients who request a medication abortion. The only reason why I am not able to do so is because of the requirement that I stock and dispense Mifeprex on site.

10. I am aware that at least one of my colleagues, who holds a position of authority at our institution, is opposed to abortion and would not consent to Mifeprex being stocked and dispensed in our health center. (For the same reason, we cannot provide surgical abortion services here.) However, I am also aware that this colleague would not interfere with my writing a prescription for Mifeprex in the privacy of my office for a patient to fill at a pharmacy—and there are two pharmacies very close to the health center where I work; one is only a block away. But for the REMS, I could and would provide medication abortion care to my patients (and would do so in compliance with all federal segregation guidelines for FQHCs that provide abortion services).

11. Because of the REMS, I have been unable to treat my patients in accordance with my medical judgment. Multiple patients have come to me with unwanted pregnancies at less than ten weeks, who requested—and were eligible for—medication abortions. However, because of the REMS, I had to deny them

this care—delaying their abortion, to the extent that they could obtain the abortion at all. Indeed, I am always reluctant to refer a patient to another health care facility, whether for abortion or any other medical service; given the financial challenges that my patients almost uniformly face, which are often compounded by other barriers and stressors (such as mental health disorders, substance use disorders, or homelessness), such a referral usually means that they will be significantly delayed in accessing medical care, or not obtain it at all.

12. There are three central concerns with delaying abortion care. First, if a patient is delayed past ten weeks of pregnancy, she typically will no longer be able to obtain a medication abortion and will instead need to have an in-office clinical procedure, which may be an inferior option given her circumstances. Second, while abortion is extremely safe, and far safer than remaining pregnant and carrying to term, the risk of complications increases as the pregnancy progresses. I can recall at least one patient who came to me at a point in pregnancy when she was still eligible for a medication abortion but, because I could not write her a prescription for Mifeprex, ended up having a more invasive and time-consuming second-trimester dilation and evacuation abortion procedure over a month later. Third, delaying a patient's abortion means that the patient stays pregnant longer, and thus must incur the serious risks and discomforts associated with pregnancy for longer.

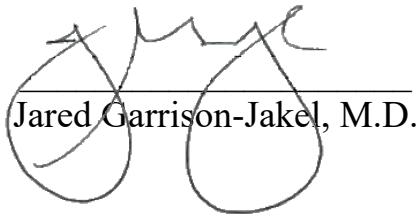
13. Moreover, because of the REMS, at least one of my patients was prevented from having a desired abortion at all. This patient had a history of sexual trauma and struggled with substance use disorders. She was extremely distressed to learn that she was pregnant, and presented to me seeking a medication abortion. To add to the complications of her situation, she did not feel that she could disclose her desire for an abortion to her partner. I initially referred her to the nearest clinic providing first-trimester abortion services, but she was unable to make the journey to that clinic for her appointment. I saw her again in her second trimester, when she reiterated that she did not want to carry the pregnancy to term. At that point, I referred her to the nearest provider of second-trimester abortions, which is approximately three hours round-trip from Guerneville. I know that the care team at that facility worked diligently to support her in accessing abortion care, including trying to arrange transportation for her. Nevertheless, because of the many challenges in her life, she missed multiple appointments there as well. This patient ultimately ended up carrying the pregnancy to term. I have grave concerns about how this unintended pregnancy has affected her life; when I'd seen her, she communicated that the pregnancy had worsened her suffering around her sexual trauma history and medication dependency. Moreover, this patient did not obtain adequate prenatal care during her first or second trimesters because this was not a pregnancy she had intended to carry to term. Needless to say, denying this patient

the care she so desperately wanted and needed was not in accordance with my best medical judgment.

14. In short, the Mifeprex REMS has prevented me from fulfilling my personal, professional, and ethical obligations to provide my patients with the medical care they need, which I am qualified to and would otherwise provide.

15. I am aware that the FDA just announced that, for the remainder of the COVID-19 Public Health Emergency, it is suspending enforcement of the requirement that patients obtain Mifeprex in person at a health center and instead allowing patients to obtain their medication by mail or from a mail-order pharmacy acting under the supervision of a certified REMS prescriber. Although this is an important step in the right direction, even under this short-term policy, the FDA continues to treat Mifeprex differently than any other drug I prescribe. I am working to understand what this "supervision" requirement entails (such as with regard to billing) and determine whether or not I will be able to take advantage of this temporary policy shift. Regardless, a permanent fix is essential to ensure that my patients can access medication abortion care without facing needless, and sometimes insurmountable, hurdles.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on April 14th, 2021, in Guerneville, California.



Jared Garrison-Jakel, M.D.