Exhibit E

Declaration of Graham T. Chelius, 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 GRAHAM T. CHELIUS, 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

Graham T. Chelius, M.D., declares and states as follows:

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

2. I am a plaintiff in the above-captioned litigation, which challenges the U.S. Food and Drug Administration's Risk Evaluation and Mitigation Strategy ("REMS") for Mifeprex. I provide this declaration in support of that litigation. I do so in my individual capacity, and not on behalf of any entity with which I am associated or where I practice, including my employer, Hawaii Health Systems Corporation.

3. I am a board-certified Family Medicine physician based on the island of Kaua'i in Hawai'i. I practice medicine at Kauai Veterans Memorial Hospital ("Kauai Veterans") and its associated clinics, West Kauai Clinics. Kauai Veterans is located on the western side of the island in the town of Waimea, Kaua'i. Kauai Veterans currently employs about 275 people.

4. I am currently the Chief of Staff at Kauai Veterans, a position I have held since February 2018. Immediately before that, and after serving for several years as a board member, I served as the Chief Medical Officer for the Hawaii Health Systems Corporation's Kaua'i Region (which, in addition to Kauai Veterans, included Samuel Mahelona Memorial Hospital, on the eastern side of the

island in Kapa‘a, Kaua‘i), but resigned from that position in December 2017 in favor of this new opportunity as Chief of Staff. In my role as Chief Medical Officer, I was primarily responsible for managing the relationship between Hawaii Health Systems Corporation and the physicians who serve the Kaua‘i region, including participating in contract negotiations, overseeing physician staffing assignments, and responding to any complaints brought against physicians by both patients and staff. As Chief of Staff, I have very similar responsibilities, but rather than acting as a representative of the administration I am an elected representative of the physicians who form the medical staff. Both my current and former positions require that I be involved in resolving most conflicts that arise among the small clinical team at Kauai Veterans.

5. I received my medical degree from the University of Wisconsin in 2001, and completed my residency in Family Medicine at North Colorado Medical Center. Since January 2009, I have been practicing medicine in Hawai‘i at Kauai Veterans.

6. In my current role as Chief of Staff, I continue to treat patients. Within my specialty of Family Medicine, I focus in particular on women’s health, including obstetrics, and on chemical dependency treatment.

7. During the twelve years that I have been practicing medicine in Hawai‘i, I would estimate that I have cared for more than 2,750 pregnant patients

and delivered over 1,100 babies on the island of Kaua‘i. While many of my patients have much-wanted pregnancies, a substantial percentage choose to end their pregnancies, and come to me seeking abortion care. Most of these patients are medically eligible for the FDA-approved medication abortion regimen: Mifeprex followed by the drug misoprostol.

8. However, I am unable to prescribe Mifeprex to patients who need this medication because, as detailed below, complying with the requirements in the REMS that I procure, stock, and dispense Mifeprex at my health care facility—rather than issuing a prescription, from the privacy of my office, for my patient to fill at a pharmacy—would damage my professional standing locally, disrupt the workplace dynamics I am responsible for maintaining, interfere with my ability to continue to serve the many patients I now serve, and jeopardize my patients' confidentiality. The Mifeprex REMS deters clinicians and harms patients by imposing unique, unnecessary, and onerous requirements on their care. Put plainly, the REMS impedes my and other clinicians' ability to safely and appropriately care for our abortion and miscarriage patients as we would patients seeking any other service.

9. The distribution restriction substantially interferes with my ability to practice medicine in accordance with my professional judgment. Because of the Mifeprex REMS, I am unable to provide medication abortions to my patients, even

in situations when my best medical judgment would strongly counsel in favor of providing this care.

10. There is only a narrow window in which a patient can take the Mifeprex-misoprostol regimen for early pregnancy termination: this method has been approved by FDA only for the first ten weeks of pregnancy, and that is the period during which clinicians generally prescribe it. But patients cannot know they are pregnant until four weeks, and many patients do not realize they are pregnant until their sixth to eighth week. By the time a patient sees me, they typically have only a few weeks—indeed, often only a few days—in which to take the medications. If they cannot access Mifeprex within the window of availability, the only option is a surgical abortion. Nevertheless, because of the REMS, I am unable to provide medication abortion care in these time-sensitive situations.

11. There are no abortion providers on Kaua‘i, a federally designated "medically underserved area." The closest provider of abortion services is on O‘ahu, which can be reached only by airplane. I have seen the anxiety and confusion in my patients' eyes when I tell them that they have to fly to O‘ahu to obtain an abortion. I have heard them describe their frustration, anger, and heartbreak. For some patients—many of whom are already experiencing significant anxiety as a result of the unwanted pregnancy, and some of whom are also struggling with the challenges and trauma of poverty, drug addiction,

joblessness, and/or domestic violence—this news is simply devastating.

12. Traveling to O'ahu for a surgical abortion costs my patients money and time, and causes them stress. Many are forced to make significant personal and financial sacrifices in order to get the health care they need. They must find the money to pay, or if possible make arrangements for insurance to pay, for the costs of transportation to and from the airports on both islands, and for the flights themselves. They must arrange to take time off from work or school, and arrange for child care if they have children, which most do. If a loved one is accompanying them to O'ahu for support, that person must bear these costs as well. This travel and related logistics also impose significant psychological and emotional strain on many of my patients, and in my experience can be especially hard on young women, women struggling with substance abuse, women for whom English is not their first language, and women who are homeless.

13. Raising the money and making arrangements to travel is often time-consuming. Given the circumstances of my patients' lives, it is not uncommon for it to take several weeks, a month, or longer. Indeed, even for those of my patients fortunate enough to have insurance coverage for the abortion procedure and the travel to obtain it (though, of course, still not for child care, missed work, or food away from home), it typically takes one to two weeks just for the paperwork to be approved. As previously noted, delays often mean that patients are no longer

eligible for medication abortion at all, and instead must have a surgical procedure. Moreover, while abortion is very safe, the risks increase as pregnancy advances. And, on top of that, patients whose abortions are delayed also face health risks associated with continuing a pregnancy for additional days, weeks, or months. For such patients, delaying their abortion means they are sicker, longer.

14. I recall one patient whose experience powerfully illustrates many of the harms caused and burdens created by the REMS. She is a woman whom I had been treating for substance use disorder and who had previously seen us for obstetrical care for her first child. She came to my office seeking an abortion prior to 10 weeks of pregnancy. After evaluating her, I concurred that a medication abortion was an appropriate treatment, that she could utilize the Mifeprex-misoprostol regimen, and that she should do so without delay. I wanted to—and would have—provided her with the medication abortion she desired if I could have written a prescription for Mifeprex for her to fill at a pharmacy. But, because of the REMS, I could not provide that care to my patient. Instead, she was forced to travel to O‘ahu.

15. Because of the complications in this woman’s life, by the time she was finally able to make the journey to O‘ahu, more than six weeks had passed. At that point, she had to have a two-day dilation and evacuation (“D&E”) abortion instead of the medication abortion she had wanted. Not only is D&E a significantly

more complex and invasive procedure, but it also required her to bear the costs of staying on O'ahu—in a hotel, away from her home and her family—overnight. This was utterly unaffordable for her. Indeed, I understand that she called her sister on the day of her first appointment to tell her that she was on O'ahu for an abortion and had only $20 in her pocket. Her sister jumped on the plane to help my patient find lodging and provide her with emotional support during the procedure—which of course meant that my patient's sister also had to bear the costs of a round-trip flight, hotel, and food during her stay. Fortunately, her sister managed to drop everything and come to her aid, but otherwise I don't know how she would have managed to get to and from her appointments or where she would have stayed overnight.

16. I still feel frustrated and upset that my patient and her family had to bear the emotional trauma, financial burdens, and medical risks of this experience. And she is far from the only patient I have had who was eligible for medication abortion at the time I saw her, but ultimately had to not only fly to O'ahu to get the care they needed, but by the time they did so were too late for a medication abortion and had to have a procedure instead. Again, none of this would be necessary if I could have simply written this patient, and other patients like her, a prescription for Mifeprex when she was in my office early in her pregnancy.

17. While that patient *was* ultimately able to get an abortion—not all of my patients are. In some cases, the travel burdens created by the Mifeprex REMS are simply untenable, and my patients end up carrying pregnancies to term and having children against their will. For instance, one patient who struggles with chemical dependency never was able to get to O‘ahu, despite her expressed desire for an abortion and despite extensive assistance with the travel arrangements. As a result, she was forced to carry the pregnancy to term (and her child was exposed to drugs throughout the entire pregnancy). I have continued to care for such patients through the course of their pregnancies and beyond, and have seen firsthand the emotional, physical, and financial burdens that an unwanted pregnancy can cause.

18. Sadly, the situation is even worse for women who live on Ni‘ihau, which is a sparsely populated island just west of Kaua‘i. There are no paved roads, and no cell coverage—let alone health care—on Ni‘ihau. Because of the lack of access to reproductive health care on-island, women on Ni‘ihau have to schedule transportation by boat to Kaua‘i just to see a doctor. My hospital delivers virtually all the babies for pregnant women on Ni‘ihau. If a woman on Ni‘ihau wants to terminate her pregnancy, the obstacles are even greater for her than for a woman on Kaua‘i. But if the REMS did not exist, she could simply go to Kaua‘i to obtain Mifeprex the same day, instead of going to Kaua‘i only to then get referred to an O‘ahu-based abortion provider and facing all the associated obstacles. I mention

Ni‘ihau just to show how burdens can aggregate and compound into an entirely insurmountable barrier to accessing safe abortion care.

19. I became a doctor to make my patients' lives easier, less painful, and more fulfilling. But, because of the REMS, I must watch them suffer medical, emotional, and financial burdens when I cannot provide them with the abortion care that they desire. In addition, as a physician, I am concerned about continuity of care—yet the restrictions imposed by the Mifeprex REMS mean that I must needlessly hand off my patients to someone else for care, breaking that continuity for absolutely no medical reason. While I am confident that the providers to whom I refer my patients in O‘ahu provide high-quality care, it pains me to have to turn my patients away and send them off island to get care they need and that I am perfectly competent to provide. The Mifeprex REMS thus prevents me from providing uninterrupted, comprehensive primary health care to my patients, as I strive to do whenever possible. It violates my fundamental beliefs as a health care provider to have to deny a patient's request for time-sensitive, medically indicated care only because of medically unjustified restrictions like the Mifeprex REMS.

20. For the past several years, some of my patients have been able to avoid most of these burdens by participating in the Telemedicine Abortion Study ("TelAbortion"), which is run through the University of Hawai‘i. This study—which I understand operates as a temporary waiver of the REMS—allows certain

qualifying patients to receive Mifeprex by overnight mail from the study's principal investigators on O'ahu without having to fly to that island for care. Recognizing how difficult the journey to O'ahu is for many of my patients, wherever possible, I have assisted them in participating in the study. I believe this model of care delivery – mailing Mifeprex following a telemedicine visit – is safe and effective and a valuable option for my patients.

21. But the TelAbortion study's process carries its own burdens and complexities, and therefore excludes the most vulnerable, highest-risk patients. The cost of participation in TelAbortion presents the first hurdle. While the State of Hawai'i generally covers the cost of abortion services through its Medicaid program, it does not cover the cost of Mifeprex obtained through the TelAbortion study. Thus, Medicaid enrollees must pay out-of-pocket for Mifeprex provided through the study. This effectively excludes or deters many lower-income patients from participating.

22. The logistics are another hurdle. In most cases, the study protocols require that a participating patient first have a blood test and ultrasound performed, and then mail, fax, or email the results to a physician at the University of Hawai'i. Then, that physician must connect with the patient by secure videoconference at a set appointment time. Some of my patients—including some who are homeless, poor, or live in extremely remote parts of Kaua'i—do not have reliable internet or

cell phone service, access to technology with secure videoconferencing capability, or the ability to use this technology in a private space where they can speak confidentially. In such cases, I often have to step in to help them. On several occasions, I have stayed late at my office to let a patient use my computer to participate in the study, but this is not always possible: my patients' schedule, my schedule, and the schedule of the physicians on O'ahu do not always align, and certainly do not always align before the patient's window for a medication abortion closes. Helping my patients participate in the TelAbortion study has taken, and continues to take, many hours of my time—and even so, some of my patients still cannot successfully use it.

23. A third hurdle is that participating patients must have a physical address to which a package can be securely and confidentially mailed. But my patients who are homeless do not have such a safe address. So the study also cannot provide relief to such patients.

24. For all patients, even if they can gather the resources to participate in TelAbortion, the processes and requirements of participating in a research study delay care. I have on numerous occasions seen patients who were still within the window for a medication abortion, but did not have enough time to access it through the study.

25. Critically, I understand that the TelAbortion study is only temporary. When it ends, it will no longer exist as an option for me and my patients.

26. The harms and burdens I have described that both my patients and I are experiencing flow directly from my inability to issue a prescription for Mifeprex to be filled at a pharmacy or by mail order as I can do with countless other equally or less safe drugs. Most of these harms and burdens would be entirely eliminated, or substantially reduced, if the REMS were eliminated.

27. In addition, the REMS imposes a broader set of harms by deterring and blocking qualified clinicians from becoming medication abortion providers through its unique and unnecessary barriers. First, in order to comply with the requirement in the REMS that I procure, stock, and dispense Mifeprex at my medical facility, I would have to risk serious damage to my professional standing in my workplace and to my respected role in the local community. Abortion is an issue about which people hold very strong views, and some of my colleagues and staff members strongly oppose it. In my tight-knit workplace, attempting to establish a policy for procuring, stocking, and dispensing Mifeprex at our facility would create internal conflict, undermining the team cohesion that I am responsible for developing and maintaining as Chief of Staff. It would also jeopardize my ability to continue in that elected position, threaten initiatives I am undertaking to improve care within our hospital system, and reduce the time I have

to treat patients. I cannot afford these personal and professional risks.

28. To be clear, many of my colleagues and staff already know that I provide abortion referrals. I know that some staff oppose even this; some have directly expressed such views to me. But if I were to comply with the Mifeprex REMS, I would be doing more than just supporting access to abortion in my *individual* professional capacity—I would also have to involve, and win the approval of, multiple colleagues and staff members in the process of procuring, stocking, dispensing, and billing for Mifeprex within our health care facility. Asking or demanding that my colleagues who have deeply held views against abortion participate or assist in providing abortions would cause significant conflict among my staff—conflict that, as Chief of Staff, I would also be required to manage, if possible. The negative consequences for my professional standing and for carefully nurtured workplace dynamics, which benefit all of our patients, deter me from attempting to comply with the Mifeprex REMS.

29. Relatedly, I also have had serious personal safety concerns about the requirement in the REMS that I register with the drug manufacturer and drug distribution company as an abortion provider. I understand that they must keep confidential the list of clinicians registered to prescribe Mifeprex. But particularly in light of the many recent health care hacking incidents, I have been concerned about being inadvertently or maliciously exposed as an abortion provider, and the

resulting likelihood of public backlash to me and my family.

30. Of course, my name is now public in the context of this litigation, and my experience since filing this lawsuit has validated my earlier concerns. Since the lawsuit was filed, I have received numerous phone calls and letters from strangers relating to this litigation. Many of those communications were positive and supportive. But a few were negative and concerning. Based on security consultations, I now carefully examine envelopes for toxic material, and have tried to remember to only open packages that I have been expecting. We also installed a security system at our house. In a country where abortion clinic shootings are commonplace and abortion providers have been assassinated, I have feared risking my and my family's safety by following through with what the Mifeprex REMS requires.

31. I ultimately made the difficult choice to publicize my desire to provide abortion care through this lawsuit, because I believe this case has the potential to expand access to medication abortion for patients all across the country. My family and I felt that this goal was worth the risk to our safety and privacy. But we did not make that choice lightly, and I expect that I am not the only physician who has found the REMS requirement that I add my name to a list of all medication abortion providers in the country a serious deterrent to providing this care.

32. I am also concerned that compliance with the Mifeprex REMS would jeopardize my patients' privacy. By requiring that my facility be responsible for the purchasing, stocking, dispensing, and billing of Mifeprex—discrete responsibilities held by discrete members of our staff—the REMS injects many more people into the abortion care process. This raises real confidentiality concerns in the small town community in which I practice. Everybody knows you and you know everybody in Waimea, a town of fewer than 2,000 people on an island of just over 65,000. In fact, it is not uncommon for members of my staff to bump into my patients at the grocery store, gym, or on the street. For myself, going to either of the two grocery stores in Waimea is a social event due to the fact that I will certainly know someone either working or shopping at the store.

33. Additionally, many members of the community have a family member, friend, or neighbor employed at Kauai Veterans, and, as a result, members of our community are sometimes nervous about seeking intimate medical care from us out of fear for their confidentiality. Certain elements of a person's medical history (history of abortion, sexually transmitted diseases such as HIV or gonorrhea, a history of rape, struggles with substance use disorder) are closely guarded by patients due to real or perceived stigma from those in the general population and medical providers.

34. For instance, I have a patient who, while pregnant, asked that a specific doctor not be involved in her care because she was afraid that the provider might divulge her medical history to family members of the doctor whom the patient also knew. Fortunately, I was able to sufficiently reassure this patient that I trust this physician to respect her confidentiality, which resulted in this patient continuing to receive care from us. But there is no doubt that, in our community, patients struggle with the decision of whether to get adequate medical care due to concerns about their confidentiality. And, indeed, it would be entirely reasonable for a patient to fear for the privacy of her abortion decision if she happens to know, for instance, some of the numerous people who may be involved with the billing, ordering, recording, and physical dispensing of medication at our facility (which, again, is a perfectly plausible scenario in our small town).

35. By contrast, if the Mifeprex REMS did not exist, I would be able to write a prescription for Mifeprex for my patient without needing to let anyone else know about the prescription except, at most, the patient's nurse, a medical records clerk, and the patient's trusted pharmacist (or a pharmacy on the other side of the island, or a mail-order pharmacy, if that is the patient's preference). The risk to my patients' confidentiality is thus substantially higher under the Mifeprex REMS.

36. The Mifeprex REMS also presents significant logistical hurdles. In order to stock and dispense Mifeprex onsite, I would need to first get a policy created for storing and dispensing the drug in the clinic, and then secure approval from the Pharmacy and Therapeutics committee at Kauai Veterans. I would also need to complete and submit all of the paperwork associated with becoming a certified prescriber under the Mifeprex REMS and setting up an account with the drug distribution company—a process that would take even more time and effort because the purchasing agreement would need to go through our contracting office, which has to follow burdensome state contracting guidelines and rules.

37. Of course, I am not now a certified prescriber (though I could easily satisfy the stated criteria for prescribing clinicians), because the certification requires me to provide a billing address and a shipping address where the Mifeprex can be sent to and then dispensed from—which, for the reasons I have stated, I am unable to do. And regardless of any certification requirement, I now provide and will always provide only medical care within the scope of practice for which I'm qualified. That is a well-recognized, basic standard of the medical profession.

38. As I have already noted, this approval process would be extremely challenging in the tense political climate surrounding abortion at my hospital, and it would almost certainly be subject to interference by colleagues and others who vehemently oppose abortion and therefore would object to a decision to stock

Mifeprex in our hospital system. As Chief of Staff tasked with maintaining good working relationships in my hospital, I find these risks unacceptable. They would not only interfere with my supervisory role, and the long-term positive changes for overall patient care that I am attempting to accomplish in that role, but also take valuable time away from my own practice.

39. In addition, I understand that the Mifeprex REMS would also require me to provide my patients with, and discuss and sign, a "Patient Agreement Form" describing the proper usage of, and risks associated with, Mifeprex as of March 2016. This special form requirement is unnecessary and singles out abortion in a manner that other medications, even much less safe medications, are not.

40. Informed consent counseling is a bedrock of medical care, taught as a core skill in medical school and reinforced by the American Medical Association's Code of Medical Ethics. I do not need any special requirement or form to ensure that I provide every patient with informed consent counseling, including discussion of proper usage and risks and what to do in the event that they need follow-up or emergency care. In fact, much less safe medications that I use in my chemical dependency practice, such as Sublocade®, which are controlled substances and are very high risk for patients, do not require any such "patient agreement form." Nor do the many other medications that I prescribe, that patients fill at a pharmacy, and that they take at home.

41. The bottom line is that, because of the REMS, I have been unable to provide my patients with essential health care that they need and that I am fully capable of providing. The REMS delays care, and forces patients to jump through hoops that are unnecessary, stigmatizing, and confusing. For some patients, the Mifeprex REMS makes abortion beyond reach. I greatly hope that Plaintiffs' motion for summary judgment once and for all lifts the unjustified REMS requirements from this safe, important drug, so that many other clinicians and I can provide it via prescription to our patients who need it.

42. I learned on April 13, 2021, that FDA has suspended the in-person dispensing requirement and authorized use of a mail-order pharmacy for providing patients with Mifeprex during the COVID-19 Public Health Emergency. I am exploring whether it will be possible for me to prescribe through a mail-order pharmacy under the special "supervision" requirement still imposed by FDA, and what kinds of contracts and/or billing practices may be necessary under FDA's non-enforcement guidance (which, of course, continues to treat Mifeprex differently than virtually all other drugs). I understand further that, even if I am able to take advantage of this in the short-term, this temporary allowance expires when the public health emergency ends. In short, there is an urgent need for

permanent relief through this litigation.

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

Executed on 4/14, 2021

Graham T. Chelius, M.D.