Exhibit K

Declaration of Charisse M. Loder, M.D., M.Sc.

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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 CHARISSE M. LODER, M.D., M.Sc., 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

Charisse M. Loder, M.D., M.Sc., 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 an obstetrician-gynecologist trained in abortion care and a member of the Society of Family Planning ("SFP"). I am a Clinical Assistant Professor of Obstetrics and Gynecology at the University of Michigan Medical School. My practice is located at the Women's Clinic at Von Voigtlander Women's Hospital in Ann Arbor, Michigan. I have also practiced as an obstetrician-gynecologist at Planned Parenthood in Ann Arbor.

3. I received my undergraduate degree from Cornell University in 2003, and my medical degree from Pennsylvania State University in 2011. I did my residency in Obstetrics and Gynecology at the University of Rochester, where I served as Chief Resident, and then completed a fellowship in Family Planning and received a Master of Science degree in Health and Health Care Research at the University of Michigan.

4. In my current practice, I provide a range of obstetrics and gynecology care, and specialize in miscarriage management, complex contraception and sterilization, and abortion care.

5. I submit this declaration in support of Plaintiffs' Motion for Summary Judgment. I do so only in my individual capacity and as a member of SFP, not on behalf of any institution with which I am affiliated.

6. Mifeprex is an important drug for the provision of abortion and miscarriage care. I advocated to make this medication available within the Women's Clinic in order to offer our patients the best possible care at our own institution, without having to refer them elsewhere.

7. While I am currently able to prescribe mifepristone to my patients, attempting to bring the Women's Clinic at the University of Michigan into compliance with the mifepristone (brand name Mifeprex®) Risk Evaluation and Mitigation Strategy ("REMS") was an extremely complicated process that took five years (and a substantial investment of time, resources, and professional capital by me and other colleagues). During these five years, my colleagues and I were forced to refer patients who needed medication abortion care to other institutions. When patients are referred elsewhere for abortion care, many experience delays or are even prevented from accessing this time-sensitive care. We were also unable to offer Mifeprex for miscarriage and second-trimester abortion care, even though Mifeprex enhances the efficacy of those treatments. There is absolutely no medical reason for FDA to impose these barriers to patients obtaining this safe and effective medication.

8. My involvement in the process of trying to make Mifeprex available at the University of Michigan began when I arrived at the University six years ago, in 2015. But conversations surrounding Mifeprex at the University of Michigan began seven years ago, in 2014. As of 2014, the only patients who could access mifepristone through the University of Michigan were those seeking treatment for Cushing's syndrome: University clinicians were able to prescribe mifepristone under the brand name Korlym, and the patients filled those prescriptions through a mail-order pharmacy. However, patients in need of mifepristone under the brand name Mifeprex, for reproductive health care, could not access the medication through any University provider.

9. As a first step, I had to get approval to add Mifeprex to the University's drug formulary from the University's Pharmacy and Therapeutics Committee ("the Committee"), which is composed of pharmacists and physicians from a variety of clinical specialties. As discussed above, I was not the first physician to attempt to do so; in 2014, other physicians had participated in multiple meetings with the Committee during which they advocated for adding Mifeprex to the formulary. Ultimately, these conversations stalled because those physicians were unable to invest the immense amounts of time required to move this process forward.

10. Between 2015 and 2016, I participated in approximately four Committee meetings relating to Mifeprex. To assist in the Committee's evaluation of Mifeprex, the Committee asked me and my colleagues to provide literature on Mifeprex's safety and indications for use, which we did. These meetings were each about an hour long, and I individually spent at least 20 additional hours researching and preparing presentations about Mifeprex's safety and efficacy, as well as writing guidelines for its use.

11. Finally, in 2016, the Committee approved Mifeprex for the University formulary. None of this would have been necessary—the Committee would not have been involved at all—if we could simply issue our patients a prescription to fill at a pharmacy instead of having to stock and dispense Mifeprex onsite.

12. But getting Mifeprex on our hospital's formulary still did not mean that University of Michigan clinicians could start prescribing Mifeprex to patients. Placing a drug "on formulary" means that the drug is approved for safe use by the hospital. But, in order to make Mifeprex available "in clinic" for patients, the University of Michigan first had to order and stock this medication. And it took me *three* more years of advocacy to achieve this second step.

13. In 2018, a pharmacist in the gynecology department suggested that I form a task force to develop protocols for Mifeprex use in-clinic because the process had stalled out. I believe that my colleague suggested that I create such a

task force in order to alleviate concerns throughout the University about how to comply with the Mifeprex REMS and to accelerate the process of actually stocking and dispensing Mifeprex. I have never heard of such a task force being formed for the introduction of other drugs or devices into University practice. For example, we frequently integrate new intrauterine contraceptive devices (IUDs) into our practice, and have never had to develop protocols about how to prescribe them. But I believed that without a physician champion and a committee specifically focused on this issue, Mifeprex would never be made available in our clinic.

14. Accordingly, I organized and created a multidisciplinary task force to develop various protocols for ordering, stocking, prescribing, and dispensing Mifeprex at the Women's Clinic. This task force is made up of gynecology and family medicine physicians, nurses, clinic managers, pharmacists, and electronic medical record (EMR) specialists. The task force was charged with finalizing protocols to address how Mifeprex is ordered, administered, and stored, as well as addressing safety and reimbursement concerns surrounding the storage and dispensing of Mifeprex at our clinic. In a large health care institution like ours, where every organizational decision requires approval from multiple stakeholders, none of these decisions were simple.

15. I first convened this task force in October 2018, and the task force met every six weeks until Mifeprex was available in clinic. The task force met for

about an hour each time—and that is only the tip of the iceberg. Since October 2018, I have spent at least 80 hours of my time preparing for and/or completing follow-up work relating to task force meetings (such as preparing education materials for clinical staff), as well as participating in numerous *non*-task force meetings with stakeholders to discuss protocols to ensure compliance with the REMS as we integrate Mifeprex into clinical practice. For instance, I met with EMR representatives to propose edits to our electronic medical records in order to track Mifeprex administration in patient records. I attended separate meetings with the Women's Clinic manager, insurance verification team, and billing team related to the University's financial and reimbursement concerns around the dispensing of Mifeprex onsite. And I consulted on strategies to communicate guidelines for Mifeprex administration with staff, including developing REMS-compliant protocols for nurses who may want to "opt-out" of any involvement in the dispensing of Mifeprex. If not for the REMS, I would not have had to involve all of these other clinicians and stakeholders within the University and invest so many hours of my time and professional resources into developing system-wide protocols to integrate Mifeprex into hospital practice. I would simply have written my patients a prescription.

16. The Mifeprex REMS also requires that clinicians register with the drug's distributor in order to become a certified prescriber. As an initial matter, this

requirement is medically unnecessary: Mifeprex is a safe and straightforward medication; the clinical competencies necessary to safely prescribe it are very common; and in general, and as a legal and ethical matter, my colleagues and I do not prescribe any treatment unless it is within our competency to do so. But the prescriber certification requirement also posed numerous obstacles to the provision of Mifeprex at the University of Michigan.

17. First, task force members raised concerns that the University would face legal liability if clinicians who were not acting pursuant to a REMS prescriber agreement prescribed this drug. We spent many meetings discussing protocols to prevent violations of the REMS.

18. Second, members of the task force were concerned about how to store Mifeprex to ensure that only certified prescribers can access it. As a result, the task force spent numerous meetings discussing how to properly secure the Mifeprex stock with locks, and how to determine which clinicians have access to the locked area.

19. Third, because of the prescriber certification requirement, the University of Michigan must update its EMR system and pharmacy database each time a physician registers as a certified provider. These updates are costly and require staff time. These systems must be updated constantly to alleviate a concern that someone will prescribe Mifeprex in violation of the REMS.

20. These organizational concerns related to prescriber certification stem not from any mistrust of physicians, but from concerns about compliance with the REMS.

21. I would never have been able to provide mifepristone to my patients if it were not for the tenacious advocacy and time commitment my colleagues and I invested into this effort. As it was, for more than five years, the REMS prevented me and all of my colleagues from providing that care to our patients and necessitated that we refer patients outside of the University of Michigan system. I know that many of my colleagues have had the same experience, because over the years, I have frequently been contacted by colleagues inquiring whether they were permitted to prescribe Mifeprex to their patients, and I had to tell them that—because of the REMS—the answer was no.

22. And my situation at the University of Michigan is by no means unique. I am regularly contacted by clinicians at other academic medical centers who are seeking advice on how to navigate the REMS in order to stock and dispense Mifeprex at their institutions.

23. Clinicians outside the University of Michigan have also shared with me that they have not integrated Mifeprex into their practice because they fear that completing the REMS prescriber certification requirement would place them on a registry of abortion providers and thus make them targets of anti-abortion

harassment or violence. If clinicians could simply write a prescription for Mifeprex without this obstacle and the other obstacles the REMS imposes, I believe that many more clinicians, in a wider swath of our state, would do so.

24. While abortion care is extremely safe, the risks associated with abortion increase as pregnancy advances. Therefore, delaying a patient's abortion care increases the risks she faces.

25. This delay also pushes patients past the point at which a medication abortion, or any abortion care, is available to them at all. When I worked at Planned Parenthood, I often saw patients who had been referred there by their primary provider because their provider does not provide medication abortion care. But, because of the delay caused by this referral, by the time these patients got to Planned Parenthood, they were frequently too far along in their pregnancies to be eligible for a medication abortion—even though they preferred that option and that option would have been most clinically suitable for them. Because of this delay, these patients were only eligible for aspiration or dilation and evacuation ("D&E") abortion, in-clinic procedures that are significantly more expensive than medication abortion. And some of these patients could not afford these more expensive in-clinic procedures and ultimately were unable to get an abortion at all.

26. My patients at Planned Parenthood frequently told me about the burdens they faced traveling to us for care: paying for transportation, arranging

child care, taking time (often unpaid) off from work, and more. Some of these patients traveled great distances: there are very few abortion providers in Northern Michigan or in Michigan's Upper Peninsula, and many of our patients traveled more than one and a half hours, and up to 10 hours, to obtain abortion care. Many of these patients shared that they could not access abortion care in their local community.

27. In addition to being an important part of safe, effective early abortion care, Mifeprex has other clinical indications, such as in medical management of pregnancy loss (miscarriage) and labor induction abortions during the second trimester. In both of these clinical circumstances, pretreatment with mifepristone reduces the length of the treatment and, as a result, reduces the risk of complications.

28. At the University of Michigan, my colleagues and I care for patients undergoing second-trimester labor induction in cases of pregnancy loss, or where the patient seeks abortion because of a diagnosis of fetal anomalies or due to significant risk to maternal health or life. During this process the patient experiences all the pain and physical consequences of labor. Clinicians often prescribe Mifeprex to patients going through this process, in order to make it easier and faster. When clinicians are unable to add Mifeprex to their treatment regimen,

many patients and their families suffer both emotional and physical tolls from longer labor inductions.

29. After five years of advocacy and hundreds of hours of advocacy by a few dedicated clinicians and stakeholders, Mifeprex finally became available onsite at the University of Michigan in late September 2019. But even now, the work continues: although Mifeprex is available at the Von Voigtlander Women's Hospital (where the Women's Clinic is located), I am still expending hours of effort to work to make Mifeprex available at our six OB/GYN outpatient sites, where clinicians continue to struggle to develop systems to stock and store Mifeprex consistent with the REMS. As a result, patients in those communities must travel longer distances (up to 40 miles round-trip) to get to our hospital for care, rather than being able to obtain a prescription for Mifeprex at their local outpatient site to then fill through a retail or mail-order pharmacy.

30. The Mifeprex REMS made this process extremely burdensome, requiring both an institutional champion (myself) willing to expend more than 80 hours of work and significant professional capital, and more institutional resources than I have seen for any other medication that has ever been made available in clinic at the University of Michigan. The five-year delay in Mifeprex's availability in clinic harmed patients.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 14, 2021.

Charisse M. Loder, M.D., M.Sc.