April 17, 2020

[SUBMITTED ELECTRONICALLY to secretary@hhs.gov and stephen.hahn@fda.hhs.gov]

The Honorable Alex M. Azar II
Secretary of the U.S. Department of Health & Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

The Honorable Stephen Hahn, M.D.
Commissioner of the U.S. Food & Drug Administration
10903 New Hampshire Ave., N.W.
Silver Springs, MD 20992

Re: Maintaining the Safety and Integrity of Mifepristone's Current REMS

Dear Secretary Azar and Commissioner Hahn:

We are writing to strongly urge you to uphold the integrity of the current Risk Evaluation and Mitigation Strategy (REMS) that prohibits the abortion drug mifepristone from being prescribed by abortionists through telehealth. We also applaud your Departments' efforts to increase access to telehealth for *all* Americans without sacrificing their safety or the highest standards of care.

Our network of state-based family policy councils advance policies in the states and federally to protect and strengthen families. During this period of great uncertainty, it is essential for families to be assured that their medical care will continue to be timely, comprehensive, and held to the highest standards. These families must also know they can expect to have broader access to non-critical medical services through telehealth, without their safety being compromised.

The REMS currently in place for Mifeprex and its generic counterpart, mifepristone, continues to be necessary to protect women—a conclusion the FDA itself has reached time and time again. It is vitally important that during a time when a global pandemic is crippling our nation, the U.S. Department of Health & Human Services (HHS) and the U.S. Food & Drug Administration (FDA) remain steadfast in their missions to protect and enhance the well-being of all Americans by keeping people at the center of care. By maintaining the current REMS for mifepristone, both Departments succeed in this mission.[1]

The FDA requires the REMS to monitor the risks, side effects, and safety of certain drugs, like mifepristone, that can and do have serious adverse consequences. The REMS for mifepristone also includes Elements to Assure Safe Use (ETASU) which, by *definition*, must be "commensurate with the specific serious risk listed in the drug labeling [and] cannot be unduly burdensome on patient access to the drug."[2] The FDA

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[1] ORAL TESTIMONY FROM ALEX M. AZAR II ON THE PRESIDENT'S FY 2021 BUDGET BEFORE HOUSE COMMITTEE ON WAYS AND MEANS, (Thursday, February 27, 2020 at 9:30a.m.) https://www.hhs.gov/about/agencies/asl/testimony/2020-02/oral-testimony-before-house-ways-and-means-committee-on-the-presidents-fy-2021-budget.html.

[2] FDA, REMS UPDATE, PDUFA STAKEHOLDER MEETING (March 8, 2013) https://www.fda.gov/media/86417/download.

has been more than clear why the distribution of mifepristone is subjected to the REMS with ETASU stating:

> *As of December 31, 2018, there were reports of 24 deaths of women associated with Mifeprex since the product was approved in September 2000, including two cases of ectopic pregnancy resulting in death; and several cases of severe systemic infection (also called sepsis), including some that were fatal.*[3]

Mifepristone is also contraindicated in many cases, including women who have an IUD, those being currently treated with long-term corticosteroid therapy, and those who take anticoagulants.[4] The bottom line is that the chemical abortion pill mifepristone is known by the FDA to have serious adverse consequences that more than justify its current REMS, which also prohibits mifepristone's prescription through telemedicine, the mail, or through a pharmacy.

Contrary to the *Becerra Letter* submitted to your Departments on March 30, this REMS has not been "unduly burdensome."[5] Indeed, the REMS has been maintained by the FDA for years, and according to the *Becerra Letter*, at least three million women have accessed this drug—a number that is far underrepresented because there are many states that do not report these numbers to the CDC.[6] These facts demonstrate that the FDA itself has not found the REMS to be unduly burdensome, nor have the women accessing the drug. HHS and the FDA continuously highlight their commitment to ensuring patients are treated "like a human being, not a number" when they maintain the integrity of the current REMS for mifepristone, ensuring reasonable legal safeguards to protect the life and safety of each and every woman who may obtain a prescription[7].

In addition to your Departments' commitment to ensuring the highest standards of care for patients, the FDA has publicly committed *all* its available resources to flattening the curve and slowing the spread of COVID-19. The FDA is working night and day to move new treatments, conduct lab research, administer Emergency Use Authorizations, manage Clinical Trial Conduct, and so much more to address the pandemic that hit our nation. It is imperative that the FDA does not waste resources by unnecessarily reevaluating the necessity of REMS restrictions for mifepristone amidst this national crisis.

It is also worth noting that the REMS for mifepristone is regularly reassessed by the FDA to determine its continued efficacy and necessity. The FDA recently *re*evaluated mifepristone's REMS in 2016 and concluded that "certain restrictions continued to be necessary to ensure the safe use of Mifeprex [Brand name for mifeprisone]."[8] The FDA again reevaluated mifepristone in 2019 and made technical changes to its REMS, but

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[3] FDA, *Questions and Answers on Mifeprex*, (April 12, 2019) https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.
[4] *Id.*
[5] State of California Office of the Att'y Gen. Xavier Becerra, MARCH 20, 2020 OFFICIAL LETTER TO SECRETARY ALEX M. AZAR II & COMMISSIONER STEPHEN HAHN, (March 30, 2020) (*regarding waiving REMS for Mifepristone and urging FDA to use enforcement discretion to allows prescribers to use telehealth for Mifepristone*);
[6] CDC, TC Jatlaoui et al., *Abortion Surveillance—United States, 2016; MMWR Surveill. Summ., 2019*; 68 (No. SS-11): 1-41. https://www.cdc.gov/mmwr/volumes/68/ss/ss6811a1.htm.
[7] Azar, *supra* note 1.
[8] Questions and Answers, *supra* note 3.

left substantive changes in place.[9] As we all know, the FDA is *always* reviewing new information regarding REMS of drugs and their adverse events and takes necessary and appropriate action *as needed*. There is no need for the FDA to divert focus away from its COVID-19 responses to second-guess its many prior conclusions for an abortion drug that is considered by many states to *not* rise to the level of *essential* or *emergency* medical care—an imperative distinction while we face a global contagion.

During the COVID-19 crisis, as states have desperately worked to obtain scarce medical resources, many states have made the difficult choice to prohibit *all* non-urgent medical care, usually defined as care that can be safely postponed or delayed for a certain period of time because it does not involve a medical emergency. In some states, abortion services have been deemed non-urgent, alongside other elective procedures like reconstructive surgeries, dental exams, colonoscopies, and more. While the definition of what constitutes an "essential" medical procedure has received a lot of media attention, it is legally within a state's emergency powers to expand or restrict medical health care in times of emergencies. In fact, many states, including but not limited to, Arizona, Alaska, Florida, Louisiana, Maryland, Mississippi, Minnesota, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, and Utah have all defined abortions as *non-essential* medical procedures and they are currently prohibited.[10] States have already made this choice to reserve the use of critical medical resources during this unprecedented pandemic. The federal government must also use its resources to ensure states are equipped to address medical *emergencies* while also protecting the supply chain of critical medicines and medical devices. The use of mifepristone is neither for a medical emergency, nor for fighting COVID-19.

Finally, the *Becerra Letter* urged your Departments to lift telehealth restrictions on mifepristone alone. Certainly, HHS and the FDA have a duty to ensure that telehealth related federal funding is administered swiftly, yet responsibly. Many federal restrictions on telehealth services have already been loosened or lifted in light of COVID-19. We recognize telehealth during this time can play a significant role in flattening the curve of COVID-19 and expanding the reach of resources to the underserved populations for whom the *Becerra Letter* expressed concern. Yet, we urge your Departments to support the work of the National Consortium of Telehealth Resource Centers (NCTRC) and Health Resources and Services Administration (HRSA) and its other agencies in expanding telehealth services for *all* Americans for *comprehensive* medical services.

In the year 2015, for example, abortion provider Planned Parenthood and its affiliates only provided 2.5 million total services compared to the 27.5 million services provided by Federally Qualified Health Centers. The 27.5 million services were all provided in underserved communities.[11] FQHC's are also served directly by NCTRC and HRSA. There are only 661 abortion clinics that are licensed to prescribe mifepristone. Compare that number to the well over 10,000 locations for FQHC's that provide *comprehensive* care for families, not just abortion-seeking women alone. This is a 1400% difference. These facts prove that current efforts to expand telehealth services

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[9] *Id.*

[10] Some state declarations that abortion is non-essential medical care are facing legal challenges.

[11] Elayne J. Heisler et. al., CONG. RESEARCH SERV., R44295, FACTORS RELATED TO THE USE OF PLANNED PARENTHOOD AFFILIATED HEALTH CENTERS (PPAHSC) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS), 11, (May 18, 2017).

throughout *all* FQHC's will only serve to create greater access to health care for all who need health care services of various kinds.

In conclusion, we urge you to maintain the integrity of REMS for mifepristone in order to continue to ensure abortion drugs are subjected to the same rigorous standards of care as other pharmaceuticals. We applaud all efforts by HHS and the FDA in recognizing the many ways telehealth can be beneficial to women and families during this pandemic. We encourage your Departments to continue to hold the safety of women's health care to the highest standards, ensuring increased access to care does not come at the patient's expense.

Thank you for your leadership and service to our Nation.

Sincerely,

Jim Minnery
Executive Director
Alaska Family Council

Cathi Herrod
President
Center for Arizona Policy

Jonathan Keller
President
California Family Council

Debbie Chaves
Executive Director
Colorado Family Action

Peter Wolfgang
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