



April 14, 2020

Secretary Alex M. Azar II  
U.S. Department of Health & Human Services  
200 Independence Ave., S.W.  
Washington, DC 20201

Commissioner Stephen Hahn  
U.S. Food & Drug Administration  
10903 New Hampshire Ave., N.W.  
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Hahn:

The following letter is submitted as a comment by the American Center for Law and Justice (ACLJ), on behalf of itself and its members.<sup>1</sup> The ACLJ is an organization dedicated to the defense of constitutional liberties secured by law. ACLJ attorneys have argued before the Supreme Court of the United States in a number of significant cases involving the freedoms of speech and religion.<sup>2</sup>

Recently, the Attorney General of California, Xavier Becerra, and twenty other state Attorneys General sent you a letter (hereinafter “the letter”)<sup>3</sup> requesting increased access to the abortion pill, through mitigation of the FDA’s Risk Evaluation and Mitigation Strategy (“REMS”) and the use of telehealth for the prescribing of RU-486 (“Mifepristone”).<sup>4</sup> The letter claims, “The REMS create unnecessary delays for women who need access to time-sensitive healthcare and force them to travel unnecessarily.”<sup>5</sup> For the reasons set forth below, it is both unwise and unsafe to exploit crisis-period-approval

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<sup>1</sup> These comments are joined by more than 20,000 ACLJ members who have signed our Petition to Stop the Left from Exploiting COVID-19 to Expand Abortion, *available at* <https://aclj.org/pro-life/stop-the-left-from-exploiting-covid-19-to-expand-abortion>.

<sup>2</sup> See *Sumnum v. Pleasant Grove*, 555 U.S. 460 (2009); *NOW v. Scheidler*, 547 U.S. 9 (2006); *McConnell v. FEC*, 540 U.S. 93 (2003); *Schenck v. Pro-Choice Network of Western New York*, 519 U.S. 357 (1997); *Lamb’s Chapel v. Center Moriches Sch. Dist.*, 508 U.S. 384 (1993); *Bray v. Alexandria Women’s Health Clinic*, 506 U.S. 263 (1993); *Bd. of Educ. v. Mergens*, 496 U.S. 226 (1990); *Bd. of Airport Comm’rs v. Jews for Jesus*, 482 U.S. 569 (1987).

<sup>3</sup> Letter from Xavier Becerra, Attorney Gen., California, et al., to Alex Azar, Secretary, HHS, and Stephen Hahn, Commissioner, FDA (Mar. 30, 2020) (on file with author).

<sup>4</sup> *Id.*

<sup>5</sup> Letter from Xavier Becerra, *supra* note 3.

during the COVID-19 outbreak to enhance access to abortion for which Attorney General Becerra and others advocate.

## I. Overview

The FDA's REMS policy is intended to "mitigate the risk of serious complications associated with mifepristone" chiefly by "[e]nsuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber."<sup>6</sup> This program is implemented only for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh the risks of its use.<sup>7</sup>

The purpose of REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program. Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber. Informing patients about the risk of serious complications associated with mifepristone.<sup>8</sup>

This is how REMS operates in all cases where drugs fit into this safety program. The REMS protocol focuses "on preventing, monitoring and/or managing a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event."<sup>9</sup>

## II. Risks of the use of Mifepristone and Dangers of Lifting REMS

Although the FDA declared that Mifepristone is safe and effective, it puts perfectly healthy women in the hospital, and it may not work in a safe or effective way nearly 25% of the time it's implemented.<sup>10</sup> Sadly, despite carefully screening to eliminate all but the most physically ideal candidates, 2% of those participating in U.S. clinical trials of Mifepristone hemorrhaged.<sup>11</sup> Additionally, one out of one hundred women who took the drug had to be hospitalized,<sup>12</sup> and during the clinical trials of Mifepristone, several women required surgery to stop the bleeding, with some requiring transfusions.<sup>13</sup> In an

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<sup>6</sup> *Approved Risk Evaluation and Mitigation Strategies (REMS): Mifepristone*, FDA, <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=390> (last updated Apr. 11, 2019).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> Irving M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States*, 338 NEW ENGLAND J. MED. 1243–44 (1998).

<sup>11</sup> U.S. FOOD & DRUG ADMIN., NEW DRUG APPLICATION FOR THE USE OF MIFEPRISTONE FOR INTERRUPTION OF EARLY PREGNANCY 56 (July 19, 1996), <https://wayback.archive-it.org/7993/20170403223214/https://www.fda.gov/ohrms/dockets/ac/96/transcpt/3198t1a.pdf>.

<sup>12</sup> Spitz et al., *supra* note 10, at 1243.

<sup>13</sup> *Id.*

environment less regulated than that of a clinical trial, complications are more serious and more common, especially for those women who do not have immediate access to emergency medical care.<sup>14</sup>

Thus, eliminating REMS and other medical precautions and safety procedures will only increase the risk of serious medical complications in women using Mifepristone. This will not only pose a greater risk to the health of these women, but it will place additional and unnecessary burdens and strains on hospitals and medical centers already struggling to cope with the current outbreak.<sup>15</sup>

While the letter sent by General Becerra touts a low risk of death or medical complications,<sup>16</sup> even if this were factually accurate,<sup>17</sup> any additional strain on the medical system is reason to keep the REMS precautions in place because of the certain risk of burdening the medical systems further.<sup>18</sup> While the courts currently recognize constitutional protections for abortion, these protections need not be upheld to the detriment of public health and safety and thus can be subject to restrictions during times of emergency.<sup>19</sup>

Instructively, just this week, the Fifth Circuit allowed temporary restrictions on abortion during the COVID-19 crisis in its granting of a writ of mandamus to the Governor of Texas.<sup>20</sup> In granting the writ, Judge Duncan emphasized that while “individual rights secured by the Constitution do not disappear during a public health crisis, . . . the Court plainly state[s] that rights c[an] be reasonably restricted during th[e]se times.”<sup>21</sup> Thus, while General Becerra’s letter argues the medical importance of lifting REMS precautions, it ignores the clearly established medical emergency created by COVID-19. Lifting these precautions would only further burden the medical system and take the resources and

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<sup>14</sup> See U.S. FOOD & DRUG ADMIN, *supra* note 11, at 278–80, 291–92 (statement of Cassandra Henderson).

<sup>15</sup> *U.S. Coronavirus Deaths Surpass 8,000 While Hospitals Struggle to Treat Patients*, CBS NEWS (Apr. 4, 2020), [cbsnews.com/video/u-s-coronavirus-death-surpass-8000-while-hospitals-struggle-to-treat-patients/](https://www.cbsnews.com/video/u-s-coronavirus-death-surpass-8000-while-hospitals-struggle-to-treat-patients/).

<sup>16</sup> Letter from Xavier Becerra, *supra* note 3.

<sup>17</sup> The letter omits citations to any valid authority proving vital points of their argument, i.e., that Mifepristone is “*four times* safer than Viagra and *fourteen times* safer than carrying a pregnancy to term.” *Id.* Additionally, the General’s letter references a 2016 report by the Center for Drug Evaluation and Research, which notes that the rate of bleeding that requires medical intervention is between .5% to 4.2%. Center for Drug Evaluation and Research, 69 (2016), [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2016/020687Orig1s020MedR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf). However, even if only 4 out of every 100 women were to need medical intervention, this is an additional four individuals who are not only put at risk of further harm, but who are now also taking up needed hospital supplies and equipment in an already overburdened system.

<sup>18</sup> See *In re Greg Abbott*, Order Granting Mandamus, No. 20-50264, 1, 4–5 (Apr. 7, 2020) (Duncan, J.) (“The surge of COVID-19 cases causes mounting strains on healthcare systems, including critical shortages of doctors, nurses, hospital beds, medical equipment, and personal protective equipment (“PPE”)”).

<sup>19</sup> The letter claims these precautions impose “significant burdens” to women in rural communities, thus trying to claim for these unknown women that their constitutional rights are being thwarted. Letter from Xavier Becerra, *supra* note 3. However, the Fifth Circuit recently reaffirmed the ability of constitutional rights to be temporarily “curtailed” when faced with a society-threatening epidemic. *In re Greg Abbott*, at 13.

<sup>20</sup> *In re Greg Abbott*, at 12.

<sup>21</sup> *Id.* (citing *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905)).

personal protective equipment (PPE) greatly needed from medical professionals on the front lines of this crisis.

### **III. Attorney General Becerra has routinely opposed REMS and other regulations on abortion procedures that relate to women's health.**

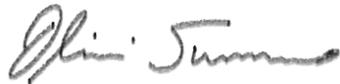
Further, General Becerra and the Attorneys General of the concurring states have routinely opposed REMS precautions<sup>22</sup> and now seek to exploit a national health emergency to further their political interests to the detriment of the greater public at large.

One example from their history of opposing REMS and other healthcare regulations surrounding abortions occurred when General Becerra led a multistate coalition in filing an amicus brief in support of a lawsuit challenging four Arkansas laws that regulated abortion.<sup>23</sup> General Becerra also joined another coalition of 22 states in filing an amicus brief supporting a constitutional challenge to a Louisiana law requiring abortion providers to maintain hospital admitting privileges at local hospitals.<sup>24</sup> These actions show that General Becerra wants to remove any legal barrier to obtaining an abortion, without regard to the regulations or laws that medical institutions and states have implemented in order to protect the health and safety of women.

### **IV. Conclusion**

In sum, constitutional rights, including access to abortion, are never absolute. Given the ongoing health crises resulting from COVID-19, now is not the time to lift medical cautions that have been put in place for the protection and safety of all those in the medical system. This is the exact opposite to the approach advocated by General Becerra. He would like the REMS restrictions lifted “[i]n light of the unprecedented COVID-19 crisis. . . .”<sup>25</sup> A crisis should not be the catalyst by which states can circumvent the rules that have been put in place to protect lives. The regulation of Mifepristone should remain in place during this time, especially when the hospitals are under great pressure.<sup>26</sup>

Sincerely,



Olivia Summers  
Associate Counsel

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<sup>22</sup> *Attorney General Becerra Issues Response to Trump Administration's Baseless Allegations of Weldon Violation*, Xavier Becerra: Attorney General (Jan. 24, 2020), [oag.ca.gov/news/press-releases/attorney-general-becerra-issues-response-trump-administration's-baseless](https://oag.ca.gov/news/press-releases/attorney-general-becerra-issues-response-trump-administration's-baseless).

<sup>23</sup> *Attorney General Becerra Leads Multistate Amicus Brief Defending Women's Reproductive Rights*, Xavier Becerra: Attorney General (Jan. 7, 2020), [oag.ca.gov/news/press-releases/attorney-general-becerra-leads-multistate-amicus-brief-defending-women's](https://oag.ca.gov/news/press-releases/attorney-general-becerra-leads-multistate-amicus-brief-defending-women's).

<sup>24</sup> *Attorney General Becerra Joins Amicus Brief to Supreme Court in Support of Women's Reproductive Rights*, Xavier Becerra: Attorney General (Dec. 3, 2019), [oag.ca.gov/news/press-releases/attorney-general-becerra-joins-amicus-brief-supreme-court-support-women's](https://oag.ca.gov/news/press-releases/attorney-general-becerra-joins-amicus-brief-supreme-court-support-women's).

<sup>25</sup> See Letter from Xavier Becerra, *supra* note 3.

<sup>26</sup> *U.S. Coronavirus Deaths Surpass 8,000 While Hospitals Struggle to Treat Patients*, *supra* note 15.