

October 7, 2025

Department of Health and Human Services (HHS) Freedom of Information Officer Hubert H. Humphrey Building, Room 729H 200 Independence Avenue, SW Washington, D.C. 20201

Email: FOIARequest@hhs.gov

Phone: 202-690-7453 Fax: 202-690-8320

RE: FOIA Request Regarding Records of and Concerning the Abortion Pill.

To Whom It May Concern:

This letter is a request ("Request") in accordance with the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the corresponding department/agency implementing regulations.

The Request is made by the American Center for Law and Justice ("ACLJ")<sup>1</sup> on behalf of itself and its members who demand accountability of our government and who respect the value of life. The ACLJ respectfully seeks expedited processing and a waiver of fees related to this.

To summarize, this Request seeks records from the U.S. Department of Health and Human Services ("HHS") regarding HHS communications and records and the information provided to the public regarding the abortion pill mifepristone during the Biden Administration. The purpose of this request is to seek information that will then educate the American public about the HHS's considerations, practices, and procedures in relation to the abortion pill.

## **Background**

Pursuant to U.S. Department of Health and Human Services ("HHS") FOIA regulation 45 C.F.R.

<sup>&</sup>lt;sup>1</sup> The ACLJ is a not-for-profit 50l(c)(3) organization dedicated to the defense of the sanctity of human life and constitutional liberties secured by law. The ACLJ regularly monitors governmental activity and works to inform the public of such affairs. The ACLJ and its global affiliated organizations are committed to ensuring governmental accountability and the ongoing viability of freedom and liberty in the United States and around the world.

§ 5.21(3), this Background "provide[s] details that will help . . . identify and find the records" requested to the extent known.

During a hearing on September 4, 2025, HHS Secretary Robert F. Kennedy Jr. revealed that the Biden Administration concealed and misrepresented the dangers and potential adverse effects of the abortion pill mifepristone and misoprostol.<sup>2</sup>

STEVE DAINES: Chairman -- Chairman Crapo, thank you. Senator Kennedy, welcome. It's good to see you here again. I want to begin my time by talking about the issue of federal deregulation of chemical abortion drugs. Since mifepristone was approved in 2000, 25 years ago, the FDA has steadily stripped away safeguards related to the -- this drug, no longer requiring a doctor's prescription, no follow up visits, no adverse event reporting, and now allowing it to be sent through the mail.

Earlier this year, there was a new study that analyzed 865,000 real world insurance claims, and it found that nearly 11 percent of women experienced a serious adverse event within 45 days of taking mifepristone. To put that in perspective, that is 22 times higher than the FDA's longstanding estimate of less than 0.5 percent.

While these findings alone are shocking, my conversations with those in the medical profession, credible medical professionals, lead me to believe that even this study may indeed underrepresent the scale of the problem. For years, we've heard the misleading and frankly very harmful lie that's being sold to women that this drug is, and I quote, "safe as Tylenol." These lies sadly have real world consequences.

Just last year, two women died as a result of taking chemical abortion pills because they were able to access them without appropriate medical oversight. And by the way, that's all allowed by the FDA. Mr. Secretary, I am grateful that you and FDA Commissioner Makary have already begun the process of reviewing this new data on the safety of mifepristone.

We talked about this during your confirmation hearing. My question is could you provide any update on the status and the scope of that review, and whether the FDA intends to replicate studies like the one that I referenced?

ROBERT KENNEDY: I think those are -- I don't know if they're going to do an insurance claim study. That's one way to do it. I don't know exactly whether they're doing epidemiological -- epidemiological studies or observational studies. I don't know exactly what they're doing. But I know -- I talked to Marty Makary about it yesterday, and he said those studies are progressing and that they're ongoing.<sup>3</sup>

Later in the hearing Sec. Kennedy was questioned by Senator Ron Wyden, who posited

<sup>&</sup>lt;sup>2</sup> Kennedy Says Biden Admin "Twisted the Data" to Cover Up How Abortion Hurts Women, LIFENEWS (Sept. 4, 2025, 12:35 PM), https://www.lifenews.com/2025/09/04/kennedy-says-biden-admin-twisted-the-data-to-cover-up-how-abortion-hurts-women/.

<sup>&</sup>lt;sup>3</sup> Senate Finance Committee holds Health Care Agenda: The President's 2026 Health Care Agenda, 119th Cong. 25 (2025) (Statement of Robert Kennedy, Sec., U.S. Dep't of Health and Human Services).

that the drug was "safer than Tylenol," and accuses Sec. Kennedy of bias. Sec. Kennedy noted that the science will be good and done by the best scientists.

RON WYDEN: Mr. Secretary, we'll keep this brief. I want to ask about mifepristone. I was the first member of Congress to hold a hearing on this drug, which now has served more than 7.5 million women. And of course, it is used for reproductive health and medication abortion. It has been documented again and again as safe.

And people say safer than Tylenol. And the reason that I'm asking the question is that I'm getting reports that you've said you're going to conduct a complete review of mifepristone safety. And what we're hearing is it's not based on new clinical trials or data from the scientific community, but on one reviewed paper that's not a peer reviewed paper by a political organization and project 2025 sponsor whose stated mission is to advance an anti-abortion agenda.

So what I'd like to hear today is for you to say that you'll commit that your best scientists, without bias, will be permitted to conduct this entirely unnecessary safety review. I don't see any evidence for it. You've called for it. But what I'd like to do is make sure that it's done right and I'm very troubled by what I've heard about it. Your thoughts.

ROBERT KENNEDY: You have my commitment.

RON WYDEN: OK.

ROBERT KENNEDY: That'll be good science and good scientists.4

Sec. Kenedy asserted that the Biden administration "twisted the data to bury one of the safety signals<sup>5</sup> – a very high safety signal of 11%." The safety warnings were removed, even though 11% of the women taking mifepristone and misoprostol experienced medical problems because of it, some of which were life-threatening or so severe that it would prevent them from ever being able to have children.<sup>7</sup>

JAMES LANKFORD: OK. That'd be very helpful to be able to see. It'd be very helpful for consumers across the country. On this, you and I spoke as well, um and you've made public statements on this and the FDA commissioner has made public statements on the issue of reviewing the safety issues of mifepristone. Your comments early on were every drug needs to be treated the same, needs to look at the same and not have political biases and how things are actually examined.

There were a lot of changes on the allocation of mifepristone for elective abortions under the Biden administration. It's now open to anyone without a prescription on it. You don't have to go through a doctor on it. There's all kinds of issues that are happening now on it. So the question was, you said that there

<sup>&</sup>lt;sup>4</sup> *Id*. at 51

<sup>&</sup>lt;sup>5</sup> The European Medicines Agency defines a "safety signal" as "[i]nformation on a new or known adverse event that is potentially caused by a medicine and that warrants further investigation. Signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature." Safety signal, EUROPEAN MEDICINES AGENCY, https://www.ema.europa.eu/en/glossary-terms/safety-signal (last visited Sept. 8, 2025).

<sup>&</sup>lt;sup>6</sup> Kennedy Says Biden Admin "Twisted the Data" to Cover Up How Abortion Hurts Women, supra note 2.

<sup>&</sup>lt;sup>7</sup> *Id*.

would be a review on that just to be able to look at it and make sure we're following all safety protocols.

Do you know a timing on that review?

ROBERT KENNEDY: I can't give you the exact timing. I talked to Marty Makary about it yesterday and he said it is progressing apace. We're getting data in all the time, new data that we're reviewing and we know that during the Biden administration, they actually twisted the data, to bury one of the safety signals. It was a very high safety signal, around 11 percent.

So we're going to make sure that that doesn't happen anymore. We're producing honest science and gold-standard science on that and I'll keep you abreast of where we are.

JAMES LANKFORD: Great. Thank you. Just go where the science leads on that. During the Biden administration the Title 10 regulation that requires title ten family planning programs' recipients to physically and financially separate from abortion activities, their Title 10 activities and eliminate them promoting or providing abortion with those funds, that was flipped from the original Trump rule that was done under the first presidency.

During your confirmation, you had committed to go back and look at that again and to be able to see. My question is do you know the timeline for agency action for when that rule on Title 10 and the separation payments rule will be either reviewed or will actually be reinstated to the original Trump rule under his first presidency?

ROBERT KENNEDY: I don't know if they're -- I just don't know the answer to your question, whether they're actually reviewing the rule right now. I can tell you that the NGOs that have that issue, that refuse to separate their payment streams and separate their operations are not getting funded.<sup>8</sup>

The Biden administration got rid of the requirement to see a doctor to be able to acquire mifepristone and misoprostol. It also removed the requirement to pick up the medicine in person. The in-person requirement was removed due to COVID and initially, it was supposed to be a temporary arrangement. In a 2021 E-mail from Janet Woodcock, the acting FDA commissioner to Drs. Phipps and Grobman, Woodcock stated. "CDER intends to exercise enforcement discretion during the COVID-19 PHE with respect to the in-person dispensing requirement of the Mifepristone REMS Program, including any in-person requirements that may be related to the Patient Agreement Form." However, the FDA made this change permanent in December 2021. While the FDA used four studies to justify its decision, the data from those

<sup>9</sup> Lankford Highlights PBM Transparency, Biden Administration's Mifepristone Deception In Finance Committee Hearing, JAMES LANKFORD (Sept. 4, 2025), https://www.lankford.senate.gov/news/press-releases/lankford-highlights-pbm-transparency-biden-administrations-mifepristone-deception-in-finance-committee-hearing/. 
<sup>10</sup> The Associated Press, *The FDA finalizes rule expanding the availability of abortion pills*, NPR (Jan. 3, 2023, 11:04 PM), https://www.npr.org/2023/01/03/1146860433/the-fda-finalizes-rule-expanding-the-availability-of-abortion-pills.

<sup>&</sup>lt;sup>8</sup> Senate Finance Committee, supra note 3, at 21

<sup>&</sup>lt;sup>11</sup> Letter from Janet Woodcock, M.D., Acting FDA Comm'r, to Maureen G. Phipps, M.D., M.P.H., Am. Coll. of Obstetricians and Gynecologists, William Grobman, M.D., M.B.A., Soc'y for Maternal-Fetal Med. (Apr. 12, 2021) <sup>12</sup> Sarah Mc Cammon & Jonathan Franklin, *FDA relaxes controversial restrictions on access to abortion pill by* 

studies had many limitations. Dr. Woodcock admitted as much in her E-mail, stating the following.

CDER found that although there are limitation to the study designs, the overall finding from the studies do not appear to show increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic.<sup>14</sup>

The FDA states on its website that there is no longer an in-person requirement; as well as that under the new REMS that mifepristone as well mifeprex can be dispensed by or under the supervision of a certified prescriber. <sup>15</sup> The U.S. Post-Marketing Adverse Events Summary report that from September of 2000 through 2024, 36 women have died and 97 experienced ectopic pregnancies while using mifepristone. 16 The FDA claimed there were very few adverse events from mifepristone in 2020, without acknowledging the fact that the requirement to report adverse events has been removed since 2016 and therefore, they do not, in fact, know the number of adverse events that occurred in 2020. 17 The other three studies revealed that there was a high rate of cases where the woman needed surgery due to the abortion pill's desired effect's failure. They also had many women whose outcome remained unknown due to a failure to follow up with them. Despite this and despite these studies not replicating the conditions of use the FDA approved, the FDA still relied on them and considered them to be the support they needed for their decision. The fourth study the FDA used was a study made by researcher Abigail Aiken who reported that telemedicine abortions were 99.2% effective. <sup>18</sup> However, she relied on a U.K. reporting system that was often unaware of the adverse events. She did not use the data that showed that there were at least 5 to 10 times more complications than were reported.

The FDA approved a generic version of the abortion pill produced by Evita Solutions on September 30, 2025. The generic version is subject to the same REMS as Mifepristone. 19

There are reports that mifepristone was prescribed off-label to men who then administered this drug to women without them knowing.<sup>20</sup> There have been many and varied accounts of this

mail, NPR (Dec. 16, 2021, 5:08 PM), https://www.npr.org/2021/12/15/1064598531/the-fda-could-permanently-lift-some-restrictions-on-abortion-pills.

<sup>&</sup>lt;sup>13</sup> https://www.raps.org/news-and-articles/news-articles/2021/12/fda-removes-in-person-dispensing-requirement-for-a

<sup>&</sup>lt;sup>14</sup> Letter from Janet Woodcock, *supra* note 11

<sup>&</sup>lt;sup>15</sup> Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, Question 29 (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

<sup>16</sup> https://www.fda.gov/media/185245/download?attachment.

<sup>&</sup>lt;sup>17</sup> Tessa Cox & Mia Steupert, M.A., *Fact Sheet: Three Problems with the FDA's Abortion Drugs Complications Data*, Lozier Institute (Mar. 22, 2024), https://lozierinstitute.org/fact-sheet-three-problems-with-the-fdas-abortion-drugs-complications-data/.

<sup>18</sup> https://pubmed.ncbi.nlm.nih.gov/33605016/

<sup>&</sup>lt;sup>19</sup> https://www.pharmacytimes.com/view/fda-approves-generic-mifepristone-tablets-for-abortion

<sup>&</sup>lt;sup>20</sup> Breaking: HHS Sec. Kennedy Reveals Biden Admin "Twisted" Abortion Drug Data, SUSAN B. ANTHONY PRO-LIFE AMERICA (Sept. 4, 2025), https://sbaprolife.org/newsroom/press-releases/breaking-hhs-sec-kennedy-revealsbiden-admin-twisted-abortion-drug-data.

occurring all over America. <sup>21</sup> For example, a Massachusetts man gave his pregnant girlfriend medication abortion without her knowing. <sup>22</sup> The two had met online through a dating app and were together for a few months. <sup>23</sup> He told her that he was giving her iron pills or other vitamins. <sup>24</sup> She ended up having a miscarriage. <sup>25</sup> Massachusetts has very lenient abortion laws, with abortions available by physician, physician assistant, nurse practitioner, or nurse midwife permitted to commit the abortion, <sup>26</sup> while after 24 weeks an abortion may only be done by a physician, for any medical reason to include the preservation of mental health. <sup>27</sup> Further, a 39-year-old man from New York gave mifepristone to a woman, who was unaware of what drug it was, and caused her miscarriage. <sup>28</sup>

An Illinois man "allegedly inserted four Mifepristone pills into his girlfriend's vagina," causing her to experience medical complications that ultimately resulted in a miscarriage. <sup>29</sup> He said he made this decision not to have a baby for her. <sup>30</sup>

A US Marine tried to convince the woman he got pregnant to have an abortion.<sup>31</sup> He texted her that since they were not in love, "it would be messed up to bring a child into the world without

Another occurrence in Texas involves a married man who had an affair that resulted in pregnancy. He apparently told his wife that he hoped he could convince his girlfriend to have an abortion, but his girlfriend told him that she wanted to keep the baby. He gave her some cookies and a drink. After she miscarried, the authorities did some investigation that revealed that there was mifepristone and misoprostol in the cookies. *Man accused of secretly giving girlfriend abortion drug, killing their unborn baby*, FOX10 NEWS (June 12, 2025, 5:58 AM), https://www.fox10tv.com/2025/06/12/man-accused-secretly-giving-girlfriend-abortion-drug-killing-their-unborn-baby/.

<sup>&</sup>lt;sup>21</sup>A husband in Texas told his wife how important hydration was during pregnancy and kept giving her glasses of water. When she commented that the water was cloudy, he told her that it was because of the dirty pipes. He also gave her an opened orange juice bottle.<sup>21</sup> In all those drinks he put an abortion-inducing medication. She suspected him after she drank the first glass of water because after half an hour of drinking the water, she experienced cramping and severe bleeding and eventually, had to go to the emergency room. After she saw him when he slipped a small plastic bag's contents into the drink he gave her and saw open packs of Cyrux in the trash, she became convinced of what he was doing and gave evidence to law enforcement. Lauren Aratani, *Texas man faces charges for allegedly slipping abortion drug in wife's drink*, THE GUARDIAN (Nov. 14, 2022), https://www.theguardian.com/us-news/2022/nov/14/texas-mason-herring-abortion-drug-wife-drink-criminal-charges.

<sup>&</sup>lt;sup>22</sup> Christina Hager, *Massachusetts man accused of secretly giving girlfriend abortion pill to end pregnancy*, CBS NEWS (May 29, 2024, 8:08 AM), https://www.cbsnews.com/boston/news/abortion-pill-misoprostol-boyfriend-arrested-pregnant-girlfriend/.

<sup>&</sup>lt;sup>23</sup> *Id*.

<sup>&</sup>lt;sup>24</sup> *Id*.

<sup>&</sup>lt;sup>25</sup> Id.

<sup>&</sup>lt;sup>26</sup> Mass. Gen. Laws ch. 112 § 12M

<sup>&</sup>lt;sup>27</sup> Mass. Gen. Laws ch. 112 § 12N

<sup>&</sup>lt;sup>28</sup> Nancy Flanders, *This New York man obtained the abortion pill. Guess what he did with it.*, LIVE ACTION (July 17, 2023, 7:43 PM), https://www.liveaction.org/news/new-york-man-arrested-abortion-pill.

<sup>&</sup>lt;sup>29</sup> Zoe Hussain, *Illinois man allegedly drugged pregnant girlfriend with abortion pills to cause miscarriage*, NEW YORK POST (Aug. 26, 2025, 1:46 AM), https://nypost.com/2025/08/26/us-news/illinois-man-allegedly-drugged-pregnant-girlfriend-with-abortion-pills-to-cause-miscarriage/.

<sup>30</sup> *Id* 

<sup>&</sup>lt;sup>31</sup> Zoe Hussain, *Texas woman claims US Marine got her pregnant, then spiked her drink with abortion pills after she refused to 'get rid of it': lawsuit*, NEW YORK POST (Aug. 12, 2025, 9:20 PM), https://nypost.com/2025/08/12/usnews/texas-woman-claims-us-marine-got-her-pregnant-then-spiked-her-drink-with-abortion-pills-after-she-refused-to-get-rid-of-it-lawsuit/.

both parents raising them."<sup>32</sup> He consistently told her to "get rid of it."<sup>33</sup> She wrote to him that hearing him say that was "like an electric shock."<sup>34</sup> He was relentless, though, and even brought abortion pills to her house and left them there, in case she changed her mind.<sup>35</sup> He threatened to testify against her in a custody battle over her three children with her ex-husband.<sup>36</sup> However, she did not change her mind.<sup>37</sup> She even named the baby Joy, determined to keep the baby.<sup>38</sup> When he realized that nothing he could say or do would change her mind, he changed his tactics.<sup>39</sup> He proposed that they should have a "trust-building" night.<sup>40</sup> On that night he put at least 10 misoprostol pills into her hot chocolate.<sup>41</sup> Within thirty minutes, she was hemorrhaging and had to be taken to the hospital.<sup>42</sup> By that time, he had already run away.<sup>43</sup> She lost her baby Joy.<sup>44</sup> A mother in Louisiana coerced her minor daughter to take mifepristone.<sup>45</sup> The daughter miscarried.<sup>46</sup>

These horror stories are not limited to American however, they also span globally, one occurrence is in Japan.<sup>47</sup> The man tricked his girlfriend into taking mifepristone while telling her it was treatment for a sexually transmitted disease.<sup>48</sup> Police believe the man ordered the abortion drug over the internet the same day his girlfriend took the pregnancy test.<sup>49</sup> The pregnant girlfriend had refused his demands to get an abortion, when arrested he admitted that he "did not want to marry her" and that due to "economic conditions" he didn't want a child at the time.<sup>50</sup>

Another example is found in Dereham, Norfolk, where a man crushed up mifepristone—which was ordered and delivered through the mail—and placed in his girlfriend's orange juice. <sup>51</sup> The man received the drug from a friend, who posed as a woman in need of an abortion during a phone consultation. <sup>52</sup> The availability of online abortion drugs in the UK also started during covid, but was subsequently made permanent there as well. <sup>53</sup>

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32 Id.
33 Id.
34 Id.
35 Id.
36 Id.
37 Id.
38 Id.
39 Id.
40 Id.
41 Id.
42 Id.
43 Id.
44 Id.
45 Ashshar Chassi, Naw York doct.
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<sup>&</sup>lt;sup>45</sup> Aabshar Ghassi, *New York doctor and Louisiana mother indicted for enabling minor's abortion by mifepristone*, JURIST NEWS (Feb. 1, 2025, 9:03 AM), https://www.jurist.org/news/2025/02/new-york-doctor-and-louisiana-mother-indicted-for-enabling-minors-abortion-by-mifepristone/.

<sup>™</sup> Id.

<sup>&</sup>lt;sup>47</sup> Laura Nicole, *Man arrested for tricking pregnant girlfriend into taking abortion pill*, Live Action (Mar. 2, 2021), https://www.liveaction.org/news/abortion-pill-man-arrested-tricking-girlfriend.

 $<sup>^{48}</sup>$   $\bar{I}d$ .

<sup>&</sup>lt;sup>49</sup> *Id*.

<sup>&</sup>lt;sup>50</sup> *Id*.

<sup>&</sup>lt;sup>51</sup> Clare Worden, Call to end abortion pills by post after poisoning, BBC (Dec. 9, 2024).

<sup>&</sup>lt;sup>52</sup> *Id*.

<sup>&</sup>lt;sup>53</sup> *Id*.

As already briefly mentioned, while during the Clinton administration reporting the adverse events was required, during the Obama and Biden administrations this was no longer required.<sup>54</sup> This made it easy to exaggerate the safety of mifepristone and misoprostol and mislead about its potential negative effects. The drug label states that the rate of serious side effects was less than 0.5% in clinical trials, when, in fact, the rate is at least 22 times as high as that summary figure.<sup>55</sup>

Although it is said that the abortion pills are safe, two women died after taking them.<sup>56</sup>

## **Records Requested**

For purposes of this Request, the term "record" means "any information" that qualifies under 5 U.S.C. § 552(f), and includes, but is not limited to, the original or any full, complete and unedited copy of any log, chart, list, memorandum, note, correspondence, writing of any kind, policy, procedure, guideline, agenda, handout, report, transcript, set of minutes or notes, video, photo, audio recording, or other material. The term "record" also includes, but is not limited to, all relevant information created, stored, received or delivered in any electronic or digital format, e.g., electronic mail, instant messaging or Facebook Messenger, iMessage, text messages or any other means of communication, and any information generated, sent, received, reviewed, stored or located on a government or private account or server, consistent with the holdings of Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145 (D.C. Cir. 2016) (rejecting agency argument that emails on private email account were not under agency control, and holding, "If a department head can deprive the citizens of their right to know what his department is up to by the simple expedient of maintaining his departmental emails on an account in another domain, that purpose is hardly served.").

For purposes of this Request, the term "aides" used herein has the definition as "a person whose job is to help someone important, such as a member of a government or a military officer of high rank."

For purposes of this Request, the term "staff" used herein has the definition as "a group of people who work for an organization for a special purpose, or who work for a manager within an organization."

For purposes of this Request, all terms otherwise used herein have the definitions given by FOIA, 5 U.S.C. § 552 et seq.

For purposes of this Request, the terms "HHS official" or "HHS employee" include, but are not limited to, any person who is (1) employed by or on behalf of the HHS in any capacity; or (2) contracted for services by or on behalf of the HHS in any capacity.

<sup>&</sup>lt;sup>54</sup> Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, ETHICS & PUBLIC POLICY CENTER (Apr. 28, 2025), https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/. <sup>55</sup> Id

<sup>&</sup>lt;sup>56</sup> Amir Daftari, *Two Deaths Linked to Abortion Pills Despite Experts Saying They Are Safe*, NEWSWEEK (Sept 20, 2024, 11:14 AM), https://www.newsweek.com/harris-speech-georgia-after-abortion-deaths-safe-ruling-1956828.

For purposes of this Request, the term "Patient Protection and Affordable Care Act; Updating Payment Parameters and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule (CMS-9906)," includes RIN: 0938-AU60.

For purposes of this Request, and unless otherwise indicated, the timeframe of records requested herein is January 20, 2021, through the date of receipt of this Request.

Pursuant to FOIA, 5 U.S.C. § 552, ACLJ hereby requests that the HHS produce the following records:

- 1. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed in the custody of the CDER Center Director, Deputy Director, Chief of Staff, General Counsel, or any of their senior staff or assistants, of a GS-14 or appointee or Capstone level or of the Senior Executive Service or that concern or in any way discuss the changes made to individuals' access to the abortion pills, mifepristone or mifepristone and misoprostol.
- 2. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed in the custody of the CDER Center Director, Deputy Director, Chief of Staff, General Counsel, or any of their senior staff or assistants, of a GS-14 or appointee or Capstone level or of the Senior Executive Service or that concern or in any way discuss the changes made to individuals' access the adverse events of mifepristone or mifepristone and misoprostol and what would be shared with the public regarding those adverse events.
- 3. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed in the custody of the Drug Safety Oversight Board, its Director, Deputy Director, Chief of Staff, General Counsel, or any of their senior staff or assistants, of a GS-14 or appointee or Capstone level or of the Senior Executive Service or that concern or in any way discuss the abortion pill, mifepristone or mifepristone and misoprostol.
- 4. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed in the custody of the CDER Center Director, Deputy Director, Chief of Staff, General Counsel, or any of their senior staff or assistants, of a GS-14 or appointee or Capstone level or of the Senior Executive Service or that concern or in any way discuss the generic mifepristone of Evita Solutions.

## **CONCLUSION**

If this Request is denied in whole or in part, ACLJ requests that, within the time requirements imposed by FOIA, your agency support all denials by reference to specific FOIA exemptions and provide any statutory or judicially required explanatory information, including but not limited to a *Vaughn* Index.

Moreover, the ACLJ is entitled to expedited processing of this Request as well as a waiver of all

fees associated with it. The ACLJ reserves the right to appeal a decision to withhold any information sought by this request and/or to deny the separate application for expedited processing and waiver of fees.

Thank you for your prompt consideration of this Request. Please furnish all applicable records and direct any responses to:

Jordan Sekulow, Executive Director Benjamin P. Sisney, Senior Litigation Counsel John A. Monaghan, Senior Litigation Counsel American Center for Law and Justice





I affirm that the foregoing request and attached documentation are true and correct to the best of my knowledge and belief.

Respectfully submitted,

Joelan Schlass

Jordan Sekulow Executive Director Benjamin P. Sisney Senior Litigation Counsel

John A Monaghan

Senior Litigation Counsel

Jahn A Monaghan