

June 7, 2021

Food and Drug Administration Division of Freedom of Information 5630 Fishers Lane Room-1035 Rockville, MD 20857

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

RE: FOIA Request for records concerning the FDA's exercise of enforcement discretion regarding RU-486 ("Mifepristone") from the FDA's Risk Evaluation and Mitigation Strategy ("REMS") requirements

Dear FOIA Officer:

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")¹ on behalf of itself and its members who demand accountability of our government and who respect the value of life. The ACLJ respectfully seeks a waiver of fees related to this Request as set forth in an accompanying memorandum.

To summarize, this Request seeks records from the FDA regarding its "literature search for studies pertinent to the in-person dispensing requirement in the Mifepristone REMS Program" and its review of the "postmarketing adverse events that reportedly occurred from January 27, 2020 –

¹ The ACLJ is a not-for-profit 50l(c)(3) organization dedicated to the defense of 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.

January 12, 2021, with mifepristone use for medical termination of early pregnancy," and the FDA and/or HHS decision to permit the use of mifepristone without medical supervision. The purpose of this request is to seek information that will then educate the American public about the FDA and HHS's oversight, considerations, practices, and procedures in its approval of, and spending of U.S. tax-payer dollars on, "medical termination of early pregnancy."

Background

Pursuant to Food and Drug Administration (FDA) FOIA regulation 21 C.F.R. §20.40(b), this Background "describes the records being sought, in a way that they can be identified and located . . . [and] include[s] all the pertinent details that will help identify the records sought," to the extent known.

Pursuant to Department of Health and Human Services ("HHS") FOIA regulation 45 C.F.R. § 5.21(3), this Background "provide[s] details that will help . . . identify and find the records" requested to the extent known.

According to an April 12, 2021, twitter post by the American College of Obstetricians and Gynecologists: "BREAKING: ACOG win! The @US_FDA Acting Commissioner Janet Woodcock has notified @ACOG and @MySMFM that the agency will "exercise enforcement discretion" regarding #mifepristone through the duration of the #COVID19 public health emergency."

Attached to the tweet is a letter from Acting Commissioner of Food and Drugs, Janet Woodcock, M.D. The letter states the FDA's intent to exercise "enforcement discretion," i.e., to not enforce at all, the requirement of "the in-person dispensing of mifepristone for medical termination of early pregnancy" or the prohibition of "dispensing [the abortion pill]... through the mail...." It further cites the FDA's "literature search for studies pertinent to the in-person dispensing requirement in the Mifepristone REMS Program" and its review of the "postmarketing adverse events that reportedly occurred from January 27, 2020 – January 12, 2021, with mifepristone use for medical termination of early pregnancy." ⁵

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,

² Letter from Janet Woodcock, Acting Commissioner, Food & Drug Administration, to Maureen Phipps, CEO, American College of Obstetricians and Gynecologists (ACOG), & William Grobman, President, Society for Maternal-Fetal Medicine (Apr. 12, 2021),

https://www.aclu.org/sites/default/files/field_document/fda_acting_commissioner_letter_to_acog_april_12_2021.pd f [hereinafter ACOG Letter].

³ 21 C.F.R. §20.40(b).

⁴ ACOG Action (@ACOGAction), TWITTER (Apr. 12, 2021, 9:27 AM), https://twitter.com/ACOGAction/status/1381781110980501512.

⁵ ACOG Letter, *supra* note 2.

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 terms "FDA official" or "FDA employee" include, but are not limited to, any person who is (1) employed by or on behalf of the Food and Drug Administration in any capacity, including but not limited to employees of the Center for Drug Evaluation and Research (CDER); or (2) contracted for services by or on behalf of the Food and Drug Administration or the Center for Drug Evaluation and Research in any capacity.

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

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

- 1. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss the ethical, legal, scientific and/or moral considerations in exercising "enforcement discretion" regarding the requirement of "in-person dispensing of mifepristone for medical termination of early pregnancy" and/or the prohibition of "the dispensing... through the mail...," including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, and attachments to any electronic mail or message.
- 2. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss the "four publications that included relevant clinical data," including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or

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⁶ ACOG Letter, *supra* note 2, at 1.

message accounts, personal electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message carbon copied to non-agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.

- 3. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss the "postmarketing adverse events that reportedly occurred from January 27, 2020 January 12, 2021, ... along with available information about deviations or noncompliance events associated with the ... REMS Program ...," including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, personal electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.
- 4. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss or define the "relevant clinical outcome data," including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, personal electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.
- 5. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss or define the criteria used for the "literature search," including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, personal electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, and attachments to any electronic mail or message.

⁷ *Id*.

⁸ *Id*.

⁹ *Id*.

- 6. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss or define the weight that was given in the decision making process to the fact that the FDA "does not receive reports for every adverse event or medication error that occurs with a product," including the use of Mifepristone, and therefore any decision to relax REMs regulations for the administration of Mifepristone is based on admittedly incomplete knowledge, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, personal electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message carbon copied to non-agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients to any electronic mail or message forwarded to non-agency account recipients to any electronic mail or message.
- 7. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by any FDA official or employee that concern or in any way discuss or define the use of international data collected on the adverse side-effects of Mifepristone (or RU 486) in order to supplement the incomplete data accessible to the FDA, including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, personal electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients to any electronic mail or message.
- 8. All records prepared, generated, forwarded, transmitted, sent, shared, saved, received, or reviewed by HHS Secretary Becerra or his immediate subordinates that concern or in any way discuss direction or instruction to exercise "enforcement discretion" regarding the requirement of "in-person dispensing of mifepristone for medical termination of early pregnancy" and/or the prohibition of "the dispensing... through the mail...," including but not limited to any text messages, any record located on backup tapes, archives, any other recovery, backup, storage or retrieval system, FDA electronic mail or message accounts, non-FDA electronic mail or message accounts, FDA servers, or non-FDA servers, and personal servers, as well as any electronic mail or message carbon copied to agency account recipients, any electronic mail or message carbon copied to non-agency account recipients, any electronic mail or message forwarded to agency account recipients, any electronic mail or message forwarded to non-agency account recipients, any electronic mail or message forwarded to non-agency account recipients to any electronic mail or message.

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¹⁰ Questions and Answers on FDA's Adverse Event Reporting System (FAERS), U.S. FOOD & DRUG ADMIN. https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers (last updated June 4, 2018).

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 statutorily or judicially required explanatory information, including but not limited to a *Vaughn* Index.

Moreover, as explained in an accompanying memorandum, 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 201 Maryland Ave., NE Washington, D.C. 20002-5703 (202) 546-8890 (202) 546-9309 (fax) sekulow@aclj.org bsisney@aclj.org jmonaghan@aclj.org

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

Respectfully submitted,

Joelan Schlaw

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John A Monaghan

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MEMORANDUM IN SUPPORT OF REQUESTED FEE WAIVER

The American Center for Law and Justice ("ACLJ") respectfully submits this Memorandum requesting a fee waiver in support of its Freedom of Information Act Request ("FOIA") request to the U.S. Food and Drug Administration ("FDA").

I. FEE WAIVER REQUEST

The ACLJ is a not-for-profit 501(c)(3) organization dedicated to the defense of constitutional liberties secured by law. The ACLJ's mission is to educate, promulgate, conciliate, and where necessary, litigate, to ensure that those rights are protected under the law. The ACLJ regularly monitors governmental activity with respect to governmental accountability. The ACLJ and its globally affiliated organizations are committed to ensuring the ongoing viability of freedom and liberty in the United States and around the world. By focusing on U.S. constitutional law and international law, the ACLJ and its affiliated organizations are dedicated to the concept that freedom and liberty are universal, God-given, and inalienable rights that must be protected. Additionally, the ACLJ and its affiliated organizations support training law students from around the world in order to protect religious liberty and safeguard human rights and dignity.

The ACLJ requests a fee waiver under 5 U.S.C. § 552(a)(4)(A)(iii). Under this section, fees may be waived or reduced if the requester falls within a category established under § (a)(4)(A)(ii), which includes a "representative of the news media," § (a)(4)(A)(ii)(II), and if "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester," § (a)(4)(A)(iii). The ACLJ qualifies for a fee waiver as a "representative of the news media," § (a)(4)(A)(ii)(II), and because the information sought is "not for a commercial purpose," § (a)(4)(A)(iii). Moreover, the ACLJ intends to widely disseminate the information obtained to the public because as explained in detail *infra*, "it is likely to contribute significantly to the public understanding of the operations or activities of the government," § (a)(4)(A)(iii), agency, and actors mentioned in the FOIA request.

A. The ACLJ Qualifies as a News Media Representative.

The ACLJ qualifies as a "representative of the news media," as defined under 5 U.S.C. § 552(a)(4)(A)(ii), because the ACLJ, for the purposes explained above, "gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." *Id.* The ACLJ's audience is generally comprised of those interested in our mission and legal activities as described above. The ACLJ reaches a vast audience through a variety of media outlets, including the Internet (World Wide Web page, www.aclj.org), radio, television, press releases, and direct mailings to our supporters.

For example, the ACLJ's Internet site received an average of 600,000 unique visitors per month in 2017, with over 24,000,000 page views. Our current email list holds 1,050,000 active names (actual list size is 3,937,795). In 2017, the ACLJ sent 288,000,000 emails.

The ACLJ's radio audience consists of more than 1,150,000 estimated daily listeners on more than 1,050 radio stations nationwide, including SiriusXM satellite radio. Additionally, the ACLJ hosts a weekly television program, Sekulow, broadcast on eight networks: Cornerstone Television, Daystar Television Network, AngelOne, KAZQ, TBN, VTN, The Walk TV, and HisChannel. See http://aclj.org/radio-tv/schedule (listing schedule).

The ACLJ also disseminates news and information to over 1,000,000 addresses on its mailing lists. In 2015, the ACLJ sent 15,000,000 pieces of mail.

Moreover, our Chief Counsel, Jay Sekulow, has regularly appeared on various news and talk show programs to discuss the issues and events important to the ACLJ and its audiences. These include shows on FOX News, MSNBC, CNN, ABC, CBS, and NBC. In addition to television programs, Jay Sekulow has also appeared on national radio broadcasts. Beyond broadcast outlets, Jay Sekulow's comments appear regularly in the nation's top newspapers, in print and online editions, including but not limited to the Wall Street Journal, New York Times, Washington Times, Washington Post, L.A. Times, and USA Today. His comments also appear in major national newswire services that include, but are not limited to, Associated Press, Reuters, and Bloomberg.

B. The ACLJ's FOIA Request Meets Standards Set Forth Under HHS/FDA Regulations Promulgated Under FOIA.

HHS and FDA will reduce or waive fees normally charged for processing FOIA requests,

- (1) Is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government; and
- (2) It is not primarily in the commercial interest of the requester.

HHS and FDA, in making its determination, considers an iteration of the following four factors regarding whether disclosure of the information "is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government":

- (1) Whether the records to be disclosed pertain to the operations or activities of the Federal Government:
- (2) Whether disclosure of the records would reveal any meaningful information about Government operations or activities that is not already public knowledge;
- (3) Whether disclosure will advance the understanding of the general public as distinguished from a narrow segment of interested persons. Under this factor, the Food and Drug Administration may consider whether the requester is in a position to contribute to public understanding. For example, the Food and Drug Administration may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information to the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence; and
- (4) Whether the contribution to public understanding will be a significant one, i.e., will the public's understanding of the Government's operations be substantially greater as a result of the disclosure.

HHS and FDA, in making its determination, also considers the following two factors regarding whether disclosure of the information "is not primarily in the commercial interest of the requester":

- (1) Whether disclosure would further a commercial interest of the requester, or of someone on whose behalf the requester is acting. Commercial interests include interests relating to business, trade, and profit. Both profit and nonprofit-making corporations have commercial interests, as well as individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.
- (2) If disclosure would further a commercial interest of the requester, whether that effect outweighs the advancement of the public interest as defined

in paragraph (b) of this section.

As the U.S. Court of Appeals for the D.C. Circuit has noted, "Congress amended FOIA to ensure that it is 'liberally construed in favor of waivers for noncommercial requesters." *Judicial Watch, Inc. v. Rossotti,* 326 F.3d 1309, 1312 (D.C. Cir. 2003) (citing *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1284 (9th Cir. 1987) (quoting 132 Cong. Rec. 27, 190 (1986) (Sen. Leahy))).

The ACLJ's FOIA request meets the HHS/FDA's factors as listed above, qualifying the ACLJ for a waiver of fees, as set forth below.

The subject of the request concerns the operations or activities of the government.

Releasing the requested records to the ACLJ will contribute significantly to the public's understanding of United States Government operations and activities. The ACLJ has requested information and records specifically concerning the FDA's "literature search for studies pertinent to the in-person dispensing requirement in the Mifepristone REMS Program," its review of the "postmarketing adverse events that reportedly occurred from January 27, 2020 – January 12, 2021, with mifepristone use for medical termination of early pregnancy," and the FDA decision to permit the use of mifepristone without medical supervision. This information is required to determine what ethical, moral, and legal obligations the relevant U.S. government actors considered in its approval of, and spending of U.S. tax-payer dollars on, "medical termination of early pregnancy." Within this request, all communications by the HHS and any of its personnel, and all other HHS actions related thereto, are relevant to shed light on identifiable activities of the government.

The requested information has significant informative value and disclosure of the records would reveal meaningful information about Government operations or activities that is not already public knowledge.

The ACLJ's request will contribute and provide meaningful understanding of United States Government operations or activities undertaken by and within the FDA. The Request will reveal records indicating why FDA officials and other government actors choose to exercise enforcement discretion regarding RU-486 ("Mifepristone") from the FDA's Risk Evaluation and Mitigation Strategy ("REMS") requirements. Responsive records will also reveal the involvement, if any, of any other governmental agencies or officials in these decisions. This information will allow the American public to hold its government officials accountable if it is discovered that FDA officials engaged in activities and/or communications and/or arrived at decisions inconsistent with the desires of the American public as an increasing number of Americans are in favor of limitations and restrictions on abortions and the ways in which they are performed.

Disclosure of the requested information will advance the understanding of the general public as distinguished from a narrow segment of interested persons, and the requester has expertise in the subject area as well as the intention and ability to disseminate the information to the public.

Releasing the requested information to the ACLJ will contribute "significantly" to the public's understanding of United States Government operations and activities. The ACLJ has researched and litigated to uphold governmental transparency and accountability. The ACLJ is qualified to analyze and assess the adequacy or propriety of FDA officials' actions and decisions at issue.

The ACLJ intends to release the information, once analyzed and assessed, to the public through its numerous media outlets. Those outlets include but are not limited to its Internet website (www.aclj.org), email list, radio programs, television programs, press releases, and regular mailing list, as described above. The ACLJ has been disseminating relevant information concerning fundamental and constitutional freedoms and governmental accountability, since its founding in 1990, and has since then expanded its work and notoriety on an international level, achieving credibility in a wide range of media outlets, as described above.

Disclosure of the requested information will contribute significantly to public understanding of government operations or activities.

Releasing the information described above will significantly contribute to the public's understanding through ACLJ review and assessment of the materials and information, and subsequent dissemination of the information to the public. Such review, assessment, and dissemination will help the public understand what actions FDA officials took in connection with its oversight, considerations, practices, and procedures in its approval of, and spending of U.S. tax-payer dollars on, "medical termination of early pregnancy."

The requester has no commercial interest that would be furthered by the requested disclosure.

The ACLJ has no commercial interest in the information sought or its dissemination thereof. The ACLJ is a not-for-profit 50l(c)(3) organization dedicated to the defense of constitutional liberties secured by law. The information sought by the ACLJ is in furtherance of its not-for-profit mission statement.

The requester's primary and in fact, only, interest in disclosure of the requested information is non-commercial.

Again, the ACLJ has *no* commercial interest in the information sought or its dissemination thereof. Rather, its interest is purely to further its not-for-profit mission. Therefore, its interest cannot be founded "primarily" in a commercial interest. This is especially so because the ACLJ cannot operate for a commercial purpose under its grant of 501(c)(3) tax-exempt status.

For these reasons, the ACLJ is entitled to a fee waiver.

* * * * *

Accordingly, the ACLJ respectfully submits a request for waiver as to its contemporaneously submitted FOIA Request.

III. CERTIFICATION

In satisfaction of certification requirements under 5 U.S.C. § 552(a)(6)(E)(vi) and corresponding regulations, the ACLJ incorporates by reference herein all relevant facts and information as stated in the ACLJ's FOIA request in support thereof and certifies that the information provided and stated herein is true and correct to the best of the undersigned's knowledge and belief.

Respectfully submitted,

Joelan Schlas

Jordan Sekulow Executive Director Benjamin P. Sisney Senior Litigation Counsel

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John A Monaghan

Senior Litigation Counsel

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