Congress of the United States
Washington, DC 20515

March 9, 2023

Andrew Howard
Senior Attorney
U.S. Government Accountability Office
441 G Street NW
Washington, D.C. 20548

Dear Mr. Howard:

On January 3, 2023, the U.S. Food & Drug Administration (FDA) implemented a new policy that increases access and consumption of mifepristone. We subsequently wrote to seek your review of whether the January 2023 REMS modification for mifepristone, issued by the FDA, constitutes a "rule" for purposes of the Congressional Review Act (CRA).

After careful examination of the FDA's actions and the precedent set forth by previous GAO reviews, we believe the REMS modification, which removed the in-person distribution requirement for mifepristone, constitutes a "rule" under the CRA and that the FDA failed to submit a report on this rule to Congress and to the Comptroller General, as required by the CRA. We believe the FDA's updated REMS for mifepristone is a "rule" under CRA because it has general applicability; has future effect; implements or prescribes law or policy; and is not subject to the limited exceptions to a "rule" defined by the CRA because it is not a rule of particular applicability; it does not relate to agency management/personnel; and it substantially impacts the rights and duties of non-agency parties.

Below we describe the argument that this action by the FDA constitutes a "rule" under the CRA. We submit this letter for reference and strongly request that you incorporate the contained evidence in your review.

Background:

The CRA was enacted in 1996 as a means of ensuring congressional oversight of the federal agency rulemaking process and creating a new process for congressional review of agency rules. Among other things, the CRA requires agencies to submit finalized rules to both houses of Congress and to the Comptroller General for review before a rule can take effect.[1] Congress is then afforded a period of 60 days during which it may pass a joint resolution of disapproval that, when signed by the President, will revoke the rule in question. With limited exceptions, the CRA adopted the definition of a "rule" under the Administrative Procedure Act (APA):

> '[R]ule' means the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and

[1] See 5 U.S.C. § 801(a)(1)(A)

> includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing."[2]

As stated in GAO opinion B-323772, the definition of a rule under the CRA is very broad, reflecting Congress's intention that the CRA covers a broad range of rules in both type and scope.[3] We believe the FDA's change to the REMS guidance on mifepristone passes every reasonable test for the definition of a "rule" under the CRA.

General Applicability:

A "rule" under the CRA must first be determined to have "general applicability" as a statement of policy or an interpretation of law. Previous GAO determination B-287557 described that the "general applicability" test does not require a finding that a rule is generally applicable to the population as a whole, but rather has general applicability within its intended range. The U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) has ruled that most agency statements fulfill this condition, specifically posing the rhetorical question "what isn't?" with respect to a statement of general applicability.[4] The FDA's updated REMS removes the in-person distribution requirement for mifepristone and permits brick-and-mortar pharmacies and mail-in services to distribute this drug to individuals. As a statement outlining new guidance with substantial effect on all entities distributing or prescribing mifepristone, the REMS modification has "general applicability" within its intended scope (all parties distributing or prescribing mifepristone).

Future Effect:

Second, a "rule" under the CRA must have "future effect," or be prospective in nature, rather than retrospective. Justice Scalia contended this to be the primary manner of distinguishing between a "rule" and an "order," where "rules have legal consequences only for the future." The FDA's updated REMS for mifepristone has a "future effect" because it does not hold any ruling or determination over past distribution and prescription of mifepristone but rather is concerned with future distribution and prescription of this drug.

Implements or Prescribes Law or Policy:

Third, a rule under the CRA must be "designed to implement, interpret, or prescribe law or policy." Courts have held that agency budgets and purely "educational" agency documents or those that "reprint" or "restate" existing law are not rules.[5] The FDA's updated REMS is not purely educational, and it seeks to "implement, interpret, or prescribe law or policy." It reinterprets federal law prohibiting the United States Postal Service and private carriers from mailing abortion-inducing drugs (18 U.S.C. §§ 1461–1462), suspends the previous in-person

[2] See 5 U.S.C. § 551(4)
[3] https://www.gao.gov/assets/b-323772.pdf
[4] Indep. Equip. Dealers Ass'n v. EPA, 372 F.3d 420, 428 (D. C. Cir. 2004)
[5] Am. Trucking Ass'n v. United States, 755 F.2d 1292, 1296 (7th. Cir. 1985); Golden & Zimmerman, LLC v. Domenech, 599 F.3d 426, 431 (4th Cir. 2010).

distribution requirement, and implements new policy to permit the distribution and prescription of mifepristone at traditional brick-and-mortar pharmacies and through online and mail-in service providers.

Exceptions Under CRA:

The CRA exempts from the definition of a "rule" any (1) rules of particular applicability, (2) rules relating to agency management or personnel, and (3) rules that do not substantially affect the rights or obligations of non-agency parties. The FDA's REMS modification for mifepristone is not a rule of particular applicability because it applies to all mifepristone sponsors and distributors, and any healthcare providers who prescribe this drug. The REMS modification applies to sponsors, distributors, providers, and patients, and does not relate to agency management or personnel. Finally, the REMS modification sets out new conditions on which mifepristone may be prescribed and distributed, which affects the rights and duties of patients, doctors, pharmacies, and sponsors.

Statement on Reproductiverights.gov:

Further, language posted on the HHS-administered website reproductiverights.gov in late-December 2022 seems to indicate that HHS, under the leadership of Xavier Becerra, saw the removal of the in-person distribution requirement for mifepristone as a regulation constituting a rule. On December 22, 2022, we found the following language posted on the home page of reproductiverights.gov:

> "Federal regulation permits medication abortion to be dispensed by telehealth and sent by mail via certified prescribers and pharmacies, in addition to in-person dispensing in clinics, medical offices, and hospitals."[6]

The following day, on December 23, this language was removed, and is still not listed on the website. The use of the term "regulation" indicates the administration viewed the removal of the in-person distribution requirement for mifepristone as a generally applicable rule that interprets or implements policy or prescribed law. The suspicious removal of this language just ten days before the FDA released a REMS modification for mifepristone effectively reshaping the federal government's policy on the distribution of abortion-inducing drugs only supports this interpretation.

[6] https://web.archive.org/web/20221222163316/https:/reproductiverights.gov/

Your Right to Access Abortion Services

Following the Supreme Court's decision to overturn Roe v. Wade, access to abortion will depend on the state you live in even more than before.

- Medication abortion has been approved by the FDA since 2000 as a safe and effective option. Federal regulation permits medication abortion to be dispensed by telehealth and sent by mail via certified prescribers and pharmacies, in addition to in-person dispensing in clinics, medical offices, and hospitals.
- Under federal law, federal Medicaid funds can cover abortion services only in the circumstances of rape, incest or if the patient's life is in danger. However, there are over a dozen states that provide coverage for abortion services using state Medicaid funds. To find out more on state funding of abortions under Medicaid visit this website.
- If you need help paying for an abortion, abortion funds may be able to provide financial assistance. Information about abortion funds and resources to help are available at AbortionFinder.org
- If you need information on your state's laws or legal help, you may consider this website: AbortionFinder.org

After conducting a careful review of the FDA's actions and the precedent set forth by previous GAO reviews, we conclude that the FDA's REMS modification, which removed the in-person distribution requirement for mifepristone, constitutes a "rule" under the CRA. This rule is generally applicable, has exclusively a future effect, is designed to reinterpret current federal law on the mailing of abortion-inducing drugs, and implements new policy permitting the distribution of mifepristone at traditional brick-and-mortar pharmacies and through mail-in providers. We urge you to take this evidence into consideration as you conduct a review of whether the January 2023 REMS modification for mifepristone constitutes a "rule" for purposes of the CRA. The FDA did not submit this policy to Congress and we believe it is imperative that all agency rules remain subject to the full spectrum of congressional oversight afforded by law. Please respond with your determination within 30 days.

Thank you for your attention to this important matter.

Sincerely,

Marco Rubio
U.S. Senator

Andrew S. Clyde
Member of Congress

Cindy Hyde-Smith
U.S. Senator

Rick Scott
U.S. Senator

James Lankford
U.S. Senator

Mike Braun
U.S. Senator

Lance Gooden
Member of Congress

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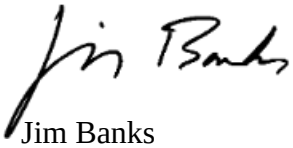

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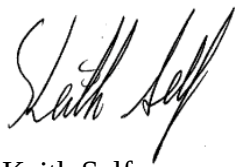

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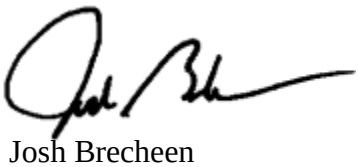

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