

United States Senate

WASHINGTON, DC 20510

March 25, 2026

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

Evan Masingill
Chief Executive Officer
GenBioPro, Inc.
P.O. Box 32011
Las Vegas, NV 89103

Mr. Masingill:

We write with deep concern regarding GenBioPro, Inc.'s (GenBioPro) business practices and the adequacy of its oversight and implementation of the Mifepristone Risk Evaluation and Mitigation Strategy (REMS) Program required for its product's marketing.

GenBioPro is one of three sponsors approved by the U.S. Food and Drug Administration (FDA) to market the chemical abortion drug, mifepristone, for use in a regimen with misoprostol to terminate a pregnancy through 10 weeks gestation.¹ GenBioPro was approved to sell a generic version of mifepristone in 2019, and has marketed the drug in the U.S. since that time.² According to GenBioPro, its generic version of mifepristone accounts for two-thirds of the market.³ Mifepristone is one of two products sold by GenBioPro (along with generic misoprostol) and the company has stated that "its mifepristone business constitutes approximately 95% of its revenue."⁴ GenBioPro has also stated that it would face "catastrophic financial and operational distress [that] puts in question [its] continued viability" if it was prevented from selling the chemical abortion drugs.⁵

GenBioPro's chemical abortion drug, mifepristone, is subject to a shared system REMS program, along with the brand version Mifeprex and the other generic version, "to mitigate the risk of serious complications associated with mifepristone."⁶ The Mifepristone REMS Program has undergone significant changes since it was initially established in 2011, including allowing the drug to be prescribed through 10 weeks gestation (up from seven weeks initially), removing the requirement that prescribers report non-fatal adverse events to the drug manufacturer, and perhaps most

¹ Mifepristone, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemisDetails.page&REMS=390#tabs-3> (last visited Mar. 25, 2026).

² Letter from Ctr. for Drug Evaluation & Rsch. to GenBioPro, Inc. (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

³ Reply In Support of Application for Stay, *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, at 24 (2024).

⁴ Brief for *Amicus Curiae* GenBioPro, Inc. Supporting Petitioners, *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, at 1 (2024).

⁵ *Id.* at 19.

⁶ Mifepristone, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemisDetails.page&REMS=390#tabs-3> (last visited Mar. 25, 2026).

concerningly, removing the requirement that the drug be dispensed through an in-person visit with a provider.⁷ While we have long urged FDA to reinstate these needed REMS requirements that were recklessly removed by Democrat administrations,⁸ we are concerned that GenBioPro is not meeting its legal responsibilities to ensure compliance with even the few remaining REMS requirements.

Under the current Mifepristone REMS Program approved in September 2025, the drug may only be dispensed under the supervision of certified prescribers or by certified pharmacies, on prescriptions issued by certified prescribers, and patients must be informed about the risk of serious complications associated with the drug.⁹ In order to become a certified prescriber, a health care provider must, among other requirements, be qualified to (1) assess the duration of pregnancy accurately, (2) diagnose ectopic pregnancies, (3) provide surgical intervention in cases of incomplete abortion or severe bleeding, or have plans to provide such care through others, and (4) assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.¹⁰ Certified prescribers must also follow the guidelines for use of mifepristone. These guidelines include ensuring (1) the Patient Agreement Form is reviewed with and signed by the patient, (2) the risks of the mifepristone treatment regimen are fully explained to the patient, (3) the patient is provided with a copy of the Patient Agreement Form and Medication Guide, and (4) the signed Patient Agreement Form is placed in the patient's medical record.¹¹

GenBioPro, for its part, must ensure that all prescribers of mifepristone are specially certified in accordance with these requirements and must de-certify prescribers who do not maintain compliance with certification requirements.¹² GenBioPro must also monitor its distribution data to ensure compliance with the Mifepristone REMS Program, ensure that adequate records are maintained to demonstrate that the REMS requirements have been met, and annually audit new pharmacies and distributors.¹³ Finally, GenBioPro must report to FDA any deaths associated with mifepristone, whether or not considered drug-related, within 15 days of receiving the information.¹⁴

We are concerned that GenBioPro is not ensuring the REMS requirements are met, especially as it pertains to the online prescribing of mifepristone. On its website, GenBioPro states that women

⁷ See New Drug Application (NDA): 020687, *Drugs@FDA: FDA-Approved Drugs*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020687> (last visited Mar. 25, 2026) (providing the documents describing the various REMS changes).

⁸ See, e.g., Letter from Sen. Lindsey O. Graham & Sen. Bill Cassidy, M.D. et al., to Robert F. Kennedy, Jr., Sec'y, U.S. Dep't of Health & Hum. Servs. & Martin A. Makary, Comm'r, U.S. Food & Drug Admin. (Oct. 9, 2025), https://www.lgraham.senate.gov/public/_cache/files/db3c8d4f-f16b-4393-9005-13461dcde9c2/letter-from-senator-graham-et-al-to-hhs-and-fda-re-mifepristone.pdf.

⁹ *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200MG*, U.S. FOOD & DRUG ADMIN. 1 (Sept. 2025), https://www.accessdata.fda.gov/drugsatfda_docs/remts/Mifepristone_2025_09_30_REMS_Full.pdf.

¹⁰ *Id.*

¹¹ *Id.* at 1–2.

¹² *Id.* at 2.

¹³ *Id.* at 5.

¹⁴ *Id.*

should not take mifepristone if they have a pregnancy that is more than 10 weeks gestation.¹⁵ However, under the heading “How Do I Get a Medical Abortion?” GenBioPro directs consumers six third-party websites to locate a mifepristone provider, each of which include sellers that openly advertise selling the drug to women beyond the 10-week limit.¹⁶ It seems unlikely that GenBioPro is effectively enforcing compliance with the Mifepristone REMS Program when it appears to actively facilitate access to its drug outside of the window for which it is approved by FDA.

Furthermore, because many online clinics allow individuals, including men, to order the drugs anonymously, it is unclear how prescribers can ensure that the Patient Agreement Form is reviewed with the patient, signed by the patient, and placed in the patient’s medical record. It is also unclear how an online prescriber could adequately explain the risks of the mifepristone treatment regimen to the patient in accordance with the existing REMS. In terms of patient safety, many online sellers of mifepristone appear to automatically prescribe the drug after an individual merely fills out a cursory intake form, raising questions about whether prescribers could accurately assess gestational age or be able to diagnose an ectopic pregnancy—failures that could lead to serious adverse events for the patient.¹⁷ Additionally, it is unclear how online prescribers can satisfy the REMS requirement to provide surgical intervention themselves, or arrange such care through others, if the individual ordering the drug is anonymous and may be located many states away from the prescribing clinician. Finally, patient anonymity and the lack of an adequate doctor-patient relationship raise concerns about whether patient deaths associated with mifepristone obtained through online prescribers could be reported to GenBioPro, which would again be in violation of the REMS requirements. Notably, many online prescribers advise patients that they do not have to tell a doctor that they took the chemical abortion drugs if they later must seek care for serious adverse events.¹⁸

There is substantial evidence that women are being harmed not only by serious adverse events associated with your company’s drug,¹⁹ but also by coercion and other risks resulting from inadequate implementation of REMS safeguards intended to protect patients.²⁰ It is also clear that

¹⁵ *How Do I Get a Medical Abortion?*, GENBIOPRO, <https://genbiopro.com/products/mifepristone/patient/about-medical-abortion/> (last visited Mar. 25, 2026).

¹⁶ *See id.* (These resources include: Planned Parenthood health centers, National Abortion Federation (NAF) member clinics, Abortion Care Network (ACN) member clinics, Abortion Clinics Online (ACOL) listings, I Need an A, and Abortion Finder—all of which list providers who will prescribe mifepristone beyond the 10-week gestational limit for which the drug is approved.).

¹⁷ *See, e.g.*, Video posted by AAPLOG (@aaplog), X (Mar. 11, 2026, at 7:26 PM), (showing how there is little to no actual medical review before prescribing chemical abortion drugs on websites like Aid Access).

¹⁸ *See, e.g.*, *How to use abortion pills*, AID ACCESS, <https://aidaccess.org/en/how-to-use-abortion-pills> (last visited Mar. 25, 2026).

¹⁹ *See, e.g.*, Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, ETHICS & PUB. POL’Y CTR. (Apr. 28, 2025), <https://media.eppc.org/2025/04/25-04-The-Abortion-Pill-Harms-Women.pdf> (finding that there is a serious adverse event rate of 10.93 percent for women who take chemical abortion drugs).

²⁰ *See, e.g.*, Anna Callahan, *Abortion Drugs Fuel Abuse: The Women Poisoned Against Their Will*, SUSAN B. ANTHONY PRO-LIFE AMERICA (Feb. 26, 2026), <https://sbaproplife.org/latest-news/abortion-drugs-fuel-abuse-the-women-poisoned-against-their-will> (listing various cases where women were coerced into having a chemical abortion against their will or without their knowledge).

the removal of the requirement to report non-fatal adverse events has significantly downplayed the danger mifepristone poses to women. Further, the removal of the in-person dispensing requirement has allowed the drug to be widely prescribed with few guardrails to ensure it is being taken safely, without coercion, and with prompt care available for serious complications. GenBioPro has advocated for the erosion of these safeguards, as the company has repeatedly sought to expand access to chemical abortion and even argued for the removal of REMS requirements before its generic version of mifepristone was approved by FDA.²¹ But it is extremely concerning that GenBioPro appears to be doing little to nothing to fulfill its legal obligation to implement the few remaining safeguards to protect women from serious harm.

With chemical abortions provided by online clinics now estimated to account for 27 percent of all abortions in the U.S. (about 160,000 abortions in the first half of 2025),²² GenBioPro must immediately implement the Mifepristone REMS Program requirements and de-certify prescribers who do not comply. By willingly refusing to do so, GenBioPro is putting its profits above the health and safety of women and children.

Given these serious concerns regarding GenBioPro's compliance with its legal obligations under the Mifepristone REMS Program, we request that you answer the following questions, on a question-by-question basis, **no later than April 8, 2026**. We request that all documents, data, and any other responsive materials be unredacted, produced in electronic form, and Bates stamped.

1. Where does GenBioPro currently manufacture mifepristone? Please provide the name and address of each facility where mifepristone is currently manufactured. Please also provide the name and address of any manufacturing facility where mifepristone has been manufactured since its date of approval in 2019.
2. Please provide the dates, final classifications, and related findings of all FDA inspections of facilities manufacturing GenBioPro's generic mifepristone product since its date of approval in 2019.
3. Where does GenBioPro currently import the active pharmaceutical ingredient (API) for mifepristone? Please provide the name and address of each facility where the API for mifepristone is currently imported from. Please also provide the name and address of any facility where the API for mifepristone has been imported from since its date of approval in 2019.
4. Please produce a list of all current and former distributors GenBioPro is or was contracted with to distribute mifepristone into the U.S. since its date of approval in 2019. Please also include the dates that each contract began (and ended, if applicable).
5. Has GenBioPro engaged any third-party vendors to administer the Mifepristone REMS Program? If so, please identify any such vendors currently engaged, provide the term of

²¹ See *About GenBioPro*, GENBIOPRO, <https://genbiopro.com/about-genbiopro/> (last visited Mar. 25, 2026) (“Before coming to market, we advocated for reduced dosage requirements, an expanded treatment window, broader prescriber privileges, and fewer required patient visits.”).

²² *#WeCount report, April 2022 to June 2025*, SOC'Y OF FAM. PLAN., <https://societyfp.org/research/wecount/wecount-june-2025-data/> (last visited Mar. 25, 2026).

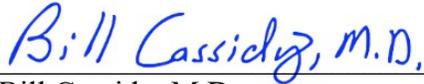
these contracts, and describe the functions each vendor performs in support of REMS administration.

6. How many individuals are currently certified to prescribe GenBioPro's mifepristone in the Mifepristone REMS Program? Please produce an Excel spreadsheet showing how many prescribers are certified in each state.
7. How many pharmacies are currently certified to dispense GenBioPro's mifepristone in the Mifepristone REMS Program? Please produce an Excel spreadsheet showing how many pharmacies are certified in each state. Please also include the name, address, and date of certification for each pharmacy.
8. Please produce a list of all audits GenBioPro has conducted on its certified pharmacies since mifepristone's date of approval in 2019. Please also provide the name and address of each pharmacy, the date of each audit, and the results of each audit.
9. Please produce a list of all audits GenBioPro has conducted on its distributors since mifepristone's date of approval in 2019. Please also provide the name and address of each distributor, the date of each audit, and the results of each audit.
10. Please produce a list of all deaths associated with mifepristone that GenBioPro has reported to FDA since mifepristone's date of approval in 2019. Please also provide the date of each death, the state each death occurred in, the date each death was reported to GenBioPro, and the date each death was reported to FDA.
11. Please produce the annual REMS assessments GenBioPro has submitted to FDA since mifepristone's date of approval in 2019.
12. Please produce all postmarketing studies on fatal and/or non-fatal adverse events that GenBioPro has conducted or is aware of since mifepristone's date of approval in 2019.
13. Please produce an Excel spreadsheet that includes the number of mifepristone drugs sold on a quarterly basis since mifepristone's date of approval in 2019. Please include in this spreadsheet a breakdown of number of mifepristone drugs sold by state.
14. Please produce an Excel spreadsheet that includes the cost, revenue, and profit from the sale of mifepristone on a quarterly basis since mifepristone's date of approval in 2019.
15. Please produce a list of all prescribers that GenBioPro has de-certified since mifepristone's date of approval in 2019. Please include the date each prescriber was certified, the date each prescriber was de-certified, and the reason each prescriber was de-certified.
16. Please produce a list of all pharmacies (including their addresses) that GenBioPro has de-certified since mifepristone's date of approval in 2019. Please include the date each pharmacy was certified, the date each pharmacy was de-certified, and the reason each pharmacy was de-certified.
17. Please explain why GenBioPro directs consumers on its website to online prescribers that advertise prescribing mifepristone after 10 weeks gestation when FDA only approves mifepristone for use within the first 10 weeks of pregnancy.
18. Please explain how GenBioPro ensures that online prescribers of mifepristone review the Patient Agreement Form with patients and fully explain the risks of the mifepristone treatment regimen.
19. Please explain how GenBioPro ensures that online prescribers of mifepristone consistently require patients to sign the Patient Agreement Form.

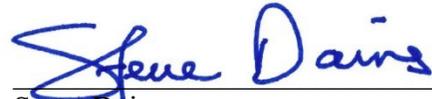
20. Please explain how GenBioPro ensures that online prescribers of mifepristone consistently put the signed Patient Agreement Form into each patient's medical record.
21. Please explain how GenBioPro ensures that online prescribers of mifepristone have the ability to assess the duration of pregnancy accurately.
22. Please explain how GenBioPro ensures that online prescribers of mifepristone have the ability to diagnose ectopic pregnancies.
23. Please explain how GenBioPro ensures that online prescribers of mifepristone have the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or make plans to provide such care through others.
24. Please explain how GenBioPro ensures that online prescribers of mifepristone assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
25. Please explain how GenBioPro ensures that all deaths associated with mifepristone are reported to it, especially for mifepristone prescribed by an online prescriber.
26. Please describe whether and how GenBioPro continually monitors non-fatal adverse events associated with mifepristone and reports them to FDA.

Thank you for your attention to this important matter and for your cooperation with our inquiry.

Sincerely,



Bill Cassidy, M.D.
Chairman
U.S. Senate Committee on Health,
Education, Labor, and Pensions



Steve Daines
United States Senator



James Lankford
United States Senator



Cindy Hyde-Smith
United States Senator



Lindsey O. Graham
United States Senator