United States Senate
WASHINGTON, DC 20510

March 25, 2026

VIA ELECTRONIC TRANSMISSION AND U.S. MAIL

Abby Long
Vice President of Marketing and Operations
Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185

Ms. Long:

We write with deep concern regarding Danco Laboratories, LLC's (Danco) 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.

Danco 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] Danco was approved to sell the brand name version of mifepristone, Mifeprex, in 2000, and has marketed the drug in the U.S. since that time.[2] Mifeprex is Danco's only product, and Danco has stated that it would have to close its business if it was prevented from selling this drug because the company would no longer generate revenue.[3]

Notably, key aspects of Danco's corporate structure and leadership are obscure despite being the sponsor of an FDA-approved drug marketed and sold to hundreds of thousands of Americans. Reporting from the *Los Angeles Times* characterizes Danco as "all but anonymous," noting that the company has fewer than 20 employees, uses a P.O. Box to avoid disclosing its headquarters' address, and is not listed on any public exchanges.[4] Danco does not make any of its sales figures public and operates largely "in obscurity."[5] The *Los Angeles Times* also notes that Danco "has had to work closely with the FDA to not disclose its address" and that "[a]ll of the documents related to the [2000] approval [of Mifeprex] have been redacted so . . . manufacturer locations don't become public."[6] Danco told the *Los Angeles Times* that it "wouldn't share the name of the company's current chief executive, board members or investors."[7] Its drug label states that

[1] Mifepristone, *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390#tabs-3 (last visited Mar. 25, 2026).
[2] Letter from Ctr. for Drug Evaluation & Rsch. to Sandra P. Arnold (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.
[3] Fiona Rutherford, *Why you've never heard of the company behind the abortion pill*, LOS ANGELES TIMES (Apr. 13, 2023), https://www.latimes.com/business/story/2023-04-13/why-youve-never-heard-of-the-company-behind-the-abortion-pill.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.*

Mifeprex is manufactured in Spain but provides no other details.[8] This level of secrecy is unusual given that most pharmaceutical companies are far more transparent, including disclosing where their drugs are manufactured, their sales numbers, their leadership teams, and other basic information about their business. *The Washington Post* once characterized Danco as "[s]ecretive and obscure" and "one of the most enigmatic companies in the pharmaceutical industry."[9]

Some of Danco's financial information became public during protracted litigation in 2022 involving private equity-backed investors seeking control of the company. In a deposition in that case, Danco's Chief Financial Officer, Angelia Van Vranken, stated that Mifeprex had "been extremely profitable," that Danco's investors had a 452 percent return on investment over 23 years, and that one of Danco's top investors and executive chair of the board of directors, W. Bradley Daniel, had earned over $10.3 million in proxy fees alone.[10] It is concerning that it took a court battle amongst private equity investors to reveal some of Danco's substantial profits.

Danco's chemical abortion drug, Mifeprex, is subject to a shared system REMS program, along with the two approved generic versions, "to mitigate the risk of serious complications associated with mifepristone."[11] 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 concerningly, removing the requirement that the drug be dispensed through an in-person visit with a provider.[12] While we have long urged FDA to reinstate these needed REMS requirements that were recklessly removed by Democrat administrations,[13] we are concerned that Danco 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

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[8] *Label: Mifeprex-mifepristone tablet*, DAILYMED (Jan. 7, 2026), https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=61626f72-7469-6f6e-4953-6d7572646572&audience=consumer.

[9] Robert O'Harrow Jr., *Drug's U.S. Marketer Remains Elusive*, WASH. POST (Oct. 11, 2000), https://www.washingtonpost.com/archive/politics/2000/10/12/drugs-us-marketer-remains-elusive/8b7b732b-0f23-4c96-9051-714cd3d9f6f8/.

[10] Hannah Levintova, *The Abortion Pill's Secret Money Men*, MOTHER JONES (April 2023), https://www.motherjones.com/politics/2023/01/abortion-pill-mifepristone-mifeprex-roe-dobbs-private-equity/.

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

[12] *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).

[13] *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.

complications associated with the drug.[14] 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.[15] 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.[16]

Danco, for its part, must ensure that all prescribers of Mifeprex are specially certified in accordance with these requirements and must de-certify prescribers who do not maintain compliance with certification requirements.[17] Danco 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.[18] Finally, Danco must report to FDA any deaths associated with Mifeprex, whether or not considered drug-related, within 15 days of receiving the information.[19]

We are concerned that Danco is not ensuring the REMS requirements are met, especially as it pertains to the online prescribing of Mifeprex. On its website, Danco states that women should not take Mifeprex if they have a pregnancy that is more than 10 weeks gestation.[20] However, under the heading "How Do I Get Mifeprex?" Danco directs consumers to six third-party websites to locate a Mifeprex provider, each of which include sellers that openly advertise selling the drug to women beyond the 10-week limit.[21] It seems unlikely that Danco 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 these 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

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[14] *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/rems/Mifepristone_2025_09_30_REMS_Full.pdf.
[15] *Id.*
[16] *Id.* at 1–2.
[17] *Id.* at 2.
[18] *Id.* at 5.
[19] *Id.*
[20] *How Do I Get Mifeprex?*, DANCO, https://www.earlyoptionpill.com/how-do-i-get-mifeprex/ (last visited Mar. 25, 2026).
[21] *See id.* (These resources include: Abortion.com, Abortion Clinics Online, Abortion Care Network, Abortion Finder, I Need An A, and Plan C—all of which list providers who will prescribe Mifeprex beyond the 10-week gestational limit for which the drug is approved.).

to the patient in accordance with the existing REMS. In terms of patient safety, many online sellers of Mifeprex appear to automatically prescribe the drug after an individual 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.[22] 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 prescriber. Finally, patient anonymity and the lack of an adequate doctor-patient relationship raise concerns about whether patient deaths associated with Mifeprex obtained through online prescribers could be reported to Danco, 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.[23]

There is substantial evidence that women are being harmed not only by serious adverse events associated with your company's drug,[24] but also by coercion and other risks resulting from inadequate implementation of REMS safeguards intended to protect patients.[25] It is also clear that the removal of the requirement to report non-fatal adverse events has significantly downplayed the danger Mifeprex 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. Danco has advocated for the erosion of these safeguards, as the company repeatedly sought to expand access to its drug and eliminate the REMS for Mifeprex altogether.[26] But it is extremely concerning that Danco 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),[27] Danco must immediately implement the Mifepristone REMS Program requirements and de-certify prescribers who do not

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[22] *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).
[23] *See, e.g.*, *How to use abortion pills*, AID ACCESS, https://aidaccess.org/en/how-to-use-abortion-pills (last visited Mar. 25, 2026).
[24] *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).
[25] *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://sbaprolife.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).
[26] *See* Carrie N. Baker, *Abortion Pills: US History and Politics* 80 (2024) (Dr. Mitchell Creinin, a medical consultant for Danco, stated, "Danco fought hard to remove the REMS multiple times, but the FDA made it really clear throughout the whole process the REMS was not going away," and "Danco fought tooth and nail to get rid of the REMS.").
[27] *#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).

comply. By willingly refusing to do so, Danco is putting its profits above the health and safety of women and children.

Given these serious concerns regarding Danco'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 Danco currently manufacture Mifeprex? Please provide the name and address of each facility where Mifeprex is currently manufactured. Please also provide the name and address of any manufacturing facility where Mifeprex has been manufactured since its date of approval in 2000.
2. Please provide the dates, final classifications, and related findings of all FDA inspections of Mifeprex's manufacturing facilities since its date of approval in 2000.
3. Where does Danco currently import the active pharmaceutical ingredient (API) for Mifeprex? Please provide the name and address of each facility where the API for Mifeprex is currently imported from. Please also provide the name and address of any facility where the API for Mifeprex has been imported from since its date of approval in 2000.
4. Please produce a list of all current and former distributors Danco is or was contracted with to distribute Mifeprex into the U.S. since its date of approval in 2000. Please also include the dates that each contract began (and ended, if applicable).
5. Has Danco engaged any third-party vendors to administer the Mifepristone REMS Program? If so, please identify any such vendors currently engaged, provide the term of these contracts, and describe the functions each vendor performs in support of REMS administration.
6. How many individuals are currently certified to prescribe Mifeprex 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 Mifeprex 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 Danco has conducted on its certified pharmacies since Mifeprex's date of approval in 2000. 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 Danco has conducted on its distributors since Mifeprex's date of approval in 2000. 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 Mifeprex that Danco has reported to FDA since Mifeprex's date of approval in 2000. Please also provide the date of each death, the state each death occurred in, the date each death was reported to Danco, and the date each death was reported to FDA.

11. Please provide a list of all non-fatal adverse events associated with Mifeprex that Danco reported to FDA from Mifeprex's date of approval in 2000 through 2016 when the requirement to report non-fatal adverse events was removed. Please also provide the date of each adverse event, the state each adverse event occurred in, the date the adverse event was reported to Danco, and the date each adverse event was reported to FDA.
12. Please produce the annual REMS assessments Danco has submitted to FDA since Mifeprex's date of approval in 2000.
13. Please produce all postmarketing studies on fatal and/or non-fatal adverse events that Danco has conducted or is aware of since Mifeprex's date of approval in 2000.
14. Please produce an Excel spreadsheet that includes the number of Mifeprex drugs sold on a quarterly basis since Mifeprex's date of approval in 2000. Please include in this spreadsheet a breakdown of number of Mifeprex drugs sold by state.
15. Please produce an Excel spreadsheet that includes the cost, revenue, and profit from the sale of Mifeprex on a quarterly basis since Mifeprex's date of approval in 2000.
16. Please produce a list of all prescribers that Danco has de-certified since Mifeprex's date of approval in 2000. Please include the date each prescriber was certified, the date each prescriber was de-certified, and the reason each prescriber was de-certified.
17. Please produce a list of all pharmacies (including their addresses) that Danco has de-certified since Mifeprex's date of approval in 2000. Please include the date each pharmacy was certified, the date each pharmacy was de-certified, and the reason each pharmacy was de-certified.
18. Please explain why Danco directs consumers on its website to online prescribers that advertise prescribing Mifeprex after 10 weeks gestation when FDA only approves Mifeprex for use within the first 10 weeks of pregnancy.
19. Please explain how Danco ensures that online prescribers of Mifeprex review the Patient Agreement Form with patients and fully explain the risks of the mifepristone treatment regimen.
20. Please explain how Danco ensures that online prescribers of Mifeprex consistently require patients to sign the Patient Agreement Form.
21. Please explain how Danco ensures that online prescribers of Mifeprex consistently put the signed Patient Agreement Form into each patient's medical record.
22. Please explain how Danco ensures that online prescribers of Mifeprex have the ability to assess the duration of pregnancy accurately.
23. Please explain how Danco ensures that online prescribers of Mifeprex have the ability to diagnose ectopic pregnancies.
24. Please explain how Danco ensures that online prescribers of Mifeprex have the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or make plans to provide such care through others.
25. Please explain how Danco ensures that online prescribers of Mifeprex assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
26. Please explain how Danco ensures that all deaths associated with Mifeprex are reported to it, especially for Mifeprex prescribed by an online prescriber.

27. Please describe whether and how Danco continually monitors non-fatal adverse events associated with Mifeprex 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

CC: Angelia J. Van Vranken, Chief Financial Officer, Danco Laboratories, LLC