

United States Senate

WASHINGTON, DC 20510

Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185

February 1, 2023

To the Senior Leadership and Board of Directors of Danco Laboratories, LLC:

Following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, the reproductive rights of all Americans are under attack. Currently, access to abortion has been restricted, or will likely be restricted, in twenty-four states.¹ Not only do these laws take away the reproductive rights of women, but they also endanger the lives of people experiencing early-pregnancy miscarriage. Women in need of mifepristone for early-pregnancy miscarriages are experiencing barriers to effective and safe treatment because this drug is commonly used in medical abortions. To open up access to this treatment option, we urge you to submit a supplemental New Drug Application (sNDA) to the Food and Drug Administration (FDA) to add miscarriage management as an indication to the mifepristone label.

Following the reversal of *Roe v. Wade*, several states have restricted—and sometimes fully banned—medication abortion, which requires the use of mifepristone and misoprostol. However, these drugs are also used for miscarriage management. Because miscarriage management is not included as an indication to the mifepristone label, health care providers are left without clear legal guidance. As a result, patients experiencing early pregnancy loss who need mifepristone cannot easily access this critical treatment, placing them at risk of serious injury and death.

Updating mifepristone's label will make this drug accessible for miscarriage management without fear of criminal action against health care providers. Currently, some health care providers have instead prescribed a misoprostol-only regimen for miscarriage management to avoid the issue entirely. This treatment option requires patients take high doses of misoprostol to ensure effectiveness while creating serious side effects like severe cramping as a result—making it a longer, more dangerous, and psychologically taxing process. As a holder of the approved mifepristone NDA, it is your company's authority—and responsibility—to submit an sNDA to the FDA to formally consider adding miscarriage management as an indication to the mifepristone label. The FDA has stated that it would review such an application and meet to discuss the potential submission.²

¹ Elizabeth Nash & Isabel Guarnieri, *Six Months Post-Roe, 24 US States Have Banned Abortion or are Likely to Do So: A Roundup*, GUTTMACHER INST. (Jan. 2023), <https://www.guttmacher.org/2023/01/six-months-post-roe-24-us-states-have-banned-abortion-or-are-likely-do-so-roundup>.

² Letter from Patrizia A. Cavazzoni, Dir., Ctr. for Drug Evaluation & Research, Food & Drug Admin., to Maureen G. Phipps, Am. Coll. of Obstetricians and Gynecologists (Jan. 3. 2023), <https://www.regulations.gov/document/FDA-2022-P-2425-0003>.

Studies estimate that as many as 26% of all pregnancies end in miscarriage, with 80% of miscarriages occurring in the first trimester.³ Miscarriage is also more common among pregnant Black people, people who earn low-incomes, and people who are exposed to environmental pollutants.⁴ Over a million women in America experience a miscarriage every year.⁵ People experiencing miscarriage deserve access to safe and effective treatment, without added and unnecessary pain.

Despite its well-recognized safety and efficacy, physicians are not prescribing mifepristone in cases where it would be the best treatment option for people experiencing miscarriage.⁶ We urge you to take action and submit an sNDA to add miscarriage management to the mifepristone label, ensuring that patients experience miscarriage will not be denied access to appropriate early pregnancy loss medication.

Sincerely,



Mazie K. Hirono
United States Senator



Margaret Wood Hassan
United States Senator



Elizabeth Warren
United States Senator



Richard Blumenthal
United States Senator

³ Carla Dugas & Valori H. Slane, *Miscarriage*, NAT'L LIBR. MED. (June 27, 2022), <https://www.ncbi.nlm.nih.gov/books/NBK532992/>.

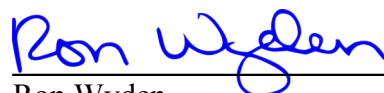
⁴ Siobhan Quenby et al., *Miscarriage Matters; The Epidemiological, Physical, Psychological, and Economic Costs of Early Pregnancy Loss*, LANCET (May 1, 2021), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00682-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00682-6/fulltext).

⁵ Courtney Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, NEW ENG. J. MED. (June 7, 2018), <https://www.nejm.org/doi/full/10.1056/NEJMoa1715726>.

⁶ Pam Belluck, *They had Miscarriages, and New Abortion Laws Obstruction Treatment*, N.Y. TIMES (July 17, 2022), <https://www.nytimes.com/2022/07/17/health/abortion-miscarriage-treatment.html>.



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