May 9, 2025

VIA: Certified Mail

RE: New Study Reveals Much Greater Rate of Harms to Women in Chemical Abortions

Dear Pharmacy CEOs:

We want to bring to your immediate attention a new study issued on April 28, 2025, by the Ethics and Public Policy Center (attached) that reveals alarming new data regarding the serious harms to women caused by the chemical abortion pill mifepristone. This compelling new data suggests that **pharmacies that distribute this dangerous drug are putting American women and girls at risk of emergency complications.**

We are alerting you of these significant findings to strongly urge you to take proactive steps to mitigate further harm to women. The safest course of action is to cease dispensing mifepristone until the FDA can conduct a further review as requested in the recent Ethics and Public Policy Center study (the "EPPC study" or "study"). At a minimum, your pharmacists should provide patients with adequate warnings of the true risks of mifepristone abortions.

Pharmacies that continue to provide misleading data while having actual knowledge of the harm of mifepristone could run afoul of common law and state statutory duties.

The EPPC study has shown that mifepristone abortions result in serious adverse events for more than 1 in 10 women—22 times the rate that currently appears on the drug's FDA-approved label.[1]

Furthermore, the FDA's removal between 2016 and 2023 of critical safeguards for risks the FDA previously identified in its 2000 mifepristone approval puts patients in serious jeopardy. Questions have arisen about whether a desire to profit from mifepristone drove the removal of safeguards, as mifepristone abortions have increased to constitute two-thirds of all abortions. Both federal and state enforcement agencies have acted upon previous failures by the FDA *and by pharmacies* in dispensing drugs causing widespread patient harm, as demonstrated by the opioid litigation settlements that cost pharmacies billions of dollars.

[1] https://eppc.org/stop-harming-women/.

The EPPC study—which is markedly superior to studies relied on by the FDA—found that 10.93 percent of women experienced sepsis, infection, hemorrhaging, or another serious adverse event within 45 days of being prescribed mifepristone, yet the manufacturer only reports a serious adverse event rate of "less than 0.5 percent" of these same serious adverse events in clinical trials on mifepristone's FDA-approved label.[2]

The EPPC study is superior to the studies relied on by the manufacturer and the FDA in four main respects:

First, it is substantially larger. The EPPC study examined data from an all-payer insurance claims database for 865,727 women prescribed mifepristone from 2017 to 2023—a data set with *28 times* the collective number of participants for all clinical trials cited by the FDA.[3]

Second, the EPPC study broadly represents women prescribed mifepristone abortion in the US, as opposed to a "prescreened group of generally healthy women recruited into various clinical trials conducted at different times around the world."[4]

Third, the study is more recent (with all data from 2017–2023) than the studies relied on by the FDA (all of which are over a decade old).

Fourth, the study represents the quality of real-world, pre- and post-abortion experiences, not the controlled regimen of care typically provided in clinical trials.[5] In fact, it appears that certain clinical trials the FDA relied on to eliminate key patient protections in 2016 *actually provided some of those protections to the participants of the trials*.[6] The women represented by the EPPC study—like virtually all women prescribed mifepristone today in the US—did not receive these key safeguards.

Continuing to dispense mifepristone for abortions may lead to liability for both the pharmacy and your pharmacists. Courts have found that a pharmacist has a common law duty to warn the patient or her prescribing doctor where he or she possesses specific knowledge regarding danger to a particular customer.[7] Your pharmacy is now aware that the most credible data shows one in ten women experiences a serious adverse event from mifepristone—information that doctors and patients may not yet have. Your pharmacy therefore has actual knowledge regarding a significant danger specific to every woman who receives a prescription

---

[2] https://eppc.org/stop-harming-women/ at 1, 4 (citing https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf).
[3] https://eppc.org/stop-harming-women/ at 1 (noting that the manufacturer of mifepristone and the FDA relied on 10 clinical trials with a total of 30,966 participants).
[4] https://eppc.org/stop-harming-women/ at 2.
[5] https://eppc.org/stop-harming-women/ at 2.
[6] Joint App. at JA548–JA562, *Food & Drug Admin. v. Alliance for Hippocratic Medicine* (U.S. 2024), *available at* https://www.supremecourt.gov/DocketPDF/23/23-235/298587/20240123210020119_FDA%20v.%20Alliance%20-%20Joint%20Appendix%20Volume%202%20-%20Final.pdf.
[7] *Correa v. Schoeck*, 479 Mass. 686, 695 (Mass. 2018) (citing *Cottam v. CVS Pharmacy*, 436 Mass. 316, 322–23 (Mass. 2002)); *see also Happel v. Wal-Mart Stores*, 199 Ill.2d 179, 186 (Ill. 2002) (finding a duty to warn "where there is unequal knowledge, actual or constructive [of a dangerous condition], and the defendant[,] possessed of such knowledge, knows or should know that harm might or could occur if no warning is given") (brackets in original).

for mifepristone and likely has a duty to warn the patient or her physician of these risks.[8] Pharmacies aware of the true risks of mifepristone abortions may also run afoul of state pharmacy statutes if they do not counsel patients about the risk of adverse effects. Forty-eight states require pharmacists to counsel or offer to counsel patients when filling a prescription, most of which define counseling to include informing patients about their medications "to prevent medical errors and harm."[9] In many states, the pharmacist is required to cover matters that, *in the exercise of the pharmacist's professional judgment*, he or she deems appropriate or significant, including the risk of adverse effects.[10] It would not be a reasonable exercise of professional judgment for a pharmacist to fail to counsel a patient that she has a one-in-ten risk of suffering a serious adverse effect from a mifepristone abortion.

Since 2016, the FDA has increasingly eliminated the safety protections it originally required for mifepristone prescriptions, sacrificing women's health. The FDA's 2000 mifepristone approval memorandum acknowledged the drug's dangers, stating that "access to . . . emergency services is critical for the safe and effective use of the drug."[11] To help combat these dangers, the original FDA-approved drug label for Mifeprex (the brand name of mifepristone) instituted a number of additional critical safeguards by requiring (1) three in-person office visits; (2) a maximum gestational age of seven weeks; (3) the drugs to be prescribed only by a physician; (4) the drugs to be dispensed only in a physician's office; (5) the patient to take the drugs only in the office; (6) an in-office follow-up; (7) and reporting by physicians of adverse events.[12]

By the time the FDA implemented the current Risk Evaluation and Mitigation Strategy (REMS) in 2023, the FDA had eliminated the requirement of in-office visits; allowed mifepristone to be dispensed through the mail; increased the maximum gestational age to 10 weeks; eliminated the requirements that the drugs be prescribed only by a physician and be taken only in the doctor's office; and gutted the reporting requirement for adverse events.[13] The current protocol allows as little as one telehealth visit with any approved healthcare provider (not necessarily a physician); allows patients to self-administer drugs obtained from a mail-order pharmacy; and does not require prescribers to report adverse reactions unless they know that a patient has died.[14]

The market share of mifepristone has increased dramatically since the FDA removed key safety measures and allowed dispensing by mail, raising questions about skyrocketing profits for

---

[8] Patients and doctors are likely unaware of the magnitude of the risk due to the FDA's failure to require adequate safeguards for mifepristone.

[9] https://healthlaw.org/wp-content/uploads/2018/09/State-Pharmacy-Laws.pdf.

[10] *See, e.g.*, https://law.lis.virginia.gov/vacodefull/title54.1/chapter33/ (Virginia); https://publications.tnsosfiles.com/rules/1140/1140-03.20240314.pdf (Tennessee); https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C/Section21A#:~:text=Section%2021A.,on%20behalf%20of%20such%20patient (Massachusetts); https://www.law.cornell.edu/regulations/texas/22-Tex-Admin-Code-SS-291-33 (Texas); https://www.law.cornell.edu/regulations/california/16-CCR-1707.2#:~:text=(C)%20a%20pharmacist%20shall%20be,minimum%20of%2040%20hours%20per (California).

[11] https://wayback.archive-it.org/7993/20161024033545/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111366.pdf.

[12] https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

[13] https://eppc.org/stop-harming-women/ at 3 (see chart comparing the safeguards for mifepristone in 2000, 2016, and 2013).

[14] https://eppc.org/stop-harming-women/ at 3 (see chart comparing the safeguards for mifepristone in 2000, 2016, and 2013).

investors in Danco Labs, the company that produces Mifeprex. Mifepristone/Mifeprex abortions accounted for roughly one-third of the total number of abortions in the US in 2016 when the FDA began to relax the safety protocols, but account for roughly two-thirds of all abortions today.[15] Danco, which was the only US retailer of mifepristone until 2019, "boasts that more than 5 million U.S. women have used its abortion pill since it was approved in 2000."[16] Whereas research and development for most drugs are funded by the federal government and pharmaceutical companies, the R&D for Mifeprex—the only drug Danco makes—was funded entirely by private investors; and court filings indicate that the average return on investment for Danco investors was about ***452 percent*** over a 23-year period.[17] Even *Mother Jones* noted that Danco "investors have come to view the desperation of pregnant women as an important problem to solve—but also a golden ticket" and that profit "seems to have become a driving motivation: one where women faced with impossible circumstances are reduced to the impersonal language of customer capture."[18]

Profit was also a driving motivation in the marketing of prescription opioids. In a 1996 OxyContin launch party, then-Purdue Pharma board member Richard Sackler infamously declared that "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white . . ."[19] Fast-forward 25 years, and pharmacies were agreeing to pay billions of dollars for their role in the opioid crisis.[20] Not only have the opioids crisis and the surge in mifepristone prescriptions both raised concerns about the role of profits over patient welfare, but in both situations, the manufacturer's label failed to provide adequate safeguards against serious adverse events.[21] The heightened sensitivity toward such issues caused by the opioid crisis may result in legal liability for pharmacies for prescribing mifepristone as information about the true harms becomes more widely known.

Our research shows that your pharmacy has begun dispensing mifepristone prescriptions. In light of the serious risk of harm to women from mifepristone abortions, and particularly the women prescribed this drug by your pharmacy, the safest course of action is to immediately cease dispensing mifepristone until the FDA can conduct a further review as requested in the EPPC study. At a very minimum, your pharmacists should provide patients with adequate warnings of the true risks. Individual pharmacists who, in their professional or moral judgment, object to dispensing mifepristone should not be required to do so. With this new and reliable information, it would be unreasonable and careless of your pharmacies to rely on the outdated and incorrect drug information provided by the manufacturer.

---

[15] *See* https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020.
[16] https://eppc.org/stop-harming-women/ at 2 (citing Danco Laboratories, https://www.earlyoptionpill.com).
[17] https://www.motherjones.com/politics/2023/01/abortion-pill-mifepristone-mifeprex-roe-dobbs-private-equity/.
[18] https://www.motherjones.com/politics/2023/01/abortion-pill-mifepristone-mifeprex-roe-dobbs-private-equity/.
[19] https://finance.yahoo.com/news/opioid-crisis-purdue-sacklers-141623926.html.
[20] https://www.forbes.com/sites/brucejapsen/2022/11/01/reports-cvs-walgreens-and-walmart-agree-to-12-billion-opioid-settlement/.
[21] *See* https://journalofethics.ama-assn.org/article/how-fda-failures-contributed-opioid-crisis/2020-08 (noting that the FDA improperly approved a broad indication, rather than a narrow indication, on Purdue Pharma's label for extended-release oxycodone).

We are available to discuss this matter with your further and would be happy to meet with you to help you implement the best course of action to protect women from harm and protect the reputation of your company.

Sincerely,

Daniel Cameron
CEO, 1792 Exchange

Douglas H. Napier
Executive Chairman, 1792 Exchange

Enclosure: ***"The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event"***, April 28, 2025, Ethics and Public Policy Center
CC: Board of Directors