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Fact Sheet
Data Reveals the FDA's Removing of In-Person Dispensing Requirement Increased the Dangers of the Abortion Pill

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March 10, 2026

Data reveals that the rate of serious adverse events following a chemical abortion (mifepristone) was significantly higher after the FDA's in-person dispensing requirement was removed. That is especially true of the incidence of mifepristone being inappropriately prescribed for women with an ectopic pregnancy, a life-threatening condition that can be diagnosed by a physician only in an in-person visit.

Our database covers prescriptions of mifepristone for abortion from January 1, 2017 through December 31, 2023. The in-person dispensing requirement was in effect through more than the first half of that period, until a federal judge enjoined it on July 13, 2020. It was also briefly in effect from January 12, 2021 (when the Supreme Court stayed the federal judge's injunction) until April 12, 2021 (when the FDA announced that it was suspending the requirement during the Covid-19 pandemic). In December 2021, the FDA announced that it would revise the REMS to eliminate the in-person dispensing requirement, and the change was finalized in January 2023.

It is instructive to compare the rate of serious adverse events from January 1, 2017 through July 13, 2020 (Period 1) with the rate of serious adverse events from July 13, through December 31, 2023 (Period 2). (Period 2 includes three months in which the in-person requirement was in effect, but this inclusion operates to understate the estimated effect of removing the in-person requirement.)

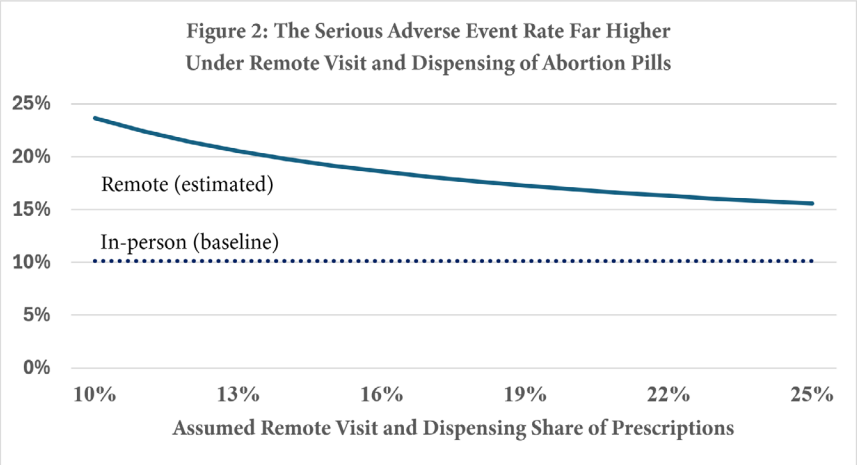
Our data shows that the rate of serious adverse events for **Period 1 was 10.15%** and that the rate of serious adverse events for **Period 2 was 11.50%**—a statistically significant difference of **1.35 percentage points**, which is itself roughly triple the "less than 0.5 percent" rate of serious adverse events reported on the drug label. Our data similarly shows that the rate of ectopic pregnancy was **0.27% in Period 1** and **0.41% (52% higher) in Period 2**.

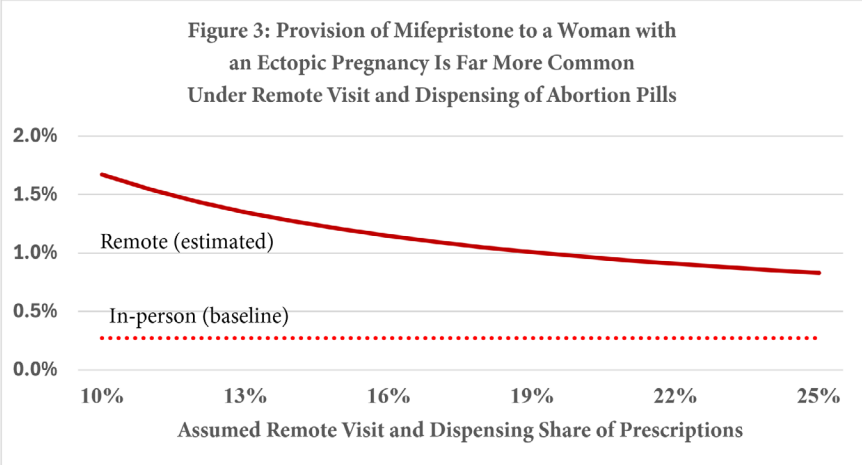
Figure 1: Abortion Pill Harms Increased When In-Person Safeguards Were Removed

	Overall	**Period 1** In-person visit and dispensing requirement fully enforced	**Period 2** In-person visit and dispensing requirement in flux, then removed	**Change**
Serious adverse event rate	10.93%	10.15%	11.50%	+1.35%
Prescription of mifepristone to a woman with an ectopic pregnancy	0.35%	0.27%	0.41%	+0.14%

The estimated strength of the relationship between remote dispensing of mifepristone and the higher rate of serious adverse events depends on the percentage of mifepristone prescriptions in Period 2 that were dispensed

remotely. We do not have firm data on that percentage. Data from pro-abortion researchers indicates that the share of virtual abortion clinics rose from 0% in 2020 to 4% in 2021 to 9% in 2022, the remote dispensing share of abortions rose from 5% in the second quarter of 2022 to 19% by the fourth quarter of 2023, and chemical abortion accounted for 63% of all abortions in 2023. Putting this information together implies that the remote dispensing share of mifepristone abortions reached roughly 30% by the last quarter of 2023 but was likely substantially lower in earlier years. We will consider a range of possibilities in two illustrative scenarios:





If remote dispensing of mifepristone accounted for 10% of all prescriptions in Period 2 (which is a reasonable but rough estimate for the entire period, given the information presented above on the increase in remote dispensing from 0% to 30% market share over 3 years), this would imply a rate of serious adverse events of **23.65% for remote dispensing—13.50 percentage points higher** than for in-person dispensing. A serious adverse event would be 2.33 times as likely under remote dispensing as under in-person dispensing, and more than 47 times the "less than 0.5 percent" rate of serious adverse events reported on the drug label. Under this 10% scenario, the provision of mifepristone to a woman with an ectopic pregnancy would be **more than six times as likely** with remote dispensing as with in-person dispensing.

If remote dispensing of mifepristone accounted for 25% of all prescriptions in Period 2 (which is near the upper end of plausible estimates), this would imply a rate of serious adverse events of 15.55% for remote dispensing—5.40 percentage points higher than for in-person dispensing. A serious adverse event would be 1.53 times as likely under remote dispensing as under in-person dispensing, and more than 31 times the "less than 0.5 percent" rate of serious adverse events reported on the drug label. Under this 25% scenario, the provision of mifepristone to a woman with an ectopic pregnancy would be more than three times as likely with remote dispensing as with in-person dispensing.

(These calculations assume that the serious adverse event rate for in-person dispensing in Period 2 remained at the 10.15% average level observed in Period 1. Our data indicates that the rate was between 9.6% and 11.0% on a rolling four-quarter basis during Period 1. Comparable figures for Period 2 ranged between 11.2% and 12.2%, underscoring that the serious adverse event rate increased under remote dispensing.)