Photo: hapabapa/Getty Images

Oct 31, 2025, 4:00 PM ET

Federal judge claims FDA's abortion pill safety regulations are 'illegal'

Abortion Pill · By Carole Novielli

A federal judge in Hawaii has ruled that a 2023 decision by the Food and Drug Administration (FDA) to keep the abortion drug mifepristone under a REMS safety system (a "drug safety program"

drug mifepristone under a REMS safety system (a "drug safety program" the FDA can require for certain medications that come "with serious safety concerns") was "illegal" and has ordered the FDA "to reconsider the mifepristone REMS in accordance with this order and the law."

Pro-life groups say the decision "disregards reality" and could put women at increasingly greater risk of harm — not to mention preborn children.

Key Takeaways:

- A federal judge has ruled that the FDA's 2023 safety regulations on the abortion pill (mifepristone) are "illegal" because the agency failed to consider information and statements submitted by pro-abortion medical groups and researchers a number of years ago.
- The 2023 regulations were put in place by the Biden administration; while the safety regulations on the drug remained in place, the drug was allowed to be dispensed by pharmacies.
- Though the restrictions currently remain in place, the judge has instructed "the FDA to consider relevant evidence the agency allegedly disregarded."
- Newer analyses and research, however, have come to light, showing that the real-world adverse events rate for mifepristone is immensely higher than the rate listed on the FDA label.
- Additionally, complications and adverse events have been intentionally buried by both the abortion industry and its political allies for decades; this has skewed the safety data for the drug.

- It isn't just complications that have been covered up; today, 25 years after the drug's approval in the U.S., its original reviewers remain undisclosed.
- Pro-life groups believe the ultimate goal is to push this unsafe drug to over-the-counter status, ignoring real-world harms to women and preborn children.

The Lawsuit:

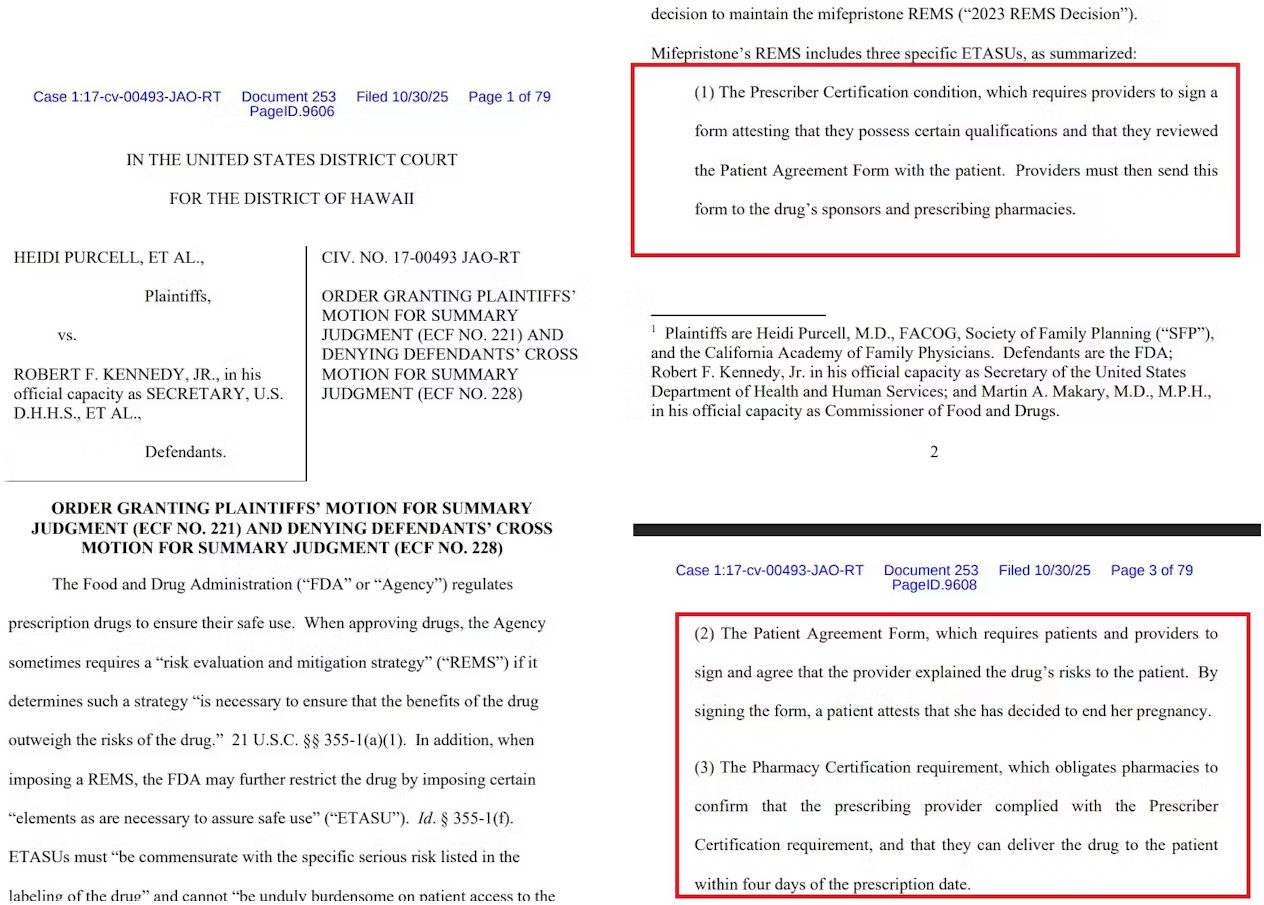
The case, *Purcell v. Kennedy* (formerly known as *Chelius v. Becerra*) dates to 2017 and "involves a challenge to the FDA's regulation of mifepristone, a drug used as part of a regimen for medication abortion." According to CivilBeat.org, "the original lead plantiff... was Kaua‘i OB-GYN Graham Chelius, who hoped to expand access to the pill for patients on the small island who often had to travel to O‘ahu for abortion care. Another Kaua‘i OB-GYN, Heidi Purcell, took over as lead plaintiff last year."

Purcell claimed "the FDA's imposition of these burdensome conditions on the prescription of mifepristone are unwarranted relative to the drug's safety," the court document stated.

Plaintiffs were originally challenging the 2016 REMS; however, when the FDA announced a review in 2021, the court closed its case "for almost two years, until the Court reopened it in February 2023 after the parties indicated that Plaintiffs intended to seek leave to amend their complaint to challenge the 2023 REMS Decision," according to the suit.

"Plaintiffs ask the Court to declare the 2023 REMS Decision unlawful under the Administrative Procedure Act ('APA'), but do not currently seek vacatur of the restrictions," the lawsuit added.

The 2023 REMS decision was made by the Biden-Harris administration's FDA, which announced it would allow retail pharmacies to dispense the drug; however, the drug remained under the REMS safety guidelines.



Case 1:17-cv-00493-JAO-RT Document 253 Filed 10/30/25 Page 1 of 79 PageID.9606

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, ET AL.,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY, U.S. D.H.H.S., ET AL.,

Defendants.

CIV. NO. 17-00493 JAO-RT

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT (ECF NO. 221) AND DENYING DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT (ECF NO. 228)

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT (ECF NO. 221) AND DENYING DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT (ECF NO. 228)

The Food and Drug Administration ("FDA" or "Agency") regulates prescription drugs to ensure their safe use. When approving drugs, the Agency sometimes requires a "risk evaluation and mitigation strategy" ("REMS") if it determines such a strategy "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. §§ 355-1(a)(1). In addition, when imposing a REMS, the FDA may further restrict the drug by imposing certain "elements as are necessary to assure safe use" ("ETASU"). *Id.* § 355-1(f). ETASUs must "be commensurate with the specific serious risk listed in the labeling of the drug" and cannot "be unduly burdensome on patient access to the

decision to maintain the mifepristone REMS ("2023 REMS Decision").

Mifepristone's REMS includes three specific ETASUs, as summarized:

(1) The Prescriber Certification condition, which requires providers to sign a form attesting that they possess certain qualifications and that they reviewed the Patient Agreement Form with the patient. Providers must then send this form to the drug's sponsors and prescribing pharmacies.

[1] Plaintiffs are Heidi Purcell, M.D., FACOG, Society of Family Planning ("SFP"), and the California Academy of Family Physicians. Defendants are the FDA; Robert F. Kennedy, Jr. in his official capacity as Secretary of the United States Department of Health and Human Services; and Martin A. Makary, M.D., M.P.H., in his official capacity as Commissioner of Food and Drugs.

2

Case 1:17-cv-00493-JAO-RT Document 253 Filed 10/30/25 Page 3 of 79 PageID.9608

(2) The Patient Agreement Form, which requires patients and providers to sign and agree that the provider explained the drug's risks to the patient. By signing the form, a patient attests that she has decided to end her pregnancy.

(3) The Pharmacy Certification requirement, which obligates pharmacies to confirm that the prescribing provider complied with the Prescriber Certification requirement, and that they can deliver the drug to the patient within four days of the prescription date.

Biased 'evidence'?

The lawuits claims:

- "[T]he FDA received letters urging the elimination of the REMS, including from researchers and providers of medical abortion."

- The providers' "evidence demonstrated that 'some the restrictions placed on mifepristone at its initial approval are no longer necessary for the safe and effective use of the drug.'"

- The FDA "arbitrarily excluded certain categories of evidence from its 2021 REMS review, including statements from 'preeminent medical societies urging elimination of the mifepristone REMS,'" along with "qualitative studies and physician narratives especially as they pertained to the burdens on patient access to the drug," and a study from Canada that allegedly "examin[ed] the effects of the country's removal of REMS-like restrictions on mifepristone."

What is **not** mentioned by the lawsuit or the Court is the fact that those "medical societies," researchers, and providers — including the American College of Obstetricians and Gynecologists (ACOG), which routinely and regularly aligns its standards to whatever the abortion industry is doing — cannot remotely be considered impartial.

Live Action News has documented that studies claiming that dispensing abortion pills is safe are often funded by financial investors in the abortion pill's manufacturers — and many of these studies fail to disclose clear conflicts of interest.

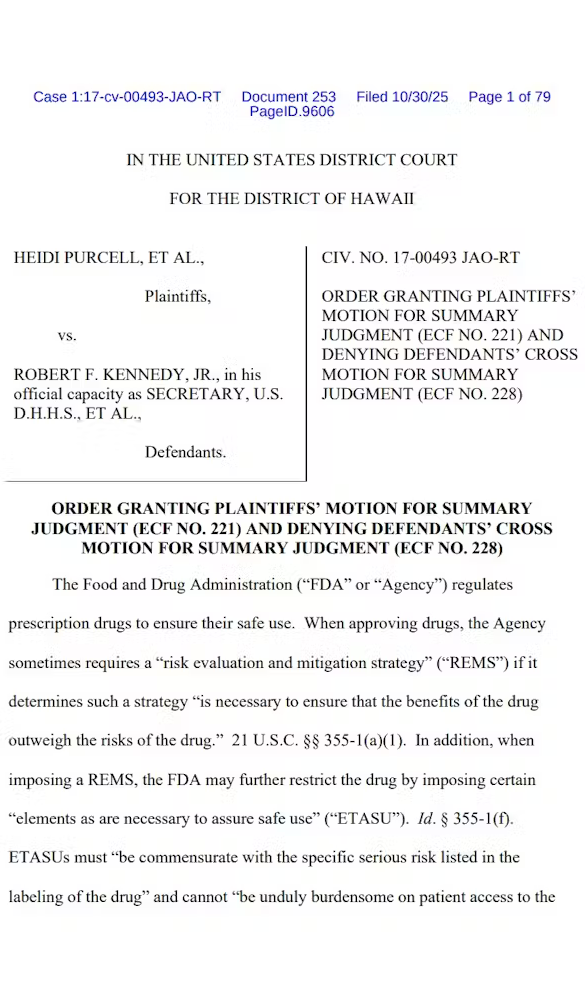
The Ruling:

The ruling — written by the Trump-nominated (2017) Judge Jill A. Otake, who was confirmed by the Senate as a U.S. District Judge for the District of Hawai'i in 2018 — states that the FDA's decision was "arbitrary and capricious" and violated the Administrative Procedures Act "by failing to provide a reasoned explanation for its restrictive

Act" by failing to provide a reasoned explanation for its restrictive treatment of the drug, which was compounded by its decision to limit the scope of information it considered when evaluating the REMS."

The judge also claimed the FDA "neglected to consider certain required statutory factors and generally failed to sufficiently explain the logic behind any reasoning it did provide."

"Otake's ruling instructs the FDA to consider relevant evidence the agency allegedly disregarded. In the meantime, the restrictions remain in place," the Associated Press reported.



Case 1:17-cv-00493-JAO-RT Document 253 Filed 10/30/25 Page 1 of 79 PageID.9606

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

HEIDI PURCELL, ET AL.,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY, U.S. D.H.H.S., ET AL.,

Defendants.

CIV. NO. 17-00493 JAO-RT

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT (ECF NO. 221) AND DENYING DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT (ECF NO. 228)

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT (ECF NO. 221) AND DENYING DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT (ECF NO. 228)

The Food and Drug Administration ("FDA" or "Agency") regulates prescription drugs to ensure their safe use. When approving drugs, the Agency sometimes requires a "risk evaluation and mitigation strategy" ("REMS") if it determines such a strategy "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. §§ 355-1(a)(1). In addition, when imposing a REMS, the FDA may further restrict the drug by imposing certain "elements as are necessary to assure safe use" ("ETASU"). *Id.* § 355-1(f). ETASUs must "be commensurate with the specific serious risk listed in the labeling of the drug" and cannot "be unduly burdensome on patient access to the

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS Plaintiffs' Motion for Summary Judgment and DENIES Defendants' Cross Motion for Summary Judgment. The Court declares the 2023 REMS Decision unlawful under the APA and remands the matter to the Agency to reconsider the mifepristone REMS in accordance with this order and the law. Because Plaintiffs did not seek vacatur of the REMS and its ETASUs in their Motion, the mifepristone REMS and ETASUs will remain in place pending the outcome of the Agency remand.

As Plaintiffs did not move for summary judgment on their constitutional claims, and because the Court denies Defendants' Cross Motion on the claims, they technically remain pending at this time. However, as they appear to be coextensive with Plaintiffs' successful APA challenge to the 2023 REMS Decision, the Court questions what becomes of the constitutional claims now. The Court thus DIRECTS the parties to file a joint status report of no more than ten pages within 14 days of this order setting forth their positions on how this case will proceed.

78

Case 1:17-cv-00493-JAO-RT Document 253 Filed 10/30/25 Page 79 of 79 PageID.9684

IT IS SO ORDERED.

DATED: Honolulu, Hawai'i, October 30, 2025.

Jill A. Otake
United States District Judge

Timeline

- 2000: abortion pill mifepristone (200mg) was approved.

- 2016: Obama FDA expanded the REMS to allow the drug to be prescribed further in the pregnancy but removed requirements that prescribers report adverse events other than deaths.

- April 2021: under guise of the COVID-19 pandemic, the Biden administration FDA temporarily enabled abortion pill distribution and expanded the REMS to limited mail-order pharmacy distribution.

- December 2021,: Biden FDA further weakened the REMS by eliminating the in-person dispensing requirement and enabling the abortion pill to be permanently shipped by mail.

- January 2023: Biden FDA announced it would allow retail pharmacies to dispense the drug, however, the drug remained under the REMS.

The Reaction:

This ruling, according to Mark Wiltz, Director of Government Affairs for Live Action, could force mifepristone out of the REMS, where it could then be sold over the counter, placing even more preborn lives (and women's lives) at risk.

Wiltz told Live Action News:

> "This ruling accelerates the abortion industry's long-term goal to push abortion out of the medical setting entirely. The industry wants abortion to happen unseen and unrecorded. Quietly, in

> private bathrooms, with women left to bear the physical and emotional consequences alone."
>
> That is not healthcare. That is outsourcing the harm. The casualties will be real women who were told this would be simple, and real children whose lives will end out of public view." Wiltz vows to "continue to speak plainly about what this drug does and to whom it harms."
>
> *— Mark Wiltz, Director of Government Affairs, Live Action*

Erik Baptist, Senior Counsel and Director of the Center for Life with Alliance Defending Freedom, told Live Action News:

> “This decision disregards reality. Mifepristone is a high-risk drug. And the FDA’s actions have created an even more unsafe environment for women. The FDA’s own label for mifepristone warns that roughly one in twenty-five women end up in the emergency room after taking abortion drugs as directed.
>
> Emerging evidence suggests the real-world number is much higher. And when the FDA authorized mail-order abortion drugs, the agency predicted that the number of women ending up seeking emergency or urgent care would likely increase.
>
> Worst of all, the FDA admitted that the studies it relied on to make this change were 'inadequate' to show that its abortion-drugs-by-mail scheme would be safe. Nor did the FDA take into account that men would be able to obtain mifepristone and coerce women into

> taking the drug, or even spike women's drinks with abortion drugs without their knowledge.
>
> Courts should be holding the FDA accountable for failing to protect women's safety—not directing the agency to remove the remaining safeguards for this high-risk drug. We expect the Trump administration to zealously appeal this dangerous decision."
>
> *— Erik Baptist, Senior Counsel, Alliance Defending Freedom*

The Unrevealed Reviewers:

The original reviewers of mifepristone are largely unknown to this day, 25 years after the approval of the drug as an abortion pill in the U.S.

Live Action News has called upon the FDA to release the full record, including any conflicts surrounding experts or reviewers who approved the drug or allowed for its expansion.

The lawsuit mentioned "reviewers" of mifepristone without naming who they were or what their associates are:

> One reviewer... [explained] that "the Patient Agreement Form, which requires a patient's signature, does not add to safe use conditions for the patient for this REMS and is a burden for patients."
>
> That reviewer continued that it was "standard of care for patients undergoing pregnancy termination to undergo extensive counseling and informed consent," such that the Patient

> Agreement Form requirement is duplicative.

At least one "expert" interviewed in 2020 by Columbia University journalists acknowledged his name as a reviewer was kept secret, admitting, “It’s definitely not standard. It’s not routine; you can look up almost every other drug that I was the primary medical officer for and my name would appear right there on the review.”

Was the data properly analyzed, or did bias in favor of abortion take precedence over actual safety? There is currently no way to know.

FDA hid abortion pill experts approval drug

Rejected Requirements:

The lawsuit alleged that bortion pill "clinicians" are "following the profession’s ethical standards and guidelines" and that the data showed “strong adherence to evidence-based guidelines.”

But in reality, Live Action News has documented how Bad Actors are flouting the REMS, even marketing abortion drugs as "missed period" pills or shipping "advance provision" ('just in case') pills in violation of the FDA's REMS safety standards, which require prescribers of the drug to be able to properly date an actual pregnancy, among other requirements.

This suggests that those who obtain the drugs **need to actually be pregnant**.

These bad actors, however, get away with it because the FDA has granted policing power *to those who profit from the drug* — namely to Danco or generic manufacturers GenBioPro (GBP) and Evita Solutions, LLC, who appear unwilling to decertify prescribers who violate safety requirements.

Skewing Safety Data:

The lawsuit stated:

> ... the FDA neglected to discuss the implications of the fact that, during the COVID-19 timeframe when the FDA declined to enforce the in-person dispensing requirements, pharmacies dispensed mifepristone without a Pharmacy Certification ETASU.
>
> The Agency itself, in eliminating the in-person dispensing requirement, noted that there did not appear to be an increase in adverse safety events during that time.

And yet, this claim is ridiculous when considering the fact that it was

And yet, this claim is ridiculous when considering the fact that it was the Biden FDA which "declined to enforce the in-person dispensing requirements," and it would be foolish to assume that no pro-abortion ideology played a role in this decision.

Secondly, the safety mechanism put in place by the FDA for reporting adverse events has been corrupted for decades. Here's how we know:

- Based on the drug's REMS, complications were to be reported by the drug's manufacturer to the FDA **after being informed by prescribers** that there had been a death or a serious complication resulting from the drug.
- Prescribers would (in theory) be notified directly by the client who took the abortion pill. That person **should have been instructed to contact the prescriber** if there were any concerns or complications.

But this is not what's been happening.

In fact, in 2016, **without explanation**, the Obama administration got rid of the safety requirement that called for reporting of **adverse events... *other than death***.

Therefore, even if someone were to experience a catastrophic injury after taking mifepristone and and survive, ***this would no longer be reported to the drug's manufacturer or to the FDA.*** As previously noted by Live Action News (emphases added):

> *An argument from silence really proves nothing at all. If there **is no data about non-fatal injuries**, then the safety of the*

> *drug remains **unproven**.*

Big Abortion has for decades sought to hide adverse events by instructing abortion clients at the point of sale to visit the emergency room if experiencing complications and to *lie* to staff, claiming their complications are a result of natural miscarriage. To seal the deal, Big Abortion has also implied that ER staff should lie about and bury abortion pill complications.

This scheme has almost certainly skewed **decades** of adverse events data on the abortion pill.

The Bottom Line:

The FDA recently announced plans to review mifepristone, following an analysis of hospital data which alleged that adverse events occur at a rate approximately ***22 times higher*** than the rate reported on mifepristone's label.

In addition, pending lawsuits allege approval of the drug was 'political,' that states have the right to regulate abortion, that mail-order expansion is harming women, and that the Federal Comstock law already prohibits the mailing of abortion drugs.

is accepted for publication, you will be notified within three weeks. Guest articles are not compensated (see our Open License Agreement). Thank you for your interest in Live Action News!

Abortion Pill · By Carole Novielli

Guest Column

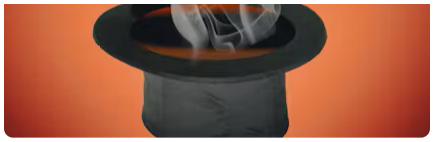
One woman's adoption story: 'You were not rejected. You were chosen.'

Oregon Right to Life · Nov 1, 2025

More In Abortion Pill

Abortion Pill

Smoke & Mirrors: Big Abortion claims 'junk



science' threatens abortion pill

Carole Novielli · Oct 29, 2025

Abortion Pill

National Survey: Americans want safety protocols on abortion pill

Nancy Flanders · Oct 28, 2025

Guest Column

Canadian woman nearly bleeds to death after taking abortion pill

Clare Marie Merkowsky · Oct 24, 2025

Abortion Pill

UK researcher: 54,000 women hospitalized in 5 years for abortion pill complications

Carole Novielli · Oct 17, 2025

Abortion Pill

Washington state says its stockpiled abortion pills will expire soon

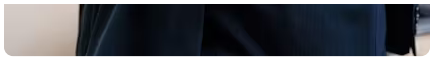
Carole Novielli · Oct 16, 2025

More From Carole Novielli

Investigative

Group behind pro-abortion 'storytelling' site also bankrolls 'fake' advocacy groups

Carole Novielli · Nov 1, 2025



Investigative

Planned Parenthood of WI uses loophole to keep federal Medicaid funds and commit abortions

Carole Novielli · Oct 31, 2025

Investigative

Pro-abortion groups admit women can experience post-abortion trauma

Carole Novielli · Oct 30, 2025

Abortion Pill

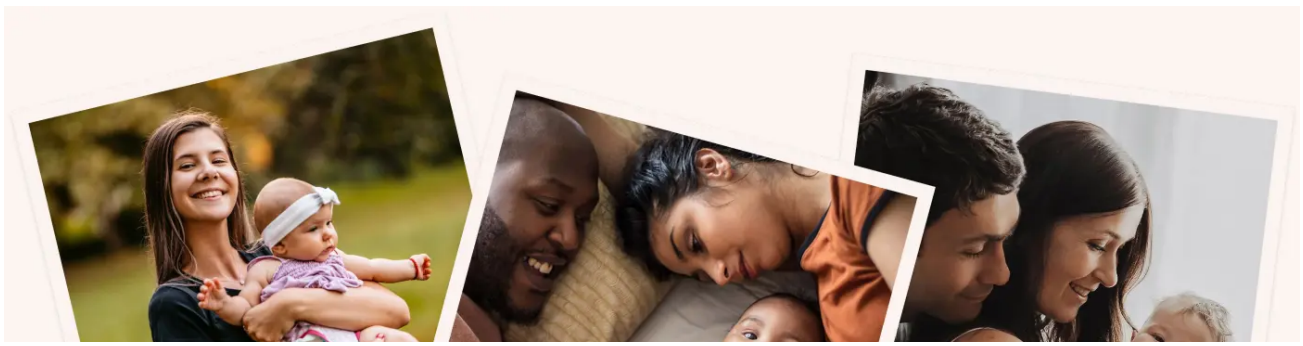
Smoke & Mirrors: Big Abortion claims 'junk science' threatens abortion pill

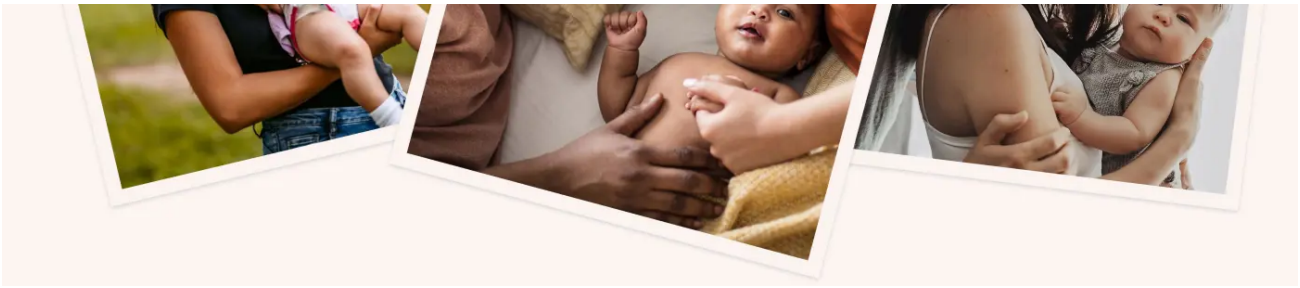
Carole Novielli · Oct 29, 2025

Investigative

DC clinic removed from National Abortion Federation website after 'legal notice'

Carole Novielli · Oct 27, 2025





Our fight is 24/7.
Never miss an update.

Get the latest news from the pro-life movement right in your inbox.

Your email address

I want to support the life-changing work of Live Action. Give Today

About

Donate

Shop

Jobs

Press Releases

Contact Us

Learn

News

Investigations

Video Series

Get To Know Us

Our Mission

Meet Lila Rose

Help & Healing

Join over 8 million pro-life followers