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REPLY TO DC

Fall 2025

The Honorable Martin A. Makary
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

CC: **The Honorable Robert F. Kennedy Jr.**
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Lee Zeldin
Administrator, U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Dear Commissioner Makary,

Along with numerous others, we are gravely concerned by the FDA's recent approval of Evita Solutions LLC's Abbreviated New Drug Application (ANDA) for generic mifepristone tablets.[1]

Though we believe it vital to underscore mifepristone's known safety concerns, particularly as the most recent, reliable evidence shows a complication rate based on real-world events that is *22 times higher* than the rate reported on the FDA-approved drug label, we more narrowly wish to draw your attention to the known and potential environmental harms associated with the abortion drug regimen. Related, while we understand the rationale that federal law (presumably the Federal Food, Drug, and Cosmetic Act[2]) may have required the FDA to approve the Evita Solutions ANDA, we respectfully propose that other portions of federal law provide the FDA with the requisite

authority to pause and revoke approval for all generic and brand-name versions of the abortion drug mifepristone.

As the following excerpt from our recent Special Report on *Abortion in Our Water* summarizes, while "[ANDAs] may rely on previous findings that 'the **reference listed drug (RLD),** is safe and effective,'"[3] the RLD in question (Mifeprex[4]) is *neither safe nor effective.*[5] Indeed, in addition to increasing instances of coerced or forced abortions,[6] serious adverse events, ranging from hemorrhage to sepsis and more,[7] affect 1 in 10 women.[8] Furthermore, in both the New Drug Application (NDA) and subsequent ANDAs (approved in 2019 and 2025) for the abortion drug regimen,[9] the FDA failed to adequately adhere to the Clean Water Act (CWA) and the National Environmental Policy Act (NEPA), both of which make clear that where a federal agency's activity or actions (e.g., approving a drug) may pollute the environment, a detailed environmental analysis is required:

- The CWA states that "each officer, agent, or employee [of a department, agency, or instrumentality of the executive, legislative, and judicial branches of the Federal Government] **in the performance of his official duties [e.g., approving drug applications, including ANDAs], shall be subject to, and comply with, all Federal, State, interstate, and local requirements, administrative authority, and process and sanctions respecting the control and abatement of water pollution.**"[10] According to the CWA, mifepristone and its active metabolites would qualify as pollutants ("chemical wastes") that are discharged into wastewater systems and likely to enter our water supply, given conventional wastewater treatment plants do not fully remove these types of contaminants.[11] Under the CWA, fetal remains generated from chemical abortions also qualify as "pollutants" that may be discharged into our water systems, threatening environmental safety as said remains can lead to clogs,[12] and consequently, could contribute to sewer system overflows.[13]
- The NEPA similarly outlines that **even major federal actions [e.g., an ANDA approval] with no "reasonably foreseeable significant effect on the quality of the human environment," or whose significance is unknown, shall at the least include an environmental assessment,** unless an exclusion applies – and none should.[14] According to the Code of Federal Regulations, "in considering the degree of the effects, agencies should consider . . . Effects that would violate Federal, State, Tribal, or local law protecting the environment."[15] Fetal remains being flushed into the sewer system threatens the violation of various state's medical waste regulations and other state water-quality laws.

None of the above was adequately considered in the original environmental assessment for mifepristone.[16] Consequently, the abortion industry continues to instruct women to sit on the toilet[17] during chemical abortions, with the full knowledge that fetal remains of 10+ weeks gestation, which can range upwards of one inch in size,[18] will be flushed into our sewers. This not only traumatizes women, who can see a fully formed baby floating in their toilet,[19] but (as outlined above) can adversely impact our environment by contributing to sewer system overflows, among

other things. Wastewater treatment systems are not meant to process such medical waste and human remains — morgues and medical waste facilities exist for this purpose. Indeed, consider if another industry established a standard practice of instructing its clientele to flush something that was large enough to cause a sewer system overflow. There would undoubtedly be calls to prohibit such a practice. Yet the abortion industry, with the assistance of "deep state" actors at the FDA, seems impervious to such scrutiny.

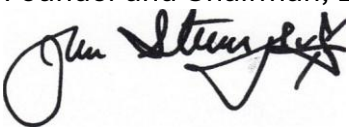
A final point: The Evita Solutions ANDA was submitted in 2021.[20] In other words, it had been in process for four years. It seems not only illogical but irresponsible that the FDA would suddenly provide final approval for it, predicated on an RLD that should not have been approved in the first place, particularly in light of Health and Human Services Secretary Robert F. Kennedy Jr.'s promised safety review of mifepristone and acknowledgement that "recent studies already point to serious risks when mifepristone is used without proper medical oversight."[21] Indeed, reasonable FDA reviewers should have concluded the original NDA was insufficient, lacked a legally compliant environmental assessment, and therefore not only denied approval of the Evita Solutions ANDA, but, as recommended by 22 Attorneys General, considered "withdrawing mifepristone from the market until [FDA] completes its review and can decide on a course of action based on objective safety and efficacy criteria."[22]

Rather than perpetuate the dangerous, unsupervised use of mifepristone by allowing a generic version of the drug to flood the market (which — according to the principles of a free market — will likely drive down costs and increase access to said drug), we respectfully propose the FDA both consider the advice of the aforementioned Attorneys General, and at the least, revoke approval for the Evita Solutions ANDA pending a thorough, legally compliant environmental assessment.

We would sincerely appreciate the opportunity to discuss these matters further at a time and place convenient to you.

Sincerely,

Mathew D. Staver, Esq.
Founder and Chairman, Liberty Counsel Action



John Stemberger
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Jonathan Alexandre
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Endnotes

[1] Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.
[2] Office of the Law Revision Counsel, 21 U.S.C. §355(j), accessed October 7, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim.
[3] Liberty Counsel Action, "Abortion in Our Water: A Special Report," 2025, https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf. See also: "Determining Whether to Submit an ANDA or a 505(b)(2) Application Guidance for Industry," U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER), May 2019, https://www.fda.gov/media/124848/download.
[4] Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf. Specifically, the letter states "We have determined your Mifepristone Tablets, 200 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Mifeprex (mifepristone) tablets, 200 mg, of Danco Laboratories, LLC NDA – 020687."
[5] Jamie Bryan Hall and Ryan T. Anderson, "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event," Ethics and Public Policy Center, April 28, 2025, https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/.
[6] Carole Novielli, "Woman sues baby's father and abortion pill business for wrongful death of preborn child," Live Action, August 11, 2025, https://www.liveaction.org/news/woman-sues-father-abortion-pill-wrongful-death; Melanie Israel, "Abortion Pills, Coercion, and Abuse," The Heritage Foundation, September 23, 2025, https://www.heritage.org/life/commentary/abortion-pills-coercion-and-abuse.
[7] Jamie Bryan Hall and Ryan T. Anderson, "The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event," Ethics and Public Policy Center, April 28, 2025, https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/.
[8] Ibid.
[9] Letter to the Population Council, from the Food and Drug Administration, "NDA 20-687," September 28, 2000, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf; Letter to GenBioPro, Inc., from the Food and Drug Administration, "ANDA APPROVAL," April 11, 2019; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf; Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=216616.
[10] Office of the Law Revision Counsel, 33 U.S.C. §1323, accessed October 8, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title33/chapter26&edition=prelim. For more detail on the CWA and NEPA, see: Liberty Counsel Action, "Abortion in Our Water: A Special Report," 2025, https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf.
[11] Edward T Furlong, Angela L Batt, Susan T Glassmeyer, Mary C Noriega, Dana W Kolpin, Heath Mash, Kathleen M Schenck, **"**Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals," *Science of the Total Environment*, February 2017, https://www.sciencedirect.com/science/article/abs/pii/S0048969716305551?via%3Dihub. For further information on this point, see Liberty Counsel Action's White Paper, "Stemming the Tide of Chemical Abortions Contaminating Our Water," 2025, https://lcaction.org/LCA-PDFs/StemmingtheTideofChemicalAbortionsContaminatingOurWater.pdf and Liberty Counsel Action, "Abortion in Our Water: A Special Report," 2025, https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf.
[12] Jason Miles, "Plumber finds fetus inside pipe while working at apartment complex, officials say," KFYR TV, September 12, 2023, https://www.kfyrtv.com/2023/09/12/graphic-plumber-finds-fetus-inside-pipe-while-working-apartment-complex-officials-say/. As noted in the article, detectives said a plumber working outside of apartment buildings in Houston "found a fetus when he opened a pipe outside of one of the buildings. The fetus is believed to just be weeks old. Neighbors said they had been complaining about backups since Friday." See also: Alejandra Yañez, Update: Tenant finds fetus while working on apartment plumbing in Mission," ValleyCentral.com, February 1, 2023, https://www.valleycentral.com/news/local-news/plumber-finds-fetus-in-mission-pipes-sources-say/, which outlines that "a tenant was working to unclog a pipe when he found the remains [of a fetus]."
There are also numerous examples of wastewater treatment plants discovering babies in their systems; for examples, see:

- The Associated Press, "Fetus found in sewage at wastewater plant," May 31, 2022, https://apnews.com/article/mississippi-wastewater-natchez-8021c8d89b77a8f82716ec3b2d8b78e1;
- Dailymail.com Reporter, "Remains of fetus found at wastewater treatment plant in southern California," April 7, 2019, https://www.dailymail.co.uk/news/article-6896445/Remains-fetus-wastewater-treatment-plant-southern-California.html;"
- Bonnie Campo, "Fetus Found By Deer Creek Waste Water Treatment Facility Workers," March 16, 2018, https://www.newson6.com/story/5e3490e2527dcf49dad7d914/fetus-found-by-deer-creek-waste-watertreatment-facility-workers, which notes, "Two contract employees with the Oklahoma City Utilities Department discovered human remains at city's Deer Creek Wastewater Treatment Facility . . . The employees have been questioned by investigators, and been offered counseling services;"
- Jessica Schmidt, "Human fetus discovered inside Cincinnati wastewater treatment plant," Fox19 Now, February 14, 2017, https://www.fox19.com/story/34495350/human-fetus-discovered-inside-cincinnati-wastewater-treatment-plant/, which states, "Workers at the Cincinnati wastewater treatment plant on Gest Street reported that they found a human fetus . . . Counseling has been made available to all staff involved in the incident . . . The coroner's office determined the fetus was a 16-18 week old non-viable fetus;"
- Mario Diaz, "Fetus found at Newark sewage treatment facility for second time this month," Pix 11, March 22, 2017, https://pix11.com/news/fetus-found-at-newark-sewage-treatment-facility-for-second-time-this-month/; which states, "A horrific discovery Wednesday morning at the Passaic Valley Sewerage Commission treatment facility as a fetus was located within the plant's operating system. It is the second time this month that workers have been presented with this kind of tragedy;"
- Associated Press, "Authorities investigating fetus found at wastewater plant," March 7, 2016, https://www.spokesman.com/stories/2016/mar/07/authorities-investigating-fetus-found-at-wastewate/;
- The Associated Press, "2 fetuses found at wastewater treatment plant," August 16, 2016, https://apnews.com/article/16fb077a579d483da1343bd547bb9f33;
- Kate King, "Fetus discovered at sewage plant," CT Post, October 3, 2010, https://www.ctpost.com/local/article/fetus-discovered-at-sewage-plant-685219.php, which states, "Workers at the Stamford wastewater treatment facility on Harbor View Avenue discovered a dead human fetus while sifting through sewage Saturday morning."

[13] According to the EPA, combined sewer system overflows (CSOs) "are a major water pollution and public health concern for approximately 700 communities in the United States. CSOs can contain bacteria, debris, and other hazardous substances that can be harmful to people, pets, and wildlife. CSOs can also cause beach closures, shellfish bed closures, algae growth, reduced oxygen levels in waterways, and aesthetic impacts from floating debris or oil slicks." See: "Combined Sewer Overflow Basics," U.S. Environmental Protection Agency, updated August 28, 2025, https://www.epa.gov/npdes/combined-sewer-overflow-basics. The EPA also states, "[p]reventable toilet and sewer backups can pose a threat to human health and present an extra challenge to our water utilities and their workforce. Flushing anything other than toilet paper [wipes, tampons, etc.] . . . can damage internal plumbing, local sewer systems and septic systems." See: "EPA Encourages Americans to Only Flush Toilet Paper," United States Environmental Protection Agency, March 30, 2020, https://www.epa.gov/newsreleases/epa-encourages-americans-only-flush-toilet-paper.

[14] Office of the Law Revision Counsel, 42 U.S.C. §4336, accessed October 7, 2025, https://uscode.house.gov/view.xhtml?path=/prelim@title42/chapter55&edition=prelim. While the Evita Solutions ANDA was submitted in 2021 and this NEPA language is from 2023, prior NEPA language and corresponding regulations (as outlined in the Code of Federal Regulations (CFR)), which would have applied to the NDA approved in 2000 and ANDA approved in 2019, required essentially the same thing. Specifically, the NEPA previously stated, ". . . *every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment,"* is to include *"a detailed statement by the responsible official on—(i) the environmental impact of the proposed action"* and *"any adverse environmental effects which cannot be avoided should the proposal be implemented."* See: 42 U.S.C. §4332, 1995 Edition, https://www.govinfo.gov/content/pkg/USCODE-1995-title42/html/USCODE-1995-title42.htm, and 42 U.S.C. §4332, 2021 Edition, https://www.govinfo.gov/content/pkg/USCODE-2021-title42/html/USCODE-2021-title42.htm. The 1998 CFR outlines that even in cases where an exclusion applies (to the requirement of an environmental document), the "FDA will require at least an EA [environmental assessment] for any specific action [e.g. approving a drug] that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment." See: Code of Federal Regulations, Title 21, Chapter

1, §25.21, April 1998, https://www.govinfo.gov/content/pkg/CFR-1998-title21-vol1/pdf/CFR-1998-title21-vol1.pdf. This language remained in similar form in 2025; see: Code of Federal Regulations, Title 21, Chapter 1, §25.21, April 1, 2025, https://www.govinfo.gov/content/pkg/CFR-2025-title21-vol1/pdf/CFR-2025-title21-vol1.pdf. A 1998 FDA guidance adds more clarity, outlining "extraordinary circumstances . . . can be based on the production, use, or disposal from use of the FDA-regulated article." Given that,

1. A "disposal from use" of the FDA-regulated articles (abortion drugs) would be necessary, as after the drug(s) is(are) used to end a pregnancy, human remains and medical waste must be disposed of, and
2. Failure to dispose of said remains properly could significantly affect the quality of the human environment (contributing to sewer system overflows, leading to possible violations of state laws, etc.),

the "extraordinary circumstance" of human fetal remains and medical waste generation should have been considered in all subsequent approvals of the two-drug abortion pill protocol, including the 2025 approval of the Evita Solutions ANDA. (Note: The guidance document goes into yet greater detail, reiterating that, "The Food and Drug Administration (FDA) is required under the NEPA to consider the environmental impacts of approving drug and biologics applications as an integral part of its regulatory process.") See: Environmental Assessment of Human Drug and Biologics Applications | Guidance for Industry," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research Center for Biologics Evaluation and Research, July 1998, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/environmental-assessment-human-drug-and-biologics-applications.

A final point: While the 2021 CFR states that, "If an extraordinary circumstance is present, the agency nevertheless may categorically exclude the proposed action **if** the agency determines that there are circumstances that lessen the impacts or other conditions sufficient to avoid significant effects," the FDA could not have applied this exclusion, given it did not consider the extraordinary circumstance in the first place. Furthermore, unless the FDA puts mitigation measures in place to ensure proper disposal of the human fetal remains and medical waste resulting from chemical abortion, there are no circumstances or conditions that would "lessen the impacts" or "avoid significant effects" of the "proposed action." See: Code of Federal Regulations, Title 40, Chapter 5, §1501.4, 2021, https://www.govinfo.gov/content/pkg/CFR-2021-title40-vol37/pdf/CFR-2021-title40-vol37.pdf.

[15] Code of Federal Regulations, Title 40, Chapter 5, §1501.3, 2021, https://www.govinfo.gov/content/pkg/CFR-2021-title40-vol37/pdf/CFR-2021-title40-vol37.pdf. The specific excerpt is as follows:

". . .(b) In considering whether the effects of the proposed action are significant, agencies shall analyze the potentially affected environment and degree of the effects of the action. Agencies should consider connected actions consistent with §1501.9(e)(1). (1) In considering the potentially affected environment, agencies should consider, as appropriate to the specific action, the affected area (national, regional, or local) and its resources, such as listed species and designated critical habitat under the Endangered Species Act . . . (2) In considering the degree of the effects, agencies should consider the following, as appropriate to the specific action:

(i) Both short- and long-term effects.

(ii) Both beneficial and adverse effects.

(iii) Effects on public health and safety.

(iv) ***Effects that would violate Federal, State, Tribal, or local law protecting the environment***."

While again (as outlined in footnote 14) the Evita Solutions ANDA was submitted in 2021 and this CFR language is from 2021-2023, prior CFR language, which would have applied to the NDA approved in 2000 and ANDA approved in 2019, required essentially the same thing, as it outlined that "significantly as used in NEPA" is to include consideration of "*whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment*." See: Code of Federal Regulations, Title 40, Chapter 5, §1508.27, July 1, 2008, https://www.govinfo.gov/content/pkg/CFR-2008-title40-vol31/pdf/CFR-2008-title40-vol31.pdf (2008 was selected because the ANDA approved in 2019 was submitted on February 3, 2009), and Code of Federal Regulations, Title 40, Chapter 5, §1508.27, 1995 (1995 was selected because the NDA was submitted in March of 1996). (Of note, in 2021, this portion of the CFR, 1508.2, became "Reserved." However, as clearly outlined, the 2021-2023 additional language retained the same principle (that environmental analysis should consider whether the action may have the effect of violating Federal, State, or local environmental laws), as did the 2024 CFR, which was modified again to read, "*In considering whether an adverse effect of the proposed action is significant, agencies shall examine both the context of the action and the intensity of the effect. In assessing context and intensity, agencies should consider the duration of the effect. . . (2) Agencies shall analyze the intensity of effects considering the following factors, as applicable to the proposed action and in relationship to one another:*

(i) The degree to which the action may adversely affect public health and safety.

(ii) The degree to which the action may adversely affect unique characteristics of the geographic area such as

historic or cultural resources, parks, Tribal sacred sites, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.
(iii) ***Whether the action may violate relevant Federal, State, Tribal, or local laws or other requirements or be inconsistent with Federal, State, Tribal, or local policies designed for the protection of the environment.***
(iv) The degree to which the potential effects on the human environment are highly uncertain.
(v) The degree to which the action may adversely affect resources listed or eligible for listing in the National Register of Historic Places.
(vi) The degree to which the action may adversely affect an endangered or threatened species or its habitat, including habitat that has been determined to be critical under the Endangered Species Act of 1973.
(vii) The degree to which the action may adversely affect communities with environmental justice concerns.
(viii) The degree to which the action may adversely affect rights of Tribal Nations that have been reserved through treaties, statutes, or Executive Orders." See: Code of Federal Regulations, Title 40, Chapter 5, §1501.3, 2024, https://www.govinfo.gov/content/pkg/CFR-2024-title40-vol37/pdf/CFR-2024-title40-vol37.pdf.)
Finally of note, in February 2025, the Council on Environmental Quality issued an Interim Final Rule that "rescinded its NEPA implementing regulations at 40 C.F.R. parts 1500–1508." Even so, in a memorandum issued by the Council, they state, "*Federal agencies must revise their NEPA implementing procedures (or establish such procedures if they do not yet have any) consistent with E.O. 14154, the 2023 and 2025 statutory amendments to NEPA (as applicable), and case law.* ***While these revisions are ongoing, agencies should continue to follow their existing practices and procedures for implementing NEPA consistent with the text of NEPA, E.O. 14154, and this guidance****" (emphasis added).** It similarly states, "*although CEQ rescinded its NEPA implementing regulations at 40 C.F.R. parts 1500–1508, agencies should consider voluntarily relying on those regulations in completing ongoing NEPA reviews or defending against challenges to reviews completed while those regulations were in effect*." See: Katherine R. Scarlett, "Memorandum for heads of federal departments and agencies," Executive Office of the President | Council on Environmental Quality, September 29, 2025, https://ceq.doe.gov/docs/ceq-regulations-and-guidance/Agency-NEPA-Implementation-Guidance.pdf.

[16] If a legally compliant EA were conducted prior to the NDA or subsequent ANDAs, the FDA would have considered how the human fetal remains and related medical waste stemming from chemical abortions would be handled and either: (1) Determined the drug should not be approved, or (2) At the least, outlined mitigation measures that would ensure proper disposal of the human fetal remains and medical waste generated by chemical abortions. For a more detailed analysis on this, see: Liberty Counsel Action, "Abortion in Our Water: A Special Report," 2025, https://lcaction.org/LCA-PDFs/AbortionInOurWater-.pdf.

[17] Kendall @ Planned Parenthood, "What do I need to do before I take abortion pills?", Planned Parenthood, October 4, 2022, https://www.plannedparenthood.org/blog/what-do-i-need-to-do-before-i-take-abortion-pills; "Aftercare Instructions: Medication Abortion," Comprehensive Women's Health Center, accessed April 7, 2025, https://cwhccolorado.com/services/medication-abortion/aftercare-medication-abortion/index.html.

[18] While estimates vary, multiple sources suggest a 10-week fetus is at least one inch; for examples, see: Karen Miles, "How fast is your baby growing? See how fetal weight and height change by week during pregnancy," Baby Center, May 30, 2025, https://www.babycenter.com/pregnancy/your-body/growth-chart-fetallength-and-weight-week-by-week_1290794; "Better Health | Start For Life, Week 10," National Health Service, accessed October 7, 2025, https://www.nhs.uk/start-for-life/pregnancy/week-by-week-guide-to-pregnancy/1st-trimester/week-10/.

[19] Lisa Bast, "Helpline founder sees spike in women 'seeing their fully formed babies' after abortion pill," Live Action, February 20, 2024, https://www.liveaction.org/news/national-helpline-calls-chemical-abortions. See also: "Live Action's new 'I Saw My Baby' website shines a light on abortion pill trauma," Live Action, August 5, 2023, https://www.liveaction.org/news/live-action-saw-baby-abortion-pill-trauma.

[20] Letter to Evita Solutions, LLC, from the Food and Drug Administration, "ANDA APPROVAL," September 30, 2025, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/216616s000ltr.pdf.

[21] @SecKennedy, X Post, October 2, 2025, https://x.com/SecKennedy/status/1973866621245567344.

[22] "Over 20 Attorneys General Cite EPPC Abortion Pill Study in Call for the FDA to Reinstate Safeguards," Ethics and Public Policy Center, August 13, 2025, https://eppc.org/news/over-20-attorneys-general-cite-eppc-abortion-pill-study-in-call-for-the-fda-to-reinstate-safeguards/.