No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,
v.
FOOD & DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; RICHARD PAZDUR, IN HIS OFFICIAL CAPACITY AS DIRECTOR, CENTER FOR DRUG EVALUATION & RESEARCH, U S FOOD & DRUG ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Defendants-Appellees,

GENBIOPRO, INCORPORATED,
Intervenor-Appellee/Cross-Appellant,
v.
DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana (Lafayette)
No. 6:25-cv-1491

BRIEF OF *AMICUS CURIAE* ETHICS AND PUBLIC POLICY CENTER IN SUPPORT OF PLAINTIFFS-APPELLANTS

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 29.2, undersigned counsel of record supplements the Certificate of Interested Persons included in the State of Louisiana's opening brief by listing those with an interest in this amicus brief. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

The Ethics and Public Policy Center ("EPPC"), based in Washington, D.C., is a nonprofit research institution dedicated to defending American ideals and to applying the Judeo-Christian moral tradition to issues of public policy. EPPC works to promote a culture of life in law and policy and to defend the dignity of the human being from conception to natural death. In their briefings, the parties have cited a study and report prepared and published by EPPC. Through this brief, EPPC hopes to add background and further information for the Court's use.

SUMMARY OF ARGUMENT

EPPC presents two sets of arguments that support Louisiana's request for a stay of the FDA's 2023 Risk Evaluation and Mitigation Strategy (REMS) and refute claims that intervenor-defendants GenBioPro, Inc. and Danco Laboratories, L.L.C. have made in this litigation.

[1] All parties received timely notice and consented to the filing of this brief. Only *Amicus* and its counsel authored any part of this brief and made a monetary contribution to fund its preparation or submission.

***First*:** EPPC scholars conducted the largest-known study of the health effects of mifepristone-induced abortions. Drawing on an all-payer insurance claims database that includes 865,727 mifepristone abortions from 2017 to 2023, EPPC's study identified a serious adverse event rate of 10.93%, which is at least 22 times as high as the summary figure in clinical trials reported on the drug label. This same database reveals that the serious adverse event rate was significantly higher when the FDA's in-person dispensing requirement was not in effect.

These findings directly support Louisiana's showing of economic and sovereign irreparable harms and confirm the district court's conclusion that the FDA failed to adequately consider real-world risks when it loosened the REMS. GenBioPro's criticisms of EPPC's study are meritless.

***Second*:** The Comstock Act broadly prohibits sending abortion drugs by U.S. mail or by common carrier, irrespective of whether those drugs are to be used for lawful or unlawful abortions. This reading supports Louisiana's position that the 2023 REMS, which facilitates nationwide mail-order distribution of mifepristone, is contrary to law under the Administrative Procedures Act (APA).

ARGUMENT

I. EPPC's study shows that mifepristone-induced abortion is far more dangerous for women than the FDA has acknowledged.

A. Mifepristone-induced abortion presents severe health risks that are at least 22 times higher than the FDA has acknowledged.

In April 2025, EPPC scholars Jamie Bryan Hall and Ryan T. Anderson released a study on the adverse health effects of mifepristone abortions. Hall & Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Public Policy Center (Apr. 28, 2025) (EPPC Study), https://eppc.org/publication/insurance-data-reveals-one-in-ten-patients-experiences-a-serious-adverse-event/. Louisiana cited EPPC's study in its complaint, ROA.10 ¶38 & nn.18-19, and attached it as an exhibit, ROA.425 (W.D. La. No. 6:25-cv-1491, ECF No. 1-13). Their study is based on analysis of data from an all-payer insurance claims database that includes 865,727 prescribed mifepristone abortions across the United States from 2017 to 2023. This analysis reveals that within 45 days following a mifepristone abortion 10.93 percent of women experience sepsis, infection, hemorrhaging, or another serious adverse event (as classified by a team of doctors following an FDA definition and NIH

methodology). *See* U.S. Food & Drug Admin., *What is a Serious Adverse Event?* (May 18, 2023), https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event; U.S. Dep't of Health & Human Servs., *Common Terminology Criteria for Adverse Events (CTCAE), v. 5.0* (Nov. 27, 2017), https://dctd.cancer.gov/research/ctep-trials/for-sites/adverse-events/ctcae-v5-5x7.pdf. That real-world rate of serious adverse events following mifepristone abortions is at least 22 times as high as the summary figure of "<0.5 percent" in clinical trials reported on the drug label. ROA.334 (W.D. La. No. 6:25-cv-1491, ECF No. 1-9); U.S. Food & Drug Admin., *Mifeprex (mifepristone) Tablets, for Oral Use: Full Prescribing Information* 7 (rev. Jan. 2023) (FDA Label), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf.

B. The FDA's elimination of the in-person dispensing requirement makes those risks even higher.

In March 2026, Hall and Anderson published a follow-up analysis showing that the data also establish that the rate of serious adverse events was significantly higher when the FDA's in-person dispensing requirement was not in effect. Hall & Anderson, *Fact Sheet: Data Reveals the FDA's Removal of In-Person Dispensing Requirement Increased the*

Dangers of the Abortion Pill, Ethics & Public Policy Center (Mar. 10, 2026), https://eppc.org/publication/fact-sheet-data-reveals-the-fdas-removal-of-in-person-dispensing-requirement-increased-the-dangers-of-the-abortion-pill/. Their analysis indicates that a serious adverse event was between 1.53 and 2.33 times more likely with remote dispensing than with in-person dispensing. The disparity was even greater for ectopic pregnancy, a life-threatening condition that can be diagnosed by a physician (or other medical professional) only with an in-person visit. The data indicate that the provision of mifepristone to a woman with an ectopic pregnancy was between three and six times more likely with remote dispensing as compared to in-person dispensing. *Id*.

The FDA-approved drug label requires that ectopic pregnancy be ruled out as a condition prior to using mifepristone. ROA.328 (FDA Label at 1). This is because the use of mifepristone by a woman with an ectopic pregnancy poses extraordinary, heightened risk to her life and health. Yet the FDA implemented the Biden administration's determination to nullify state restrictions on abortion by revising the REMS to eliminate the in-person dispensing requirement. This produced three certain and predictable effects: (1) a sharp increase in the provision of mifepristone

to women with ectopic pregnancies in Louisiana (and elsewhere), (2) a sharp increase in emergency care for these women, and (3) a sharp increase in the Medicaid costs that Louisiana incurs for emergency care for complications caused by out-of-state mifepristone.

C. GenBioPro's attacks on EPPC's study are meritless.

GenBioPro has offered several criticisms of EPPC's analysis. ROA.2881–82 (W.D. La. No. 6:25-cv-1491, ECF No. 54-4). None has merit.

1. EPPC's study is fully replicable.

GenBioPro objects that EPPC's study is a "self-published (*i.e.*, non-peer reviewed) report authored by two non-physician, non-medical scientists." ROA.2881. As Hall and Anderson explain, this objection is a red herring. ROA.431 (EPPC Study at 6). They have made their study fully replicable for anyone who wants to analyze the insurance claims data. Hall is a data scientist with an advanced degree in statistics from Harvard University. Their study was internally reviewed and adjudicated by a panel of board-certified obstetricians and gynecologists, who carefully evaluated the clinical classifications, coding, and outcome assessments to ensure medical accuracy and consistency. *Id.*; Hall & Anderson, *Frequently Asked Questions About the Largest Study on*

Chemical Abortion, Ethics & Public Policy Center (May 7, 2026), https://eppc.org/publication/frequently-asked-questions-about-the-largest-study-on-chemical-abortion/ (EPPC Study FAQ) (Resp. to Q. 7).

GenBioPro complains that EPPC "does not even disclose certain of the databases upon which it relies." ROA.2881. EPPC has entered into a confidentiality agreement with the particular vendor of the database that it is using, in order to protect the vendor from political backlash. *See* ROA.430 (EPPC Study at 5). But substantially similar databases are widely available. Insurance-claims data is a cornerstone of public health and safety monitoring. The FDA and countless peer-reviewed journals rely on such data precisely because it reflects real-world outcomes across massive populations. GenBioPro and other critics have had more than a year to try to show that other databases generate different results. It is telling that they have failed to do so.

A simple analogy illustrates the point: Different baseball statisticians could compile a season's worth of data from daily box scores of all major league teams. If you were to look to one statistician's database to compare, say, how lefthanded and righthanded batters fared against lefthanded relief pitchers, someone who wanted to second-guess

your conclusion wouldn't demand to know which database you used but could simply use another database. If that second database generated the same conclusion, it's a strong sign that the first database is sound.

2. EPPC's "adverse events" categories are based on an FDA definition and NIH methodology.

GenBioPro claims that "EPPC's report adopts a medically unsupported, overbroad definition of 'adverse events' that is inconsistent with established standards." ROA.2881. It contends in particular that "counting abortion-related emergency room visits by themselves as serious adverse events is contrary to the FDCA and FDA guidance." ROA.2923.

But as Hall and Anderson explain, they did not at all do what GenBioPro charges. *See* EPPC Study FAQ (Resp. to Q. 1). The emergency-room visits included in the report are only those related to mifepristone-induced abortion, based on the diagnosis and procedure codes in the insurance records, and they are counted only if treatment for a serious complication related to the abortion took place. The only serious complications included were those classified as such by a team of doctors following an FDA definition and NIH methodology. ROA.2911. Hall and Anderson excluded from their analysis a full 72% of emergency-room

visits that took place within 45 days of abortion because they either were not serious enough or were not related to the abortion. EPPC Study FAQ (Resp. to Q. 1); *see also* Hall & Anderson, *Fact Sheet: Excluded Adverse Events in Real-World Study of Mifepristone*, Ethics & Public Policy Center (May 6, 2026), https://eppc.org/publication/fact-sheet-excluded-adverse-events-in-real-world- study-of-mifepristone/.

3. The life-threatening risk of an ectopic pregnancy is indisputably relevant.

Perhaps most bizarrely, GenBioPro objects that EPPC's study "captures events like ectopic pregnancies, which are not caused by mifepristone." ROA.2881. But Hall and Anderson have never claimed that mifepristone *causes* ectopic pregnancies. Their study corresponds with the FDA's own reporting, which lists ectopic pregnancy as a relevant category of adverse events for mifepristone. U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2024* (Dec. 31, 2024), https://www.fda.gov/media/185245/download. As Hall and Anderson have explained, the warning on the first page of the FDA-approved drug label requires that ectopic pregnancy be ruled out before a woman uses mifepristone, precisely because the use of mifepristone by a woman with an ectopic pregnancy poses extraordinary,

heightened risk to her health. The study reports 3,062 cases of ectopic pregnancy. These are cases in which a woman was diagnosed with this condition only *after* she had already taken mifepristone. This failure to properly diagnose the ectopic pregnancy before the abortion attempt placed at risk the lives of each of these women. *See* EPPC Study FAQ (Resp. to Q. 3). The incidence of this life-threatening risk was from three to six times as likely with remote dispensing as with in-person dispensing. *See id.* (Resp. to Q. 9).

In sum, GenBioPro utterly fails to establish any flaws in EPPC's study.

II. The Comstock Act broadly prohibits sending abortion drugs by U.S. mail or by common carrier, irrespective whether those drugs are to be used for lawful or unlawful abortions.

Louisiana's opening brief argues that the 2023 REMS is contrary to law because it violates the federal criminal statutes referred to as the Comstock Act. Opening Br. at 62. *See* 18 U.S.C. §§ 1461 & 1462. Below, Danco and GenBioPro made two contrary arguments. Their first argument is that "FDA has only the authority Congress granted it" and that that authority does not extend to considering the Comstock Act's prohibitions. ROA.2818–19 (W.D. La. No. 6:25-cv-1491, ECF No. 52-4);

see also ROA.2883 ("FDA's remit under the FDAAA is narrow and technical."). We leave it to others to address the merits of that argument. We will simply observe that the argument concedes that the FDA cannot override the Comstock Act.

Danco's and GenBioPro's second argument is that the Comstock Act "prohibits only the distribution of items intended to produce *unlawful* abortions." ROA.2819 (emphasis in original); *see also* ROA.2882–83 (Comstock "has long been construed as applicable only to *knowingly* shipping such items for the purpose of *illegal* abortions."). This argument is both irrelevant and wrong. The argument is irrelevant for the simple reason that the FDA does not purport to limit its approval of mifepristone to instances in which abortion is lawful. The argument is wrong, as the remainder of this brief demonstrates, because it parrots a deeply flawed opinion issued in 2022 by the Office of Legal Counsel ("OLC") in the U.S. Department of Justice. Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. ___ (Dec. 23, 2022) ("OLC Opinion"), *available at* https://www.justice.gov/olc/opinion/file/1560596/download.

As Judge Ho has explained, "Using the U.S. mails for the mailing of a 'drug … for producing abortion'"—or using a common carrier for that purpose—"is precisely what the Comstock Act prohibits." *Alliance for Hippocratic Medicine v. FDA*, 78 F.4th 210, 267 (5th Cir. 2023) (Ho, J., concurring in part and dissenting in part) (cleaned up); *accord Danco Laboratories v. Louisiana*, 146 S. Ct. 1192, 1193 (2026) (Thomas, J., dissenting) (agreeing with Judge Ho).

A. The 2022 OLC opinion would eviscerate sections 1461 and 1462.

The federal criminal statutes referred to as the Comstock Act broadly prohibit sending abortion drugs by U.S. mail or by common carrier. Section 1461 of Title 18 states in relevant part:

> Every article or thing designed, adapted, or intended for producing abortion … and [e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion … [i]s declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier.
>
> Whoever knowingly uses the mails for the mailing, carriage in the mails, or delivery of anything declared by this section … to be nonmailable … shall be fined under this title or imprisoned not more than five years, or both, for the first such offense, and shall be fined under this title or imprisoned not more than ten years, or both, for each such offense thereafter.

Section 1462 of Title 18 similarly prohibits anyone from "knowingly us[ing] any express company or other common carrier" to send or receive "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." It imposes the same set of penalties.

The OLC opinion that Danco and GenBioPro embrace claims that "section 1461 does not prohibit the mailing, or the delivery or receipt by mail, of mifepristone or misoprostol *where the sender lacks the intent that the recipient of the drugs will use them unlawfully*." OLC Opinion at 1–2 (emphasis added). It asserts that section 1462 is subject to the same prohibition-canceling exception. And it likewise contends that a person who orders or receives abortion drugs by mail or by common carrier does not violate section 1461 or section 1462 if that person "does not intend that they [the drugs] be used unlawfully." *Id*. at 2 n.3.

OLC proceeds to boast that its reading—or, rather, its *wholesale rewriting*—of these statutes would eviscerate them. Focusing its illustrations on those who send or deliver mifepristone or misoprostol by mail, OLC observes that such persons "typically will lack complete knowledge of how the recipients intend to use them and whether that use is unlawful under relevant law." OLC Opinion at 17. Therefore, it

contends, even a sender's or deliverer's knowledge that a package contains mifepristone or misoprostol that "will be used to facilitate an abortion" is *not* "a sufficient basis for concluding that section 1461 has been violated." *Id.* OLC provides a laundry list of "illustrative uses for mifepristone and misoprostol that the law of a given state would not prohibit": before a gestational limit in some states, for "potentially life-threatening" conditions or other statutory exceptions in others, and so on. *Id.* at 18–20. It concludes that "in light of the many lawful uses of mifepristone and misoprostol, the fact that these drugs are being mailed to a jurisdiction that significantly restricts abortion is not a sufficient basis for concluding that the mailing violates section 1461." *Id.* at 20–21.

OLC's exception would render section 1461 a virtual nullity, even for mailings to states in which abortion is broadly unlawful. Even apart from OLC's illustrations, it would be rare indeed that the sender of abortion drugs would ever have "the *intent* that the recipient of the drugs will use them unlawfully." A typical shipper of abortion drugs would not care one bit whether the recipient uses them for an unlawful abortion or flushes them down the toilet or feeds them to a pet. Even ideological shippers (e.g., abortion activists) would presumably intend at most only

that the ultimate recipient have the ability to use the drugs unlawfully if she chooses to go ahead with the abortion, not that she necessarily actually use them.

As OLC explains, section 1461 is derived from the original Comstock Act that Congress enacted in 1873, and section 1462 is derived from an 1897 enactment that extended the mailing prohibitions of the original Comstock Act to common carriers. OLC Opinion at 4, 5 n.7. In repeatedly referring to the provisions as the Comstock Act, OLC seems eager to draw on the notoriety of their draftsman Anthony Comstock, whom OLC refers to as a "prominent anti-vice crusader." *Id*. at 3. But there is a striking disconnect between Mr. Comstock's reputation for severity and the lax (if not empty) meaning that OLC would assign to sections 1461 and 1462.

Indeed, under OLC's intent test, even at its inception, the original Comstock Act could rarely if ever have been enforceable against anyone who mailed abortion drugs. To apply OLC's own statement: In light of the universal exclusion of life-threatening conditions from state abortion laws, anyone who mailed abortion drugs in 1873 "typically [would] lack complete knowledge of how the recipients intend to use them and

whether that use [would be] unlawful under relevant law." OLC Opinion at 17. Plus, for the same reasons set forth above, it would be rare that a sender in 1873 would ever have an *intent* that the drugs be used unlawfully. Further, under OLC's test, if a state in 1873 had adopted broadly permissive abortion laws, the supposedly draconian Comstock Act would have allowed a sender to mail drugs to that state with the specific intent that they be used for non-lifesaving abortions.

B. The 2022 OLC opinion is poorly supported and unsound.

There is no meaningful support for OLC's claim that section 1461 does not apply when "the sender lacks the intent that the recipient of the drugs will use them unlawfully." OLC Opinion at 17. OLC contends that there was a "well-established, consensus interpretation" among the federal appellate courts on such an exception by the middle of the 20th century and that Congress somehow ratified the supposed consensus by "perpetuating the wording" of section 1461's abortion language. OLC Opinion at 5. But far from there being such a consensus, the cases that OLC cites (and that Danco also cites, ROA.2819–20) do not remotely support its position. Congress could not have ratified a supposed "consensus interpretation" that never existed. And OLC's ratification

claim is rife with other problems, including the fact that Congress in the 1970s unsuccessfully tried to modify section 1461 to say what OLC claims it already meant.

1. There was no "consensus interpretation" that supports OLC's position.

OLC's supposed "well-established, consensus interpretation" draws upon a handful of cases from a grand total of four circuit courts, all from the first half of the twentieth century. Only one involves abortion at all; the rest relate to contraceptives. OLC Opinion at 11 n.11. *None* of the cases that OLC cites stands for the proposition that the Comstock Act provisions bar the mailing of abortion drugs only when the sender intends that the drugs be used unlawfully.

The Seventh Circuit's ruling in *Bours v. United States*, 229 F. 960 (7th Cir. 1915), actually cuts strongly and directly against OLC's position—a problem that OLC obscures by its brazenly misleading selective quotations. In that case, the Seventh Circuit held that the term *abortion* in the statute that is now codified as section 1461 "must be taken in its general medical sense" to exclude "the necessity of an operation to save life"—i.e., a procedure necessary to save the life of the mother. *Id.* at 964.

In a passage that OLC doesn't quote or even acknowledge, the Seventh Circuit declared that this statute "indicates a national policy of discountenancing abortion as inimical to the national life." *Id.* The court reasoned that while "the letter of the statute would cover all acts of abortion, the rule of giving a reasonable construction *in view of the disclosed national purpose* would exclude those acts that are in the interest of the national life." *Id.* (emphasis added). It was on that basis that the court determined that the statutory term *abortion* "must be taken in its general medical sense" to exclude "the necessity of an operation to save life"—i.e., a procedure necessary to save the life of the mother. *Id.*

OLC somehow quotes the phrase "reasonable construction" in isolation—without the Seventh Circuit's accompanying language "in view of the disclosed national purpose"—and it omits any mention of the inconvenient fact that the Seventh Circuit discerned that "national purpose" to be "discountenancing abortion as inimical to the national life." *See* OLC Opinion at 5–6.

Further, far from limiting the statute (as OLC would) to abortions that are unlawful under the laws of the particular state in which the

alleged violation occurred, the Seventh Circuit declared that "it is immaterial what the local statutory definition of abortion is, what acts of abortion are included, or what excluded." *Bours*, 229 F. at 964.

Bours is the only case that OLC cites in support of its "well-established, consensus interpretation" of section 1461 that actually involves abortion. Far from supporting OLC's position, *Bours* emphatically repudiates it. *Bours* stands for the propositions that section 1461 should be construed to implement "a national policy of discountenancing abortion as inimical to the national life" and that state laws governing which acts of abortion are lawful and which are unlawful are "immaterial" to the meaning of section 1461.

OLC next states that in *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103 (2d Cir. 1930), the Second Circuit "reasoned in dicta that the statute could not be construed as expansively as its language might suggest." OLC Opinion at 6. Fair enough. But the Second Circuit's dicta are more confused than OLC acknowledges. As OLC notes, the Second Circuit observes that the statutory language, "[t]aken literally, … would seem to forbid the transportation by mail or common carriage of anything 'adapted,' in the sense of being suitable or fitted, for preventing

conception or for any indecent or immoral purpose, *even though the article might also be capable of legitimate uses and the sender in good faith supposed that it would be used only legitimately*." 45 F.2d at 108 (emphasis added). The Second Circuit could have adequately addressed this concern by reasoning that such "legitimate uses" should be excluded from the scope of the statute. That would mean, for example, that misoprostol, which, as OLC notes, "is commonly prescribed for the prevention and treatment of gastric ulcers," OLC Opinion at 20, could be mailed for that use. Instead, the Second Circuit sloppily speculated that "[i]t would seem reasonable" to construe the statute "as requiring an intent on the part of the sender that the article mailed or shipped by common carrier be used for *illegal* contraception or abortion or for indecent or immoral purposes." 45 F.2d at 108 (emphasis added). Even worse, it mistakenly cited *Bours* as authority for this proposition. *See id*.

In the next case discussed by OLC, *Davis v. United States*, 62 F.2d 473 (6th Cir. 1933), the Sixth Circuit faulted the district court for not admitting evidence that would "show absence of intent that the goods shipped were to be used for other than a *legitimate* medical or surgical purpose." *Id*. at 474 (emphasis added). At issue were promotional

mailings for "rubber sundries," which the defendant contended were not for contraceptive purposes but instead had "a legitimate medical and surgical use in treatment and prevention of disease." *Id.* The Sixth Circuit held that "intent that the articles described in the circular or shipped in interstate commerce were to be used for *condemned* purposes is a prerequisite to conviction." *Id.* at 475 (emphasis added). So although the Sixth Circuit approvingly cited the *Youngs Rubber* dicta at length, its holding reflects the position that *legitimate* uses—uses beyond the purposes that the statute condemns—should be excluded from the scope of the statute, *not* that whatever uses are *lawful under state law* should be.

The Second Circuit's opinion in *United States v. One Package*, 86 F.2d 737 (2d Cir. 1936), which concerned the import of pessaries "for contraceptive purposes," also does not reflect the "consensus interpretation" that OLC posits. OLC contends in particular that the court in *One Package* "adopted *Youngs Rubber*'s dicta as a holding." OLC Opinion at 7. But the Second Circuit in *One Package* read *Youngs Rubber*'s dicta to mean that the statute does not apply when the drugs are "not intended for an *immoral* purpose." *One Package*, 86 F.2d at 739

(emphasis added). It declared that the Comstock Act enacted in 1873 "embraced only such articles as Congress [in 1873] would have denounced as immoral if it had understood all the conditions under which they were to be used." *Id*. The court opined that the "design" of the statute "was not to prevent the importation, sale, or carriage by mail of things which might intelligently be employed by conscientious and competent physicians for the purpose of saving life or promoting the well-being of their patients." *Id*. At a time when abortion remained broadly unlawful, the court observed that "[t]he word 'unlawful' would make this clear as to articles for producing abortion." *Id*. In other words, the court was observing that the then-existing laws barring abortion were compatible with what the Congress that enacted the Comstock Act in 1873 "would have denounced as immoral if it had understood all the conditions under which they were to be used." *Id.* That is a far cry from suggesting that section 1461 should apply only to whatever abortions the various states render unlawful at a particular time.

Two years later, in *United States v. Nicholas*, 97 F.2d 510 (2d Cir. 1938), the Second Circuit, citing *Youngs Rubber* and *One Package*, stated that it had "twice decided that contraconceptive [*sic*] articles may have

lawful uses and that statutes prohibiting them should be read as forbidding them only when unlawfully employed." *Id.* at 512. OLC acknowledges in a footnote that the court in *Nicholas* "described the relevant inquiry as being whether the articles were 'unlawfully employed,' rather than whether the sender *intended* that they be used unlawfully—the touchstone the court had adopted in *Youngs Rubber* and *One Package*"—but it argues that "this difference in phrasing does not reflect a departure relevant to our analysis." OLC Opinion at 9 n.10.

OLC's argument is slipshod: First, the Second Circuit did not "adopt[]" any "touchstone" in *Youngs Rubber*. Its discussion was dicta, as OLC elsewhere acknowledges. OLC Opinion at 6. Second, as discussed above, the Second Circuit in *One Package* did *not* adopt *Youngs Rubber*'s dicta. Third, it is sophistry to concoct a supposed "consensus interpretation" by breezily dismissing material differences in interpretation.

The last circuit-court case that OLC cites is the D.C. Circuit's 1944 opinion in *Consumers Union v. Walker*, 145 F.2d 33 (D.C. Cir. 1944). There the D.C. Circuit held merely that "Congress did not intend to exclude from the mails properly prepared information for properly

qualified people." *Id*. at 35. It cited *Nicholas*, *Davis*, *Youngs Rubber*, and *One Package* as support for that narrow proposition.

OLC notes in a footnote that the "leading cases" for its supposed "consensus interpretation" "each involved items that could be used to prevent conception rather than to produce abortion." OLC Opinion at 11 n.11. But it blithely contends that this distinction is irrelevant, even as it badly misrepresents the one case (*Bours*) that involves abortion and even as it completely ignores the passage from *One Package* (on what the 1873 Congress "would have denounced as immoral if it had understood all the conditions under which they were to be used," *One Package*, 86 F.2d at 739) that renders that distinction critical.

In sum, none of these circuit-court cases stands for the proposition that section 1461 and related Comstock Act provisions bar the mailing of abortion drugs only when the sender intends that the drugs be used unlawfully. Nor, of course, do they remotely establish a "consensus interpretation" supporting such a proposition.

2. Congress did not ratify such an interpretation.

It would of course have been impossible for Congress to ratify a "consensus interpretation" that never existed. So that is one fatal flaw in

OLC's argument. There are plenty of other problems that would defeat OLC's ratification argument even if a "consensus interpretation" had existed. Among them:

a. OLC claims that its ratification argument "is strongly reinforced by the Historical and Revision Note that was included in the 1945 report of the House Committee on the Revision of the Laws when Congress enacted title 18 of the U.S. Code into positive law." OLC Opinion at 12 (citing H.R. Rep. No. 79-152, at A96–97 (1945)). But that note does nothing more than quote the dicta from *Youngs Rubber* and briefly describe the holdings of *Nicholas* and *Davis*, all of which concern contraception. The note makes only a single mention of abortion, in its quotation of the *Youngs Rubber* dicta. It is farfetched to think that anyone who read that note would be on notice that enactment of Title 18 would mean that Congress was abandoning the "national policy of discountenancing abortion as inimical to the national life." *Bours*, 229 F. at 964.

b. OLC relies on its misreading of rulings from *four* circuit courts. But there were *nine* circuit courts when the Seventh Circuit issued its ruling in *Bours* and *ten* circuit courts when the other rulings were issued.

So even if OLC's account of these rulings were accurate, it would be odd to find a "consensus interpretation" from a *minority* of circuit courts.

OLC quotes Justice Scalia's legal treatise (READING LAW: THE INTERPRETATION OF LEGAL TEXTS (2012), co-authored with Bryan Garner) for this proposition: "If a word or phrase has been … given a uniform interpretation by inferior courts …, a later version of that act perpetuating the wording is presumed to carry forward that interpretation." OLC Opinion at 11–12 (quoting READING LAW at 322). But it ignores Scalia's query three pages later as to "how numerous must the lower-court opinions be … to justify the level of lawyerly reliance that justifies the canon." *READING LAW* at 325. Scalia opines that "seven courts" *might* be enough but that he "cannot give conclusive numbers." *Id.*

c. The most obvious way for Congress to have ratified the supposed "consensus interpretation" would have been to add the word unlawful to section 1461 (e.g., "for producing unlawful abortion"). It is heads-we-win-tails-you-lose gamesmanship to contend that making that change and *not* making that change would have the same effect.

d. Congress in fact *unsuccessfully* tried to make such a change on at least one occasion. A House subcommittee report from December 1978 proposed to modify section 1461 so that it prohibited mailing drugs (and other items) "intended by the offender … to be used to produce an illegal abortion." *See Report of the Subcommittee on Criminal Justice on Recodification of Federal Criminal Law*, 95th Congress, 2d Session (Dec. 1978) at 40 (available at https://www.ojp.gov/pdffiles1/Digitization/63344NCJRS.pdf) (proposing to substitute a new section 6701 in lieu of section 1461). In support of that proposed change, the House subcommittee report states:

> *[U]nder current law, the offender commits an offense whenever he "knowingly" mails any of the designated abortion materials*. Section 6701 of revised title 18 requires proof that the offender specifically intended that the mailed materials be used to produce an illegal abortion. An abortion is "illegal" if it is contrary to the laws of the state in which it is performed.

Id. (emphasis added).

e. As OLC notes, the House report that accompanied Congress's amendment of section 1461 in 1971 flatly states: "Existing statutes *completely prohibit* the importation, interstate transportation, and mailing of contraceptive materials, or the mailing of advertisement or information concerning how or where such contraceptives may be

obtained or how conception may be prevented." OLC Opinion at 14 n.17 (quoting H.R. Rep. No. 91-1105, at 2 (1970)) (emphasis added). OLC contends that that statement "plainly was a reference to the literal text of their provisions, as opposed to their settled meaning." OLC Opinion at 14 n.17. But OLC's anti-textual reading of the House report is not "plain[]" at all.

C. The FDAAA did not impliedly preempt sections 1461 and 1462.

Danco also contends that Congress, in enacting the Food and Drug Administration Amendments Act of 2007 (FDAAA), "'deemed' drugs like mifepristone to have an enforceable REMS" and was thus "authorizing mifepristone's distribution system to continue." ROA.2820. But this claim that Congress through the FDAAA impliedly repealed the Comstock Act provisions is farfetched. As the Supreme Court recently re-affirmed, "repeals by implication are not favored" and will not be held to have occurred "unless Congress' intention to repeal is clear and manifest, or the two laws are irreconcilable." *Maine Community Health Options v. United States*, 140 S. Ct. 1308, 1323 (2020) (internal quotations marks omitted); *see also In re Lively*, 717 F.3d 406, 410 (5th Cir. 2013) citing *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 662

(2007) ("Repeals by implication are disfavored and will not be presumed unless the legislature's intent is 'clear and manifest'"). It would be especially extraordinary to have a grandfathering-of-regulations provision impliedly repeal a criminal statute.

CONCLUSION

1. EPPC's study of the health effects of mifepristone-induced abortions establishes that the serious adverse event rate is at least 22 times as high as the summary figure in clinical trials reported on the drug label. The data also reveals that the serious adverse event rate was significantly higher when the FDA's in-person dispensing requirement was not in effect**.**

2. The Comstock Act broadly prohibits sending abortion drugs by U.S. mail or by common carrier, irrespective whether those drugs are to be used for lawful or unlawful abortions.

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CERTIFICATE OF COMPLIANCE

This brief complies with the word limit of Fed. R. App. P. 29(a)(5) because this brief contains 5,694 words, excluding parts of the brief exempted by Fed. R. App. P. 32(a)(7).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in Microsoft Word for Mac Version 16.109.3 using a proportionally spaced typeface, 14-point Century Schoolbook.

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CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2026, I electronically filed the foregoing brief with the Clerk off the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the CM/ECF system.

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