No. 26-30203

UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants / Cross-Appellees,
v.
FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, ACTING COMMISSIONER, U.S. FOOD & DRUG ADMINISTRATION; MICHAEL DAVIS, 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, INC.,
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 No. 25-cv-1491 (Hon. David C. Joseph, J.)

BRIEF FOR FORMER U.S. DEPARTMENT OF JUSTICE OFFICIALS AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES AND INTERVENORS-APPELLEES

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**Admission Pending*

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

(1) No. 26-30203, *Louisiana, et al. v. Food & Drug Administration, et al.*

(2) Pursuant to Fifth Circuit Rule 29.2, the undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

***Amici Curiae*:** Kent B. Alexander, Leslie R. Caldwell, Michael W. Cotter, Edward L. Dowd Jr., Jamie S. Gorelick, William C. Killian, Jim Lewis, Kenneth Magidson, Denise E. O'Donnell, David W. Ogden, Sarah R. Saldaña, Donald K. Stern, Anne Tompkins, John W. Vaudreuil, John F. Walsh, Seth P. Waxman

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INTEREST OF AMICI CURIAE[1]

Amici are sixteen former high-ranking U.S. Department of Justice officials who served as Deputy Attorney General, Solicitor General, Assistant Attorney General, and/or U.S. Attorney. Amici were responsible for enforcing federal criminal laws, including the Comstock laws, 18 U.S.C. §§ 1461-1462, and represented the United States in criminal matters in all levels of the judiciary around the country. A full list of amici appears in the Appendix.

Amici hold diverse views regarding the moral and jurisprudential questions surrounding abortion but agree that Plaintiffs-Appellants' argument that the 2023 Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone violates the Comstock laws is erroneous. The Food & Drug Administration ("FDA") was not authorized to consider, interpret, or apply federal criminal laws as part of its drug-approval process, including its 2023 REMS decision. Further, Plaintiffs gravely misinterpret the Comstock laws, expanding their scope beyond Congress's intent. Plaintiffs' misreading of the Comstock laws fails to account for the holdings of all four courts of appeals to have addressed the question and the construction embraced by the U.S. Justice Department, the sole agency responsible for

[1] All parties have consented to the filing of this amicus brief. No counsel for a party authored this brief in whole or in part, and no entity or person other than amici and their counsel made a monetary contribution to fund the preparation or submission of this brief.

prosecuting violations of the Comstock laws. The Court need not address Plaintiffs' misinterpretation of the Comstock laws at all, but if it does so, amici urge the Court to reject Plaintiffs' strained interpretation.

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs' argument that FDA's 2023 actions violated the Comstock laws is erroneous. First, the Comstock laws provide no basis to enjoin or invalidate the challenged FDA actions. Regardless, Plaintiffs' interpretation of the Comstock laws ignores the decades-long understanding of the Comstock laws shared by Congress, the Judiciary, and the Executive Branch.

As a threshold matter, the Comstock laws are irrelevant to the validity of the challenged FDA actions. Congress charged FDA with determining whether a drug is safe and effective and set forth specific factors the agency is required to consider when imposing a REMS. Those factors do not include consideration, application, or interpretation of any criminal laws. Congress did not authorize FDA to limit access to safe and effective medication based on its interpretation and application of the Comstock laws. Accordingly, FDA's determinations did not purport to address whether distributions of the drug were or were not lawful under the Comstock laws (just as they did not purport to declare whether such distributions were or were not lawful under other criminal statutes). The Comstock laws are therefore irrelevant to the validity of the challenged FDA actions under the APA.

But even if the Comstock laws were relevant to FDA's actions, those actions would be valid because they accord with those statutes. Plaintiffs misinterpret the Comstock laws to reach items intended to produce both lawful and unlawful abortions. As four circuits concluded in decisions issued between 1915 and 1944—decisions resting on lengthy statutory analyses—the Comstock laws reach the distribution of items only if intended to produce unlawful abortions. This unanimous interpretation is the only one that both makes sense of all the Comstock laws—not just 18 U.S.C. §§ 1461-1462 but also 19 U.S.C. § 1305—and also avoids absurd and likely unconstitutional implications. And critically, this interpretation was acknowledged by Congress in 1948 and (if more were needed) further ratified repeatedly since then by Congress's reenactments and amendments of the Comstock laws without relevant alteration.

Adopting Plaintiffs' erroneous interpretation of the Comstock laws would risk a profound destabilization of medical care. Plaintiffs' construction of the Comstock laws cannot be limited to telemedicine abortion or mifepristone; it necessarily would affect in-person abortion and a broad range of other kinds of healthcare. That is because mifepristone and other drugs and items used for in-person abortion are likewise delivered through the mails. And many abortion-inducing drugs and devices are used for non-abortion-related care. For instance, mifepristone is regularly used to treat miscarriages, and misoprostol is frequently

used during labor and delivery. This Court should reject Plaintiffs' broad-ranging interpretation.

ARGUMENT

I. THE COMSTOCK LAWS ARE IRRELEVANT TO THE VALIDITY OF THE CHALLENGED FDA ACTIONS

The Comstock laws, however interpreted, are irrelevant here. FDA's actions were within the bounds of its legal authority to assess, pursuant to specific, statutorily enumerated factors, whether mifepristone would be safe and effective under specified conditions. Indeed, FDA would not be authorized to consider the Comstock laws in deciding whether to approve mifepristone and what restrictions to apply to it.

A. FDA Had No Power Or Duty To Consider The Comstock Laws In Deciding Whether Or With What Use Restrictions To Approve Mifepristone

As is true with any agency, FDA's "power to regulate … must always be grounded in a valid grant of authority from Congress." *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120, 126, 161 (2000). In terms of approving a drug for use in the United States, Congress specified that FDA's role is to assess whether the drug is safe and effective for the indicated use. If FDA determines the drug *is* safe and effective, it must approve the drug. This approval serves only to remove one particular legal barrier to the drug's distribution, namely the bar on distribution of drugs not approved by FDA as safe and effective.

Whether any *other* laws restrict or prohibit distribution of a drug is a "factor[] which Congress has not intended [the agency] to consider." *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Company*, 463 U.S. 29, 43 (1983).

The Food, Drug, and Cosmetic Act ("FDCA") requires that FDA, in deciding whether to approve a drug application, consider whether the drug will be safe and effective under the conditions of use described in the proposed label. *See* 21 U.S.C. § 355(b)(1)(A)(i), (d); *Merck Sharp & Dohme Corporation v. Albrecht*, 587 U.S. 299, 302 (2019). The statute specifies seven "[g]rounds for refusing [a drug] application," five relating to safety and efficacy, one requiring the filing of patent information, and one relating to the label's accuracy. *See* 21 U.S.C. § 355(d). The FDCA gives FDA no authority to deny a drug application for any other reason. To the contrary, the FDCA commands that, if none of the patent-filing or safety-and-efficacy grounds for denial is present, FDA "shall" approve the application. *Id.*; *see also* 21 C.F.R. §§ 314.105, 314.125. Therefore, FDA cannot deny a drug application based on any potential restrictions on distribution imposed by the Comstock laws (or any other law FDA does not administer).

FDA's framework for REMS is similarly focused on safety and efficacy as well as assuring patient access. The FDCA requires an applicant to propose a REMS if FDA determines one "is necessary to ensure that the benefits of the drug

outweigh the risks." 21 U.S.C. § 355-1(a)(1); *see also id*. § 355-1(a)(2), (b)(1), (4), (5). Accordingly, a REMS must identify means to mitigate risks to patients' health. *See id*. § 355-1(c), (e)-(f). Nothing authorizes FDA to consider the Comstock laws (or, again, any other law FDA does not administer) in the REMS process. Nor has Congress expected FDA to have done so. Indeed, although members of Congress have engaged in exacting oversight of FDA's approval of mifepristone, including via initiating U.S. Government Accountability Office investigations and subcommittee hearings, they have not questioned FDA approval on the grounds that the agency failed to consider the Comstock laws. *See* GAO-08-751, *FDA: Approval and Oversight of the Drug Mifeprex* 1 (Aug. 2008) (identifying Congressional requesters); GAO-18-292, *FDA: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* 28 (Mar. 2018) (same).

To be sure, FDA's approval is a necessary condition for introducing a drug into interstate commerce; the FDCA provides that "[n]o person shall introduce … into interstate commerce any new drug, unless" FDA has approved the drug. 21 U.S.C. § 355(a); *see also, e.g.*, *Mutual Pharmaceutical Company v. Bartlett*, 570 U.S. 472, 476 (2013) ("drug manufacturers must gain approval from the [FDA] before marketing any drug in interstate commerce"). But FDA approval means nothing with respect to the applicability of federal laws outside FDA's purview;

FDA's approval (and REMS decisions) do not purport to override such laws. In fact, FDA routinely approves drugs that are restricted by laws FDA does not administer. One such law is the Controlled Substances Act, which is enforced by the U.S. Department of Justice and criminalizes the distribution, dispensing, and possession of many FDA-approved substances, such as fentanyl and methadone. *See* 21 U.S.C. §§ 811(a), 812, 823, 841(a)(1), 844(a).

That FDA did not consider the Comstock laws in approving mifepristone or in the REMS process is therefore entirely unsurprising. Indeed, it would be not only unlawful but also entirely impractical for FDA to catalog and evaluate the countless laws it does *not* administer or have expertise on but that nonetheless *might* apply to the drugs it reviews—even if Congress itself had not drawn those laws to FDA's attention—including continually monitoring changes in such laws and reevaluating its prior decisions in light of those changes.

B. FDA's Actions Do Not Purport To Declare Any Distributions Of Mifepristone Lawful Under The Comstock Laws (However Interpreted)

FDA's 2023 REMS conforms to FDA's limited statutory authority. In adopting the REMS, FDA explained that "[u]nder the Mifepristone REMS Program, mifepristone may be dispensed in person or by mail." *See* FDA, *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 17, 2025); *see also* FDA, *Approved Risk Evaluation and*

Mitigation Strategies (REMS), Mifepristone (Sept. 30, 2025). In doing so, FDA expressed nothing more than its determination that such distribution would not undermine mifepristone's safety or efficacy and was consistent with the statutory factors Congress expressly directed the agency to consider. Those are, as explained, the only considerations FDA may assess. The agency certainly did not purport to opine on whether any particular distributions of mifepristone are lawful under the Comstock laws.

II. FDA'S ACTIONS ACCORD WITH THE COMSTOCK LAWS BECAUSE THE COMSTOCK LAWS REACH ONLY DISTRIBUTIONS INTENDED FOR UNLAWFUL ABORTION

Because FDA's authority in approving medications does not encompass interpreting or applying federal criminal statutes like the Comstock laws, the proper interpretation of those laws has no bearing on the validity of the agency's challenged actions. But even if the Comstock laws were relevant here, Plaintiffs' interpretation—that 18 U.S.C. §§ 1461-1462 prohibit distribution of items intended to produce not only *unlawful* abortions but also *lawful* ones—is incorrect.

For more than a century, the Comstock laws have been understood—by Congress, the Judiciary, and the Executive Branch—not to prohibit sending or receiving abortion-related items where an individual lacks the intent that the items be used for unlawful abortion. Indeed, as every circuit court to address the question has recognized, Plaintiffs' reading is absurd and raises serious

constitutional concerns, especially given the interaction between §§ 1461-1462 and § 1305. Critically, Congress's 1948 reenactment of the Comstock laws explicitly took note of those judicial decisions and specifically adopted the courts' interpretation. Congress then repeatedly ratified that interpretation. And for nearly a century, the Executive Branch has recognized this settled meaning too, including in a 2022 opinion issued by the Department of Justice's Office of Legal Counsel reaffirming this construction.

A. Congress Enacted §§ 1461-1462 Specifically Intending That They Be Interpreted To Reach Items Only If Intended For Unlawful Abortion

The Comstock laws were enacted in the late 1800s. *See* Act of Mar. 3, 1873, ch. 258, § 2, 17 Stat. 598, 599; Act of Feb. 8, 1897, ch. 172, 29 Stat. 512. In 1909, Congress revised the Comstock laws to substantially the language found today at 18 U.S.C. §§ 1461-1462. One section—what is now § 1461—prohibited "knowingly deposit[ing]" in the mails "every article or thing designed, adapted, or intended for preventing conception or producing abortion, or for any indecent or immoral use." Pub. L. No. 60-350, § 211, 35 Stat. 1088, 1129 (1909). Another provision—what is now § 1462—prohibited "bring[ing] … into the United States" and "knowingly deposit[ing] … with any express company or other common carrier for [interstate] carriage … any drug, medicine, article, or thing designed, adapted, or intended for preventing conception, or producing abortion, or for any

indecent or immoral use[.]" *Id.* § 245, 35 Stat. at 1138. While those provisions speak plainly to reach mailings for "*any* indecent or immoral purpose," 18 U.S.C. § 1461 (emphasis added); *accord id.* § 1462, they contain no similar language suggesting they reach items related to *any* abortion or *any* contraception. Indeed, the Act referred to "producing abortion" or "procuring abortion," which then had a specialized criminal-law meaning and referred not to all abortions, but specifically to the particular crime of producing or procuring an abortion that violated the law, either because it occurred after detectable fetal movement, known at the time as "'quickening,'" or because it was not therapeutic.[2]

Between 1915 and 1944, four federal circuit courts issued six decisions interpreting this statutory language. Each one rejected the proposition that these provisions reached all items for preventing conception and producing abortion regardless of the intended circumstances of their use. The Seventh Circuit, for example, explained that it was not "reasonable" to suppose Congress intended "the statute [to] cover all acts of abortion." *Bours v. United States*, 229 F. 960, 964-965 (7th Cir. 1915). The Second Circuit likewise observed that "[i]t would seem reasonable" to interpret the statute "as requiring an intent on the part of the sender

[2] *See* Siegel & Ziegler, *Comstockery: How Government Censorship Gave Birth to the Law of Sexual and Reproductive Freedom, and May Again Threaten It*, 134 Yale L.J. 1068, 1096-1098 & n.139 (2025).

that the article mailed or shipped by common carrier be used for *illegal* contraception or abortion or for indecent or immoral purposes." *Youngs Rubber Corporation v. C.I. Lee & Company*, 45 F.2d 103, 107-108 (2d Cir. 1930) (emphasis added); *accord United States v. Nicholas*, 97 F.2d 510, 512 (2d Cir. 1938); *United States v. One Package*, 86 F.2d 737, 738-739 (2d Cir. 1936). And the Sixth Circuit adopted the Second Circuit's reading based on the "soundness of its reasoning" and because "the statute must be given a reasonable construction." *Davis v. United States*, 62 F.2d 473, 474-475 (6th Cir. 1933). Finally, the D.C. Circuit chose "to follow the interpretation which has been adopted in other circuits." *Consumers Union of United States v. Walker*, 145 F.2d 33, 35 (D.C. Cir. 1944). No court of appeals has ever adopted a contrary construction.[3]

In 1948, against the backdrop of this uniform judicial precedent, Congress reenacted these provisions at 18 U.S.C. §§ 1461-1462, without change to the relevant language. *See* Pub. L. No. 80-772, 62 Stat. 683, 768-769 (1948). This action—without more—"is convincing support for the conclusion that Congress

[3] Contrary to amici's suggestion, the fact that some of these cases involved the mailing of contraception items rather than abortion-producing items is irrelevant. *See* Ethics and Public Policy Center Br., Dkt. 198 at 17; Members of Congress Br., Dkt. 185 at 18. The statutory language defining the requisite mens rea applies to all the unmailable items listed in the Comstock laws, *see* 18 U.S.C. §§ 1461, 1462, and so the construction given to that language applies equally to abortion-producing items as to contraception items.

accepted and ratified the unanimous holdings of the Courts of Appeals" regarding the proper interpretation of the provisions. *Texas Department of Housing & Community Affairs v. Inclusive Communities Project, Inc.*, 576 U.S. 519, 536 (2015). That is because "[i]f 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." Scalia & Garner, *Reading Law: The Interpretation of Legal Texts* 322 (2012); *accord Texas Department of Housing*, 576 U.S. at 537 (citing cases to the same effect).

But here there is more: Congress's attention was specifically drawn to most of the circuit decisions discussed above. In particular, a note included in the House Judiciary Committee's 1947 report accompanying the bill stated: "The attention of Congress is invited to the following decisions of the Federal courts construing [proposed § 1461] and section 1462." H.R. Rep. No. 80-304, at A104-A105 (1947). These "decisions" to which Congress's "attention" was "invited" were four of the relevant circuit cases. First, the report explained that *Youngs Rubber* concluded that "the more reasonable interpretation" of the language "as used in [proposed § 1461] and section 1462" was "to construe the whole phrase 'designed, adapted or intended' 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.'" *Id*. at A105 (emphasis added). The report further observed that

Nicholas "rul[ed] directly on this point" when it found that "importation or sending through the mails" of the "articles or publications" was "not forbidden absolutely, but only when such articles or publications are *unlawfully* employed." *Id*. (emphasis added). Finally, the report added that "[t]he same rule was followed" by *Davis* and *One Package*. *Id*.

Revisers' notes issued in connection with the 1948 codification project have been described by the Supreme Court as "obviously authoritative." *United States v. National City Lines, Inc*., 337 U.S. 78, 81 (1949); *see also Ex parte Collett*, 337 U.S. 55, 71 (1949) ("flatly reject[ing]" the notion that "Congress did not appreciate what it was enacting" in light of a revisers' note); *United States v. Thompson*, 319 F.2d 665, 669 (2d Cir. 1963) ("[T]he revisers' notes to the 1948 codification of the Judicial Code … are authoritative guides to congressional intent."); *Acron Investments, Inc. v. Federal Savings & Loan Insurance Corporation*, 363 F.2d 236, 240 (9th Cir. 1966) (similar). Congress thus understood when it enacted §§ 1461-1462 that the language "as used in" those sections had been consistently interpreted to reach items for producing abortion only if intended to produce unlawful abortion. The fact that Congress enacted that language with that understanding and without expressing any reservation about that interpretation

shows conclusively that Congress intended by its enactment of §§ 1461-1462 to ratify that judicial interpretation.[4]

Indeed, having been alerted to this uniform precedent, Congress not only left the statutory text unchanged, but titled the new 18 U.S.C. § 1461 "Mailing obscene or *crime-inciting* matter" (emphasis added). Congress's framing of § 1461 as a statute concerned with conduct inciting crime reflects its understanding that the Act does not apply in connection with lawful abortions. *See Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) ("'[T]he title of a statute and the heading of a section' are 'tools available for the resolution of a doubt' about the meaning of a statute.'") (citation omitted).

B. Congress Repeatedly Ratified The Circuits' Unanimous Interpretation Of The Comstock Laws

While no more is needed to establish that Congress intended §§ 1461-1462 to reach abortion items only if intended for unlawful abortion, the decades-long

[4] Amici Members of Congress (Br., Dkt. 185 at 19), suggest there was no pre-1948 consensus by pointing to three court of appeals decisions involving prosecutions under the Comstock laws that did not expressly address whether the statute reached mailing for lawful abortions. Those decisions do not suggest that the cases in fact concerned *lawful* abortions. *See, e.g.*, *Weathers v. United States*, 126 F.2d 118, 119 (5th Cir. 1942) (referring to the abortions at issue as "a State crime"). And in any event, the revisers' note—which pointed to the consensus of courts to squarely address the issue—is the "authoritative" word on Congress's intent in reenacting the Comstock laws in 1948. *Supra* p.13.

post-1948 dialogue between Congress, the courts, and the executive agencies charged with enforcing the Comstock laws confirms that intent.

For example, in 1950 and again in 1955, Congress revised §§ 1461-1462 while preserving the key language. Pub. L. No. 81-531, §§ 1-2, 64 Stat. 194, 194 (1950); Pub. L. No. 84-95, §§ 1-2, 69 Stat. 183, 183 (1955). As explained, that shows Congress's ongoing intent to ratify the circuits' unanimous interpretation of the laws. In 1957, a district court recognized that "[t]he cases" interpreting §§ 1461-1462 hold "that only contraceptives [and abortion items] intended for 'unlawful' use were banned." *United States v. 31 Photographs*, 156 F. Supp. 350, 357 (S.D.N.Y. 1957) (citing *Bours*, *One Package*, *Nicholas*, *Youngs Rubber*, *Davis*, and *Consumers Union*). The next year, Congress again revised §§ 1461-1462 while preserving the abortion-related language—once again ratifying the interpretation that had just been recognized in *31 Photographs*. Pub. L. No. 85-796, § 2, 72 Stat. 962, 962 (1958).

Not long after that, another district court deemed it "well established that the defendants should not be convicted [under §§ 1461-1462] unless it is established beyond a reasonable doubt that at the time they mailed the sample packages of prophylactics that they intended them to 'be used for *illegal* contraception.'" *United States v. H.L. Blake Company*, 189 F. Supp. 930, 934-935 (W.D. Ark. 1960) (emphasis added) (citing *Bours*, *Nicholas*, *One Package*, *Youngs Rubber*,

and *Davis*). And in 1961, Justice Harlan similarly noted the "judicial interpretation … that the absolute prohibitions of the [Comstock] law … exclude professional medical use." *Poe v. Ullman*, 367 U.S. 497, 546 n.12 (1961) (Harlan, J., dissenting) (citing *Youngs Rubber*, *Davis*, and *One Package*). The following year, still another district court explained that it was "clear under the authorities that in order to make out an offense under [§§ 1461-1462], the Government should be required to allege and prove that … devices are shipped and received with intent that they be used for illegal contraception or abortion." *United States v. Gentile*, 211 F. Supp. 383, 385 n.5 (D. Md. 1962) (citing *Youngs Rubber*, *Davis*, and *Nicholas*).

Against this backdrop, Congress took up §§ 1461-1462 in the early 1970s. And it again left the language of §§ 1461-1462 intact with respect to abortion (while removing references to contraception in response to *Griswold v. Connecticut*, 381 U.S. 479 (1965)). Pub. L. No. 91-662, §§ 3-4, 84 Stat. 1973, 1973 (1971). Notably, in the leadup to the 1971 amendment, the United States Postal Service ("USPS") informed Congress that both USPS and the federal courts had adopted the long-standing, repeatedly ratified, narrow interpretation of the Act described above, as described in a House Report that accompanied the amendment. *See* H.R. Rep. No. 91-1105, at 3-4 (1970). Specifically, the Postmaster General informed the House Committee on Ways and Means that the Act had been

construed not to extend to mailing items "for lawful purposes[,]" and advocated for the removal of prohibitions related to contraception (which had become broadly lawful, and against which the Act had become "as presently written[,] … unenforceable"). *Id*. at 4. Amicus Ethics and Public Policy Center emphasizes that the same House Report states that existing statutes "completely prohibit" the importation and mailing of contraceptive materials. Br., Dkt. 198 at 27-28 (citing H.R. Rep. No. 91-1105 (1970)). But amicus takes this language entirely out of context. The statement was clearly an introductory reference to the literal text of the provisions, as opposed to their settled meaning, as the Report then discussed the Postmaster General's description of the settled narrow construction of the statute. H.R. Rep. No. 91-1105, at 3-4.

In 1994 and 1996, Congress again amended §§ 1461-1462 without material alteration. *See* Violent Crime Control and Law Enforcement Act, Pub. L. No. 103-322, § 330016, 108 Stat. 1796 (1994); Communications Decency Act, Pub. L. No. 104-104, tit. V, § 507(a), 110 Stat. 133, 137 (1996). These repeated post-1948 ratifications are still further evidence of Congress's understanding and approval of the circuits' unanimous interpretation of §§ 1461-1462 as excluding distributions intended for legal abortions. Some amici reference a failed amendment to § 1461 that would have confirmed that the statute applied only to "'illegal abortion[s].'" Ethics and Public Policy Center Br., Dkt. 198 at 27; Members of Congress Br.,

Dkt. 185 at 20-21; Advancing American Freedom Br., Dkt. 159 at 19-20. But as the Supreme Court has consistently warned, "failed legislative proposals are 'a particularly dangerous ground on which to rest an interpretation of a prior statute.'" *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 187 (1994).

Moreover, Congress re-enacted the Comstock laws while abortion was being openly, publicly, and legally provided—even before the Supreme Court recognized a federal constitutional right to abortion. In 1970, prior to the three most recent reenactments of the Comstock laws and before *Roe*, "a total of 16 states had liberalized their abortion laws." CDC, *Abortion Surveillance Annual Summary 1972*, at 2 (Apr. 1974). Those States "reported to the CDC" "over 193,000 legal abortions," *id.* at 1-2 & tbl.1. In 1972, more than 500,000 abortions were reported by just 17 States, *id*. at 2 & tbl. 1. If Congress understood the Comstock laws to prohibit sending items intended for lawful abortions, such widespread provision of legal abortion—formally reported to an arm of the Executive Branch—certainly put Congress on notice that neither the public nor the coordinate branches of government shared that understanding. But Congress took no responsive action, which one would have expected if there were such a stark discrepancy between Congress's intent and public understanding. Rather, Congress "perpetuat[ed] the wording" of the Comstock laws consistently interpreted by courts to prohibit only

conduct intended to result in unlawful abortions, and Congress is accordingly "presumed to carry forward that interpretation." *Texas Department of Housing*, 576 U.S. at 536.

Although some of the congressional ratification actions postdate *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), they are still meaningful because *Roe* and *Casey* did not prohibit all restrictions on abortions and some States permitted abortions that were not constitutionally protected. *See, e.g.*, Ore. Rev. Stat. § 435.240 (formerly Ore. Rev. Stat. § 659.880); D.C. Code § 2-1401.06 (repealed Feb. 23, 2023); N.J. Stat. § 10:7-2; Colo. Rev. Stat. § 25-6-403. Applying the Comstock laws to the distribution of items for producing abortions that were lawful in those States, therefore, would not necessarily have infringed the constitutional right to abortion and thus would have been an option for Congress every time it amended the Comstock laws. But, as explained, Congress simply reenacted the same language long understood *not* to reach items related to those lawful abortions. Thus, Congress's actions—both before *Roe* and after it—made clear that Congress intended for the Comstock laws to reach only unlawful abortions.

Furthermore, amici are aware of no prosecutions brought under the Comstock laws for sending or receiving materials related to the provision of lawful

abortion care since Congress's 1948 codification of the Act. Even before the Supreme Court recognized a federal constitutional right to abortion in *Roe v. Wade*, 410 U.S. 113 (1973), the Comstock laws were not used to bring prosecutions for sending or receiving supplies for lawful abortion care, despite the fact, as noted above, that more than half a million abortions were openly provided—and indeed reported to the federal government—the year before *Roe* was decided, *supra* p.18. Nor have there been such prosecutions after the Supreme Court's decision in *Dobbs*. And following that decision, the Department of Justice's Office of Legal Counsel ("OLC") issued an opinion in response to a request from USPS, reiterating that 18 U.S.C. §§ 1461-1462 do not prohibit sending or receiving mifepristone or misoprostol when the sender or receiver does not intend for the recipient of the drugs to use them unlawfully. *See Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 46 Op. O.L.C. __, slip op. at 1-2 & n.3, 20-21 & n.27 (Dec. 23, 2022). The OLC Opinion joined the longstanding and uniform recognition by legislative, judicial, and executive actors that the Comstock laws do not apply to sending or receiving items for use in abortion care absent the intent they be used unlawfully.

C. The Comstock Laws' Text And Structure Show Congress Intended That They Reach Only Items Intended For Unlawful Abortions

Even without Congress's actions in 1948 and thereafter, the Comstock laws' text and structure would require that §§ 1461-1462 be interpreted to reach items only if intended for unlawful abortion.

As the Supreme Court has explained, a court's "duty … is to construe statutes, not isolated provisions." *King v. Burwell*, 576 U.S. 473, 486 (2015) (quotation marks omitted). Sections 1461-1462 must therefore be read in harmony with 19 U.S.C. §1305(a), which prohibits the "import[ation]" of "any drug or medicine or any article whatever for causing *unlawful* abortion" (emphasis added) and which also derives from the originally enacted Comstock Act, Act of Mar. 3, 1873, ch. 258, §3, 17 Stat. 598, 599. Moreover, statutory "interpretations … which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available." *Griffin v. Oceanic Contractors, Inc*., 458 U.S. 564, 575 (1982).

Plaintiffs' interpretation of §§ 1461-1462 is not faithful to these canons. Indeed, it creates two absurdities in light of § 1305(a). First, it would mean that items intended for lawful abortion could be imported under § 1305(a) but not then distributed under §§ 1461-1462, or at least not distributed through the primary modes of interstate distribution for imported items. Such a regime makes no sense.

Second, it would mean that items intended for lawful abortion could be imported under § 1305(a), but the importer could be prosecuted for doing so under § 1462, which prohibits importing abortion-producing items. Creating such a trap—where a person could be convicted of a crime for an act that another federal law expressly permits—is not only senseless but also would raise serious due-process concerns, contrary to the admonition that "statutes should be read where possible to avoid unconstitutionality." *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215, 287 (2022).

The court of appeals decisions discussed earlier recognized these problems. For example, in *One Package* the Second Circuit found it "hard to suppose" that Congress intended that "articles intended for use in procuring abortions were prohibited in all cases" under §§ 1461-1462 but "only prohibited when intended for use in an 'unlawful abortion'" under § 1305. 86 F.2d at 739. Concurring, Judge Learned Hand amplified the point, observing that "it is of considerable importance that the law as to importations should be the same as that as to the mails; we ought not impute differences of intention upon slight distinctions in expression." *Id.* at 740.

And even apart from § 1305, the Seventh Circuit recognized, it is not "reasonable" to suppose Congress intended "the statute [to] cover all acts of abortion." *Bours*, 229 F. at 964. As the Second Circuit elaborated, "[t]he intention

to prevent a proper medical use of drugs or other articles merely because they are *capable* of illegal uses is not lightly to be ascribed to Congress." *Youngs Rubber*, 45 F.2d at 108 (emphasis added). Therefore, the court said, it would not be "reasonable" to read the statute "to forbid the transportation by mail or common carriage of anything 'adapted' … for preventing conception … 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." *Id*.; *see also Davis*, 62 F.2d at 474-475. And the Second Circuit affirmed the reasoning in *One Package*, rejecting the notion that Congress intended to "bar [distribution of] articles for preventing conception though employed by a physician in the practice of his profession in order to protect the health of his patients or to save them from infection," 86 F.2d at 739; *see also id*. at 740 (Hand, J., concurring) ("It seems unreasonable to suppose that the national scheme of legislation involves such inconsistencies and requires the complete suppression of articles, the use of which in many cases is advocated by such a weight of authority in the medical world."). Likewise, the D.C. Circuit concluded that, consistent with its "duty to avoid absurdity or injustice," the statutory language should not be "tak[en] out of context" but rather should be construed to make exception for legitimate medical use. *Consumers Union*, 145 F.2d at 34-35.

Reading the Comstock laws contrary to the narrow construction Congress ratified also would disrupt and displace the States' authority to regulate abortion within the bounds of the federal Constitution and any federal statutory protections. "[I]f Congress intends to alter the 'usual constitutional balance between the States and the Federal Government,' it must make its intention to do so 'unmistakably clear in the language of the statute.'" *Will v. Michigan Department of State Police*, 491 U.S. 58, 65 (1989) (citation omitted). Plaintiffs' interpretation of the Comstock laws as essentially an indirect ban on abortion care in States that choose to keep abortion legal runs counter to this "clear statement" requirement. Indeed, when overturning *Roe* and *Casey*, the Supreme Court underscored that States would be free to permit abortion. *See Dobbs*, 597 U.S. at 217-218 ("[T]he people of the various States may evaluate those interests differently. The Nation's historical understanding of ordered liberty does not prevent the people's elected representatives from deciding how abortion should be regulated."); *see also id*. at 339 (Kavanaugh, J., concurring) ("[T]he 'States may, if they wish, permit abortion on demand[.]'" (quoting *Casey*, 505 U.S. at 979 (Scalia, J., concurring in judgment in part and dissenting in part))); *id*. ("Today's decision therefore does not prevent the numerous States that readily allow abortion from continuing to readily allow abortion."). Plaintiffs' interpretation would flatly contradict this authority, effectively nullifying state laws that permit abortion by blocking the supply of the

materials necessary to engage in conduct deemed lawful—and indeed, in many instances, constitutionally protected—by individual States.

III. PLAINTIFFS' INCORRECT INTERPRETATION OF THE COMSTOCK LAWS THREATENS TO AFFECT ALL ABORTIONS—NOT JUST TELEMEDICINE ABORTIONS—AND EVEN NON-ABORTION HEALTHCARE

The Court should reject Plaintiffs' interpretation of the Comstock laws because it is legally unsound for all the reasons discussed above. In addition, the Court should reject that interpretation because it could have devastating and far-reaching impacts on the provision of in-person abortion care and other essential healthcare—effects that underscore the implausibility of Plaintiffs' interpretation.

According to Plaintiffs, allowing for the mailing of mifepristone to patients is unlawful because the Comstock laws make it criminal to mail abortion-producing items. But nothing in the nature of that construction is limited to telemedicine abortion or to mifepristone. Mifepristone is also regularly used for *in-person* abortion care. National Abortion Federation, Abortion in Clinic: What to Expect. And the hospitals and clinics that provide that in-person care receive their supply of mifepristone through the mail or common carrier. *See, e.g.*, GenBioPro, Ordering for Dispensing. Plaintiffs' interpretation would reach such mailing, threatening to block a common method of lawful, in-person abortion care.

Plaintiffs' interpretation could also impact the availability of a wide range of other drugs, devices, and items that may be used to produce an abortion and that

hospitals and clinics receive through the mail or common carrier—not just mifepristone. *See* Felix et al., *The Comstock Act: Implications for Abortion Care Nationwide*, Kaiser Family Foundation (Apr. 15, 2024). Amici Women Injured By Abortion et al. suggest that "surgical abortions would still be available in states where abortion is legal." Br., Dkt. 194-1 at 18. But amici fail to explain why Plaintiffs' erroneous interpretation of the Comstock laws would not also reach items necessary for procedural abortions, such as manual vacuum aspirators, as the Comstock laws are not limited to drugs.

Critically, blocking the supply of many of these drugs and items could impact non-abortion healthcare as well. Mifepristone itself offers critical advantages in miscarriage management. Gordon & McCammon, *A Drug That Eases Miscarriages Is Difficult For Women To Get*, NPR (Jan. 10, 2019). In a world in which Plaintiffs' interpretation of the Comstock laws blocked the availability of this medicine, healthcare providers would be unable to treat patients experiencing miscarriage with the full range of treatments. And misoprostol, the other medication used in the two-drug medication abortion regimen, is also used in various settings outside the abortion context. Healthcare providers regularly use misoprostol for induction of labor to deliver a baby at term, to prevent and treat postpartum hemorrhage—a life-threatening complication of delivery—and for a range of other common gynecological procedures. Li et al., *Classifying*

Misoprostol and Mifepristone as Controlled Substances: Implications for the Management of Non-Abortion Related Conditions, Kaiser Family Foundation (Apr. 3, 2025).

In sum, the Court should reject Plaintiffs' incorrect interpretation of the Comstock laws, which would significantly destabilize both abortion and non-abortion healthcare across the United States.

CONCLUSION

The Court should deny Plaintiffs' request that the merits panel enter a § 705 stay of the 2023 REMS.

Respectfully submitted.

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July 22, 2026

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g)(1), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Fed. R. App. P. 29(a)(5).

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/s/ Kimberly A. Parker
KIMBERLY A. PARKER

July 22, 2026

APPENDIX

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I hereby certify that on this 22nd day of July, 2026, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

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