No. 23-10362

UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Plaintiff-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Defendants-Appellants.

On Appeal from the United States District Court for the Northern District of Texas, No. 2:22-cv-00223, Judge Matthew J. Kacsmaryk

UNOPPOSED MOTION FOR LEAVE OF FORMER U.S. DEPARTMENT OF JUSTICE OFFICIALS TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS AND REVERSAL

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May 1, 2023

SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.

No. 23-10362

The undersigned counsel of record certifies that—in addition to the persons and entities listed in defendants-appellants' and intervenor-appellant's Certificates of Interested Persons—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 so the judges of this Court may evaluate possible disqualification or recusal.

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Counsel for Amici former high-ranking U.S. Department of Justice officials

Pursuant to Federal Rule of Appellate Procedure 27 and 29(a)(3) and the Court's letter of April 19, 2023 (ECF #206), movants, former U.S. Department of Justice officials, respectfully move this Court for leave to file the accompanying 6351-word amicus curiae brief in support of appellants and reversal. All parties have consented to the filing of this amicus brief.

I. MOVANTS HAVE A SIGNIFICANT INTEREST IN THIS CASE

Movants are 58 former high-ranking Department of Justice officials who served in administrations of both major parties, including U.S. Attorneys General, Deputy Attorneys General, Assistant Attorneys General, and U.S. Attorneys. Movants held responsibility 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. Movants have a significant interest in how federal criminal laws are interpreted and in preserving the Department of Justice's role as the authoritative executive branch interpreter of the Comstock laws.

II. MOVANTS' PROPOSED AMICUS CURIAE BRIEF WOULD PROVIDE ADDITIONAL ANALYSIS OF ISSUES THAT WERE CENTRAL TO THE RULING UNDER REVIEW

This appeal seeks review of the district court's decision staying various actions by the Food and Drug Administration regarding mifepristone. Movants' brief is desirable and relevant to the case because it will provide the Court with

additional important analysis regarding issues that were central to the district court's decision: the relevance and meaning of the Comstock laws, 18 U.S.C. §§ 1461-1462. Movants' brief will explain that the district court erroneously assumed that FDA was authorized and obligated to consider, interpret, and account for federal criminal laws when approving a new-drug application or a risk evaluation and mitigation strategy ("REMS"). The brief will also explain that even if the Comstock laws bore on the validity of FDA's actions, the actions would be valid because they are consistent with the Comstock laws. The district court gravely misinterpreted the Comstock laws to expand their reach far beyond Congress's intent, as shown by the laws' text, structure, and numerous reenactments.

Movants believe their brief will assist the Court in resolving these issues. As former high-ranking Department of Justice officials who were responsible for enforcing the Comstock laws, movants are well situated to provide insight into the district court's errors regarding the Comstock laws.

Movants have diligently kept their brief to the shortest length necessary to clearly present their most important arguments, while avoiding unnecessary repetition of points already made in appellants' principal briefs.

CONCLUSION

Accordingly, movants respectfully request that this Court grant leave to file the accompanying amicus curiae brief.

Respectfully submitted,

/s/ John F. Walsh

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May 1, 2023

CERTIFICATE OF COMPLIANCE

This motion contains 427 words in compliance with Rule 27(d)(2)(A). This filing complies with the typeface and typestyle requirements of Rule 27(d)(1)(E), which refers to Rules 32(a)(5) and 32(a)(6), because it has been prepared in a proportionally spaced typeface (14-point Times New Roman) using Microsoft Word.

/s/ John F. Walsh
JOHN F. WALSH

May 1, 2023

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May 2023, 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.

/s/ *John F. Walsh*
JOHN F. WALSH

May 1, 2023

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STATEMENT OF INTEREST[1]

Amici are 58 former high-ranking U.S. Department of Justice officials who served in administrations of both major parties, including U.S. Attorneys General, Deputy Attorneys General, Assistant Attorneys General, and U.S. Attorneys. Amici held responsibility 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 begins at page i above.

Amici hold diverse views regarding the moral and jurisprudential questions surrounding abortion, but agree the district court erroneously assumed that the Food & Drug Administration was authorized to consider, interpret, and apply federal criminal laws as part of its drug approval process, and gravely misinterpreted the Comstock laws, expanding their scope beyond Congress's intent. Given the seriousness of the district court's errors in rejecting the interpretation of the Justice Department, the sole agency responsible for prosecuting violations of the Comstock laws, amici urge this Court to reverse the district court's order.

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[1] No party, party's counsel, or person other than the amici curiae, their members, and counsel who authored this brief in whole or in part contributed money intended to fund preparing or submitting this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Court should reverse the district court's order. The ruling is erroneous regardless of how the Comstock laws are interpreted, and therefore the Court need not address their meaning, but the district court also interpreted them incorrectly.[2]

First, the Comstock laws are irrelevant to the validity of FDA's mifepristone actions. Congress charged FDA solely with determining whether a drug is safe and effective. Once FDA determined mifepristone was safe and effective under the terms of use, FDA was required to approve it. FDA had no authority, duty, or capacity to account for the Comstock laws. Further, FDA's determinations could not and did not declare distribution of the drug lawful despite the Comstock laws.

Second, if the Comstock laws were relevant to FDA's actions, FDA's actions would be valid because they accord with those laws—both under the district court's broad but incorrect interpretation and under the narrow and correct interpretation long held by the courts and recognized by the executive branch.

The district court gravely misinterpreted the Comstock laws to reach items intended to produce abortion, whether unlawful or not. Across three decades, four circuits issued six decisions all concluding, after careful and compelling analysis, that the Comstock laws reach the distribution of items only if intended to produce

[2] Although the district court's analysis of the Comstock laws addressed only FDA's 2021 actions, this brief's arguments apply equally to all the challenged FDA actions.

unlawful abortions. Dismissing those decisions as "aging," ECF #183-2, at 42, overlooks how well they have aged. Their narrow interpretation is the only one that makes sense of the Comstock laws fully—not just §§1461-1462 but also 19 U.S.C. §1305—and avoids multiple absurd and unconstitutional implications. The ruling below is the only judicial decision ever to reject this interpretation.[3] Most importantly, this interpretation was knowingly adopted by Congress in 1948 and ratified over the past 75 years by Congress's repeated reenactments and amendments of the laws without relevant alteration, while fully aware of the courts' interpretation.

Even under the district court's unprecedented interpretation, however, §§1461-1462 would still allow non-in-person dispensing in various ways. Therefore, FDA's actions do not approve distribution that is categorically prohibited by the Comstock laws, however interpreted.

Finally, because the Comstock laws' meaning is both irrelevant and clear, questions about their meaning do not tilt the balance of equities toward plaintiffs.

[3] The motions panel declined to "definitively interpret" the Comstock laws. ECF #183-2, at 42.

ARGUMENT

I. THE COMSTOCK LAWS' SCOPE IS IRRELEVANT TO THE VALIDITY OF FDA'S ACTIONS

The district court concluded that FDA's 2021 actions eliminating the in-person dispensing requirement are invalid because the Comstock laws supposedly "prohibit the mailing" of mifepristone. Memorandum Opinion and Order ("Op.") at 32, D.C. Dkt. #137. But the Comstock laws, however interpreted, are irrelevant because FDA's actions do nothing more than FDA is authorized to do: assess whether mifepristone would be safe and effective under specified conditions.

A. FDA Had No Power Or Duty To Account For The Comstock Laws

Like any agency, FDA's "power to regulate … must always be grounded in a valid grant of authority from Congress." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126, 161 (2000). Congress specified that FDA serves as a limited gatekeeper: FDA assesses only whether a drug is safe and effective for the indicated use; if FDA determines the drug is safe and effective, it must approve it; and that determination merely removes a barrier to the drug's distribution. Accounting for any drug restrictions imposed by laws it does not administer—"factors which Congress has not intended [FDA] to consider"—would render FDA's actions invalid. *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 43 (1983).

The Food, Drug, and Cosmetic Act ("FDCA") requires that, in deciding whether to approve a drug application, FDA 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 Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). The statute specifies seven "grounds 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 are present, FDA "shall" approve the application. *Id.*; *see also* 21 C.F.R. §§314.105, 125. Therefore, FDA cannot deny a drug application based on the implications of the Comstock laws (or any other law FDA does not administer).

FDA's "risk evaluation and mitigation strategy" ("REMS") framework is similarly focused on safety and efficacy. The statute requires the applicant to propose a REMS if FDA determines one "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." §355-1(a)(1); *see also* §355-1(a)(2), (b)(1), (4)-(5). Accordingly, the REMS must contain means to mitigate risks to patients' health. *See* §355-1(c), (e)-(f). Nothing authorizes FDA to consider the implications of the Comstock laws or any other law FDA does not administer in the REMS process.

Moreover, it would be impracticable for FDA to catalog and evaluate all laws it does not administer that might somehow apply to the drugs it reviews—and to continually monitor changes in such laws and reevaluate its prior decisions in light of those changes.

Finally, FDA's approval is merely a necessary condition for introducing a drug into interstate commerce: "*No* person shall introduce … into interstate commerce any new drug, *unless*" FDA has approved the drug. 21 U.S.C. §355(a) (emphasis added); *see also, e.g.*, *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 476 (2013); *Wyeth v. Levine*, 555 U.S. 555, 592 (2009) (Thomas, J., concurring).

In sum, FDA approval means nothing with respect to the applicability of federal laws outside FDA's purview—FDA's approval and REMS decisions neither are subject to nor override such laws. In fact, FDA routinely approves drugs that are subject to restrictions FDA does not administer. One example is the Controlled Substances Act, which is enforced by the Attorney General 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).

Plaintiffs mistakenly rely on a remark in *FCC v. NextWave Personal Communications Inc.* that the Administrative Procedure Act requires agencies to

follow "*any* law and not merely those laws that the agency itself is charged with administering." 537 U.S. 293, 300 (2003). But that remark confirmed that an agency must comply with laws that apply to it—there, a Bankruptcy Code provision prohibiting "governmental unit[s]" from taking the very action the FCC had taken. *See id.* at 300-301; 11 U.S.C. §525(a). Here, the Comstock laws do not govern FDA's drug-approval and REMS decision-making; they govern the distribution of abortion-producing items.

B. FDA's Actions Do Not Purport To Legalize The Distribution Of Mifepristone Through Means Covered By The Comstock Laws, However They Are Interpreted

FDA's 2021 actions conform to FDA's limited statutory authority. Their reference to "dispensing of mifepristone through the mail … or through a mail-order pharmacy," PI.App.066, expressed nothing more than FDA's determination that such distribution would not undermine mifepristone's safety or efficacy, PI.App.714-715. That is, again, the only consideration FDA may assess. And its actions appropriately did not declare *lawful* the distribution of mifepristone in ways that might be prohibited by the Comstock laws, even under the district court's incorrect interpretation.

II. FDA'S ACTIONS ACCORD WITH THE COMSTOCK LAWS, HOWEVER INTERPRETED

Even if the Comstock laws bore on FDA's 2021 actions, the district court's invalidation of those actions based on the Comstock laws would be erroneous

because those actions accord with the Comstock laws, however interpreted. Make no mistake: the district court's interpretation—that §§1461-1462 prohibit distribution of items intended to produce not only unlawful abortions but also lawful ones—is incorrect. As every circuit court to address the question recognized, interpreting §§1461-1462 to reach items intended to produce *lawful* abortions is facially absurd and raises constitutional concerns, especially given the interaction between §§1461-1462 and §1305. Regardless of whether the courts' interpretation was right initially, however, Congress's 1948 reenactment of the Comstock laws specifically adopted that interpretation. Congress also ratified that interpretation by repeatedly reenacting and amending the laws without material alteration while fully aware of the courts' interpretation. The district court disregarded much of this evidence and committed myriad other errors.

However, FDA's actions would not contradict the Comstock laws even under the district court's erroneous, broad interpretation because the Comstock laws would still permit non-in-person distribution of mifepristone under some circumstances.

A. The Comstock Laws Reach Only Distribution Intended For Unlawful Abortion

1. Congress enacted §§1461-1462 specifically intending that they be interpreted to reach items only if intended for unlawful abortion

The Comstock laws were initially 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 them to have substantially the language found today at 18 U.S.C. §§1461-1462. One section—corresponding to §1461—prohibited "knowingly deposit[ing]" in the mails "every article or thing designed, adapted, or intended for preventing conception or producing abortion." Pub. L. No. 60-350, 35 Stat. 1088, 1129 (1909). Another provision—corresponding to §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." *Id.* at 1138.

Between 1915 and 1944, four federal circuit courts issued six decisions interpreting this statutory language. Each one rejected the proposition that these provisions reached items for preventing conception and producing abortion regardless of the intended circumstances of their use. *See Bours v. United States*, 229 F. 960, 964-965 (7th Cir. 1915); *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103, 107-108 (2d Cir. 1930); *Davis v. United States*, 62 F.2d 473, 474-475

(6th Cir. 1933); *United States v. One Package*, 86 F.2d 737, 738-739 (2d Cir. 1936); *United States v. Nicholas*, 97 F.2d 510, 512 (2d Cir. 1938); *Consumers Union of United States v. Walker*, 145 F.2d 33, 33, 35 (D.C. Cir. 1944). No circuit court has ever concluded otherwise.

In 1948, Congress reenacted these provisions at 18 U.S.C. §§1461 and 1462. *See* Pub. L. No. 80-772, 62 Stat. 683, 768-769 (1948). In doing so, Congress preserved the relevant language based on its express understanding that the language had been—and thus would continue to be—interpreted to apply only when the item was intended for *unlawful* contraception or abortion. 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 (1947). The report described four of the relevant circuit cases. First, the report stated that *Youngs Rubber* said the language "as used in [proposed §1461] and section 1462 … is not to be construed literally, the more reasonable interpretation being 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. Next, the report stated that *Nicholas* "held that the importation or sending through the mails of contraceptive [or abortion] articles is not forbidden absolutely, but only

when such articles or publications are unlawfully employed." *Id*. Finally, the report added that "[t]he same rule was followed" by *Davis* and *One Package*. *Id*.

Thus, Congress 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 rejection of that interpretation shows conclusively that Congress intended §§1461-1462 to have that narrow meaning. *See, e.g.*, *Ex parte Collett*, 69 S. Ct. 944, 952 (1949) (because of similar note in legislative history, "flatly reject[ing]" argument that "Congress did not appreciate what it was enacting"). The district court fatally ignored this history.

2. Congress repeatedly ratified the narrow interpretation of the Comstock laws

The decades-long dialogue among Congress, the courts, and the executive branch also shows that Congress intended §§1461-1462 to reach abortion items only if intended for unlawful abortion.

"'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.'" *Texas Department of Housing & Community Affairs v. Inclusive Communities Project, Inc.*, 576 U.S. 519, 536-537 (2015) (alterations omitted) (quoting Scalia & Garner, *Reading Law: The Interpretation of Legal*

Texts 322 (2012)); *see also, e.g.*, *Forest Grove School District v. T.A.*, 557 U.S. 230, 239-240, 243 n.11 (2009); *id*. at 256 (Souter, J., dissenting, joined by Scalia and Thomas, JJ.); *AMG Cap. Mgmt., LLC v. FTC*, 141 S. Ct. 1341, 1351 (2021); *Food Marketing Institute v. Argus Leader Media*, 139 S. Ct. 2356, 2365-2366 (2019); *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 139 S. Ct. 628, 633-634 (2019); *Minerva Surgical, Inc. v. Hologic, Inc.*, 141 S. Ct. 2298, 2315 (2021) (Barrett, J., joined by Thomas and Gorsuch, JJ., dissenting); *id.* at 2312-2313 (Alito, J., dissenting); *Negusie v. Holder*, 555 U.S. 511, 546-548 (2009) (Thomas, J., dissenting).

Congress's many actions relating to the Comstock laws show that it has repeatedly ratified the interpretation that they reach items only if intended for unlawful abortion. As already noted, by the 1940s every circuit court to reach the question had rejected the broad interpretation adopted by the district court here. And as noted, Congress, informed of that consensus, reenacted the key language without alteration in 1948; that action ratified the courts' consensus interpretation.

Then in 1950 and 1955, Congress again ratified by revising §§1461-1462 while preserving the key language. Pub. L. No. 81-531, §1, 64 Stat. 194, 194 (1950); Pub. L. No. 84-95, §§1-2, 69 Stat. 183, 183 (1955). In 1957, a federal court remarked that "[t]he cases" interpreting §§1461-1462 "held … 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*, *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).

In 1960, a federal court stated: "[I]t is 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 Co.*, 189 F. Supp. 930, 934-935 (W.D. Ark. 1960) (citing *Bours*, *Nicholas*, *One Package*, *Youngs Rubber*, and *Davis*). In 1961, Justice Harlan issued an opinion noting 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*). In 1962, another federal court stated: "It seems 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*).

After those cases, Congress next took up §§1461-1462 in the early 1970s. During that process, the Postmaster General—who administers §1461—reported to Congress that "the delivery by mail of contraceptive … materials has by court decisions, and administrative rulings based on such decisions, been considered proper in cases where a lawful and permissive purpose is present." H.R. Rep. No. 91-1105, at 3-4 (1970). Congress then removed contraception from §§1461-1462 (in response to *Griswold v. Connecticut*, 381 U.S. 479 (1965)), but left the language intact for abortion. Pub. L. No. 91-662, §§3-4, 84 Stat. 1973, 1973 (1971). 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, 108 Stat. 1796 (1994); Communications Decency Act, Pub. L. No. 104-104, Title V, §507(a), 110 Stat. 56, 137 (1996). And in the twenty-seven years since, Congress has still not altered that language.

Although some of these congressional actions post-date *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), they are meaningful because, as the district court itself observed, *Roe* and *Casey* "did not prohibit *all* restrictions on abortions," Op.38. Some abortions remained constitutionally unprotected, and yet some states permitted such abortions. *See, e.g.*, Oregon Rev. Stat. §659.880; D.C. Code §2-1401.06 (repealed Feb. 23, 2023); New Jersey Stat. §10:7-2; Colorado Rev. Stat.

§25-6-403. Applying the Comstock laws to the distribution of items for producing abortion in those states, therefore, would not necessarily have infringed the constitutional right to abortion. Accordingly, the question of whether the Comstock laws reached items intended for lawful abortions remained live.

In sum, the Comstock laws were consistently interpreted narrowly; later courts and the executive recognized that consensus; Congress knew about that consensus; and Congress repeatedly reenacted or amended the laws without material alteration. These circumstances leave no doubt that Congress ratified and adopted that interpretation.

3. 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. The district court also fatally disregarded these statutory features.

a. Sections 1461-1462 must be read in harmony with another Comstock law, which prohibits the "import[ation]" of "any drug or medicine or any article whatever for causing *unlawful* abortion." 19 U.S.C. §1305(a) (emphasis added). "[R]econciling many laws enacted over time, and getting them to 'make sense' in combination," is a "classic judicial task." *United States v. Fausto*, 484 U.S. 439,

453 (1988); *see also King v. Burwell*, 576 U.S. 473, 486, 497 (2015) ("Our duty … is to construe statutes, not isolated provisions." (cleaned up)).

Here, the court's broad interpretation of §§1461-1462 would create 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. Second, and more absurd, it would mean that items intended for lawful abortion could be imported under §1305(a) but then the importer could be punished criminally for doing so under §1462, which prohibits importing abortion-producing items ("Whoever brings into the United States …."). Creating such a trap—where a person could be convicted of a crime for an act that another federal law expressly permits—would also raise serious due process concerns. *See, e.g.*, *North Carolina v. Pearce*, 395 U.S. 711, 738-739 (1969) (Black J., concurring) ("It [would be] impossible for citizens to know which one of the two conflicting laws to follow, and would thus violate one of the first principles of due process."), *overruled on other grounds by Alabama v. Smith*, 490 U.S. 794 (1989).

"[I]interpretations … which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available," even if the statutory language is otherwise plain. *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982); *see also Hartford Underwriters Insurance Co. v.*

Union Planters Bank, N.A., 530 U.S. 1, 6 (2000). Similarly, "statutes should be read where possible to avoid unconstitutionality." *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2276 (2022). These problems can be avoided by reading §§1461-1462 to mirror §1305, i.e., to reach items only if intended for unlawful abortion. Indeed, Congress long ago stated that §§1461-1462 and §1305 should operate "in conformity." H.R. Rep. No. 71-7, at 160 (1929). Accordingly, the Supreme Court has interpreted the two sets of provisions together. *See, e.g.*, *United States v. 12 200-Ft. Reels of Super 8mm. Film*, 413 U.S. 123, 130 n.7 (1973).

Thus, 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 738-739. Concurring, Judge Learned Hand amplified the point: "[I]t 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.

b. Even without §1305, however, the district court's broad interpretation of §§1461-1462 makes no sense. As the circuits have consistently 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 put it, "The 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. Therefore, the court said, it would not be "reasonable" to take the statutory language "literally … 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.* The Sixth Circuit deemed that "reasoning" "sound[]." *Davis*, 62 F.2d at 474-475. The Second Circuit affirmed that reasoning in *One Package*, adding that it is "hard to suppose" 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 738-739; *see id.* at 740. Likewise, the D.C. Circuit concluded that, consistent with its "duty to avoid absurdity or injustice," the statute should not be "tak[en] out of context and read[] literally" but rather should be construed to make exception for legitimate medical use. *Consumers Union*, 145 F.2d at 34-35.

4. The district court's contrary reasoning is thoroughly flawed

The flaws in the district court's reasoning begin with its disregard of Congress's 1948 reenactment of §§1461-1462 and of the relationship between §§1461-1462 and §1305. But there are many other flaws:

a. The court relied on precedent stating that "[w]here the law is plain, subsequent reenactment does not constitute an adoption of a previous administrative construction." Op.33 (cleaned up); *see also* Op.34-35. That precedent does not apply here for three reasons. First, Congress's 1948 reenactment imbued §§1461-1462 with a specific meaning and thus takes this beyond the ordinary situation of implied congressional ratification. Second, even without that action, the plain meaning of §§1461-1462 would not be what the district court claimed. As explained in Part II.A.3, *supra*, the district court's view of §§1461-1462's plain meaning yields various absurdities and constitutional concerns. *See King*, 576 U.S. at 486 ("oftentimes the meaning—or ambiguity—of certain words or phrases may only become evident when placed in context"). Further, the text is at most ambiguous because whereas it says, "for *any* indecent or immoral purpose," §1461 (emphasis added); *accord* §1462, it contains no such clarifying language regarding abortion (e.g., "for producing *[any]* abortion").[4] And third, the precedent cited by the district court involved a very different situation: "clear inconsistency" between the statute's plain language and "a previous administrative construction." *Brown v. Gardner*, 513 U.S. 115, 121-122

[4] Such ambiguity would trigger the constitutional rule of lenity, which "requires ambiguous criminal laws to be interpreted in favor of the defendants subjected to them." *United States v. Santos*, 553 U.S. 507, 514 (2008) (Scalia, J., concurring, joined by Souter, Ginsburg, Thomas, JJ.); *accord id.* at 528 (Stevens, J., concurring).

(1994); *Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991) ("administrative interpretation" was "contrary to [statute's] plain" language). Here, the proper interpretation of the Comstock laws—that they apply only to distribution intended for unlawful abortion—was adopted by the courts, not an agency, and does not clearly contradict the laws' plain text.

b. The district court impugned the doctrine of ratification by reenactment, hypothesizing that reenactments could be motivated by other reasons, such as counteracting a "sunset" provision, laziness, or inattention. Op.34 (citing Nelson, *Statutory Interpretation* 481 (2011)). The court's cherrypicked academic sources do not supersede the Supreme Court precedent noted above recognizing ratification by reenactment. In any event, it is implausible to suppose that Congress did not intend to ratify when it repeatedly reenacted and amended the provisions without materially altering the relevant language while knowing that language had been widely interpreted narrowly for many decades—indeed, that is inconceivable given the 1948 reenactment.

c. The district court denied a judicial "consensus" against which Congress reenacted the laws, but that denial is misguided. First, however one might parse the relevant Comstock cases is irrelevant; what matters is what Congress understood them to mean. As described above, the 1947 House report gave the cases a consistent reading: §§1461-1462 reach abortion items "only"

when intended for "unlawful" or "illegal" abortion. H.R. Rep. No. 80-304, at A104-A105. *That* is the understanding on which Congress enacted §§1461-1462 in 1948 and thus *that* is the meaning Congress gave those provisions. As described above, later cases—*31 Photographs* in 1958, *H.L. Blake* in 1960, Justice Harlan's opinion in *Poe* in 1961, and *Gentile* in 1962—reiterated that characterization of the earlier precedents and thus reinforced Congress's repeated ratification of that meaning.

Second, in any event, the circuit precedents themselves said they embodied a consensus that §§1461-1462, like §1305, reach items only if intended for unlawful abortion. *Youngs Rubber* cited *Bours* for its conclusion that "the whole phrase 'designed, adapted or intended' … requir[es] an intent on the part of the sender that the article mailed or shipped by common carrier be used for illegal contraception or abortion." 45 F.2d at 108. *Davis* relied on *Bours* and *Youngs Rubber* to reach the same conclusion. 62 F.2d at 475. *One Package* said "the courts"—*Bours*, *Youngs Rubber*, and *Davis*—"have read an exemption into the act" embodied in "[t]he word 'unlawful.'" 86 F.2d at 739. *Nicholas* cited *Youngs Rubber*, *One Package*, and *Davis* for the proposition that the laws "should be read as forbidding [distribution of abortion items] only when unlawfully employed." 97 F.2d at 512. And *Consumers Union* "follow[ed] the interpretation which has been adopted in other circuits"—citing the Second and Sixth Circuit decisions—"namely, that

Congress did not intend to exclude from the mails properly prepared information intended for properly qualified people." 145 F.2d at 35 & n.11.

Yet, the district court insisted that the circuits did not agree on the exemption's precise scope, suggesting variation regarding whether it is for "lawful," "legitimate," or "[]moral" uses, and whether what is lawful, legitimate, or moral is determined by state or federal authority. Op.37. There is no need to resolve such questions now. As the district court conceded, there was at least a judicial consensus that §§1461-1462 did not reach items intended for some abortion uses; Congress's actions in 1948 and later embraced and ratified at least that much; abortion is recognized as lawful, legitimate, and moral around the country (to varying degrees); therefore, §§1461-1462 indisputably allow some distribution of abortion drugs through the mails or common carriers in interstate commerce.

Regardless, the district court's questioning of the judicial consensus was mistaken. As *One Package* recognized, §§1461-1462 must be qualified with "unlawful" to get them to make sense with §1305, since that is the word that §1305 uses. *See* 86 F.2d at 739-740. Further, as the quotations from *One Package* and other circuit precedents above (as well as other portions of those opinions) make clear, the courts treated notions of lawful, legitimate, and moral as equivalent. *One Package* encapsulated this equivalence: "[W]e are satisfied that [the Comstock

laws] embraced only such articles as Congress would have denounced as *immoral* if it had understood all the conditions under which they were to be used. Its design … 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. The word '*unlawful*' would make this clear as to articles for producing abortion." *Id.* at 739 (emphasis added).

An amicus supporting plaintiffs agrees that the concepts were used interchangeably, but contends that they all mean that the exemption is only for "legitimate" or "moral" uses, not "lawful" ones. Brief of Amicus Curiae the American Center for Law and Justice in Opposition to Stay 7-11, *Danco Laboratories v. Alliance for Hippocratic Medicine*, Nos. 22A901, 22A902 (U.S. Apr. 17, 2023). That oddly selective reading of the cases is incorrect. Discerning "morality" is "a task impossible of assured execution" for the courts, *Johnson v. United States*, 186 F.2d 588, 589 (2d Cir. 1951), because "[a]bortion presents a profound moral issue on which Americans hold sharply conflicting views," *Dobbs*, 142 S. Ct. at 2240. As *One Package* observed in the passage quoted above, the "word 'unlawful'" supplies a judicially workable standard and "makes clear" that the Comstock laws exclude moral and legitimate uses insofar as abortion laws embody judgments about what is moral or legitimate. Additionally, again,

harmony with §1305 requires that §§1461-1462 be read to reach only "unlawful" abortions.

In stating that §§1461-1462 should be construed to "exclude those acts that are in the interest of the national life" and therefore that they do not reach items for abortion "to save life," *Bours*, 229 F. at 964, the Seventh Circuit did not mean that would be the only circumstance excluded from §§1461-1462. Further, never during the lifetime of the Comstock laws has there been a federal or national policy that abortion is categorically unlawful (or immoral or illegitimate). *See Dobbs*, 142 S. Ct. at 2236 ("many States in the late 18th and early 19th century did not criminalize pre-quickening abortions"). Not until 2003 was a federal abortion ban enacted, and it remains very narrow, focused only on one rarely used method of abortion. *See* 18 U.S.C. §1531; *Gonzales v. Carhart*, 550 U.S. 124, 134-137 (2007). To the extent that Congress's enactment of the Comstock laws may have reflected "a national policy of discountenancing abortion as inimical to the national life," *Bours*, 229 F. at 964, that policy is only what was embodied in the Comstock laws—which begs the question of what abortion uses Congress intended those laws to cover.

One amicus supporting plaintiffs goes so far as to claim *Bours* said that "the statutory term *abortion* 'must be taken in its general medical sense' to exclude 'the necessity of an operation to save life'" and that "which acts of abortion are lawful"

is "immaterial" to the meaning of §§1461-1462. Amicus Brief on Behalf of Ethics and Public Policy Center in Support of Respondents ("EPPC Br.") 8-9, *FDA v. Alliance for Hippocratic Medicine*, Nos. 22A901 & 22A902 (U.S. Apr. 18, 2023). That argument confuses what *Bours* said about the "definition of abortion"—it "must be taken in its general medical sense" and thus "the local statutory definition of abortion is" "immaterial"—with what "acts of abortion" "the statute … cover[s]." 229 F. at 964. But again, what is dispositive is not how one might read *Bours* fresh today but how subsequent courts and then Congress understood it.

Finally, the court suggested there were too few judicial decisions to establish a consensus. *See* Op.33 n.28. But congressional ratification is not a mere matter of counting circuits. The purpose of inquiring whether a judicial interpretation was "settled" is to determine if courts can justifiably "presume Congress knew of and endorsed" that interpretation through its reenactment. *Jama v. Immigration & Customs Enforcement*, 543 U.S. 335, 349 (2005). Given that six decisions from four circuits reached the same conclusion over several decades, a host of later courts recognized that consensus, *see supra* pp.9-10, 12-14, no court ever concluded otherwise, and Congress was demonstrably aware of those decisions (through the 1947 House report and the 1970 Postmaster General submission), there is no need to *presume*; Congress *knew* and would have been derelict if it had disagreed yet repeatedly bypassed easy opportunities to change the statutory text.

In any event, Supreme Court precedent makes clear that four circuits suffices. *See Davis v. United States*, 495 U.S. 472, 482 (1990) (ratification based on decisions by two circuits and Tax Court); *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich LPA*, 559 U.S. 573, 590 (2010) ("no reason to suppose that Congress disagreed with [three circuits'] interpretations when it enacted" statute); *cf. Jama*, 543 U.S. at 351 (decision by two circuits insufficient).

d. The district court asserted that "the legislative history" of the Comstock laws "supports" its broad interpretation. Op.35. The court pointed to an "unsuccessful[]" attempt by a congressional subcommittee in 1978 to insert "illegal" into the Comstock laws and the accompanying subcommittee report stating that "current law" was not limited to items intended for illegal abortion. Op.35-36. Never-enacted bills and statements by legislators on the meaning of previously enacted laws, however, "should not be taken seriously, not even in a footnote." *Sullivan v. Finkelstein*, 496 U.S. 617, 632 (1990) (Scalia, J., concurring). Such sources are not legislative history at all and "offer[] a particularly dangerous basis on which to rest an interpretation of an existing law a different and earlier Congress did adopt." *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020) (cleaned up). Certainly, such "evidence" cannot overcome the voluminous contrary evidence that Congress intended the Comstock laws to reach

items only if intended for unlawful abortion—particularly since the subcommittee missed the 1948 reenactment.

e. An amicus argued that limiting §§1461-1462 to items intended for unlawful abortions "would render [them] a virtual nullity." EPPC Br. 4-5. That argument, however, is disingenuous given how extensively some states have restricted abortion. Moreover, that argument depends on assessing circumstances that would constitute the requisite knowledge or intent, and there is no occasion here for the Court to wade that deeply into the Comstock laws' meaning. Unsurprisingly, the courts in practice have not considered the laws a nullity despite their limitation to unlawful abortion. *See, e.g.*, *Bours*, 229 F. at 964-965; *Davis*, 62 F.2d at 475; *31 Photographs*, 156 F. Supp. at 357; *Blake*, 189 F. Supp. at 935-936.

B. FDA's Actions Are Consistent With The Comstock Laws Under The Court's Incorrect Interpretation

Even under the district court's erroneous interpretation of the Comstock laws, however, FDA's 2021 actions would still accord with the Comstock laws. Besides prohibiting distribution by the U.S. Postal Service (§1461), the Comstock laws prohibit distribution only if by a "common carrier" "in interstate or foreign commerce." §1462. They do not prohibit distribution by common carriers within a state, or interstate distribution by proprietary, contract, or private non-commercial carriers (e.g., the prescriber or a prescriber's employee). Thus, even under the district court's broad interpretation, the Comstock laws' prohibitions

leave room for FDA's 2021 elimination of the in-person dispensing requirements, since mifepristone could still be distributed in various ways plainly outside the Comstock laws.[5]

III. THE COMSTOCK LAWS ARE IRRELEVANT TO THE BALANCE OF THE EQUITIES

Contrary to the prior motions panel's assertion, the meaning of the Comstock laws does not "introduce[] uncertainty into the ultimate merits of the case," ECF #183-2, at 41-42, because, as explained, the laws' meaning is irrelevant to this case and anyway is clear: they exclude distribution intended for lawful abortion. On the other hand, the district court's ruling creates baseless uncertainty regarding the effect of scores of federal criminal laws on FDA drug approvals and suggests an enormously burdensome expansion of FDA's duties to now include identifying and accounting for every potentially applicable legal restriction, even those it has no responsibility for, or expertise in, administering. These equitable considerations favor denying the preliminary relief.

CONCLUSION

The Court should reverse the district court's order.

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[5] On the difference between common carriers and other types of carriers, see, e.g., 48 C.F.R. §47.001; *Maislin Industries, United States, Inc.* v. *Primary Steel, Inc*., 497 U.S. 116, 133 (1990); *The Fri*, 154 F. 333, 338 (2d Cir. 1907); *Stephenson* v. *Binford*, 287 U.S. 251, 265-266 (1932); *Contract Carriage by Common Carriers Under the Shipping Act of 1916*, 70 Yale L.J. 1184, 1185 (1961).

Respectfully submitted.

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May 1, 2023

CERTIFICATE OF COMPLIANCE

This amicus brief supporting appellants' motions contains 6351 words, excluding the parts of the brief exempted by rule. This filing complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in a proportionally spaced typeface (14-point Times New Roman) using Microsoft Word.

/s/ *John F. Walsh*
JOHN F. WALSH

May 1, 2023

CERTIFICATE OF SERVICE

I hereby certify that on this 1st day of May 2023, 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.

/s/ *John F. Walsh*
JOHN F. WALSH

May 1, 2023