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

MOTION FOR LEAVE OF FORMER U.S. DEPARTMENT OF JUSTICE OFFICIALS TO FILE BRIEF AS *AMICI CURIAE* SUPPORTING APPELLANTS' MOTIONS TO STAY THE DISTRICT COURT RULING PENDING APPEAL

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April 11, 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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- Kent B. Alexander, U.S. Attorney, Northern District of Georgia (1994-1997)
- Donna A. Bucella, U.S. Attorney, Middle District of Florida (1999-2001)
- Leslie R. Caldwell, Assistant Attorney General for the Criminal Division, U.S. Department of Justice (2014-2017)
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Counsel for Amici former high-ranking U.S. Department of Justice officials

Movants, former U.S. Department of Justice officials, respectfully move this Court for leave to file the accompanying 5,197-word amicus curiae brief supporting appellants' motions to stay the district court's order pending appeal.

Movants have requested the consent of all parties. Additionally, while the Federal Rules of Appellate Procedure and the Court's Rules do not specify a word limit for amicus briefs in support of motions to stay, movants asked for consent to 5,200 words out of an abundance of caution. Appellants and intervenor consented in full. Appellees do not oppose movants' filing of this amicus brief, but indicated they oppose "any expanded word limit."

I. MOVANTS' UNOPPOSED REQUEST FOR LEAVE TO FILE AN AMICUS BRIEF SUPPORTING APPELLANTS' MOTIONS TO STAY

The Federal Rules of Appellate Procedure and the Court's Rules do not address submission of an amicus curiae brief with respect to motions. However, consistent with its inherent authority, the Court, like other circuits, routinely accepts amicus briefs filed in connection with a stay request or similar motions. *See, e.g.*, *In re Abbott*, 800 F. App'x 296 (5th Cir. 2020) (reflecting filing of an amicus brief in connection with a mandamus petition and temporary stay request); *Brooks v. Estelle*, 697 F.2d 586, 588 (5th Cir. 1982) (reflecting that amicus filed a brief and presented argument in connection with an application filed in the Fifth Circuit for a stay of execution); Order, *Stromberg v. Qualcomm Inc.*, Nos. 19-15159 (9th Cir. July 23, 2020), Dkt. 43 (accepting amicus curiae briefs submitted

in support of or opposing the appellant's motion for partial stay of a preliminary injunction pending appeal).

Although Federal Rule of Appellate Procedure 29(a) applies to amicus filings only during a court's consideration of a case on the merits, not in support of a stay, movants here address Rule 29(a)'s two requirements: (a) their interest in this case and (b) "the reason why [their] amicus brief is desirable and why the matters asserted are relevant to the disposition of the case." Fed. R. App. P. 29(a)(3).

A. Movants' Interests

Movants are 55 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. 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 an interest in ensuring that DOJ remains the agency responsible for prosecuting under the Comstock laws and that the Comstock laws are correctly interpreted. Movants respectfully submit that their participation will aid the Court in understanding the Comstock laws and the proper scope of the Food & Drug Administration ("FDA")'s authority (which does not include consideration of

federal laws like the Comstock laws). Movants thus request that this Court grant their motion for leave to appear as amici curiae and to accept for filing their brief as lodged.

B. Relevance And Desirability Of An Amicus Curiae Brief

This appeal seeks review of the district court's decision to stay various FDA actions regarding mifepristone. Movants' amicus brief is desirable and relevant to the case because it focuses on the district court's decision with respect to the Comstock laws. Movants' brief will explain that the district court erroneously assumed that FDA was authorized to consider, interpret, and apply federal criminal laws as part of its new-drug approval process, and gravely misinterpreted the Comstock laws to expand their scope beyond Congress's intent. As former high-ranking U.S. Department of Justice officials who were tasked with the responsibility for enforcing the Comstock laws, movants are well situated to provide insight into the district court's errors regarding the Comstock laws.

II. REQUEST FOR LEAVE TO FILE AN AMICUS BRIEF OF 5,197 WORDS

The Federal Rules of Appellate Procedure and the Court's Rules do not impose a word limit on amicus briefs in support of stays. Movants propose to file

a brief of 5,197 words. Appellants consent to that length, but appellees have indicated they oppose any expanded word limit.[1]

Movants have good cause to file an amicus brief of 5,197 words. Movants' brief addresses several complex questions of administrative law and statutory interpretation regarding the meaning of the Comstock laws and their relationship to FDA's authority. These questions were central to the district court's ruling and consumed a substantial portion of its opinion. Movants believe their brief will assist the Court in resolving these issues, and that these issues warrant full ventilation given the ruling's profound and startling impact on FDA's authority and duties, and given the seriousness of the district court's errors. 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 the parties' principal briefs.

CONCLUSION

Accordingly, movants respectfully request that this Court grant leave to file the accompanying 5,197-word amicus curiae brief.

[1] Federal Rule of Appellate Procedure 29(a)(5) limits amicus briefs filed during a court's consideration of a case on the merits to one-half the maximum length authorized for the party's principal brief. If applied here, that would limit amicus briefs to 2,600 words. Even if the Court were to extend that rule here, the Court should grant an enlargement for the reasons stated above. *See* Fed. R. App. P. 29(a)(5).

Respectfully submitted,

/s/ David M. Lehn

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April 11, 2023

CERTIFICATE OF COMPLIANCE

This motion contains 888 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/ David M. Lehn
DAVID M. LEHN

April 11, 2023

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April 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/ *David M. Lehn*
DAVID M. LEHN

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STATEMENT OF INTEREST[1]

Amici are 55 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 new-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 DOJ, the sole agency responsible for prosecuting violations of the Comstock laws, amici urge this Court to grant appellants' motions for stay pending appeal, to facilitate orderly resolution of these questions.

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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

The Court should stay the district court's order pending appeal. The government and Danco Laboratories's appeals of the order are likely to succeed. Contrary to the district court's ruling, the scope of the Comstock laws is irrelevant to the FDA's mifepristone actions. Regardless, FDA's actions accord with the Comstock laws—both under the court's broad (but incorrect) interpretation and under the narrow (and correct) interpretation adopted uniformly by the circuits and by DOJ, in both its briefs and a prior memorandum issued by its Office of Legal Counsel, *see Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 46 Op. O.L.C. 2 (Dec. 23, 2022). This brief further analyzes of the relevance and meaning of the Comstock laws.

The balance of equities also requires a stay. The court's revocation of mifepristone's decades-old approval exposes countless women to serious health risks and impedes their access to essential medical care. It abruptly throws suppliers, distributors, and prescribers of mifepristone into chaos. Based on amici's extensive experience developing policy for and enforcing the federal criminal laws, amici believe the court's ruling is wrong and creates baseless confusion regarding the effect of scores of federal criminal laws on FDA drug approvals. The ruling places FDA in the impracticable position of having to identify and account for every potentially applicable legal restriction when

reviewing drug applications, even those it has no responsibility for, or expertise in, administering, and in the untenable position of navigating conflicting court orders, *see* Order Granting in Part Plaintiff's Motion for Preliminary Injunction, *Washington v. FDA,* No. 1:23-cv-03026 (E.D. Wash. Apr. 7, 2023), ECF #80.[2]

ARGUMENT

I. WHETHER THE COMSTOCK LAWS LIMIT THE DISTRIBUTION OF MIFEPRISTONE IS IRRELEVANT TO THE VALIDITY OF FDA'S 2021 ACTIONS

The court concluded that FDA's 2021 actions, which eliminated the in-person dispensing requirement, are invalid because (the court said) the Comstock laws "prohibit the mailing" of mifepristone. Op.32. But the court never explained why the Comstock laws affect those actions' validity, and with good reason: the Comstock laws are irrelevant to the validity of FDA's actions, however those laws are interpreted. FDA's charge is to determine whether a drug is safe and effective under the proposed label's conditions of use; it has no power or duty to account for any potentially applicable restrictions in the countless laws it does not administer. FDA's 2021 actions accord with that limited statutory charge.

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

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

Like any agency, FDA has only the authority that Congress granted it. *E.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126, 161 (2000). Congress specified that FDA serves as a limited gatekeeper: FDA determines only whether a drug is safe and effective for the indicated use, and that determination is only a threshold requirement for the drug's introduction into interstate commerce. FDA has no authority, and thus no duty, to account for any restrictions imposed by laws it does not administer. Accounting for such restrictions—"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") provides that FDA's approval is merely a necessary condition for introducing a new drug into interstate commerce: "*No* person shall introduce … into interstate commerce any new drug, *unless*" FDA has issued "an approval of an application … with respect to such 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 deciding whether to approve a drug, FDA's sole duty is to "protect the public health by ensuring that … [the drug is] safe and effective." 21 U.S.C.

§393(b)(2). The FDCA specifies that FDA's approval decision turns on whether the applicant sufficiently showed the drug will be safe and effective under the conditions of use described in the proposed label. *See* §355(b)(1)(A)(i), (d); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019); *Mutual Pharmaceutical*, 570 U.S. at 476. Indeed, the statute enumerates five grounds for denying an application once patent information is timely filed, all related to safety and efficacy. *See* 21 U.S.C. §355(d).

The REMS framework is similarly focused on safety and efficacy. The statute requires the applicant to submit a proposed "risk evaluation and mitigation strategy"—a REMS—if FDA "determines that a [REMS] is necessary to ensure that the benefits of the drug outweigh the risks of the drug." §355-1(a)(1). Correspondingly, the statutorily defined factors FDA must consider in making such a determination concern only the drug's expected risks and benefits. *See id*.

Nowhere does the FDCA indicate that Congress intended or authorized FDA to consider whether the distribution of a drug might be restricted in some way under laws administered by another governmental entity. Nor has FDA interpreted the FDCA to permit that. *Cf.* 21 C.F.R. §314.125(b) (enumerating reasons for denying applications); 21 C.F.R. §§314.500-.560. Therefore, FDA approval means nothing with respect to the applicability of laws outside its purview.

FDA routinely and validly approves drugs that are subject to restrictions under statutes or regulations that FDA does not administer; that is, non-FDCA legal restrictions commonly coexist with FDA's approval and do not preclude it. As just one example, the Controlled Substances Act, enforced by the Attorney General, makes it a crime to "knowingly or intentionally … manufacture, distribute, or dispense, or possess … a controlled substance" under certain circumstances. 21 U.S.C. §§811(a), 841(a)(1), 844(a). That prohibition applies to many drugs that have been approved by FDA without invalidating those approvals.[3] Additionally, Congress allowed "state tort" law to apply sometimes to FDA-approved drugs. *Wyeth*, 555 U.S. at 574-575. Nothing in the FDCA requires FDA to canvass all potentially applicable restrictions imposed by laws it does not administer when approving a new drug.

Such a duty would also be impractical. FDA lacks the resources and expertise to catalog and evaluate all the potentially applicable laws that it does not administer to determine whether they might restrict the manufacture, distribution, sale, prescription, dispensing, possession, or use of every drug it considers for approval. That is particularly true for the Comstock laws, which had never been

[3] Most drugs subject to the Controlled Substances Act's restrictions have "a currently accepted medical use," §812(b), including such FDA-approved drugs as fentanyl, methadone, alprazolam (Xanax), zolpidem (Ambien), and diazepam (Valium). 21 U.S.C. §812; *see* §§823, 841.

enforced against mifepristone in the two decades it was on the market before FDA's 2021 actions. The district court's failure to explain why FDA had to consider the Comstock laws in its 2021 actions speaks volumes: there is no basis for its unprecedented ruling.

B. Consistent With FDA's Limited Authority, Its 2021 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: they do not purport to declare lawful the distribution of mifepristone in ways that might be prohibited by the Comstock laws, even under the court's incorrect interpretation. The 2021 actions' reference to "dispensing of mifepristone through the mail … or through a mail-order pharmacy," PI.App.066, merely expressed FDA's determination that such distribution would not undermine the safety or efficacy of mifepristone, PI.App.714-715; *see* 21 C.F.R. §314.520 (allowing restrictions on distribution if necessary to ensure safe use)—the only considerations FDA is authorized to assess. That determination removed the FDCA's barrier to interstate distribution of mifepristone in specified ways, without claiming to limit enforcement of other applicable restrictions.

II. FDA'S 2021 ACTIONS ARE CONSISTENT WITH THE COMSTOCK LAWS, HOWEVER INTERPRETED

Even if FDA's 2021 actions' validity depended on their intersection with the Comstock laws, the court's invalidation of those actions would be erroneous because those actions are consistent with the Comstock laws even under the district court's interpretation. Make no mistake: the court's interpretation is gravely incorrect; Congress intended the Comstock laws to prohibit only distribution intended to produce unlawful abortions.

Further, even under the court's erroneous broad interpretation, the Comstock laws still permit non-in-person distribution of mifepristone under some circumstances.

A. FDA's 2021 Actions Are Consistent With The Comstock Laws When Correctly Interpreted To Reach Only Distribution Intended To Produce Unlawful Abortion

The court gravely erred in interpreting the Comstock laws so broadly. Across three decades, four circuits carefully considered the meaning of the Comstock laws and uniformly agreed, based on cogent reasoning, that Congress intended the Comstock laws to reach the distribution of abortion-producing items only if intended to produce unlawful abortions. *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). Their conclusion has been decisively reinforced and adopted by Congress over the subsequent 75 years, in which it repeatedly reenacted or amended the laws without alteration, while fully aware of those circuit precedents. The proper construction of the Comstock laws establishes a wide legal ambit for non-in-person distribution of mifepristone and further confirms that FDA's 2021 actions are consistent with the Comstock laws.

1. The Comstock laws' text and structure require that it be read to reach only distribution intended for unlawful abortions

The district court asserted that the "plain text of the Comstock Act controls" and that the "statute plainly does *not* require intent on the part of the seller that the drugs be used unlawfully." Op.34-35. But the court overlooked a critical facet of the Comstock laws' text: the relationship between §§1461-1462 and 19 U.S.C. §1305, which prohibits the "import[ation]" of "any drug or medicine or any article whatever for causing unlawful abortion," §1305(a). Sections 1461-1462 must be read with §1305(a)'s qualification. "[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 only way to get §§1461-1462 and §1305 to

make sense in combination is to read §§1461-1462 to reach abortion items only when intended to cause *unlawful* abortion.

Even when a statute's language is plain, "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); *see also Hartford Underwriters Insurance Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000). Here, the court's broad interpretation of §§1461-1462 would create two absurdities. First, it would mean that an item intended to cause lawful abortion could be imported lawfully under §1305(a) but then could not be 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 an item intended to cause lawful abortion could be imported lawfully under §1305(a) but then the importer could be punished criminally for doing so under §1462, which prohibits not only the distribution of abortion-producing items but also their importation ("Whoever brings into the United States").

It makes no sense for Congress to allow importation of items for lawful abortion, but prohibit their mailing or interstate distribution by common carrier for that purpose once here. And for Congress to have created a trap where a person could be convicted of a crime for an act that another provision of the U.S. Code

expressly permits would both be absurd and raise a serious due process concern. *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). Of course, "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 the distribution of items intended to produce abortion only if the intended abortion would be unlawful. Indeed, Congress long ago stated that §§1461-1462 and §1305 should be read "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-Foot Reels of Super 8mm. Film*, 413 U.S. 123, 130 n.7 (1973) (giving the same meaning to words "used to describe regulated material in 19 U.S.C. s 1305(a) and 18 U.S.C. s 1462").

Most pertinent, in *One Package* the Second Circuit—addressing the provisions restricting the distribution of contraceptives and abortion items—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.

2. The history of §§1461-1462 shows that Congress intended them to reach abortion items only if intended to produce unlawful abortion

It is well established that "'[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.'" *Texas Department of Housing & Community Affairs v. Inclusive Communities Project, Inc.*, 576 U.S. 519, 536-537 (2015) (ellipses 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, J.J., dissenting); *id.* at 2312-2313 (Alito, J., dissenting); *Negusie v. Holder*, 555 U.S. 511, 546-548 (2009) (Thomas, J., dissenting).

The history of §§1461-1462 also shows unequivocally that Congress intended those provisions to reach abortion-producing items only if intended to produce unlawful abortion. In 1948, Congress expressly acknowledged the prior interpretation given to the Comstock laws and codified those provisions in §§1461-1462 without material change. In the seventy-five years since, Congress has repeatedly reenacted or amended §§1461-1462 still without touching the key language.

a. The district court ignored conclusive evidence that Congress intended to limit the Comstock laws to items intended to produce unlawful abortion

The court ignored conclusive evidence that Congress intended §§1461-1462 to reach abortion items only if intended to produce unlawful abortion. In the 1940s, Congress undertook the project of recodifying federal criminal laws. Through that project, Congress reenacted the longstanding provisions of the Comstock laws addressing the distribution of abortion items via U.S. mail and the importation and distribution of abortion items via common carrier in interstate commerce as 18 U.S.C. §§1461-1462. *See* Pub. L. No. 80-772, 62 Stat. 683, 768-769 (1948).

Critically, Congress did so based on its understanding that the courts had interpreted the language being reenacted to reach abortion items only if intended to produce unlawful abortion, and without altering that language or otherwise

rejecting the prior interpretation. 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 proceeded to describe four of the circuit cases to have addressed the meaning of the Comstock laws' restrictions on the distribution and importation of contraceptives and abortion items. First, the report stated that in *Youngs Rubber*, the court said that 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.'" H.R. Rep. No. 80-304, at A105. Next, the report stated that in *Nicholas*, the court "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." H.R. Rep. No. 80-304, at A105. Finally, the report added, "The same rule was followed in" *Davis* and *One Package*. H.R. Rep. No. 80-304, at A105.

That Congress then reenacted the same language without material change establishes that it intended to adopt the interpretation described in the House report and accordingly intended §§1461-1462 to mean that the importation and

distribution of items for producing abortion would be prohibited only if intended to produce unlawful abortion. *See, e.g.*, *Ex parte Collett*, 69 S. Ct. 944, 952 (1949) ("flatly reject[ing]" argument that "Congress did not appreciate what it was enacting" in light of similar note in legislative history).

b. The Subsequent History of the Comstock Laws Confirms That Congress Intended Them to Be Limited to Items Intended to Produce Unlawful Abortion

The subsequent dialog between Congress, the courts, and the executive branch confirms that Congress intended §§1461-1462 to reach abortion items only if intended for producing unlawful abortion.

In 1950 and 1955, Congress revised §§1461-1462 while preserving the key language—again foregoing an opportunity to depart from the prior understanding identified in the 1947 House report. 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's predecessors "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. Pub. L. No. 85-796, §2, 72 Stat. 962, 962 (1958).

Reaffirmations continued. 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). 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).

After those cases, Congress next took up §§1461-1462 in the early 1970s. During that legislative process, the Postmaster General 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 present permissive purpose is present." H.R. Rep. No. 91-1105, at 3-4 (1970). On the heels of that report, Congress removed contraception

from §§1461-1462 (partially in response to *Griswold v. Connecticut*, 381 U.S. 479 (1965)) but otherwise left the abortion-related language intact. Pub. L. No. 91-662, §§3-4, 84 Stat. 1973, 1973 (1971).

Then again in 1994 and 1996, Congress amended §§1461-1462 but did not alter the abortion-related language. 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 not altered that language. Although some of this history post-dates *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeast Pennsylvania v. Casey*, 505 U.S. 833 (1992), it is meaningful because, as the district court observed, those precedents "did not prohibit *all* restrictions on abortions," Op.38. Thus, the states could—and did—permit constitutionally unprotected 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, and distributing items for producing abortion in such states implicated the Comstock laws because those items could have been used for abortions not protected by *Roe* and *Casey*. Op.38.

In sum, the long history of courts and the executive recognizing the narrow judicial interpretation of the Comstock laws and the documented congressional awareness of that interpretation, followed by Congress's numerous reenactments

and amendments of the Comstock laws without material alteration, leaves no doubt that Congress adopted that interpretation.

c. The district court's reasoning is thoroughly flawed

The district court disagreed based on unsound reasoning.

The court cited 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). That precedent does not support the court's conclusion for three reasons. First, as explained in Part II.B.1, consideration of §1305 shows that the Comstock laws' text does not have the plain meaning the court believed and at worst is ambiguous. *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"). Second, that precedent involved a very different situation: "clear inconsistency" between the statute's plain language and the prior agency interpretation. *Brown v. Gardner*, 513 U.S. 115, 121-122 (1994) ("congressional reenactment has no interpretive effect where regulations clearly contradict requirements of statute" (cleaned up)); *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 it applies only to distribution intended to produce unlawful abortion—accords with the laws' plain text. And third, Congress's 1948 reenactment based on the 1947

House report informing Congress how the courts had interpreted §§1461-1462 takes this case out of the ordinary situation of claimed implied congressional ratification and establishes the specific meaning that Congress intended.

The district court also cast doubt on the possibility of inferring Congress's intent from its reenactment of previously interpreted language, 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 certainly do not supersede the Supreme Court precedent noted above recognizing that Congress may adopt a prior interpretation by reenacting the text. In any event, it is implausible to think Congress retained language that had been widely subjected to a particular interpretation for nearly 100 years without ever altering that language, while amending the same provisions seven times, yet did not intend to ratify that interpretation. And the notion that Congress did not intend to adopt the narrow interpretation is inconceivable given that Congress was specifically aware of that interpretation and reenacted the language anyway in 1948.

Further, the court's rejection of a settled judicial "consensus" about how to interpret §§1461-1462 is also misguided. First, however one might read the relevant Comstock cases, the fact is that, as described above, the 1947 House report gave the cases a consistent reading: §§1461-1462 reach abortion items

"only" when intended to be used to produce "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 intended those provisions to have.

Second, there actually was a clear judicial consensus. The district court read *Davis* and *One Package* to exclude from the Comstock laws "legitimate" or "moral" uses, not "lawful" ones. Op.37. But as *One Package* made clear, these are equivalent concepts in context. The Second Circuit explained that *Bours* interpreted the Comstock laws not to reach distribution for medically appropriate use despite the absence of the word "unlawful" in the statute; that *Youngs Rubber* interpreted the Comstock laws "in the same way," i.e., to exclude items intended for "legitimate use" or not for "illegal uses"; and that *Youngs Rubber* and *Davis*, which "relied on" *Youngs Rubber*, interpreted the Comstock laws to exclude items "not intended for an immoral purpose." 86 F.2d at 738-739. *One Package* summarized all these cases together as "read[ing] an exemption into the act covering such articles even where the word 'unlawful' is not used." *Id.* at 739. And accordingly, *One Package* expressly stated that an "exception" for "[]lawful" uses "should apply to articles for preventing conception" or producing abortion—consistent with its view that §§1461-1462 should be read in conformity with §1305. *Id.*; *see supra* II.B.1. The same court subsequently reiterated that it had

"twice decided that … statutes prohibiting [contraceptives and abortion items] should be read as forbidding them only when unlawfully employed"—and cited *Davis* as consonant with those decisions. *Nicholas*, 97 F.2d at 512.

Relatedly, the district court suggested that there were too few judicial decisions to establish the requisite consensus for implied ratification. *See* Op.33 n.28. But there were six decisions from four circuits issued over thirty years—*Bours* (7th), *Youngs Rubber*, *One Package*, *Nicholas* (2d), *Davis* (6th), and *Consumers Union* (D.C.), the last of which the district court ignored—plus a host of later judicial opinions recognizing that consensus, *see supra* p.8-9. Contrary to the district court's academic source, Supreme Court precedent makes clear that four circuits suffices. *See 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 v. Immigration & Customs Enforcement*, 543 U.S. 335, 351 (2005) (decision by two circuits insufficient).

Finally, 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 1970 to insert "illegal" into the Comstock laws and the accompanying subcommittee report stating that "current law" was not limited to distribution of items intended to

produce illegal abortion. Op.35-36. Never-enacted bills and statements by legislators on the meaning of previously enacted laws "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 an effort by a subcommittee cannot overcome the voluminous contrary evidence that Congress intended the Comstock laws to reach only items intended for unlawful abortion—particularly since the subcommittee did not even address the 1948 reenactment.

3. Under the rule of lenity, any doubt should be resolved in favor of the narrow interpretation

If there were any remaining doubt about the meaning of the Comstock laws, the constitutionally based rule of lenity would require that they be interpreted narrowly to reach the distribution of abortion items only if intend to produce unlawful abortion. *See, e.g.*, *Wooden v. United States*, 142 S. Ct. 1063, 1081 (2022) (Gorsuch, J., concurring); *id.* at 1074-1075 (Sotomayor, J., concurring). Although this case is not a criminal prosecution (the typical context for applying the rule of lenity), the interpretation of a criminal statute here could impact future criminal defendants.

B. FDA's 2021 Actions Are Also Consistent With The Comstock Laws Under The Court's Incorrect Interpretation

Even under the district court's grievously erroneous interpretation of the Comstock laws, however, not all non-in-person dispensing of mifepristone would be foreclosed, and therefore FDA's 2021 actions would still be consistent with the Comstock laws.

First, the Comstock laws prohibit the distribution of certain items by common carrier only if "in interstate or foreign commerce," 18 U.S.C. §1462; they do not prohibit distribution within a state. Second, the Comstock laws prohibit distribution in interstate commerce only by a "common carrier" or the U.S. Postal Service, §§1461-1462; they do not prohibit interstate distribution by proprietary or contract carriers, or by private non-commercial carriers (e.g., the prescriber or a prescriber's employee).[4]

These limits on the Comstock laws' prohibitions, even as broadly interpreted by the district court, leave room for FDA's 2021 elimination of the in-person dispensing requirements, since mifepristone could still be distributed in various ways not even arguably covered by the Comstock laws.

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[4] 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).

CONCLUSION

The Court should stay the District Court's decision pending appeal.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This amicus brief supporting appellants' motions contains 5,197 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/ David M. Lehn
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April 11, 2023

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of April 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/ *David M. Lehn*
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