Nos. 23-235 & 23-236

IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

DANCO LABORATORIES, L.L.C., *et al.*,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,
Respondents.

ON WRITS OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRIEF FOR FORMER U.S. DEPARTMENT OF JUSTICE OFFICIALS AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE[1]

Amici are 23 former high-ranking U.S. Department of Justice officials who served in administrations of both major parties, including as U.S. Attorney General, 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 the Fifth Circuit's judgment should be reversed. They further agree that the district court not only erroneously assumed that the Food & Drug Administration was authorized to consider, interpret, and apply federal criminal laws as part of its drug-approval process, but also gravely misinterpreted the Comstock laws, expanding their scope beyond Congress's intent. While the Fifth Circuit declined to reach the district court's holding under the Comstock laws, respondents' petition-stage briefing indicated they will ask this Court to address that holding. The district court's errors in interpreting the Comstock laws were serious, and led the court to improperly reject the holdings of all four courts of appeals and the construction embraced by the Justice Department, the sole agency responsible for prosecuting violations of the Comstock laws. As explained below, the

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

Court need not address the Comstock laws at all. But if this Court does so, amici urge the Court to reject the district court's interpretation.

INTRODUCTION AND SUMMARY OF ARGUMENT

This Court need not address the district court's conclusion that the FDA's 2021 actions violated the Comstock laws because the Fifth Circuit expressly declined to reach that question. But should the Court address that conclusion, it should reject any effort by respondents to rely on it. That ruling is erroneous regardless of how the Comstock laws are interpreted. Thus, the Court need not address their meaning, but need only make clear (should respondents re-raise this argument) that the laws provide no basis to enjoin or invalidate the challenged FDA actions. Regardless, the district court interpreted the laws incorrectly.[2]

As a threshold matter, the Comstock laws are irrelevant to the validity of the challenged FDA 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, the agency was required to approve it; FDA could not decline to do so based on the Comstock laws. Nor did FDA's determinations 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 simply irrelevant to the validity of the challenged FDA actions.

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[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 of the challenged FDA actions.

If the Comstock laws *were* relevant to those actions, however, the actions would be valid because they accord with those laws—both under the district court's incorrect interpretation and under the correct interpretation long adopted by the courts and repeatedly ratified by Congress. Given that, this Court need not even address the proper interpretation.

If the Court chooses to do so, then it should reject the district court's interpretation. That court gravely misinterpreted 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. A Fifth Circuit motions panel here dismissed those decisions as "aging." Pet. App. 244a. (Pet. App. citations herein are to the petition appendix in case number 23-235.) But these decisions' 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 avoids absurd and likely unconstitutional implications. And critically, this interpretation was adopted 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. All this likely explains why the district court's decision here is the only judicial decision ever to reject this interpretation. Indeed, another district court recently noted that "the Comstock Act is currently understood to apply only to use of the mails in an illegal manner. Courts have held this consistently since 1915."

Doc. 54 at 14, *GenBioPro, Inc.* v. *Sorsaia*, No. 3:23-cv-00058 (D. W. Va. May 2, 2023).[3]

Finally, even under the district court's unprecedented interpretation, the Comstock laws would still allow non-in-person dispensing in various ways. FDA's actions therefore do not approve distribution that is categorically prohibited by the Comstock laws, however those laws are interpreted, and the laws thus provide no basis for the lower courts' categorical invalidation of those actions.

ARGUMENT

I. THIS COURT NEED NOT ADDRESS THE COMSTOCK LAWS

The Fifth Circuit expressly declined to reach respondents' argument that the FDA's 2021 actions violated the Comstock laws. Thus, the Court need not—and should not—consider that argument at all: Although a respondent may defend a judgment on any ground raised below, *Yeager* v. *United States*, 557 U.S. 110, 126 (2009), this Court often declines as a prudential matter to address in the first instance issues the court of appeals did not reach. *City of Austin* v. *Reagan National Advertising of Austin, LLC*, 596 U.S. 61, 76-77 (2022) (explaining as a "'court of final review and not first view,'" this Court "does not '[o]rdinarily … decide in the first instance issues not decided below'" by the court of appeals (alteration and omission in original)). It should not do so here.

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[3] The Fifth Circuit motions panel considering a stay of the district court's decision declined to "definitively interpret" the Comstock laws, Pet. App. 244a, while the merits panel declined to consider respondents' Comstock argument, Pet. App. 63a, n.8.

II. THE COMSTOCK LAWS' SCOPE IS IRRELEVANT TO THE VALIDITY OF THE CHALLENGED FDA ACTIONS

The Comstock laws, however interpreted, are irrelevant here. FDA's actions do nothing more than what FDA is authorized to do: assess whether mifepristone would be safe and effective under specified conditions.

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—and that approval serves only to remove one particular legal barrier to the drug's distribution, i.e., 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*, 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 for denial are 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 "risk evaluation and mitigation strategy" ("REMS") is similarly focused on safety and efficacy. 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 contain means to mitigate risks to patients' health. *See id.* §355-1(c), (e)-(f). Nothing authorizes FDA to consider the implications of 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, *Approval and Oversight of the Drug Mifeprex* at 1 (2008) (identifying Congressional requesters); GAO-18-292, *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* at 28 (2018) (same).

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 but that nonetheless might apply to the drugs it reviews—including continually monitoring changes in such laws and reevaluating its prior decisions in light of those changes.

FDA's approval, moreover, is merely 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) (emphasis added); *see also, e.g.*, *Mutual Pharmaceutical Company* v. *Bartlett*, 570 U.S. 472, 476 (2013). 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. 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).

Finally, respondents' brief in opposition cited (at 40) this Court's observation that the "[Administrative Procedure Act] requires federal courts to set aside federal agency action that is 'not in accordance with law'—which means, of course, *any* law, and not merely those laws that the agency itself is charged with administering." *FCC* v. *NextWave Personal Communications Inc.*, 537 U.S. 293, 300 (2003) (emphasis added) (quoting 5 U.S.C. §706(2)(A)). That is true, but it does nothing to support

respondents' claim that the FDA acted "not in accordance with law," 5 U.S.C. §706(2)(A), by staying within the scope of its congressionally delegated authority, authority that does not extend to considering the Comstock laws when determining if a drug is safe and effective for a particular use. Again, 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 Declare Any Distributions Of Mifepristone Lawful Under The Comstock Laws (However Interpreted)

FDA's 2021 actions conform to FDA's limited statutory authority. For example, its 2021 letter referring to the "dispensing of mifepristone through the mail … or through a mail-order pharmacy," J.A. 365, expressed nothing more than FDA's determination that such distribution would not undermine mifepristone's safety or efficacy. That is, as explained, the only consideration FDA may assess. The agency certainly did not purport to opine on whether any particular distributions of mifepristone are lawful under the Comstock laws.

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

Because the FDA did not purport in approving mifepristone to interpret or apply the Comstock laws, the proper interpretation of those laws has no bearing on the validity of the agency's challenged actions. The laws' meaning independently has no relevance here because—as explained in Part IV—FDA's actions are consistent with those laws even as the district court construed them. But make no mistake: The district court's 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. Indeed, as every circuit court to address the question has recognized, that reading is absurd and raises serious constitutional concerns, especially given the interaction between §§1461-1462 and §1305. And critically, Congress's 1948 reenactment of the Comstock laws specifically adopted that interpretation. Congress then repeatedly ratified that interpretation. In reaching its interpretation here, the district court brushed aside this conclusive evidence and committed several other errors.

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," §1461 (emphasis added); *accord* §1462, they contain no similar language suggesting they

reach items related to *any* abortion or *any* contraception.

In line with that text, 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 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, 33, 35 (D.C. Cir. 1944). No court of appeals has ever adopted a contrary construction.

In 1948, Congress reenacted these provisions at 18 U.S.C. §§1461 and 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 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* 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). 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.* (emphasis added). Finally, the report added that "[t]he same rule was followed" by *Davis* and *One Package*. *Id.*

Given this, 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. Under the authorities cited above, the fact that Congress enacted that language with that understanding and without expressing any rejection of that interpretation shows conclusively that Congress intended by its enactment of §§1461-1462 to ratify that judicial interpretation. Indeed, when previously faced with a similar argument made with respect to a revisers' note to the contemporaneous recodification of the judicial code, this Court has "flatly reject[ed]" the notion that "Congress did not appreciate what it was enacting." *Ex parte Collett*, 337 U.S. 55, 71 (1949). The same approach is warranted here.

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 post-1948 dialogue between Congress and the courts 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, 64 Stat. 194, 194 (1950); Pub. L. No. 84-95, §§1-2, 69 Stat. 183, 183 (1955). As explained, that shows Congress's 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) (emphasis added) (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). Then 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, tit. V, §507(a), 110 Stat. 133, 137 (1996). These repeated post-1948 ratifications are still more evidence of Congress's understanding and approval of the circuits' unanimous interpretation of §§1461-1462 as excluding distributions intended for legal abortions.[4]

Although some of these congressional 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, as the district court here observed, *Roe* and *Casey* "did not prohibit *all* restrictions on abortions," Pet. App. 158a. And, while some states prohibited abortions falling outside the protections of *Roe* and *Casey*, other states permitted such abortions. *See, e.g.*, 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 abortion that was lawful in those states, therefore, would not necessarily have infringed the constitutional right to abortion and thus would have been an option for

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[4] In 1994, Congress also enacted the Freedom of Access to Clinic Entrances ("FACE") Act, which affirmatively protects access to clinics offering reproductive care, including abortions. 18 U.S.C. §248(e)(5) (defining "reproductive health services" to include "the termination of a pregnancy"). Congress grounded its authority to enact the FACE Act on its finding that abortion clinics buy their "equipment … medicine, medical supplies, surgical instruments and other supplies" in interstate commerce—a finding that could not be squared with a position that interstate commerce in items used for lawful abortions violated the Comstock Act. H.R. Conf. Rep. No. 103-488, at 7 (1994).

Congress every time it amended the Comstock laws. But, as explained, Congress simply reenacted the same language understood *not* to reach items related to those lawful abortions falling outside the scope of *Roe* and *Casey*. Thus, Congress's actions—both before *Roe* and after it—made clear that Congress intended for the Comstock laws to reach only unlawful abortions.

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 this Court has explained, its "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); *see also Hartford Underwriters Insurance Company* v. *Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000).

The district court's 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 this Court's admonition that "statutes should be read where possible to avoid unconstitutionality," *Dobbs* v. *Jackson Women's Health Organization*, 142 S. Ct. 2228, 2276 (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.* The Sixth Circuit subsequently deemed that "reasoning" "sound[]." *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. 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.

D. The District Court's Reasoning Is Thoroughly Flawed

The infirmities with the district court's reasoning begin with the court's dismissal of Congress's 1948 reenactment of §§1461-1462 and of the relationship between §§1461-1462 and §1305.

a. The district court relied on precedent stating that "[w]here the law is plain, subsequent reenactment does not constitute an adoption of a previous administrative construction." Pet. App. 152a (alteration in original); *see also* Pet. App. 153a-155a. That precedent does not apply here for three reasons. First, Congress's 1948 reenactment imbued §§1461-1462 with a specific meaning because Congress codified those sections without modification after its attention was directed to four

circuit court cases consistently interpreting those sections to reach items for producing abortion only if intended to produce unlawful abortion. *See* H.R. Rep. No. 80-304, at A104. That takes this case beyond the ordinary situation of implied congressional ratification. Second, §§1461-1462 do not have the "plain" meaning the district court claimed. As explained in Part III.C, that meaning yields both absurdities and constitutional concerns. And third, the precedent the district court cited involved "clear inconsistency" between the statute's plain language and "a previous administrative construction." *Brown* v. *Gardner*, 513 U.S. 115, 121-122 (1994); *see also Demarest* v. *Manspeaker*, 498 U.S. 184, 190 (1991) ("administrative interpretation" was "contrary to [statute's] plain" language). Here, there is neither an "inconsistency" ("clear" or otherwise), nor an "administrative construction," but rather a judicial one.[5]

The district court also impugned the doctrine of ratification by reenactment more broadly, hypothesizing that reenactments could be motivated by other reasons, such as counteracting a "sunset" provision, laziness, or inattention. Pet. App. 153a. That simply ignores this Court's many cases recognizing and applying the doctrine. In any event, for the reasons given earlier, it is implausible that Congress did not intend to ratify the pre-1948 circuit decisions, not only in 1948 itself but also thereafter.

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[5] The district court's reliance on *Milner* v. *Department of Navy* is misplaced. 562 U.S. 562 (2011). In *Milner*, the Court did not conclude that it needed to honor Congress's adoption of a particular interpretation. Rather, it rejected the argument that the Court should embrace a particular statutory construction because lower courts followed another lower court's adoption of that construction. *Id.* at 576-577.

b. The district court separately attacked the ratification argument by denying that there was a judicial "consensus" against which Congress reenacted the laws. That too is wrong.

To begin with, however one might parse the relevant Comstock cases, what matters is what Congress understood them to mean. And as discussed, 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; *see also* H.R. Rep. No. 79-152, pt. 2, at A96-A97 (1945). *That* is the understanding on which Congress enacted §§1461-1462 in 1948 and thus *that* is the meaning Congress gave those provisions. *See Kisor* v. *Wilkie*, 139 S. Ct. 2400, 2436 (2019) (Gorsuch, J., concurring) (relying on House and Senate reports accompanying the APA to illustrate the contemporary views of "many members of Congress" regarding Congress's intention behind the APA). Moreover (and as also discussed), 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.

Indeed, the circuit decisions themselves recognized that they embodied a consensus that §§1461-1462, like §1305, reach items only if intended for unlawful abortion. *Youngs Rubber*, for example, cited *Bours* for the 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. Similarly, *Davis* relied on *Bours* and *Youngs Rubber* to reach that same conclusion. 62 F.2d at 475. Likewise *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* then 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.

Despite all this, 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. Pet. App. 157a-158a. But what matters here is that there *was* 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 that consensus; and therefore, §§1461-1462 indisputably allow some distribution of abortion drugs through the mails or common carriers in interstate commerce.

Regardless, 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); *see also Youngs Rubber*, 45 F.2d at 108 (construing the statute as "requiring an intent on the part of the sender that the article mailed or shipped by common carrier be used for illegal contraception or abortion or for indecent or immoral purposes"); *Davis*, 62 F.2d at 474 (same).

The district court, however, claimed that the Seventh Circuit's decision in *Bours* viewed the Comstock laws as reflecting a "'national policy'" disapproving of abortion. Pet. App. 157a (quoting *Bours*, 229 F. at 964). Judge Ho went even further and highlighted the Seventh Circuit's statement that §§1461-1462 should be construed to "exclude those acts that are in the interest of the national life" to conclude that the Seventh Circuit deemed such life-saving abortions the only ones to fall outside the scope of those provisions. Pet. App. 102a (quoting *Bours*, 229 F. at 964). That is wrong. In recognizing that the Comstock laws do not reach abortions necessary to save life, the Seventh Circuit did not suggest that would be the *only* circumstance excluded from §§1461-1462. And, to the extent that Congress's enactment of the Comstock laws may have reflected any national policy regarding "abortion"—discountenancing it or otherwise—that policy would extend no further than what the Comstock laws actually proscribed. As explained, their proscriptions were limited to articles intended for unlawful abortions. *See supra* pp. 8-17. Neither Judge Ho nor the district court can avoid that conclusion with a textual appeal to policy, particularly

where at no time since the original enactment of the Comstock laws has there been any 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).

Judge Ho further scrambled the Seventh Circuit's language to argue *Bours* teaches that "'it is immaterial what the local statutory definition of abortion is'" to the meaning of §§1461-1462. Pet. App. 101a-102a. That argument conflates what *Bours* said about the "definition of abortion"—that it "must be taken in its general medical sense" and thus "the local statutory definition of abortion" is "immaterial"—with what particular "acts of abortion" "the statute … cover[s]." 229 F. at 964. And regardless, what is dispositive is not how one might read *Bours* fresh today but how Congress understood it and the other cases that had unanimously embraced a particular reading of the Comstock laws prior to Congress's 1948 reenactment of them.

Finally, the district court suggested there were too few judicial decisions to establish a consensus. *See* Pet. App. 153a n.28. To the contrary, this Court's precedents make clear that four circuits is a sufficient number. *See Davis* v. *United States*, 495 U.S. 472, 482 (1990) (ratification based on decisions by two circuits and the 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). In contrast, *Jama* v. *Immigration & Customs Enforcement*, 543 U.S. 335,

351-352 (2005), rejected as "too flimsy" a ratification argument relying on two circuit decisions. Even then, the Court didn't reject the ratification argument solely based on the *number* of circuit decisions allegedly supporting a judicial consensus; rather, it found a lack of a consensus at all. Congress had crafted the statutory provision at issue in *Jama* out of two predecessor provisions, "only one of which had been construed as petitioner wish[ed]." *Id.* at 351.

c. The district court (Pet. App. 155a) and Judge Ho (Pet. App. 103a) pointed to an "unsuccessful[]" attempt by a congressional subcommittee in 1978 to insert "illegal" into the Comstock laws, and to the accompanying subcommittee report stating that "current law" was not limited to items intended for illegal abortion. Pet. App. 103a, 155a-156a. Judge Ho also pointed to unsuccessful legislation introduced in September 1996 to remove "abortion" from the Comstock laws. Pet. App. 104a. 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) (quotation marks omitted). Certainly, such "evidence" cannot overcome the voluminous, and much more reliable, contrary evidence of congressional ratification discussed above.

d. Finally, Judge Ho noted Congress's 1996 addition to the Comstock laws of the words "interactive computer service" to conclude that "it's also illegal to use the internet to ship or receive abortifacients." Pet. App. 99a-100a. But Judge Ho's unremarkable observation

that Congress amended the Comstock laws to clarify that its prohibitions applied to materials transmitted via the internet does nothing to explain how or why the Comstock laws broadly reach materials related to all abortions. Indeed, the text of the amendment demonstrates that it merely clarified that existing obscenity laws applied to the internet. Indeed, the title of the amending provision is "Clarification of Current Laws Regarding Communication of Obscene Materials Through the Use of Computers." Pub. L. No. 104-104, §507, 110 Stat. at 137. The text of the amendment itself further emphasizes that "[t]he amendments made by this section are clarifying[.]" *Id.* §507(c), 110 Stat. at 137. Thus, this amendment does nothing to shed further light on the scope of materials related to abortion covered by the Comstock laws.

IV. FDA'S ACTIONS ARE CONSISTENT WITH THE COMSTOCK LAWS EVEN UNDER THE DISTRICT COURT'S INTERPRETATION

Even under the district court's interpretation of the Comstock laws, FDA's 2021 actions would still accord with those laws. Besides prohibiting distribution by the U.S. Postal Service (in §1461), the Comstock laws prohibit distribution only if by a "common carrier" "in interstate or foreign commerce." §1462. They thus do not prohibit distributions 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 reading, 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 outside those laws' scope.[6]

CONCLUSION

The Fifth Circuit's judgment should be reversed.

Respectfully submitted.

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[6] On the difference between common carriers and other types of carriers, *see* 48 C.F.R. §47.001; *Maislin Industries, U.S., 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); and *Contract Carriage by Common Carriers Under the Shipping Act of 1916*, 70 Yale L.J. 1184, 1185 (1961).

APPENDIX

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