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

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BRIEF FOR FORMER U.S. ATTORNEY GENERAL EDWIN MEESE III AS AMICUS CURIAE SUPPORTING RESPONDENTS

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INTEREST OF AMICUS CURIAE[1]

Amicus Attorney General Edwin Meese III is a former U.S. Attorney General who led the U.S. Department of Justice from February 1985 to August 1988. Amicus was responsible for enforcing federal criminal laws, including the Comstock Act, 18 U.S.C. §§ 1461-62, and routinely represented the United States and its agencies in this Court and in lower courts throughout the nation.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The FDA's 2016 Amendments and 2021 Non-Enforcement Decision for the prescription and dispensing of mifepristone were beyond the pale of normal regulatory behavior. To be sure, abortion has long been a subject of "national controversy." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 229 (2022). But the United States defended the FDA's 2000 mifepristone protocols for sixteen years, "under three presidential administrations." Pet. App. 247a (Alito, J., dissenting from grant of applications for stay). In 2011, during the Obama Administration, the FDA even approved a Risk Evaluation and Mitigation Strategy ("REMS") for mifepristone that "impos[ed] essentially the same restrictions as those FDA required when it approved Mifeprex in 2000." Pet. App. 9a (merits panel majority).

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[1] Pursuant to Sup. Ct. R. 37.6, Amicus certifies that no counsel for any party authored this brief in whole or in part, no party or party's counsel made a monetary contribution to fund its preparation or submission, and no person other than Amicus or his counsel made such a monetary contribution.

Unfortunately, the FDA abandoned the norms of regulatory behavior in 2016 when it dramatically loosened the REMS for mifepristone and simultaneously eliminated the adverse-event reporting requirement for all non-fatal complications, no matter how severe. Shortly after President Biden assumed office in 2021, the FDA doubled down by using a year-old pandemic as an excuse to neuter the in-person dispensing requirement. The inconsistency of these actions with the decades of science that supported FDA's 2000 protocols required the agency to take an "ostrich's-head-in-the-sand approach" to the serious health risks it chose to expose women to. Pet. App. 236a (motions panel per curiam). FDA's actions were, therefore, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Dead set on facilitating its goal of allowing the shipment of chemical abortion drugs throughout the country, the FDA plowed ahead despite serious concerns that its 2021 Non-Enforcement Decision conflicted with the Comstock Act, 18 U.S.C. §§ 1461-62. Those criminal statutes prohibit the knowing use of the channels of interstate commerce to distribute "[e]very article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use," which likely includes known abortion drugs such as mifepristone. *Id.* § 1461. To bypass the plain text of the Comstock Act, the FDA "engineer[ed] exceptions to longstanding background rules" without regard to their effect on other prosecutions. *Dobbs*, 597 U.S. at 287. These are criminal laws that federal prosecutors routinely enforce. *See, e.g.*, *United States v. Isaacs*, 565 F. App'x 637, 639 (9th Cir. 2014)

(affirming convictions under §§ 1461-62); *United States v. Raymond*, No. 21-380, 2023 WL 7611601, at *2 (D.D.C. Nov. 14, 2023) (noting conviction under § 1462). The Court should refuse to vacate a preliminary injunction that prevents the FDA from facilitating the violation of criminal laws.

ARGUMENT

I. THE CHALLENGED FDA ACTIONS WERE BEYOND THE PALE OF ACCEPTABLE REGULATION.

The FDA's 2016 Amendments and 2021 Non-Enforcement Decision for mifepristone were arbitrary, capricious, and an abuse of discretion. Rather than following the science where it led, FDA brushed aside any study or data that supported maintaining its 2000 protocols so that the agency could recklessly expand access to mifepristone. Inexplicably, the 2016 Amendments ended the mandatory reporting mechanism for all non-fatal adverse events at the same time FDA dramatically loosened the requirements for prescribing mifepristone. Just five years later, FDA turned around and cited the new scarcity of adverse event data as justification for the 2021 Non-Enforcement Decision. Such regulatory misbehavior violates the Administrative Procedure Act.

A. The 2016 Amendments conflicted with the very studies FDA relied on and left FDA with inadequate means to evaluate the risks of the new REMS.

Switching between the 2000 and 2016 mifepristone protocols, in the FDA's own words, "upend[ed] the regulatory regime for mifepristone." FDA Stay Application, No. 22A902, 2023 WL 3127519, at *3 (U.S. Apr. 14, 2023). Those changes included "increasing the maximum gestational age from forty-nine days to seventy days," close to the end of the first trimester; "allowing non-physicians to prescribe mifepristone," despite their lessened ability to diagnose and recommend treatment for complications; "removing the requirement that the administration of misoprostol and the subsequent follow-up appointment be conducted in person," reducing the ability to analyze the patient's condition; "eliminating prescribers' obligation to report non-fatal adverse events," despite the numerous serious but non-fatal adverse events under the stricter protocols; and changing both "the method of administration for misoprostol" and "changing the dose" of mifepristone and misoprostol. Pet. App. 10a (merits panel majority).

In approving the sweeping 2016 Amendments, the FDA (1) failed to examine the relevant data by using studies that did not analyze the cumulative change in protocols and that contradicted the FDA's assertions about the safety of the new REMS; and (2) unreasonably eliminated the non-fatal adverse event reporting mechanism when it would be most useful.

i. The FDA failed to justify the cumulative changes of the 2016 Amendments.

The FDA "relied on zero studies that evaluated the safety-and-effectiveness consequences of the 2016" Amendments "*as a whole*." Pet. App. 235a (motions panel per curiam). The "FDA eliminated REMS safeguards based on studies that *included those very safeguards*." *Id.* Rather than addressing this problem head-on, "FDA failed to address the cumulative effect at all," neglecting "to acknowledge the question, determine if the evidence before it adequately satisfied the concern, and explain its reasoning." Pet. App. 54a (merits panel majority).

The FDA's review of the evidence does not look any better when one digs into how "FDA studied the safety consequences of eliminating one or two of the 2000 Approval's REMS in *isolation*." Pet. App. 235a (motions panel per curiam). Consider the three studies the FDA's briefing identifies as its best examples. Br. for Federal Petitioners at 38 (Jan. 23, 2024) (citing Sanhueza Smith et al. 2015, Winikoff et al. 2012, and Olavarietta 2015). These are three articles FDA cited as "[s]upport for extending the gestational age to 70 days" from 49 days. J.A. 299 & nn. 1, 3-4. Contrary to the 2016 Amendments but consistent with the 2000 protocol, all three studies included in-person follow-up appointments likely to improve success rates and to promptly address adverse events.

The only one of those three studies that came close to disaggregating the success rates of chemical abortions where gestational age was up to 49 days

with chemical abortions where gestation age stretched up to 70 days found that "[w]omen with pregnancies ≤8 weeks [gestation] had significantly higher success rates than women in the 9th or 10th weeks" of pregnancy. Sanhueza Smith et al., *Safety Efficacy and Acceptability of Outpatient Mifepristone-misoprostol Medical Abortion through 70 Days Since Last Menstrual Period Sector Facilities in Mexico City*, 44 Reproductive Health Matters 75, 75 (2015) ("Sanhueza Smith et al.") (citing success rates of 94.9% compared with 90.5%). That 90.5% success rate for later chemical abortions, even with follow-up visits and the new treatment protocol, was worse than the success rate for all three clinical studies the FDA relied on in 2000. *See* Pet. App. 6a-7a (merits panel majority). Pain levels were also "statistically significantly higher" for women in the 57- to 70-days gestation group. Sanhueza Smith et al. 2015 at 78-79.

Unlike Winikoff et al. 2012, the Olavarietta 2015 controlled trial at least included women both before and after 49-days gestational age. But that study's usefulness is limited because the trial did not disaggregate participants in the data by gestational age. The mean duration of gestation determined by ultrasound was 49.7 days, only slightly higher than the 2000 protocols' limit of 49 days. Olavarietta et al., *Nurse Versus Physician-Provision of Early Medical Abortion in Mexico: a randomized controlled non-inferiority trial*, 93 Bull. World Health Org. 249, 251 (2015) ("Olavarietta 2015"). By lumping all the women together into the final results, the Olavarietta 2015 study provides no way to determine if success rates worsened as gestational age increased. The authors did clarify that the "one serious adverse event" in this

trial occurred when a woman above 49 days gestation required hospitalization "for 38 hours due to bleeding following misoprostol administration and underwent a surgical abortion." *Id.* at 254. Nevertheless, the FDA cited the "overall success rate[]" of this study as justification for extending the gestational age all the way to 70 days. J.A. 299.

Further, while this trial allowed non-physicians to administer the drugs, the non-physicians were nurses who received over a week of "training on medical abortion management" and "20 hours of abdominal and transvaginal ultrasound training," with "an experienced obstetrician" on site to assist during the trial. Olavarietta 2015 at 250, 254. Those conditions are a far cry from what the 2016 Amendments allow.

ii. The FDA ended its collection of non-fatal adverse events despite the 2016 Amendments making that data more needed.

The FDA further abused its discretion by "fail[ing] to consider . . . whether it needed to continue to collect data of non-fatal adverse events in light of the 'major' changes to the mifepristone REMS." Pet. App. 54a (merits panel majority). The FDA had decided "to significantly loosen mifepristone's conditions for use" in ways that no study had analyzed. Pet. App. 55a. Even if the risk profile had not changed, the FDA had approved mifepristone under its Subpart H authority, meaning it "could not be administered safely without imposing certain use restrictions." Pet. App. 7a; *see also* J.A. 230 ("Subpart H applies when FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is

restricted, such as to certain physicians with special skills or experience."). By eliminating the required collection of data for all events short of death, the FDA blinded itself to the harms the other 2016 Amendments might cause and eliminated a crucial source of data for any future revisions, such as the 2021 Non-Enforcement Decision. *See* Pet. App. 236a (motions panel per curiam).

The very studies FDA cited for the 2016 Amendments warned about the lack of data regarding changes to mifepristone's dispensing requirements. For example, the one systematic review FDA relied on for extending the gestational age to 70 days was Chen & Creinen 2015. J.A. 299 & n.5. That review, without the benefit of the Sanhueza Smith et al. 2015 study, could only identify in published trials "outcomes by gestational age in 129 and 49 patients between 50-56 and 57-63 days of gestation, respectively." Chen & Creinen, *Mifepristone With Buccal Misoprostol for Medical Abortion*, 126 Obstetrics & Gynecology 12, 20 (2015). "Another obvious and important limitation of the available data is the relative lack of significant numbers of women who reported using mifepristone and buccal misoprostol beyond 63 days of gestation." *Id.* As explained above, the Sanhueza Smith et al. 2015 study cast further doubt on the effectiveness of chemical abortion for later stage abortions. Yet the FDA still chose to bury its head in the sand and ignore the need for more data.

The agency has struggled to explain why it suddenly thought required reporting of the lion's share of adverse events was no longer necessary for a drug so risky that FDA previously required a stricter

REMS program, a "Patient Agreement Form," and a "Black Box" warning. *See* Pet. App. 236a (motions panel per curiam). So the FDA has resorted to rewriting the history of how it approved mifepristone, now claiming that FDA originally approved mifepristone based on general statutory authority, "not subpart H." Br. for Federal Appellants, No. 23-10362, 2023 WL 3273780, at *45 (5th Cir. Apr. 26, 2023). That assertion is contrary to what the agency said back in 2000. J.A. 234 ("The application is approved under 21 CFR 314 Subpart H."); *see also* J.A. 230 ("The Population Council agreed to approval under Subpart H in their letter of September 15, 2000."). In 2016, FDA also agreed that the 2000 "application was approved under 21 CFR part 314, subpart H, 'Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses' (subpart H)." J.A. 239. If mandatory reporting of all adverse events was necessary in 2000, when only physicians could prescribe mifepristone and only with in-person follow-up appointments, then it was even more necessary in 2016, when FDA decided to allow non-physicians to prescribe mifepristone to a broader range of patients without in-person follow-up.

B. The 2021 Non-Enforcement Decision lacked scientific support and relied on a dataset FDA knew was inadequate.

A year into the COVID-19 pandemic, FDA decided "to exercise enforcement discretion during the COVID-19 [Public Health Emergency] with respect to the in-person dispensing requirement of the Mifepristone REMS Program." J.A. 364-65. This

decision enabled "the dispensing of mifepristone through the mail . . . or through a mail-order pharmacy." J.A. 365. Later that same year, FDA stopped pretending the change would be a temporary one. J.A. 371. The agency permanently modified mifepristone's REMS to allow dispensing by mail. The "two sources of information" supposedly supporting those decisions—the limited "published literature relating to remote prescription of mifepristone" and adverse-events data from January 2020 to January 2021—do not come close to supporting FDA's actions. Pet. App. 56a-57a (merits panel majority).

i. The FDA failed to find studies to justify ending in-person dispensing.

The FDA itself admitted that, at best, the limited studies it could find were "not inconsistent with" its 2021 Non-Enforcement Decision. J.A. 400. The FDA "did not find any large clinical studies that were designed to collect safety outcomes in healthcare systems similar to the United States." *Id.* Generalizing the four studies it cited to the United States population, *see* J.A. 364-65, was "hampered by differences between the studies with regard to pre-abortion care" and "limited in some instances by small sample sizes and lack of follow-up information on outcomes with regard to both safety and efficacy," J.A. 400.

One Hawaii study, for example, screened women for "a history of or symptoms concerning for ectopic pregnancy" and "a prior ectopic" pregnancy because mifepristone is contraindicated for ectopic pregnancies. Kerestes et al., *Provision of Medication*

Abortion in Hawai'i During COVID-19: Practical Experience with Multiple Care Delivery Models, 104 Contraception 49, 51 (2021) ("Kerestes et al. 2021"); *see* J.A. 364 & n.1 (citing Kerestes et al. 2021). The organizers of that study also knew the Rh type for most participants, including some for whom they specifically requested an Rh-type screen, which avoided Rh incompatibility concerns for Rh-negative women. Kerestes et al. 2021 at 51. A disproportionately high share of the women who received mifepristone by mail also had ultrasounds thanks to study requirements—94.7%, compared with 80.9% of the women treated completely in-clinic and only 42.3% of the women treated with telemedicine but in-person pickup. *Id.* Despite those precautions, twice as many mail-delivery patients required ER visits as the fully in-clinic patients. *Id.* at 52. Telemedicine with in-person pickup also suffered rates of ER visits nearly twice as high as patients treated in-person under conditions closer to those FDA adopted in 2000, and both the patients who required blood transfusions came from the telemedicine cohort. *Id.*

In short, Kerestes et al. 2021 suggests that allowing the prescription of mifepristone under the lax conditions FDA has allowed—complete telemedicine treatment with non-physicians prescribing and dispensing mifepristone via the mail up to 70-days gestational age—would cause severe harm to many more women. The studies FDA reviewed were, in its own words, "not adequate on their own to establish the safety of the model of dispensing mifepristone by mail." J.A. 407.

ii. The FDA relied on limited data that it knew was inadequate.

Pivoting away from those studies, FDA pointed to one year of adverse event data from the FDA voluntary event reporting system ("FAERS"). J.A. 365. FDA found a "small number of adverse events reported to FDA" from January 2020 to January 2021. *Id.* For about half of that time, a district court's injunction had allowed medical professionals to dispense mifepristone by mail. *See FDA v. ACOG*, 141 S. Ct. 578 (2021) (staying that injunction on January 12, 2021). But as the Fifth Circuit correctly observed, "FAERS data is insufficient to draw general conclusions about adverse events." Pet. App. 59a (merits panel majority). The FDA's own Q&A document for FAERS declares that "FAERS data cannot be used to calculate the incidence of an adverse event or medication error in the U.S. population." J.A. 415. "FDA does not receive reports for every adverse event or medication error that occurs with a product." *Id.* Relying on the FAERS data here, which FDA knew was inadequate, was arbitrary, capricious, and an abuse of discretion.

Even looking at the Kerestes et al. 2021 study of a mere 334 Hawaiians, which almost entirely overlapped with the time period FDA looked at, there were more blood transfusion and ER visit complications in that one study than in all the FAERS data for the entire United States. *See* J.A. 398 (identifying during later FDA follow-up that "a total of eight cases were identified in FAERS" from January 2020 through September 2021). Nevertheless,

ignoring the Kerestes et al. 2021 study FDA had already identified, FDA asserted that "no additional case reports were identified in the medical literature." J.A. 398.

If FDA had not abolished the mandatory adverse event reporting system for non-fatal events in 2016, FDA would have been in a better position to see the likely negative consequences of its 2021 Non-Enforcement Decision. Instead, the FDA was left to point to two sources of data that it knew were inadequate to justify ending in-person dispensing of mifepristone. The FDA, therefore, acted arbitrarily and capriciously.

II. THE FDA DISTORTED THE COMSTOCK ACT BY ALLOWING SHIPMENT OF CHEMICAL ABORTION DRUGS.

The FDA's recent actions are attempts to facilitate a policy goal of allowing the shipment of chemical abortion drugs throughout the country in violation of the Comstock Act, 18 U.S.C. §§ 1461-62. To justify this "doctrinal innovation," the FDA "engineer[s] exceptions to longstanding background rules" without regard to their effect on other prosecutions under the Comstock Act. *Dobbs*, 597 U.S. at 287.

Even if the Administrative Procedure Act did not obligate FDA to consider the Comstock Act before its 2021 Non-Enforcement Decision, "the overall public interest in this case" weighs heavily in favor of discouraging the violation of federal law. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 26 (2008). Private parties have no interest in the mailing and

carriage of mifepristone anymore than they have an interest in the illegal mailing and carriage of obscenity, child pornography, or like materials unmailable under the Comstock Act. *Cf.* Pet. App. 242a-244a (motions panel per curiam).

A. The FDA has promoted the mailing and carriage of drugs designed, adapted, or intended for producing abortion in violation of federal law.

The FDA is facilitating and encouraging violations of the Comstock Act. The Comstock Act prohibits "knowingly us[ing] the mails for the mailing, carriage in the mails, or delivery of," among other items, "[e]very article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use." 18 U.S.C. § 1461. It also prohibits "knowingly us[ing] any express company or other common carrier or interactive computer service . . . for carriage in interstate or foreign commerce" and "knowingly tak[ing] or receiv[ing] from such express company or other common carrier or interactive computer service" items including "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use." 18 U.S.C. § 1462. The plain text of these provisions precludes the shipment of chemical abortion drugs such as mifepristone. *See* Pet. App. 98a-101a (Ho, J., concurring in part); Pet. App. 151a-155a (district court opinion).

Nevertheless, since 2021 the FDA has unlawfully treated the Comstock Act as a nullity when regulating chemical abortion drugs. In early 2021, the agency dusted off a year-old request to suspend the in-person

dispensing requirements for mifepristone during the COVID-19 pandemic and decided "to exercise enforcement discretion during the COVID-19 [Public Health Emergency] with respect to the in-person dispensing requirement of the Mifepristone REMS Program." J.A. 364-65. The FDA acknowledged that this decision enabled "the dispensing of mifepristone through the mail . . . or through a mail-order pharmacy." J.A. 365.

The pretense of COVID-19 justifying this decision did not last long. In December 2021, FDA decided to permanently remove the in-person dispensing requirement due to the more general desire "to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks." J.A. 371. Pharmacies that dispense mifepristone, now directly to patients by mail and common carrier, would need to "be specially certified." J.A. 371.

This regulatory change created serious concerns under the Comstock Act, so the Department of Justice's Office of Legal Counsel ("OLC") issued an opinion to the United States Postal Service that the Comstock Act "does not prohibit the mailing, or the delivery or receipt by mail, of mifepristone or misoprostol where the sender lacks the intent that the recipient of the drugs will use them unlawfully." *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 46 Op. O.L.C. ___, 2022 WL 18273906, at *1 (Dec. 23, 2022). The FDA immediately issued a memorandum relying on the OLC opinion and declaring that the

Comstock Act "pose[s] no issue for FDA's approval of" the formal REMS amendment. J.A. 545.

Accordingly, the new REMS required pharmacies dispensing mifepristone to "[b]e able to ship mifepristone using a shipping service." FDA, *REMS for Mifepristone* at 3 (Jan. 3, 2023), *available at* https://perma.cc/9GWG-GQY8. FDA gave no regard to the Comstock Act declaring every drug or medicine "designed, adapted, or intended for producing abortion" "nonmailable matter," § 1461, and "unlawful" for "carriage or importation," § 1462. The FDA did not limit its distribution requirement to any non-abortion uses of mifepristone or even prohibit its shipment when the sender or recipient knows the drug will be used for abortion.

It is apparent that these actions of the FDA and other cooperating agencies were to enable the prescription and distribution of mifepristone *because* it is a drug designed, adapted, or intended for producing abortion. In July 2022, the President issued an Executive Order directing the Secretary of Health and Human Services, a department of which FDA is a part, to identify actions "to protect and expand access to abortion care, including medication abortion." Exec. Order No. 14,076, 87 Fed. Reg. 42,053, 42,053 (July 13, 2022). Accompanying the Executive Order was a Fact Sheet referring to mifepristone and stating that "[t]hese actions will build on the steps the Secretary of HHS has already taken at the President's direction following the decision to ensure that medication abortion is as widely accessible as possible." White House, *Fact Sheet: President Biden to Sign Executive Order Protecting Access to Reproductive Health Care*

Services (July 8, 2022), https://perma.cc/VQ7F-QFHG. The resulting report expressly described mifepristone as "the FDA-approved product for medication abortion." Sec'y of HHS, *Health Care Under Attack: An Action Plan to Protect & Strengthen Reproductive Care* at 7 (Aug. 2022), https://perma.cc/SQ23-2K8Q.

These administrative actions conflict with the text of the Comstock Act and Congress's "national policy of discountenancing abortion as inimical to the national life." *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915). Federal Petitioners no doubt disagree with the Comstock Act's prohibitions on shipping known abortion drugs and wish the FDA could authorize pharmacies to ship mifepristone throughout the country. But that is inconsistent with federal law.

B. The rewriting of the Comstock Act proposed by Federal Petitioners threatens to undermine prosecution of the law in other contexts.

If allowed to stand, FDA's "ad hoc nullification" of the Comstock Act's prohibitions on shipping chemical abortion drugs will lead "to the distortion of many important" rules for how the law is interpreted in other contexts. *Dobbs*, 597 U.S. at 286 (quoting *Thornburgh v. ACOG*, 476 U.S. 747, 814 (1986) (O'Connor, J., dissenting)). The Federal Petitioners rely on scattered lower court decisions about the Comstock Act's long-repealed contraception provisions to support their conclusion that there is no violation "where the sender lacks the intent that the recipient of the drugs will use them unlawfully." 46 Op. O.L.C. ___, 2022 WL 18273906, at *1; *see also* J.A. 545 (FDA adopting this interpretation of the

Comstock Act). But that approach to the Comstock Act flies in the face of how courts, including this one, have interpreted §§ 1461-62 for prosecutions of other offenses under those statutes, such as distribution of obscenity and child pornography.

Specifically, the Federal Petitioners' blinkered focus on abortion (1) improperly suggests that only senders, not recipients, are subject to prosecution under the Comstock Act; (2) imposes a sender-specific intent requirement that is at odds with the Comstock Act's mens rea; and (3) invents an unlawful use requirement that appears nowhere in the statutory text.

i. The Comstock Act allows prosecution of recipients, not just senders, of proscribed materials.

The OLC has wrongly suggested that the only individuals subject to prosecution under the Comstock Act's chemical abortion drug prohibitions are the senders of such drugs. *See* 46 Op. O.L.C. ___, 2022 WL 18273906, at *1 n.3 ("[T]hese provisions have never been applied to prosecute the recipients of abortion and contraception-related materials."). That idea is contrary to the plain text of §§ 1461-62 which, as the OLC acknowledges, "refer not only to persons who transmit such items by mail or by common carrier—the senders—but also to individuals who 'knowingly cause[]' such items to be mailed, *id.* § 1461; 'knowingly take[]' any such items from the mail for the purpose of circulating or disposing of them, *id.*; or 'knowingly take[] or receive[]' such items from an express company or common carrier, *id.* § 1462." 46 Op. O.L.C.

___, 2022 WL 18273906, at *1 n.3. Those provisions apply to recipients of *all* nonmailable material, including drugs like mifepristone designed, adapted, or intended for producing abortion. Federal Petitioners' regulatory actions thus improperly "focus on the sender" of mifepristone. *Id.* Despite OLC's suggestions to the contrary, there is more than a mere possibility that "a recipient might be covered" for knowingly receiving chemical abortion drugs. *Id.* By their plain terms, Sections 1461 and 1462 definitively apply to knowing recipients of all nonmailable materials.

Confirming Amicus's concern that adopting Federal Petitioners' reading of the Comstock Act threatens prosecutions outside the abortion context, the OLC stretches to support its novel interpretation with the possibility that the Comstock Act generally applies only to senders. *Id.* (citing *United States v. Johnson*, 855 F.2d 299, 307-11 (6th Cir. 1988) (Merritt, J., dissenting); *United States v. Sidelko*, 248 F. Supp. 813, 815 (M.D. Pa. 1965)). This footnote is the only time in its opinion that the OLC addresses Comstock Act precedent outside the abortion or contraception context. And even more tellingly, the only such precedent the OLC can find to support its view is a dissenting circuit court opinion and a district court opinion that circuit courts have repeatedly and consistently disagreed with. The circuit courts have routinely *rejected* the proposition that the Comstock Act does not apply to recipients of other nonmailable material, such as obscenity and child pornography. *See, e.g.*, *United States v. Carmack*, 910 F.2d 748, 748 (11th Cir. 1990); *United States v. Kuennen*, 901 F.2d 103, 104-05 (8th Cir. 1990); *Johnson*, 855 F.2d at

305-06 (majority); *United States v. Hurt*, 795 F.2d 765, 770 (9th Cir. 1986).

The Federal Petitioners' tunnel vision focus on chemical abortion drugs thus threatens to restrict all prosecutions under the Comstock Act by setting aside the plain text of §§ 1461-62 and the rules that normally apply to nonmailable material. The statutory prohibitions on the knowing receipt of proscribed material are generally applicable, not limited to the chemical abortion context.

ii. The Comstock Act does not require proof about how the sender intends recipients to use nonmailable material.

According to the OLC, every prosecution for mailing chemical abortion drugs "turn[s] on the nature of the sender's intent, not that of the recipient." 46 Op. O.L.C. ___, 2022 WL 18273906, at *1 n.3. On this view, "where the sender lacks the intent that the recipient of the drugs will use them" for abortion, there is no Comstock Act violation. *Id.* at *1. But that reasoning is contrary to this Court's recognition that the Comstock Act "protect[s] the public commercial environment by preventing such material from entering the stream of commerce" altogether, regardless of how the "material is intended for . . . use." *United States v. Orito*, 413 U.S. 139, 143 (1973). Under the Comstock Act, the prosecution only needs to show that "a defendant had knowledge of the contents of the materials" and "that he knew the character and nature of the materials." *Hamling v. United States*, 418 U.S. 87, 123 (1974); *see also Counterman v. Colorado*, 600 U.S. 66, 76-77 (2023)

(confirming this is the correct scienter). The knowing distribution or receipt of mifepristone, a known chemical abortion drug, under the FDA's new rules and REMS thus violates the Comstock Act.

Imposing a sender-intent mens rea requirement on prosecutors is inconsistent with the text of the Comstock Act. Section 1461 "declare[s]" that any proscribed item is "nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier." The statute then repeatedly prohibits actions using a knowingly mens rea. The law is violated whenever someone "*knowingly* uses the mails for the mailing, carriage in the mails, or delivery of anything declared by this section . . . to be nonmailable," "*knowingly* causes to be delivered by mail" nonmailable material, or "*knowingly* takes any such thing from the mails for the purpose of circulating or disposing thereof, or of aiding in the circulation or disposition thereof" violates § 1461. (Emphases added.) The only "purpose" requirement for a conviction under § 1461 applies to the last prohibition and does not extend beyond determining whether a defendant sender or recipient is "circulating or disposing" of the nonmailable material using the mails. The sender's intent for how a recipient will use the item after removing it from the mails does not matter.

Section 1462 similarly turns on whether the defendant "*knowingly* uses any express company or other common carrier or interactive computer service . . . for carriage in interstate or foreign commerce" the proscribed material or "*knowingly* takes or receives" the materials "from such express

company or other common carrier or interactive computer service." (Emphases added.)

The textual focus on using the mails and interstate carriers makes sense in light of the Comstock Act's "obvious purpose" to "prevent the channels of interstate commerce from being used to disseminate any matter" that Congress chose to proscribe, including abortion drugs. *United States v. Alpers*, 338 U.S. 680, 683 (1950). Sections 1461 and 1462 generally concern the "knowing transportation of . . . material in interstate commerce" regardless of the sender's intent. *Smith v. United States*, 431 U.S. 291, 307 (1977); *see also Kuennen*, 901 F.2d at 105 (upholding conviction for violation of § 1461 where use of the mails by recipient "can reasonably be foreseen, even though not actually intended" (quoting *Pereira v. United States*, 347 U.S. 1, 8-9 (1954)). "Because the statute's intent is to punish for the use of the mails," how the sender intends the recipient to use mifepristone, a known chemical abortion drug, is irrelevant. *Carmack*, 910 F.2d at 748. "Congress may regulate"—and has regulated—"on the basis of the natural tendency of" this material to be used for abortion, "regardless of a transporter's professed intent." *Orito*, 413 U.S. at 143.

Congress's desire to remove abortion drugs from interstate commerce is why it also declared them nonmailable. Normally the Postal Service completely prohibits the use of the mails for shipping nonmailable material, "prohibiting items because of how they can be used rather than speculating about senders and recipients." Thomas Jipping & Sarah Parshall Perry, *The Justice Department Is Wrong:*

Federal Law Does Prohibit Mailing Abortion Drugs 6, The Heritage Foundation (Feb. 8, 2023), https://perma.cc/5C6R-J96P (providing examples of items with safe and dangerous uses and with legal and illegal uses). That the OLC has gone out of its way to tell the Postal Service and FDA that the mailing of known abortion drugs turns on the sender's intent for the recipient's use demonstrates how Federal Petitioners seek to rewrite the normal rules for the Comstock Act.

Others have wrongly attempted to justify a sender-intent rule specific to "[e]very article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use," § 1461, by claiming the "whole phrase 'designed, adapted or intended'" requires "an intent on the part of the sender" for the use of the chemical abortion drug, Br. for Former U.S. Dep't of Just. Officials as Amici Curiae at 19 (Jan. 30, 2024) (quotation omitted). In addition to the flaws with that interpretation raised by the Fifth Circuit, the transformation of this phrase into one cumulative intent requirement is impossible to reconcile with the statutory text. "[D]esigned," "adapted," and "intended" are distinct participles that Congress wrote as alternative descriptions of the abortion "article[s] or thing[s]," not the mens rea of the sender. 18 U.S.C. § 1461; *see Kemp v. United States*, 41 App. D.C. 539, 545 (D.C. Cir. 1914) (ruling § 1461 prohibited mailing a letter containing information about abortion regardless of "whether defendant" physician "intended to treat the girl himself or procure another to give the treatment" because the information itself was "forbidden"). Even if recasting these adjectives into adverbs were a

textually appropriate maneuver, collapsing the entire phrase into the word "intended" would "defeat the intent and purpose of Congress" instead of "elucidat[ing] its words and effectuat[ing] its intent" in this "comprehensive statute." *Alpers*, 338 U.S. at 354 (rejecting use of ejusdem generis "to render general words meaningless" in the Comstock Act).

The participles "designed, adapted, or intended" do not focus on a specific actor. Like a passive verb that does not specify its actor, these participles clarify that an article or thing is "designed, adapted, or intended for producing abortion" as long as anyone designs, adapts, or intends for the item to produce abortion. Even the United States concedes the logic of this construction by admitting that, "[t]o the extent a recipient might be covered" by the Comstock Act's prohibitions, then "section 1461 would not prohibit that person from ordering or receiving the drugs *if she does not intend that* they be used unlawfully." 46 Op. O.L.C. ___, 2022 WL 18273906, at *1 n.3 (emphasis added). Such a move shifts the mens rea focus completely away from the sender, contrary to the OLC's approach to the statute.

iii. The Comstock Act does not require proof that a recipient will unlawfully use nonmailable material.

Federal Petitioners ignore this Court's precedents regarding nonmailable obscene material in their attempt "to graft" an unlawful use requirement onto the Comstock Act. Pet. App. 244a (motions panel per curiam). If Congress had wanted to prohibit the transportation of abortion drugs or other proscribed

items in §§ 1461-62 only when a recipient would use them unlawfully, then Congress knew how to specify that. *See, e.g.*, 19 U.S.C. § 1305(a) (prohibiting in the Tariff Act of 1930 "importing . . . any drug or medicine or any article whatever for causing *unlawful* abortion" (emphasis added)). But Congress chose a broader prohibition in the Comstock Act. *See* Pet. App. 103a (Ho, J., concurring in part).

Reading in an unlawful use requirement for the Comstock Act would twist the law in ways contrary to this Court's precedent. Sections 1461 and 1462 also prohibit the mailing and carriage of obscene material. This Court has held that an individual has a constitutional right to possess at least some obscene materials in the privacy of his home. *Stanley v. Georgia*, 394 U.S. 557 (1969). Nevertheless, that protection for lawfully possessing obscene material in the home is no defense for violating the Comstock Act by transporting obscene materials in interstate commerce. *Smith*, 431 U.S. at 307 ("*Stanley* did not create a right to receive, transport, or distribute obscene material, even though it had established the right to possess the material in the privacy of the home."). This Court has interpreted the Comstock Act as prohibiting the "interstate transportation of obscene material" and upheld its constitutionality even when "the material is intended for [] private use" in the home. *Orito*, 413 U.S. at 143; *see also United States v. Reidel*, 402 U.S. 351, 352 (1971) (holding § 1461 "constitutional as applied to the distribution of obscene materials to willing recipients who state that they are adults"). To reinterpret the Comstock Act as possessing a latent unlawfulness requirement would

thus conflict with how this Court has previously interpreted the law.

Federal Petitioners' attempt to insulate from legal challenge the nationwide distribution of chemical abortion drugs disrespects the Comstock Act's standard approach to federalism. Congress was sensitive to the idea that some States might "adopt a laissez-faire attitude toward regulation" of proscribed materials but chose to protect the more restrictive States from having those materials broadly distributed via the channels of interstate commerce. *Smith*, 431 U.S. at 307. A "State's right to abolish all regulation of obscene material," for example, "does not create a correlative right to force the Federal Government to allow the mails or the channels of interstate or foreign commerce to be used for the purpose of sending obscene material" even "into the permissive State." *Id.*

Here, Federal Petitioners have consciously attempted to turn the federal shield protecting abortion-restrictive States into a federal sword to wield against them. The OLC insists that the Postal Service may deliver mifepristone "no matter where the drugs are delivered," regardless of how tightly a State regulates abortion or whether a State itself prohibits the distribution of mifepristone. 46 Op. O.L.C. ___, 2022 WL 18273906, at *11. Federal Petitioners are incorrectly interpreting the Comstock Act in a way that they claim would preempt State laws in line with the Comstock Act's "national policy of discountenancing abortion as inimical to the national life." *Bours*, 229 F. at 964. Instead of blaming these States for "stok[ing] confusion [and] sow[ing]

fear," Federal Petitioners should have more carefully considered whether the FDA's actions were consistent with the Comstock Act. President Biden, *Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services*, The White House (Jan. 22, 2023), https://perma.cc/8D36-WPN7.

The OLC grasps at "a variety of aging" circuit court "opinions and a single footnote within one Supreme Court dissent"—all but one opinion about contraception, not abortion—to support inserting the word "unlawful" into the Comstock Act's abortion provisions. Pet. App. 243a-244a (motions panel per curiam); *see* 46 Op. O.L.C. ___, 2022 WL 18273906, at *3-5. Even supporters of the policy outcomes in those cases readily conceded at the time that they used a "liberal construction" that was "difficult to reconcile with the inclusive terminology of the statute." Recent Case, *Birth Control — Importation of Contraceptives for Medical Use Held Not Forbidden by Tariff Act*, 50 Harv. L. Rev. 1312, 1312 (1937). The text of the "Comstock Act[] made no explicit exception permitting physicians to prescribe contraceptives in their medical practice." Note, *Judicial Regulation of Birth Control Under Obscenity Laws*, 50 Yale L.J. 682, 683 (1941).

The judge-created exceptions were "[d]espite the all-inclusive terms in which contraceptives [we]re outlawed in the federal statutes," not because of the statutes' text. *Id.* at 684. Justice Harlan himself acknowledged, while advocating for expanded constitutional protection for contraception, that the text of the Comstock Act was "characteristic of the attitude of a large segment of public opinion on this matter" at the time of the law's enactment. *Poe v.*

Ullman, 367 U.S. 497, 547 n.12 (1961) (Harlan, J., dissenting). "It was only by judicial interpretation at a later date that the absolute prohibitions of the law were qualified to exclude professional medical use." *Id.* *Contra* 46 Op. O.L.C. ___, 2022 WL 18273906, at *6 (omitting from Justice Harlan's dissent the words "It was only" and "at a later date").

Despite the courts and others repeatedly criticizing the broad text of the Comstock Act's contraception provisions, Congress refused to amend the law until after this Court extended constitutional protection to contraceptives in *Griswold v. Connecticut*, 381 U.S. 479 (1965). When Congress amended the Comstock Act, "it chose to repeal only the Act's prohibition on the shipment of contraceptives." Pet. App. 104a (Ho, J., concurring in part) (citing Pub. L. No. 91-662, §§ 3-4, 84 Stat. 1973, 1973 (1971)). Public opinion on contraception had changed decisively, and Congress acted accordingly.

In contrast, Americans continue to "hold sharply conflicting views" on abortion. *Dobbs*, 597 U.S. at 223. Congress has never mustered the majorities necessary to contract the Comstock Act's broad prohibitions on the mailing or carriage of abortion drugs. Federal Petitioners want §§ 1461-62 to apply only to abortion drugs intended for unlawful use. But Congress considered and rejected an amendment to the Comstock Act after *Roe v. Wade*, 410 U.S. 113 (1973), that would have limited the provisions to "illegal abortions." *See* Pet. App. 103a (Ho, J., concurring in part) (citing H.R. 13959, 95th Cong. § 6702(1)(C)(i) (1978)).

The only circuit court case the OLC cites regarding one of the abortion prohibitions in the Comstock Act—*Bours*—flatly rejects the proposition that local law can create exceptions to this federal law's regulation of interstate commerce: "In applying the national statute to an alleged offensive use of the mails at a named place, it is immaterial what the local statutory definition of abortion is, what acts of abortion are included, or what excluded." 229 F. at 964. This "national statute" uses the "general medical sense" of the word "abortion" to include elective abortions unnecessary to save a woman's life. *Id.* Mifepristone is designed and adapted to produce abortions in those circumstances, so it is nonmailable under the Comstock Act's even more general prohibition of "knowingly us[ing] the mails for the mailing, carriage in the mails, or delivery of" "[e]very article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use." 18 U.S.C. § 1461.

Mifepristone itself is a known abortion drug "forbidden" in interstate commerce. *Kemp*, 41 App. D.C. at 549 ("Defendant's crime consisted in mailing a letter containing the forbidden information, and it is not important that it could never reach the person to whom it was addressed"). Whether the mailing results or could result in a separate violation of a State's law does not determine whether a violation of the Comstock Act occurred.

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

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Respectfully submitted,

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