IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, *et al.*,

Plaintiffs,

v.

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

Defendants.

Case No. 2:22-CV-00223-Z

BRIEF OF FOOD AND DRUG LAW SCHOLARS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTEREST OF *AMICI CURIAE*

Amici curiae are 19 U.S. food and drug law scholars from 16 academic institutions across the United States.[1] Collectively, *amici* have devoted many decades to studying the U.S. Food and Drug Administration (FDA or the Agency). *Amici* are well known in their field, and many have deep expertise in the drug approval process in particular. Several *amici* have previously submitted *amicus* briefs to courts faced with issues that implicate U.S. federal food and drug law, including the Supreme Court of the United States. A full list of *amici* is included as an Appendix to this brief.

Although *amici* represent a diverse range of ideologies and do not necessarily agree on all moral and ethical questions associated with abortion, *amici* uniformly agree that Plaintiffs have gravely mischaracterized U.S. federal food and drug law, including how it intersects with the U.S. Criminal Code. Granting Plaintiffs' preliminary injunction motion would undermine the drug approval process far beyond the context of mifepristone's approval. Accordingly, *amici* urge this Court to deny Plaintiffs' request.

INTRODUCTION

More than twenty years ago, FDA approved mifepristone, concluding that it is safe and effective for the medical termination of intrauterine pregnancy under the conditions set forth in the FDA-approved prescribing information. Since that initial approval, FDA has repeatedly and consistently confirmed that mifepristone is safe and effective for its intended use, including as recently as last month. Alleging violations of the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations, as well as violations of the U.S. Criminal Code,

[1] The views expressed herein are those of the *amici* in their individual capacities and do not necessarily represent the views of their respective institutions.

Plaintiffs now seek "immediate relief" in the form of a preliminary injunction ordering Defendants to withdraw all approvals of mifepristone.[2]

As scholars of food and drug law, we file this *amicus* brief in support of the U.S. Government's position and to underscore three points. *First*, Plaintiffs' substantive claims under the FDCA and FDA's implementing regulations lack merit. FDA has acted in accordance with applicable statutory authorities and regulatory standards in its review and approval of mifepristone.[3] *Second*, Plaintiffs' proposed remedy would profoundly undermine the well-established statutory and regulatory framework for the approval of new drugs and the due process accorded to drug marketing application holders by statute. It would also create harmful reverberations that would affect patients, healthcare providers, and the biopharmaceutical industry, all of whom rely on the expertise of FDA to make scientific determinations regarding the safety and effectiveness of our nation's medical products. *Third*, FDA's approval of mifepristone is consistent with the Comstock Act.

[2] This brief uses "mifepristone" to refer to both the branded and generic forms of this drug that are approved for the medical termination of intrauterine pregnancy.

[3] This brief focuses on the 2000 New Drug Application (NDA) approval and 2016 supplemental NDA approval (sNDA). Plaintiffs also challenge FDA's 2019 abbreviated NDA (ANDA) approval of a generic version of mifepristone. Congress granted FDA the authority to approve generic drugs that rely on the safety and efficacy data of an already-approved drug (*i.e.*, the reference listed drug (RLD)) upon a demonstration that the generic drug is the "same as" and bioequivalent to the RLD. 21 U.S.C. § 355(j)(2)(A). Plaintiffs do not argue that FDA erred in determining that the generic version of mifepristone is bioequivalent and pharmaceutically equivalent to the RLD, but instead assert that the generic approval was improper because of FDA's alleged erroneous safety and effectiveness determination for the RLD. For the reasons discussed below, this argument fails.

ARGUMENT

I. FDA Approved and Continues to Regulate Mifepristone Consistent with the FDCA and the Agency's Regulations and Policies.

FDA acted in accordance with federal law in approving and regulating mifepristone. 21 U.S.C. §§ 355, 355-1. FDA's imposition of restrictions on the use and distribution of mifepristone under 21 C.F.R. Part 314, Subpart H was lawful and consistent with the Agency's long-standing construction of the scope of these regulations and similar regulatory programs. Furthermore, any alleged defects in the original approval of mifepristone in 2000 were cured in 2011 when, at the direction of Congress, FDA approved a risk evaluation and mitigation strategy (REMS) for mifepristone under express statutory authority in section 505-1 of the FDCA (21 U.S.C. § 355-1). Indeed, FDA has completed multiple additional reviews of the safety and efficacy of mifepristone, and each time, it has determined that the scientific evidence demonstrates that mifepristone is safe and effective for its labeled use.

A. Mifepristone Was Properly Approved with Restrictions on Use and Distribution Under Subpart H in 2000 and Is Now Properly Approved Subject to FDA's REMS Authorities.

Plaintiffs allege that the *only* way FDA could have approved mifepristone in 2000 was to use its authorities under Subpart H and that the Agency's invocation of Subpart H was improper, in part because pregnancy is not an "illness." Dkt. No. 7 (Mot.) 14-17. Careful analysis of the FDCA, Subpart H, and the regulatory record for mifepristone demonstrates that these allegations lack merit.[4]

[4] Plaintiffs' contention that the 2000 approval violates Subpart H because mifepristone does not provide a "meaningful therapeutic benefit" over existing treatments is well addressed in other briefs submitted in this case, as well as in FDA's response to a 2002 citizen petition filed by Plaintiffs American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) and the Christian Medical & Dental Associations. *See* Dkt. No. 28 (Defs.' Opp'n) 27; Dkt. No. 19-1 (Danco's Opp'n) 18-19; Dkt. No. 8 (App.) 573-74 (denying the 2002 citizen petition).

1. In 2000, FDA Lawfully Approved Mifepristone and Imposed Restrictions on the Use and Distribution of the Product.

As a threshold matter, FDA's authority to approve mifepristone stems from section 505 of the FDCA (21 U.S.C. § 355), not from Subpart H. Congress has established a statutory process under which new drugs must be reviewed and approved by FDA before they may be lawfully introduced into interstate commerce. *See* 21 U.S.C. §§ 331(d), 355(a). Prior to marketing a new drug, a sponsor must file a New Drug Application (NDA) pursuant to section 505(b) of the FDCA, *see id.* § 355(b), and must demonstrate that the drug is safe and effective for the proposed indication, *see id.* § 355(d).[5] FDA's rigorous review and approval process encompasses not only a clinical assessment of the drug itself but also, among other things, the "labeling proposed to be used for such drug." *Id.* § 355(b)(1)(vi). FDA must refuse to approve an NDA if the Agency determines that there is "insufficient information to determine whether such drug is safe for use" under the proposed conditions of use, or a "lack of substantial evidence that the drug will have the effect it purports or is represented to have" under the conditions of use in the proposed labeling. *Id.* § 355(d)(4), (5); *see also* 21 C.F.R. § 314.125(b).

In 1992, pursuant to its authority under the FDCA to issue regulations to help assure the safety and effectiveness of new drugs, FDA promulgated regulations governing the approval, use, and distribution of certain drugs "studied for their safety and effectiveness in treating serious or life-threatening illnesses" that "provide meaningful therapeutic benefit to patients over existing treatments." 57 Fed. Reg. 58942, 58958 (Dec. 11, 1992) (creating 21 C.F.R. Part 314, Subpart H). Subpart H established specific regulatory mechanisms to facilitate approval of such drugs under section 505(b) of the FDCA (21 U.S.C. § 355). As relevant here, Subpart H

[5] Sponsors of generic drugs may file an ANDA that relies on the safety and efficacy data of an already-approved drug. *See* note 3, *supra*.

provides for the imposition of conditions "needed to assure safe use" for certain drugs. 21 C.F.R. § 314.520(a). In 2000, FDA approved mifepristone under this mechanism, requiring the drug to be provided by or under the supervision of physicians meeting certain qualifications and imposing specific distribution requirements. *See* App. 528.[6]

FDA's approval of mifepristone with restrictions on use and distribution as described in Subpart H was reasonable and appropriate. Plaintiffs argue that Subpart H was not an appropriate regulatory tool to use in connection with the approval of mifepristone, because pregnancy is not an "illness." This argument fails in light of FDA's consistent application of its expedited programs to drugs targeting illnesses, diseases, and *conditions*.

As Defendants discuss in their brief, FDA's reliance on Subpart H comports with FDA's "consistent construction of its own regulation," *i.e.*, that Subpart H is available for drugs intended to treat serious or life-threatening conditions, whether or not they were understood colloquially to be "illnesses." Defs.' Opp'n 26. FDA stated in the preamble to the Final Rule establishing Subpart H that the subpart applied to "*conditions* or diseases that can be serious for certain populations or in some or all of their phases." 57 Fed. Reg. 58942, 58946 (Dec. 11, 1992) (emphasis added). Subpart H was part of a larger effort by FDA in the late 1980s and early 1990s to promote the development of therapies for patients with limited treatment options. Notably, FDA did not draw distinctions among the terms "illness," "disease," and "condition" in the resulting rulemaking. In 1988, when FDA issued regulations to help expedite the development and approval of drugs for "life-threatening and severely debilitating illnesses," 53

[6] Although Plaintiffs call the approval of mifepristone an "accelerated approval," FDA uses that term to refer to a separate provision of Subpart H (21 C.F.R. § 314.510), which provides for the accelerated approval of a drug product based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity. FDA did not use that provision in connection with the approval of mifepristone.

Fed. Reg. 41516, 41518, 41523 (Oct. 21, 1988) (creating 21 C.F.R. Part 312, Subpart E), it applied these procedures to "*diseases or conditions*" meeting specified criteria, 21 C.F.R. § 312.81 (emphasis added).

When Congress codified these various mechanisms, it explicitly applied them to drugs addressing *conditions*. In 1997, Congress adopted the accelerated approval provisions of Subpart H (along with Subpart E's expedited approval procedures) as a new section 506 of the FDCA. This section applied to products "intended for the treatment of a serious or life-threatening condition." Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 112, 111 Stat. 2296, 2309 (1997) (enacting 21 U.S.C. § 356(a)(1)).[7] And, as discussed below, when Congress codified the restricted use and distribution provisions of Subpart H in 2007 through the REMS program, it applied the new REMS framework to drugs for a "disease or condition." Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926-49 (2007) (quoted language codified at 21 U.S.C. § 355-1(a)(1)(B) & (a)(1)(C)). To this day, and consistent with the FDCA, FDA uses the terms *illness*, *disease*, and *condition* "interchangeably," as explained in the Agency's guidance describing its various expedited development and review programs. U.S. Food & Drug Admin., *Guidance for Industry, Expedited Programs for Serious Conditions—Drugs and Biologics* 3

[7] Congress subsequently amended the language of section 506 to refer to products "for a serious or life-threatening disease or condition." Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Pub. L. No. 112-144, § 901(b), 126 Stat. 993, 1083 (2012) (amending 21 U.S.C. § 356(b)) (currently codified, as amended at 21 U.S.C. § 356(b)(1), (c)(1)(A)). The House Report emphasized that the amendments were "intended to clarify the existing standards for accelerated approval." H.R. Rep. No. 112-495 at 36 (2012). When adding new expedited "breakthrough therapy" and "regenerative advanced therapy" programs to section 506, Congress similarly applied such programs to drugs used to treat "serious or life-threatening disease[s] or condition[s]." FDASIA § 902 (currently codified at 21 U.S.C. § 356(a)); 21st Century Cures Act, Pub. L. No. 114-255, § 3033, 130 Stat. 1033, 1102 (currently codified at 21 U.S.C. § 356(g)).

(May 2014), https://www.fda.gov/media/86377/download. Accordingly, Plaintiffs' assertion that "[p]regnancy is not an illness" is inapposite—Subpart H (like FDA's other expedited programs) applies to all serious and life-threatening *conditions*. Mot. 14-15.

There is no doubt that pregnancy is a "condition." *See, e.g.*, 44 Fed. Reg. 10133, 10133 (Feb. 16, 1979) (affirming "FDA's authority to regulate pregnancy test kits . . . [as] in vitro products for the diagnosis of a[] 'condition'"). Nor is there room for doubt that pregnancy can be serious or life-threatening. During pregnancy, a patient is at risk of various serious medical complications including preeclampsia and eclampsia, two potentially fatal pregnancy-related high blood pressure disorders. *See, e.g.*, *What Are the Risks of Preeclampsia & Eclampsia to the Mother?*, Nat'l Insts. of Health, https://www.nichd.nih.gov/health/topics/preeclampsia/conditioninfo/risk-mother (last updated Nov. 19, 2018).[8] The risks of preeclampsia and eclampsia can persist into the postpartum period. *See id.* Other medical concerns associated with pregnancy include life-threatening hemorrhage (associated with placenta previa, placenta accreta, placental abruption, labor and delivery, or surgical delivery), thromboembolic complications, postpartum depression, and exacerbation or more difficult management of preexisting medical conditions (*e.g.*, diabetes, lupus, cardiac disease, hypertension). *See* App. 565; Chiara M. Corbetta-Rastelli et al., *Postpartum Hemorrhage Trends and Outcomes in the United States, 2000-2019*, 141 Obstet. Gynecol. 152 (2023); Ioannis T. Farmakis et al., *Maternal Mortality Related to Pulmonary Embolism in the United States, 2003-2020*, 5 Am. J. Obstet. Gynecol. MFM 100754 (2023); Nicholas P. Deputy et al., *Prevalence and Changes in*

[8] *See also Preeclampsia*, Mayo Clinic (Apr. 15, 2022) https://www.mayoclinic.org/diseases-conditions/preeclampsia/symptoms-causes/syc-20355745; *Pregnancy Complications*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-complications.html, (last updated Apr. 4, 2022).

Preexisting Diabetes and Gestational Diabetes Among Women Who Had a Live Birth—United States, 2012-2016, Ctrs. for Disease Control & Prevention (Nov. 2, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6743a2.htm?s_cid=mm6743a2_w. In 2018, the rate of maternal mortality in the United States was 17.4 deaths per 100,000 live births—more than double the rate of most other high-income countries. *See* Roosa Tikkanen et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, Commonwealth Found. (Nov. 18, 2020), https://www.commonwealthfund.org/publications/issue-briefs/2020/nov/maternal-mortality-maternity-care-us-compared-10-countries. Since 2018, the maternal mortality rate has increased to 23.8 deaths per 100,000 live births. Donna L. Hoyert, *Maternal Mortality Rates in the United States*, Ctrs. for Disease Control & Prevention, https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm (last updated Feb. 23, 2022). The risk of maternal mortality associated with childbirth is approximately 14 times higher than that associated with abortion. *See* Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. Gynecol. 215 (2012).

In addition to being authorized by FDA's regulations, the Agency's use of Subpart H in connection with the approval of mifepristone in 2000 was consistent with its treatment of other drugs that were approved with restricted use and distribution programs under Subpart H. In 2008, the U.S. Government Accountability Office (GAO) conducted an extensive audit of mifepristone's approval under Subpart H, concluding unequivocally that the approval was "consistent with the processes for the other Subpart H restricted drugs." U.S. Gov't Accountability Off., *Approval and Oversight of the Drug Mifeprex* 5-7 (Aug. 2008),

https://www.gao.gov/assets/gao-08-751.pdf. Notably, the GAO did not dispute FDA's conclusion that pregnancy is a serious condition covered by Subpart H.

2. FDA's 2011 Approval of a REMS for Mifepristone and Subsequent Approvals of Revisions to the Mifepristone REMS Cured Any Alleged Defect Regarding the Use of Subpart H in 2000.

Even if this Court were to find that FDA improperly imposed restrictions on the use and distribution of mifepristone under Subpart H in 2000, any such procedural defect was cured by the subsequent transition of mifepristone to the REMS program, which explicitly applies to drugs used to treat *conditions*. In the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress gave FDA express statutory authority to impose use and distribution restrictions to address safety risks associated with pharmaceutical products, *i.e.*, REMS. *See* Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926-49 (2007) (codified at 21 U.S.C. § 355-1). This statutory provision explicitly applies to drugs used to treat *diseases or conditions*. *See* 21 U.S.C. § 355-1(a)(1) (emphasis added). FDA can impose a REMS if "necessary to ensure that the benefits of the drug outweigh the risks of the drug," taking into account, among other things, (1) "[t]he seriousness of the *disease or condition* that is to be treated with the drug, (2) "[t]he expected benefit of the drug with respect to such *disease or condition*," and (3) "[t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug." 21 U.S.C. § 355-1(a)(1) (emphasis added). Possible components of a REMS include a medication guide or patient package insert, a communication plan for healthcare providers, and elements to assure safe use (ETASU). *See id*. § 355-1(e)-(f). Much like the restrictions on use and distribution contemplated under Subpart H, ETASU are used if the drug has been shown effective but is associated with a specific serious risk, and it "can be approved only if . . . such elements are

required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug." *Id*. § 355-1(f)(1)(A).

In section 909 of FDAAA, Congress determined that drugs previously approved with elements to assure safe use under Subpart H were "deemed to have in effect" an approved REMS and required sponsors of such drugs to submit proposed REMS for approval by September 21, 2008. Pub. L. No. 110-85, § 909(b)(1)(A). As Defendants discuss in their brief, Congress was well aware that such language would sweep mifepristone into this new statutory scheme. *See* Defs.' Opp'n 25-26 (citing statements of Senator Coburn and Senator DeMint acknowledging that mifepristone would be distributed under a deemed REMS). When FDA subsequently reviewed its records to identify applications approved before the effective date of FDAAA that were deemed to have REMS in effect under section 909 of FDAAA, mifepristone was one of the 16 drugs it identified. *See* 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

Pursuant to this congressional mandate and FDA's procedures to implement FDAAA, Danco Laboratories, LLC (Danco) submitted a supplemental NDA (sNDA) with a proposed REMS for mifepristone in 2008, and FDA approved the mifepristone REMS, as amended, in 2011. App. 599.[9] At the time of its approval, the REMS included a Medication Guide, a prescriber qualification program, an implementation system, and a timetable for submission of assessments of the REMS, all of which were designed to ensure safe use of the product. *See id.* Following the original approval of the mifepristone REMS, the Agency went on to approve three additional sNDAs containing REMS modifications (in 2016, 2019, and 2023), each of which involved comprehensive reviews by FDA of mifepristone's safety, effectiveness, and labeling.

[9] Danco submitted the first draft of a proposed REMS on September 16, 2008, and subsequently submitted amendments on December 9, 2008, November 8, 2010, and May 19 and 27, 2011. FDA approved the REMS on June 8, 2011. *See id*.

Today, mifepristone continues to be subject to a valid REMS, under which FDA provides ongoing regulatory oversight of the product, as it has for more than 20 years.

Thus, even if this Court were to conclude that FDA's reliance on Subpart H in 2000 was improper, the agency cured this alleged infirmity multiple times by following Congress's mandate and exercising a statutory authority that unequivocally encompasses products used to treat conditions, including pregnancy, and that Congress understood would cover mifepristone.

B. FDA Has Acted Consistently with Relevant Statutory and Regulatory Standards in Repeatedly Confirming that Mifepristone is Safe and Effective for Its Labeled Use.

Plaintiffs are also incorrect in asserting that FDA approved mifepristone on the basis of inadequate evidence. To the contrary, FDA has conducted multiple full and complete reviews of mifepristone's safety and efficacy, and each time, it acted properly in determining that the drug meets the approval standards of the FDCA and is appropriately labeled.

Plaintiffs challenge both the original 2000 NDA approval and the 2016 sNDA approval on the ground that the approved labels did not include the exact conditions and requirements of the underlying clinical trials as part of the use requirements for mifepristone. But neither the FDCA nor the implementing regulations require a one-to-one correspondence between the safeguards and conditions included in clinical trials and those included in the labeling approved pursuant to an NDA or sNDA. As FDA explained in its response to a 2002 citizen petition filed by Plaintiffs AAPLOG and the Christian Medical & Dental Associations, many clinical trials are conducted under conditions that are more restrictive than those set forth in the prescribing information, which is designed for post-approval clinical use. This approach helps protect clinical study subjects who, in many cases, use the study drug before FDA has made a determination regarding the safety and effectiveness of the product candidate. *See* App. 589 (denying the 2002 citizen petition). For example, in clinical studies of hormonal therapies

designed to treat symptoms of menopause, specialists performed periodic endometrial biopsies to establish the safety of hormone use, but, once the safety of the product candidates had been established, such biopsies were not recommended in the approved product labeling, nor are they routinely performed by doctors when treating patients for menopause symptoms. *See id.*[10]

In addition, Plaintiffs improperly cast FDA's 2016 approval of a supplement to the mifepristone approval as a "deregulat[ion]" of the product. To the contrary, the approval of this sNDA reflected FDA's comprehensive additional review of the safety and effectiveness of the product. The standard for the approval of efficacy supplements, such as the 2016 sNDA, are the same as those for NDAs. *See* 21 U.S.C. § 355(d) (requiring a determination by the Agency that the product continues to be safe and effective for its intended use). Likewise, the format,

[10] In their Complaint, Plaintiffs make other claims that similarly misread the requirements of the FDCA and its implementing regulations. For example, Plaintiffs allege that clinical trials of mifepristone did not support the safety and efficacy of the product because the studies were not blinded, randomized, or concurrently controlled. *See* Compl. ¶ 342. However, FDA regulations expressly allow for the use of historical controls when the course of the condition in question is well-documented within a comparable population and the effect of the drug is apparent. *See* 21 C.F.R. § 314.126(b)(2)(i)-(v). Additionally, Plaintiffs assert that approval of mifepristone with labeling requiring the later use of misoprostol was improper because the labeling for *misoprostol* did not include an indication for use with the newly approved mifepristone. *See* Compl. ¶ 345. This position is based on a miscomprehension of FDA's practices relating to cross-labeling of drugs to be used in combination. There are numerous examples of drugs that FDA has approved as safe and effective in combination with another previously approved drug without requiring any update to the other's drug's previously approved labeling. *Compare e.g.*, Xeloda (capecitabine) Tablets, for Oral Use, Prescribing Information (rev. Dec. 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/020896s044s045s046s047s048s049s050s051lbl.pdf (indicated for treatment of patients with advanced or metastatic breast cancer in combination *with docetaxel* after disease progression on prior anthracycline-containing chemotherapy) (emphasis added) *and* Taxotere (docetaxel) Injection, for Intravenous Use, Prescribing Information (rev. Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020449s086lbl.pdf (indicated as single agent for locally advanced or metastatic BC after chemotherapy failure; and with *doxorubicin and cyclophosphamide* as adjuvant treatment of operable node-positive BC) (emphasis added). A ruling supporting Plaintiffs' "mandatory cross-labeling" argument would call into question many other drug approvals and labeling, which could harm patient access to therapeutics and pharmaceutical research and development, particularly in the oncology space where combination therapies are critical to patient outcomes.

content, and review procedures are also identical in all relevant respects. *See, e.g.*, U.S. Food & Drug Admin., Ctr. For Drug Eval. & Rsch., *MAPP 6020.8* at 2 (June 13, 2016), https://www.fda.gov/media/72739/download. To review Danco's supplemental application, FDA assembled a team of experts (as it had for the original approval in 2000) to assess mifepristone's safety and effectiveness under the proposed revised conditions of use. These experts conducted medical, chemistry, pharmacology, statistical, and clinical pharmacology and biopharmaceutics reviews of all of the data submitted, including both the data submitted as part of the original application package and new data submitted as part of the sNDA application. *See* Mifeprex (Mifepristone) Tablets (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020TOC.cfm. Far from being a rushed process, as Plaintiffs allege, the 2016 sNDA approval reflected careful deliberation by the Agency and yielded a well-documented determination that the drug was safe and effective with the revised indication, labeling, and REMS. In 2018, the GAO reviewed the 2016 approval and, as it did in 2008 with respect to the 2000 NDA approval, concluded that FDA "followed its standard review process when it approved the [2016 sNDA]." U.S. Gov't Accountability Off., *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* 1 (Mar. 2018), https://www.gao.gov/assets/gao-18-292.pdf.

Just last month, FDA concluded yet another robust review of mifepristone's safety and effectiveness, this time in response to an sNDA requesting modification to the REMS and corresponding labeling revisions. The review process itself was the same in all relevant respects as the process used in 2000 and 2016. On January 3, 2023, FDA reconfirmed, once again, that mifepristone is safe and effective for its labeled use. Mifeprex (Mifepristone) Tablets (Jan. 3, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/020687Orig1s025.pdf.

II. A Preliminary Injunction Ordering Withdrawal Would Be an Unprecedented and Inappropriate Remedy.

FDA repeatedly has acted in accordance with the FDCA and its implementing regulations in making scientific determinations that mifepristone meets the safety and effectiveness standards set forth in section 505 of the FDCA (21 U.S.C. § 355). FDA's approvals of mifepristone therefore should stand. *See Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) ("[J]udgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us.").

Yet, even if the Court were to conclude that an approval was improper, a preliminary injunction ordering Defendants to withdraw the approval would not be an appropriate remedy. First, any purported violation of Subpart H is at most a procedural violation that cannot, without more, support a preliminary injunction. Second, to the extent that the Court finds that FDA erred in determining mifepristone's safety and effectiveness, the FDCA's statutory procedures for withdrawal are applicable. Finally, overriding FDA's safety and efficacy determination and forcing FDA to withdraw a longstanding drug approval would profoundly undermine the statutory and regulatory framework underpinning the approval of new drugs, thereby threatening patient access to therapeutics and chilling industry research and development.

A. Procedural Harms on Their Own Cannot Be the Basis of a Preliminary Injunction.

As discussed above, any potential error associated with invoking Subpart H for approving mifepristone was cured when the Agency subsequently subjected mifepristone to a valid, carefully tailored REMS, pursuant to section 505-1 of the FDCA (21 U.S.C. § 355-1). But even if it was not cured, to justify a preliminary injunction Plaintiffs must show *present harm or injury*, not the mere violation of a regulatory requirement.

FDA's invocation of Subpart H for approving mifepristone was at most a *procedural violation*. FDA could have approved mifepristone and included similar use and distribution conditions in the drug's approved labeling—or otherwise negotiated use and distribution controls with the manufacturer—without relying on Subpart H.[11] Before 2007 (the year in which Congress amended the FDCA to include the REMS provisions), companies sometimes *voluntarily* accepted similar risk mitigation programs without invocation of Subpart H rather than face the alternative of rejection of their NDAs. *See* Peter Barton Hutt et al., *Food and Drug Law: Cases and Materials* 1070 (5th ed. 2022). Clozaril (clozapine), Tikosyn (dofetilide), and Trovan (trovafloxacin) are three examples of drugs that FDA approved with restricted distribution programs outside of Subpart H before 2007. *See* U.S. Gov't Accountability Off., *Approval and Oversight of the Drug Mifeprex* 10-11 (Aug. 2008), https://www.gao.gov/assets/gao-08-751.pdf. Notably, FDA approved Clorazil with a restricted distribution program before it had even finalized the Subpart H regulations. *Id.* Utilization of Subpart H thus was a procedural decision made by the Agency, not a statutory or regulatory requirement.

Courts routinely hold that a procedural violation, standing on its own, does not constitute irreparable harm justifying a preliminary injunction. *See, e.g., Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531 (1987) (holding that a violation of statutory procedure does not create a presumption of irreparable harm); *Fund for Animals v. Norton*, 281 F. Supp. 2d 209, 222 (D.D.C.

[11] In opposition comments submitted in response to the 2002 citizen petition, mifepristone's sponsors stated that "the restrictions FDA imposed under Subpart H could as well have been imposed (and enforced) under Section 505 itself, without reference to Subpart H . . . . Only Section 505(d) was necessary to the approval, so even if Subpart H fails, the approval was lawful." Opposition of the Population Council, Inc. and Danco Laboratories, LLC to Citizen Petition and Request for Administrative Stay Regarding Mifeprex® (Mifepristone), Docket No. 02P-0377/CP1 at 3-4 (Mar. 13, 2003).

2003) (stating that procedural harm is "insufficient, standing alone, to constitute irreparable harm justifying issuance of a preliminary injunction" (emphasis omitted)); *Am. Ass'n for Homecare v. Leavitt*, No. 08-0992, 2008 WL 2580217, at *5 (D.D.C. June 30, 2008) ("For the purposes of a preliminary injunction, courts will not base a finding of 'irreparable injury' on a procedural violation standing alone."). Here, there is no actual injury Plaintiffs can trace to FDA's invocation of Subpart H in 2000, both because FDA could have included similar use and distribution conditions in the drug's initial approved labeling without relying on Subpart H and because FDA subsequently converted the restrictions initially imposed under Subpart H to REMS requirements under section 505-1 (21 U.S.C. § 355-1). As Defendants state in their brief, the greatest possible relief warranted would be to remand the matter to the Agency to "confirm that mifepristone has already been approved outside Subpart H." Defs.' Opp'n 27-28.

B. Ordering FDA Immediately to Withdraw Approval Based on a Disagreement with the Agency's Assessment of the Safety and Effectiveness Data Would Be Inconsistent With Statutory Requirements.

Even if the Court were to find that FDA substantively erred in determining mifepristone's safety and effectiveness, a preliminary injunction ordering FDA to withdraw the approval of the application would not be an appropriate remedy. Just as Congress granted FDA the authority to oversee the approval of new drugs and determine whether they are safe and effective under the labeled conditions of use, *see* 21 C.F.R. § 355(d), Congress also granted FDA the authority to oversee the withdrawal of an approved application, *see* 21 U.S.C. § 355(e). Withdrawal requires a finding by *FDA* that one of the relevant statutory criteria is met, as well as notice and opportunity for a hearing for the sponsor. Thus, an order requiring FDA to withdraw its approval of mifepristone immediately would conflict with FDA's statutory mandate and circumvent the provisions Congress adopted to govern withdrawal of an approved application.

Under the FDCA, the Secretary of HHS shall withdraw approval of an application if "*the Secretary* finds" that

> clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved [or] on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

21 U.S.C. § 355(e)(1), (3) (emphasis added).[12] The Secretary has delegated the responsibility for making such a finding to the Commissioner of Food and Drugs (Commissioner). *See* FDA Staff Medical Guides, Staff Manual Guides 1410.10, Delegations of Authority to the Commissioner of Food and Drugs 1.A(1) (Nov. 29, 2022), https://www.fda.gov/media/81983/download (delegating all functions vested in the Secretary under the FDCA to the Commissioner).

Any potential withdrawal on safety or effectiveness grounds therefore requires a finding by the *Commissioner* that the evidence demonstrates that the drug's benefit-risk balance merits withdrawal. As the Supreme Court has recognized, Congress has granted FDA primary jurisdiction over both the determination of a drug's safety and effectiveness under section 505(d) (21 U.S.C. § 355(d)) and the determination that there is a lack of such evidence meriting withdrawal under section 505(e) (21 U.S.C. § 355(e)). *See Weinberger v. Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609, 630 (1973) ("The Act requires the Commissioner to disapprove any application when there is a lack of 'substantial evidence' that the applicant's drug is effective. Similarly, he may withdraw approval for any drug if he subsequently determines that there is a

[12] That same provision also permits withdrawal of approval if the Secretary makes other findings not relevant to this litigation, including a finding that patent information was not filed properly or that the application contains any untrue statement of fact. *See id.* § 355(e)(2), (4)-(5).

lack of such evidence."); *see also id.* at 633 ("The [FDCA] did not provide any mechanism other than the Commissioner's suspension authority under § 505(e), whereby an NDA once effective could cease to be effective."); *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973) (stating that "Congress desired that the administrative agency" make the determination under sections 505(d) and (e)).

Moreover, under section 505(e) of the FDCA, FDA must provide "due notice and opportunity for hearing to the applicant" prior to withdrawing an approved application. 21 U.S.C. § 355(e). FDA regulations provide a specific set of procedures under which the Agency must provide notice of the opportunity for a hearing to the applicant and allow the applicant to submit data and information. *See* 21 C.F.R. §§ 314.150, 314.200.[13] Only after exhaustion of applicable administrative remedies can a party seek judicial review of the final decision regarding withdrawal. *See* 21 C.F.R. § 10.45. It would not be appropriate for a court to circumvent these statutory procedures by issuing an injunction ordering FDA to immediately withdraw approval.

C. Plaintiffs' Requested Relief Would Undermine the Drug Approval System and Have Far-Reaching Consequences for Public Health and the Pharmaceutical Industry.

Plaintiffs' requested remedy, if granted, would have far-reaching implications for patients who rely on medication and manufacturers pursuing drug development. Since 1962, the general contours of the drug approval process have remained consistent, with Congress requiring sponsors to demonstrate to FDA that a new drug is safe and effective before marketing. 21

[13] Even if the Court were to view the continued approval of mifepristone as an approval under Subpart H, despite FDA's subsequent approval of mifepristone with a REMS, the relevant withdrawal procedures require a notice of an opportunity for a hearing and, if requested, a public hearing before the FDA Commissioner or his designee. *See* 21 C.F.R. § 314.530.

U.S.C. § 355(d). FDA has the scientific and medical expertise to make the complex determinations necessary to ascertain safety and effectiveness, including determinations regarding clinical trial design, dosing, and labeling. Here, Plaintiffs ask the Court to override FDA's safety and effectiveness determinations and force it to withdraw an approved application for a drug that has been on the market for more than 20 years. Such an order would "seismically disrupt the agency's governing authority as to whether drugs are safe and effective." Danco's Opp'n 1. It would also be unprecedented: We are not aware of any case in which a court has removed a drug from the market over FDA's objection.

The effects could extend far beyond mifepristone. No drug is without risk, and a ruling for Plaintiffs could lead to challenges to FDA's benefit-risk determinations for drugs it has approved to treat other diseases and conditions. Patients who rely on life-saving medications could see their drugs removed from the market with little notice.

Additionally, Plaintiffs' remedy, if granted, would create widespread uncertainty in the pharmaceutical industry and chill research and development. FDA is the sole U.S. agency with which industry engages on issues related to drug review, approval, and labeling changes. Manufacturers are familiar with the FDCA and FDA's regulations and procedures, and they invest in clinical research and costly clinical trials against the backdrop of that framework. If courts can unilaterally overturn safety and effectiveness determinations, manufacturers would simultaneously have to navigate a patchwork of judicial decisions regarding what is required for drug approval. This would fundamentally confound the expectations of industry, leave manufacturers vulnerable to challenges to their currently marketed drugs, and discourage investment in research and development of new drugs.

III. FDA Approval of Mifepristone is Consistent With the Comstock Act.

Finally, FDA's approval of mifepristone is consistent with the Comstock Act.[14] 18 U.S.C. §§ 1461, 1462. When Congress enacted the FDCA in 1938, it authorized FDA to approve "*any* new drug" for introduction into interstate commerce and made no exception to this authority for abortifacients. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938) (creating 21 U.S.C. § 355(a)) (emphasis added). Courts interpret the statutory term "any" to mean "all" or "every." *See, e.g.*, *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018); *United States v. Oswalt*, 771 F.3d 849, 852 (5th Cir. 2014).[15]

FDA's regulatory approval decisions with respect to oral contraceptives and mifepristone, and Congress's acquiescence in those decisions, bolster the understanding that FDA's drug approval authority extends to Comstock-listed articles. Two prominent examples of drugs that FDA approved despite their inclusion in the Comstock Act at the time of approval are the oral contraceptive Enovid and mifepristone itself. In neither instance did Congress respond by limiting FDA's authority.

[14] This brief does not address other issues concerning the Comstock Act, such as whether the Act applies to the shipment of abortifacients when intended for lawful uses, *see Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 46 Op. O.L.C. ___ , (Dec. 23, 2022)), https://perma.cc/8XHW-32JD, or whether the Act remains good law.

[15] When Congress amended the Comstock Act in 1971 to remove contraceptives from coverage under that Act, the House report noted that the FDCA would "still" (*i.e.*, would continue to) regulate the "interstate transportation of drugs, medicines, and other articles for the prevention of conception." H.R. Rep. No. 91-1105, at 3 (1970) (quoting the Department of Health, Education, and Welfare's conclusion); *id.* (quoting the Department of Labor's conclusion that the FDCA "would continue to apply to imports and shipments" of contraceptives). Congress thus confirmed its understanding that FDA regulates all drugs in interstate commerce, including Comstock-listed drugs.

In 1960, FDA approved Enovid, the first oral contraceptive—despite the fact that contraceptives were a Comstock-listed article at the time, and despite the fact that the sale of contraceptives remained illegal in much of the nation.[16] *See* Martha Bailey, *"Momma's Got the Pill": How Anthony Comstock and Griswold v. Connecticut Shaped US Childbearing*, 100 Am. Econ. R. 98, 105-06 (Mar. 2010). Just two years after Enovid's approval, Congress enacted the Kefauver-Harris Amendments to the FDCA. *See* Pub. L. No. 87-781, 76 Stat. 780 (1962). Rather than curtail FDA's oversight and regulation of drug products, including with respect to contraceptives, the 1962 Kefauver-Harris Amendments strengthened FDA's authority to approve drugs for introduction into interstate commerce. And although a pending marketing application for an oral contraceptive was discussed during floor debate on the legislation, there was no suggestion that approval of the application would violate the Comstock Act or exceed FDA's authority. *See* 108 Cong. Rec. 21088 (Sept. 27, 1962). By December 1965—while contraceptives were still a Comstock-listed article—FDA had approved no fewer than seven oral contraceptives for introduction into interstate commerce. *See* U.S. Food & Drug Admin., Dep't of Health, Educ., & Welfare, *Fact Sheet: Oral Contraceptives* (Dec. 1965) (hereinafter *FDA Contraceptive Fact Sheet*).

Since FDA approved mifepristone in 2000, Congress has amended section 505 of the FDCA (21 U.S.C. § 355)—which sets forth FDA's authority to approve new drugs—no fewer than 18 times, including post-*Dobbs*. Yet Congress has never amended the statute to curtail FDA's authority to approve abortifacients.[17]

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[16] The Supreme Court had not yet decided *Griswold v. Connecticut*, 381 U.S. 479 (1965).

[17] *See, e.g.*, Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002); Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936 (2003); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat.

In sum, Congress has assigned FDA the task of ensuring that drugs submitted to it for approval are safe and effective for their intended use. The Comstock Act has no bearing on that decision. *See* 21 U.S.C. § 355(d) (listing grounds on which FDA may refuse to approve an application for a new drug); *see also FDA Contraceptive Fact Sheet* ("New drugs must be proved both *safe* and *effective* if used as directed, before clearance can be granted. But if the product *is* established as safe and effective, FDA *must* grant the clearance.") (emphases in original)). By Congress's design, enforcement of the Comstock Act was not a factor in FDA's decision to approve mifepristone.

CONCLUSION

Plaintiffs' Motion for a Preliminary Injunction should be denied.

2066 (2003); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012); Consolidated Appropriations Act, Pub. L. No. 117-328, §§ 3001-3631 (2022) ("Food and Drug Omnibus Reform Act of 2022").

Dated: February 10, 2023

Respectfully submitted,

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