IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
GREENBELT DIVISION

GENBIOPRO, INC., *Plaintiff*, *v.* U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs, U.S. Food and Drug Administration; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, in his official capacity as Secretary, U.S. Department of Health and Human Services; MERRICK GARLAND, in his official capacity as Attorney General of the United States; *and* U.S. DEPARTMENT OF JUSTICE**,** *Defendants*.	Case No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiff GenBioPro, Inc. ("GenBioPro") markets a generic version of the drug mifepristone tablets, 200 mg ("mifepristone"), which provides patients with a safe, effective, non-invasive medication option for terminating a pregnancy. GenBioPro brings this suit to enjoin the U.S. Food and Drug Administration ("FDA") from depriving GenBioPro of its constitutional and statutory rights to market mifepristone without affording GenBioPro due process of law, and to prevent Defendants from upending nearly a quarter-century of public reliance on a safe and

effective drug by bringing criminal and civil enforcement actions against GenBioPro, its agents, manufacturers, distributors, partners, and customers.

2. In 2019, when FDA approved GenBioPro's Abbreviated New Drug Application ("ANDA") to market mifepristone in the United States, FDA vested GenBioPro with property and liberty interests in its license to market the drug that entitle GenBioPro to due process protections. And while FDA's approval of GenBioPro's ANDA is relatively recent, FDA's approval of mifepristone dates back to 2000, when it approved a New Drug Application ("NDA") for the branded version of the drug, Mifeprex®, manufactured and distributed by another company, Danco Laboratories, LLC ("Danco"). Over the past 23 years, GenBioPro and the public at large have developed a fundamental reliance on FDA's approval of mifepristone as safe and effective for its intended use.

3. The Fifth Amendment to the U.S. Constitution and the Federal Food, Drug, and Cosmetic Act ("FDCA") both recognize that reliance. They independently dictate that FDA may not deprive GenBioPro of its protected ANDA rights without adequate due process. To date, FDA has not provided GenBioPro with process of any kind, yet GenBioPro has been threatened with deprivation of its ANDA rights.

4. Over the past two weeks, rulings from four federal courts have purported to dramatically alter the landscape of FDA's regulation of mifepristone.

5. First, on April 7, 2023, a federal judge in the Northern District of Texas issued a ruling that "second-guess[ed]" FDA's decision to approve mifepristone and purported to "stay[] the effective date"—or, alternatively, to "suspend"—FDA's approval of Danco's NDA for Mifeprex, GenBioPro's ANDA approval, and a number of other FDA actions related to mifepristone. Mem. Op. & Order at 57, 67, *All. for Hippocratic Med. et al. v. FDA et al.*, No. 2:22-

cv-00223-z (N.D. Tex. Apr. 7, 2023), ECF 137 ("*AHM* Order"). The court stayed the effect of the *AHM* Order for seven days.

6. Second, also on April 7, 2023, a federal judge in the Eastern District of Washington preliminarily enjoined FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1" in 17 states, including Maryland, and the District of Columbia. Order Granting in Part Pls.' Mot. for Prelim. Inj. at 30, *State of Washington et al. v. FDA et al.*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 7, 2023), ECF 80 ("*Washington* Order"). On April 13, 2023, in response to FDA's motion for clarification, the court issued a second order, clarifying that the terms of the *Washington* Order's injunction apply "irrespective of the Northern District of Texas Court ruling or the Fifth Circuit's anticipated ruling." Order Granting Mot. for Clarification at 5-6, No. 1:23-cv-3026-TOR (Apr. 13, 2023), ECF 91 ("*Washington* Clarification Order").

7. Third, on April 12, 2023, in an emergency appeal of the *AHM* Order by FDA and Danco, the U.S. Court of Appeals for the Fifth Circuit issued a decision that stayed the effect of the *AHM* Order with respect to FDA's approval of Mifeprex in 2000, but allowed the *AHM* Order's "stay" of all other FDA actions regarding mifepristone to go into effect at the expiration of the *AHM* Order's stay, on Saturday, April 15, 2023 at 1:00 a.m. EDT. Order, *All. for Hippocratic Med. et al. v. FDA et al.*, No. 23-10362 (5th Cir. Apr. 12, 2023) ("*AHM* Fifth Circuit Order").

8. Fourth, on April 14, 2023, FDA and Danco filed emergency applications in the U.S. Supreme Court to stay the *AHM* Order pending disposition of their appeals in the Fifth Circuit. Justice Alito granted an administrative stay of the *AHM* Order until 11:59 p.m. EDT on April 19, 2023. Order, *FDA et al. v. All. for Hippocratic Med. et al.*, No. 22A902 (U.S. Apr. 14, 2023);

Order, *Danco Lab'ys, LLC v. All. for Hippocratic Med. et al.*, No. 22A901 (U.S. Apr. 14, 2023). The Supreme Court is expected to rule on the applications imminently.

9. If the *AHM* Fifth Circuit Order goes into effect, the result will be chaos. On its face, the *AHM* Fifth Circuit Order leaves FDA's 2000 approval of the Mifeprex NDA in place, but purports to "stay" FDA's 2019 approval of GenBioPro's ANDA for generic mifepristone, even though that approval rests on an identical (and, indeed, augmented) scientific basis as the original Mifeprex NDA approval.

10. These circumstances are unprecedented. No court in history has ever "stayed" or "suspended" a longstanding FDA approval, and FDA has no template for responding to—or implementing—those decisions. Indeed, it is unclear what precise practical effect (if any) the rulings have on the legality of GenBioPro's ANDA without further FDA implementation. And FDA, which approves drugs on a nationwide level, has not provided any guidance to GenBioPro on how it might effect a "stay" of GenBioPro's ANDA, while at the same time complying with the *Washington* Order, which requires FDA to refrain from "altering the status quo" in Maryland, 16 other states, and the District of Columbia.

11. Amidst this tumult, GenBioPro has repeatedly requested assurances from FDA that FDA will follow its own procedures and adhere to the mandates of the FDCA and the U.S. Constitution—mandates that apply to FDA's actions with respect to all drugs—in its regulation of mifepristone. *See infra* ¶¶ 74-75, 80-81, 86-87, 133. Notwithstanding the exigent circumstances and the numerous tools available to FDA, FDA has repeatedly refused to assure GenBioPro or the public that it will afford GenBioPro adequate procedures before suspending GenBioPro's ANDA approval. Nothing in the FDCA or in the U.S. Constitution permits FDA to violate federal law in determining how to navigate these court orders or other external events. On the contrary, Congress

specifically mandated, and the Constitution requires, a procedure the agency must follow before it deprives an ANDA holder of its rights. *See infra* ¶¶ 37-46. That procedure is required regardless of external attempts to interfere with FDA's drug approvals.

12. Nonetheless, Defendants have declared that, absent a stay, GenBioPro's generic mifepristone will "become misbranded" and GenBioPro will be "without an effective drug approval" as a result of the *AHM* Order and *AHM* Fifth Circuit Order (the "FDA Decision"). Decl. of Janet Woodcock, M.D. in Supp. of App. to Stay ¶ 15, *FDA et al. v. All. for Hippocratic Med. et al.*, No. 22A902 (U.S. Apr. 14, 2023) ("Woodcock Decl."); Opp. to Mot. to Dismiss at 5, *All. for Hippocratic Med.*, No. 23-10362 (5th Cir. Apr. 12, 2023); *see also* Reply in Supp. of App. to Stay at 22, *FDA et al.*, No. 22A902 (U.S. Apr. 18, 2023) (explaining that under the *AHM* Fifth Circuit Order, "the generic version of the drug would lose its approval altogether"). FDA and the U.S. Department of Health and Human Services ("HHS") have expressed that position in a series of press statements and judicial filings since the *AHM* Order was issued. *See infra* ¶¶ 82-84, 88-90. Most recently, FDA declared in support of its Supreme Court stay application that "[a]s a result of the [lower] courts' orders, Mifepristone Tablets, 200 mg, will be misbranded because FDA's approval of the generic application will be stayed," and "the sponsors' [Danco's and GenBioPro's] drug products immediately would become misbranded and thus unlawful to introduce in interstate commerce." Woodcock Decl. ¶¶ 15; *see also id.* (declaring that "as a result of the courts' orders, Mifeprex also will be misbranded until the sponsor submits a supplemental application proposing changes to the conditions of use consistent with the courts' orders, FDA reviews and approves that supplement, and the sponsor incorporates those changes into the labeling and packaging for the product").

13. FDA and the other Defendants have thereby left GenBioPro at risk of severe civil and criminal penalties if it does not cease shipments of mifepristone. Moreover, without FDA assurances, and in light of the statements that GenBioPro's product will "become misbranded" and GenBioPro will be "without an effective drug approval," GenBioPro will suffer threats to its core business and irreparable financial harm.

14. The FDA Decision is contrary to law. In the FDCA, Congress delegated to the HHS Secretary *sole* legal authority to "suspend" a drug approval without a pre-deprivation process, and the Secretary may do so only upon a finding that the drug poses an "imminent hazard to the public health." 21 U.S.C. § 355(e). Upon such a finding, the approval holder must be given the opportunity for an expedited hearing. *See id.* According to FDA, the extreme sanction of suspension has been invoked only once in history, when a "rare but serious side effect" of the drug phenformin, in use by hundreds of thousands of patients, was found to have a 50 percent mortality rate.[1] Defendant HHS Secretary Xavier Becerra has made no such finding of "imminent hazard" here.

15. Without the requisite "imminent hazard" finding—and the procedural protections that accompany such a finding—FDA may not deprive GenBioPro of its protected property and liberty interests in marketing its ANDA for mifepristone. Nor may FDA enforce the FDCA's civil and criminal "misbranded drug" and "unapproved drug" provisions, 21 U.S.C §§ 331(a), (d), 333, 352, 355(a), against GenBioPro or its partners and customers, without affording GenBioPro a prompt and adequate process that accounts for the exigency of the moment and the irreparable harm that GenBioPro will suffer if it is forced to remove its drug from the market.

[1] *See* FDA Hist. Off., FDA, Drug Therapeutics & Regulation in the U.S. (Jan. 31, 2023), http://bit.ly/3ZYeNxi.

16. Because GenBioPro's business depends almost entirely on FDA's approval of its mifepristone ANDA, the FDA Decision, absent a stay, to preemptively characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as being "without an effective drug approval" for generic mifepristone, without affording GenBioPro the required process, threatens imminent, catastrophic, and irreparable harm to GenBioPro. That decision is unlawful and should be vacated and set aside.

17. GenBioPro accordingly brings this suit pursuant to the Administrative Procedure Act ("APA"), the Declaratory Judgment Act, and the All Writs Act, to enjoin the FDA Decision, protect GenBioPro's constitutional and statutory rights, and prevent FDA and the Department of Justice from bringing criminal and civil enforcement actions against GenBioPro and its partners and customers.

JURISDICTION AND VENUE

18. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a) and Article III of the U.S. Constitution, and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02 and 5 U.S.C. §§ 705-06.

19. In light of the extreme and irreparable harm that suspension of mifepristone would inflict on GenBioPro, FDA and HHS's decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone constitutes final agency action that is judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

20. This Court has further authority to issue orders necessary to preserve the availability of meaningful judicial review of agency action under the All Writs Act. 28 U.S.C. § 1651(a).

21. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) because this is the judicial district in which Defendants FDA and Commissioner Califf reside and this action seeks relief against federal agencies and officials acting in their official capacities; venue is also proper because a substantial part of the events and omissions giving rise to this action occurred in this district.

PARTIES

22. Plaintiff GenBioPro, Inc. is a Nevada corporation headquartered at 651 Lindell Road, Suite D1041 (P.O. Box 32011), Las Vegas, Nevada 89103. GenBioPro holds an approved ANDA for generic mifepristone, No. 091178, and sells the drug nationwide. GenBioPro sells only generic mifepristone and misoprostol, which make up the FDA-approved two-drug regimen for medication abortion. Sales of the two drugs are essentially the company's sole source of product revenue.

23. Defendant FDA is an agency of the United States government within HHS. 21 U.S.C. § 393. The Secretary of HHS has delegated to FDA the authority to administer the provisions of FDCA for approving new drug applications and abbreviated new drug applications and for enforcing the FDCA's prohibition on introducing misbranded and unapproved drugs into interstate commerce. The address of FDA's headquarters is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

24. Defendant Robert M. Califf, M.D., who is being sued in his official capacity only, is the Commissioner of Food and Drugs and the leader of FDA. He is responsible for supervising the activities of FDA, including the approval of new drug applications and enforcement of the FDCA. 21 U.S.C. § 393(d). Defendant Califf's address is 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

25. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C. Its address is 200 Independence Avenue, SW, Washington, D.C. 20201.

26. Defendant Xavier Becerra, who is being sued in his official capacity only, is the Secretary of HHS. His address is 200 Independence Avenue, SW, Washington, D.C. 20201. He is responsible for the overall operations of HHS, including FDA, and possesses the exclusive authority to suspend the approval of an NDA or ANDA upon a finding of imminent hazard to the public health.

27. Defendant Merrick Garland, who is being sued in his official capacity only, is the Attorney General of the United States. His address is 950 Pennsylvania Avenue, NW, Washington, D.C. 20530. He is responsible for the operations of the U.S. Department of Justice, and oversees all prosecutions and civil enforcement actions for alleged violations of federal law, including the FDCA.

28. Defendant the U.S. Department of Justice is an executive department of the United States Government headquartered in Washington, D.C. Its address is 950 Pennsylvania Avenue, NW, Washington, D.C. 20530.

FACTUAL ALLEGATIONS

A. FDA's Regulatory Framework for the Approval and Monitoring of Drugs

29. Drugs such as mifepristone must be approved by FDA before they may be marketed and sold, and FDA's approval process for NDAs is rigorous. Obtaining FDA approval to market a new drug is a massive undertaking, requiring an investment of billions of dollars per drug. In large part, that investment reflects the voluminous scientific and clinical data that FDA requires from new drug applicants. *See, e.g.*, 21 U.S.C. § 355(b). By statute, FDA will not approve a drug

unless the agency determines it is safe and effective for its intended use. *See generally* 21 U.S.C. § 355.

30. Generic drugs like GenBioPro's mifepristone are approved pursuant to ANDAs, which rely on that same rigorous scientific scrutiny. FDA also requires an ANDA applicant in most cases, such as with mifepristone, to submit additional studies to demonstrate the bioequivalence of its drug to the approved NDA product before FDA will approve that ANDA. *See id.* § 355(j). The overall investment for new generic drugs is smaller than an NDA but still substantial, and generic manufacturers must wait years to enter the market and demonstrate sameness through costly additional studies. *See id.*

31. Congress has granted FDA additional authority to require a "risk evaluation and mitigation strategy" ("REMS") as part of the approval and labeling for certain drugs where necessary to "ensure that the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(a); *see* 21 C.F.R. § 314.520.

32. The applicant and FDA are required to reassess a drug's REMS periodically. 21 U.S.C. § 355-1(d). After each reassessment, FDA may eliminate a REMS—or eliminate or modify a component of a REMS—if it determines via review of a supplemental application that the REMS elements are no longer necessary to ensure a medication's benefits outweigh its risks.

33. FDA's ongoing reporting and evaluation procedures ensure that the agency is apprised of scientific developments and can fulfill its mandate to ensure all approved drugs remain safe and effective for their intended use.

34. In reliance on FDA's review and approval process, drug manufacturers make significant investments in their products, with the understanding that the drug will undergo extensive scientific scrutiny before FDA will approve the drug for marketing to the public.

35. Once a drug has been through that rigorous process and received FDA approval, federal law protects the manufacturer's investment-backed right to continue marketing the drug. Specifically, the Fifth Amendment to the U.S. Constitution, Section 505 of the FDCA (codified at 21 U.S.C. § 355), and FDA regulations all ensure that an NDA or ANDA holder is afforded adequate procedural protections *before* FDA may withdraw a drug's approval. Those protections include notice, an opportunity to be heard, and, as relevant here, a requirement that FDA base any withdrawal decision on specifically enumerated scientific or medical findings. 21 U.S.C. § 355(e); 21 C.F.R. §§ 314.150, 314.200, 314.530.

B. FDA and HHS's Framework for Suspension of Drug Approvals Due to Imminent Hazard

36. There is only one exception to the FDCA's requirements for pre-deprivation procedures. The FDCA and FDA regulations authorize the HHS Secretary—and only the Secretary—to immediately suspend a drug approval when the Secretary determines, based on specifically enumerated findings of fact, that the drug presents "an imminent hazard to the public health." 21 U.S.C. § 355(e); 21 C.F.R. § 2.5. And even in cases of "imminent hazard," the approval holder is entitled to an expedited post-deprivation hearing after the suspension takes effect. 21 U.S.C. § 355(e). The FDCA provides that while "in [the Secretary's] absence the officer acting as Secretary" may suspend an approval, "the authority conferred by this proviso to suspend the approval of an application shall not be delegated." *Id.*

37. Under FDA regulations, "an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held." 21 C.F.R. § 2.5(a).

38. Congress expressly prohibited the Secretary from delegating the authority to suspend drug approvals. 21 U.S.C. § 355(e). Although the FDA Commissioner may recommend to the Secretary that an imminent hazard exists in light of "the number of injuries anticipated and the nature, severity, and duration of the anticipated injury," 21 C.F.R. § 2.5(b); *see Forsham v. Califano*, 442 F. Supp. 203, 208 (D.D.C. 1977), authority to suspend is predicated on *the Secretary* (and the Secretary alone) making the requisite findings and issuing an order suspending an approval. As noted above, the Secretary has invoked the "imminent hazard" standard only once in history. *See supra* ¶ 14.

39. The legislative history of the suspension statute makes clear that this limitation of authority to the Secretary alone was purposeful. Congress believed that suspension authority, "which could have grave effects upon a manufacturer and upon the confidence of the public in a drug which might later be found appropriate for continued availability to physicians, should only be exercised under the most extreme conditions and with the utmost care." 108 Cong. Rec. 17366 (1962). "For that reason, it is provided that it may be exercised only by the Secretary or the Acting Secretary." *Id.*

40. The sponsors of the provision further cautioned that "[i]t should not be forgotten also that there may be other remedies available to the Secretary to cope with the situation instead of using the potentially lethal weapon of immediate suspension." *Id.*

41. If the Secretary makes an imminent hazard finding and suspends a drug approval, the suspension takes effect immediately. 21 U.S.C. § 355(e). Additionally, the approval of any ANDA that references a suspended drug is also immediately suspended, unless the NDA approval suspension was not based on safety and effectiveness. *Id.* § 355(j)(6); 21 C.F.R. § 314.153(a)(1).

42. Upon finding an imminent hazard and suspending approval of a drug application, the Secretary must give the holder of the application prompt notice and the opportunity for an expedited hearing. 21 U.S.C. § 355(e); *see* 21 C.F.R. § 314.150(a)(1). The holders of any ANDAs whose approval rests on a suspended NDA must be allowed to participate in the post-suspension proceeding for the NDA. 21 C.F.R. § 314.150(a)(1); *see* 54 Fed. Reg. 28,872, 28,906 (July 10, 1989).

43. The procedural protections embodied within these statutory and regulatory provisions reflect the constitutional requirement that FDA not deprive applicants of protected property and liberty interests in approved NDAs and ANDAs without due process.

44. If HHS suspends approval for a drug, the FDCA prohibits the introduction of that drug into interstate commerce. 21 U.S.C. §§ 355(a), 331(d). Absent FDA enforcement discretion, placing a misbranded or unapproved drug into interstate commerce is a criminal violation punishable by incarceration and fines. *Id.* § 333(a); *see id.* § 331(a), (d), 352. FDA and the Department of Justice may also seek injunctions barring distribution of misbranded or unapproved drugs and may move to seize and condemn inventory. *Id.* §§ 332, 334, 337(a).

45. Suspension of an NDA or ANDA approval for safety and effectiveness reasons therefore immediately brings to a halt all manufacturing, distribution, and sale of the drug.[2]

46. The Secretary has not invoked the "imminent hazard" standard with respect to mifepristone. To the contrary, repeated studies have proven that mifepristone is safe and effective.

[2] As noted above, under certain circumstances, FDA may also initiate withdrawal procedures for a drug. 21 U.S.C. § 355(e). Once the withdrawal process has been initiated, FDA regulations detail the extensive procedures required before a drug may be withdrawn. 21 C.F.R. §§ 314.150, 314.200, 314.530. These withdrawal procedures further affirm Congress's recognition that any FDA action affecting an NDA- or ANDA-holder's rights must be based in science and must provide procedural protections such as notice and an opportunity to be heard.

Indeed, there is a greater risk of complications or mortality associated with wisdom-tooth removal, cancer screening, colonoscopies, plastic surgery, and the use of erectile dysfunction drugs, than by any abortion method (medication or procedural).

C. FDA and Congress Have Repeatedly Approved and Reapproved Mifepristone as Safe and Effective for Its Intended Use

47. Mifepristone is the initial drug in a two-drug regimen approved by FDA to facilitate a medication abortion: (1) mifepristone interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol causes uterine contractions, leading to the contents of the uterus being expelled.

48. Medical termination of pregnancy offers patients significant advantages over procedural abortion. Patients can take the medication at home, at a time of their choosing, and in complete privacy. Medication abortions do not require administration of anesthesia; many patients use over-the-counter analgesics, such as ibuprofen, to relieve the period-like cramps patients typically experience. In addition, medical termination often costs less than a procedural termination.

49. More than 80 countries have approved mifepristone for use in medication abortions. The United States joined those ranks in 2000, when FDA approved the NDA for Mifeprex for the medical termination of intrauterine pregnancy through 49 days' gestation.

50. FDA initially approved Mifeprex pursuant to regulations authorizing it to approve drugs that treat "serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments" subject to certain "restrictions as are needed to assure safe use." 21 C.F.R. §§ 314.500, 314.520. These regulations (known as "Subpart H") limited any restriction FDA could impose to those "commensurate with the specific safety concerns presented by the drug product." *Id.* § 314.520.

51. In approving Mifeprex in 2000, FDA therefore determined that it treats a serious or life threatening condition (*i.e.*, high-risk, unwanted, or unintended pregnancies), and provides a meaningful therapeutic benefit to some patients over procedural abortion. According to FDA, "unwanted pregnancy, like a number of illnesses or conditions, can be serious for certain populations or under certain circumstances." Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., FDA, to Donna Harrison, Exec. Dir., Am. Ass'n of Pro Life Obstetricians & Gynecologists (Mar. 29, 2016). FDA recognized that, despite being associated with some risks, mifepristone conferred important therapeutic benefits and therefore approved Mifeprex subject to certain restrictions.

52. In 2007, Congress expressly confirmed the legitimacy of mifepristone's Subpart H regulatory approval in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823. The FDAAA codified and expanded the Subpart H regulations by giving FDA authority to require a REMS when it determines that such restrictions are necessary to ensure that the benefits of a drug outweigh the risks. *See id.* § 901(b), 121 Stat. at 926-38 (codified at 21 U.S.C. § 355-1). As part of the legislation, Congress specified that the 16 drugs FDA had already approved with the equivalent of "elements to assure safe use" or "ETASU"—including mifepristone—would immediately be "deemed to have in effect an approved risk evaluation and mitigation strategy" (REMS). *Id.* § 909(b)(1), 121 Stat. at 950-51 (codified at 21 U.S.C. § 331 note). Thus, Congress recognized that the favorable benefit-risk determination made by FDA with respect to mifepristone was valid.

53. The FDAAA requires FDA to ensure that any elements to assure safe use of drugs subject to a REMS "[p]rovid[e] safe access for patients" while "assur[ing the drug's] safe use." *Id.* § 901(b), 121 Stat. at 930 (codified at 21 U.S.C. § 355-1(f)). Restrictions may "not be unduly

burdensome on patient access to the drug," and, "to the extent practicable," must "minimize the burden on the health care delivery system." *Id.*, 121 Stat. at 930 (codified at 21 U.S.C. § 355-1(f)(2)(C)-(D)). FDA must periodically reevaluate any elements to ensure safe use "to assess whether" they continue to meet those requirements. *Id.*, 121 Stat. at 931 (codified at 21 U.S.C. § 355-1(f)(5)(B)). Congress thereby placed guardrails on FDA's ability to burden access to mifepristone.

54. Pursuant to the FDAAA, FDA has gone above and beyond the ordinary approval processes with respect to mifepristone, repeatedly evaluating—and consistently approving—the safety and efficacy of mifepristone through multiple iterations of a REMS for the drug. Of the more than 20,000 prescription drugs FDA has approved for marketing in the United States, the agency has subjected only 302 to a REMS. And FDA has subjected only 98 of those drugs (including mifepristone) to additional elements to assure safe use.

55. In March 2008, FDA reviewed the distribution restrictions set forth in the first FDA-approved label for mifepristone and concluded that they were sufficient to constitute an acceptable REMS for the drug. 73 Fed. Reg. 16,313 (March 27, 2008). Various anti-abortion members of Congress then requested that the U.S. Government Accountability Office ("GAO")—an independent legislative investigatory and oversight body—review and audit all of FDA's actions with respect to mifepristone, from the validity of the agency's approval of the initial NDA for use in abortions, up to (and including) the 2008 REMS decision.

56. In August 2008, GAO responded to the congressional request in a lengthy report which found that the mifepristone NDA approval was supported by a four-year analysis by FDA of clinical studies involving 4,000 patients, other substantial scientific and medical data, and additional safety data from the prior extensive use of the drug overseas. Among other things, GAO

further found that the restrictions imposed by FDA on mifepristone's distribution and use were comparable to the restrictions the agency had imposed on other drugs so approved; that FDA had properly monitored the sponsor's compliance with those restrictions and the adverse drug experience through appropriate reports similar to the monitoring of all NDA holders on all FDA-approved drugs; and that all the data continued to show the drug was safe and effective when used in medication abortions. U.S. Gov't Accountability Off., GAO-08-751, Food and Drug Administration: Approval and Oversight of the Drug Mifeprex (2008).

57. After Congress mandated that Mifeprex be "deemed to have in effect" an approved REMS, in September 2008, Mifeprex's manufacturer Danco submitted a supplemental new drug application proposing a REMS for Mifeprex. FDA approved the proposed REMS in June 2011. In doing so, FDA once again determined that mifepristone was safe and effective for use as approved.

58. In 2015, Danco submitted a supplemental new drug application to FDA to revise Mifeprex's label and REMS in light of extensive data from dozens of clinical studies. In 2016, FDA approved most of Danco's proposed modifications to the label and REMS, including: increasing the gestational age through which Mifeprex is indicated from 49 days to 70 days; reducing the number of patient visits to a clinic; and expanding those who could be certified to prescribe Mifeprex to include "healthcare providers," rather than just "physicians." FDA determined that other REMS requirements, such as the in-person dispensing requirement, remained necessary to ensure that the drug's benefits outweigh its risks and to assure Mifeprex's safe use.

59. In 2018, in response to a further congressional request, GAO reviewed the subsequent decisions by FDA to modify the mifepristone REMS in various respects. GAO once again concluded—now based on approximately 100 studies involving approximately 50,000

women—that the drug continued to be safe and effective, and that FDA had acted properly in framing those restrictions. U.S. Gov't Accountability Off., GAO-18-292, Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts (2018).

D. GenBioPro's Mifepristone ANDA and the Mifepristone REMS Program

60. Relying on the repeated regulatory and congressional approval of mifepristone, GenBioPro's predecessor submitted an ANDA application to market generic mifepristone in the United States on February 3, 2009. The ANDA referenced the original NDA for Mifeprex, as approved in 2000. FDA's substantive review on bioequivalence was completed prior to the 2016 changes to the Mifeprex approved labeling and REMS.

61. For almost a decade after the ANDA was submitted, GenBioPro expended significant additional efforts—and millions of dollars—to bring generic mifepristone to market and grow its mifepristone business.

62. On April 11, 2019, FDA approved GenBioPro's application to manufacture and market generic mifepristone. As required by the FDCA, GenBioPro's generic mifepristone and Danco's Mifeprex must have substantively identical labels, in recognition of the fact that they are "bioequivalent" and have "the same therapeutic effect" and thus have the same benefits and risks. *See* 21 U.S.C. § 355(j)(2)(A)(iv)-(v), (j)(4)(F)-(G). That finding was based on a thorough review of the data and additional information submitted by GenBioPro to support approval of the ANDA, in addition to FDA's review of the safety and effectiveness of mifepristone for its indication and the conditions of use recommended in its labeling and REMS.

63. As with Mifeprex, FDA subjected GenBioPro's generic mifepristone to a REMS pursuant to 21 U.S.C. § 355-1(i), determining that the branded and generic mifepristone should share a single REMS, to be called the "Mifepristone REMS Program."

64. FDA continued its review of the Mifepristone REMS Program during the COVID-19 pandemic. In addition to analyzing newly published scientific literature, FDA evaluated safety information submitted to the agency during the COVID-19 public health emergency, reports of adverse events related to the drug, the first REMS assessment report for the Mifepristone REMS Program, and other information provided by the public.

65. In April 2021, FDA announced it would stop enforcing the in-person dispensing requirement of the Mifepristone REMS Program. The agency determined that requiring a patient to visit a clinic during the COVID-19 public health emergency could pose serious risks to patients and healthcare personnel and that new clinical data demonstrated that the in-person dispensing requirement was not necessary to ensure mifepristone remained safe for patients.

66. In December 2021, FDA announced a determination that while certain elements of the Mifepristone REMS Program remained necessary to assure the drug's safe use based on current data, other elements needed modification "to reduce burden on patient access and the health care delivery system and to ensure the benefits of [mifepristone] outweigh [its] risks." FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Dec. 16, 2021), https://perma.cc/V7RX-ZUAX.

67. On January 3, 2023, FDA published a new, shared REMS for mifepristone (the "2023 REMS") covering both Mifeprex and generic mifepristone. FDA, *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG* (Jan. 2023), https://bit.ly/3ZZLoD4. The 2023 REMS was the product of another thorough, independent review of the scientific evidence underlying FDA's determination that mifepristone is safe and effective. Consistent with FDA's April 2021 and December 2021 determinations, the 2023 REMS no longer limits mifepristone dispensing to certain healthcare settings; patients may receive mifepristone by

mail or from a specially certified pharmacy. In doing so, FDA yet again determined that mifepristone was safe and effective for its intended use.

68. The *AHM* Order, described in detail *infra*, ¶¶ 77-78, does not purport to "stay" or "suspend" FDA's approval of the 2023 REMS. In fact, it does not mention the 2023 REMS, which was released after the *AHM* complaint was filed; the *AHM* plaintiffs never amended their complaint to add a challenge to the 2023 REMS. The *AHM* Fifth Circuit Order nonetheless purports to have "stay[ed]" the 2023 REMS, even though that agency action was not before the district court and had not been ruled upon below. *See AHM* Fifth Circuit Order at 6 & n.2, 18, 40.

69. Since 2019, when GenBioPro received approval from FDA to sell generic mifepristone, GenBioPro has marketed and sold more than 850,000 units of the product throughout the United States. Between 2017 and 2020 (the year after GenBioPro began marketing its product), medication abortions in the United States increased by 45 percent, even as the overall number of abortions has declined since the 1990s. Medication abortion now accounts for the majority of pregnancy terminations in the United States.

E. The *Alliance for Hippocratic Medicine* Action and the FDA Decision

70. On November 18, 2022, an action was filed in the U.S. District Court for the Northern District of Texas challenging FDA's approvals of Danco's NDA for Mifeprex and GenBioPro's ANDA for mifepristone, as well as other FDA actions related to mifepristone. Complaint, *All. for Hippocratic Med. et al. v. FDA et al.*, No. 2:22-cv-00223-z (N.D. Tex. Nov. 18, 2022) ("*AHM*"), ECF 1.

71. GenBioPro was not and is not a party to the *AHM* action.

72. The *AHM* plaintiffs filed a motion for preliminary injunction with their complaint. *AHM*, ECF 6 (Nov. 18, 2022). The proposed order accompanying the motion suggested directing FDA to "[w]ithdraw or suspend" its approvals of the Danco NDA and the GenBioPro ANDA.

AHM, ECF 6-1 (Nov. 18, 2022); *see also AHM*, ECF 7 (Nov. 18, 2022), at 2, 7, 25 (requesting an order to FDA to "withdraw or suspend" mifepristone approvals). The proposed order did not ask for a "stay." Nor did it specify the process by which FDA was to withdraw or suspend the NDA and the ANDA.

73. On January 13, 2023, FDA filed its response to the plaintiffs' preliminary injunction motion. *AHM*, ECF 28 (Jan. 13, 2023). FDA explained that the relief sought in the motion—court-ordered withdrawal or suspension of an FDA-approved drug on safety and effectiveness grounds—would be "extraordinary and unprecedented." *Id.* at 31. FDA noted it could find no example of a court previously second-guessing FDA's safety and effectiveness determination about a widely available drug, especially one that has been on the market for two decades. *Id.*

74. On March 1, 2023, GenBioPro sent a letter to FDA Commissioner Robert M. Califf. Letter from Evan Masingill, Chief Exec. Officer, GenBioPro, Inc., to the Honorable Robert M. Califf, M.D., Comm'r, FDA (Mar. 1, 2023) ("March 1 Letter") (Exhibit A). The March 1 Letter asked FDA for its express assurance that any withdrawal of approval for GenBioPro's ANDA for mifepristone would follow all applicable procedures afforded by law to GenBioPro as the ANDA holder, and that FDA would permit GenBioPro to continue marketing and selling mifepristone until those procedures have been completed. *Id.* at 3.

75. On March 24, 2023, FDA responded to the March 1 Letter by declining to provide the assurances sought by GenBioPro. Letter from Patrizia Cavazzoni, MD, Dir., Ctr. for Drug Evaluation and Rsch., FDA, to Evan Masingill, Chief Exec. Officer, GenBioPro, Inc. (Mar. 24, 2023) ("March 24 Response") (Exhibit B). The March 24 Response acknowledged the pending *AHM* lawsuit, noting that the plaintiffs' complaint sought "a preliminary and permanent injunction

ordering Defendants to withdraw mifepristone . . . as [an] FDA-approved chemical abortion drug[].” Ex. B (quoting *AHM*, ECF 1 at 110 (Nov. 18, 2022)). As justification for denying GenBioPro’s request, the March 24 Response stated that “FDA will, of course, need to review the [*AHM*] Court’s opinion and order before determining what steps may be necessary to comply with it.” *Id.*

76. Nowhere in its March 24 Response did FDA indicate that it would, in fact, follow all applicable procedures afforded by law and regulation to GenBioPro in any withdrawal or suspension of approval for GenBioPro’s ANDA. Instead, FDA’s letter indicated that Defendants would *not* follow statutory and regulatory procedures if they deem it “necessary to comply with” a court order. *Id.* In doing so, FDA refused to commit to upholding its duties under the FDCA and implementing regulations for any withdrawal or suspension of approval for GenBioPro’s ANDA.

77. On April 7, 2023, the *AHM* court issued a ruling granting in part the plaintiffs’ preliminary injunction motion. The order invoked 5 U.S.C. § 705 and purported to “stay[] the effective date of FDA’s September 28, 2000 Approval of mifepristone” and subsequent actions on mifepristone that the plaintiffs challenged, including REMS modifications in 2016 and 2021 and the approval of GenBioPro’s ANDA in 2019. *AHM* Order at 67. The court explained that if its application of § 705 is reversed, it “alternatively would have ordered” FDA to “suspend” the 2000 approval of mifepristone and all subsequent actions challenged by the *AHM* plaintiffs, including the 2019 approval of GenBioPro’s ANDA (but not including the 2023 REMS). *See id.*

78. The *AHM* Order stayed its effectiveness for seven days to allow the defendants to seek emergency relief from the U.S. Court of Appeals for the Fifth Circuit. *Id.*

79. On the same day that the *AHM* Order was issued in the Northern District of Texas, a court in the Eastern District of Washington preliminarily enjoined FDA from “altering the status

quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in Plaintiff States," which include Maryland, 16 other states, and the District of Columbia. Order Granting in Part Pls.' Mot. for Prelim. Inj. at 30, *State of Washington et al. v. FDA et al.*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 7, 2023), ECF 80. On April 10, the defendants (FDA, HHS, and their respective leaders) filed a motion seeking clarification of their obligations in light of the "significant tension" between the *Washington* Order and the *AHM* Order. Defs.' Mot. for Clarification at 2, *State of Washington, et al.*, No. 1:23-cv-3026-TOR (E.D. Wash. Apr. 10, 2023), ECF 81. The Washington court later issued an order clarifying that terms of its injunction apply "irrespective of the Northern District of Texas Court ruling or the Fifth Circuit's anticipated ruling." Order Granting Mot. for Clarification at 5-6, No. 1:23-cv-3026-TOR (Apr. 13, 2023), ECF 91 ("*Washington* Clarification Order").

80. On April 9, 2023, GenBioPro again wrote to Commissioner Califf requesting, in light of the *AHM* Order, that FDA: immediately commit to not withdraw, suspend, or otherwise act to impair GenBioPro's ANDA approval by making changes to GenBioPro's registration or product listing with FDA; not withdraw, suspend or otherwise take action impairing GenBioPro's ANDA based on a change in the validity of the Mifeprex approval; issue a non-enforcement order declaring that it will not take any enforcement action against GenBioPro or its distributors, customers, and partners; and issue an interim final rule declaring that GenBioPro's ANDA will remain effective pending public comment and further judicial review of the *AHM* Order. Letter from Evan Masingill, Chief Exec. Officer, GenBioPro, Inc., to the Honorable Robert M. Califf, M.D., Comm'r, FDA (Apr. 9, 2023) ("April 9 Letter") (Exhibit C).[3]

[3] The April 9 Letter was submitted to FDA through official channels on April 10 and April 11.

81. The April 9 Letter requested a response as soon as possible in light of the exigency of the circumstances. *Id.* at 5. To date, FDA has not responded to the April 9 Letter.

82. On April 10, 2023, FDA filed an emergency motion to stay the *AHM* Order in the Fifth Circuit. Emergency Mot. Under Circuit Rule 27.3 for a Stay Pending Appeal, *All. For Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023) ("Stay Motion"). In the Stay Motion, FDA stated that the *AHM* Order "suspend[ed] FDA's approvals of mifepristone and thereby effectively prohibit[ed] [manufacturers] from introducing mifepristone into interstate commerce." *Id.* at 5.

83. On April 12, 2023, in its reply in support of the Stay Motion, FDA stated that it interprets the *AHM* Order as "[e]ffectively requiring Danco Laboratories and GenBioPro to cease distribution of mifepristone." Reply in Supp. of Emergency Mot. Under Circuit Rule 27.3 for a Stay Pending Appeal at 11, *All. for Hippocratic Med.*, No. 23-10362 (5th Cir. Apr. 12, 2023) ("Stay Reply").

84. Later that day, in an opposition to the *AHM* plaintiffs' motion to dismiss the appeal, FDA asserted that the result of the *AHM* Order is that GenBioPro and Danco are "without an effective drug approval," and that "without an effective drug approval," GenBioPro and Danco cannot "lawfully introduce that drug into interstate commerce." Opp. to Mot. to Dismiss at 5, *All. for Hippocratic Med.*, No. 23-10362 (5th Cir. Apr. 12, 2023).

85. Late in the evening of April 12, 2023, the U.S. Court of Appeals for the Fifth Circuit issued the *AHM* Fifth Circuit Order, which granted in part and denied in part the *AHM* defendants' emergency motions for a stay pending appeal. Order at 1, *All. for Hippocratic Med. et al. v. FDA et al.*, No. 23-10362 (5th Cir. Apr. 12, 2023). The *AHM* Fifth Circuit Order stayed the district court's purported stay of Danco's approval for Mifeprex, but declined to stay the effect of the

district court ruling on all other actions challenged by the *AHM* plaintiffs, including the 2019 approval of GenBioPro's ANDA, and denied an administrative stay. *See id.* at 1, 42.

86. On April 13, 2023, GenBioPro again wrote to Commissioner Califf requesting that FDA: confirm that GenBioPro's ANDA remains in effect as currently approved and that GenBioPro is permitted to continue marketing and selling mifepristone under its 2019 approval and subsequent REMS actions; commit that FDA will not withdraw, suspend, or otherwise take action that would impair GenBioPro's ANDA approval and associated rights; confirm that FDA will issue a non-enforcement order declaring that it will not, under any circumstances, take any enforcement action against GenBioPro or its distributors, customers, and partners based on the *AHM* Order; provide immediate guidance confirming that mifepristone may continue to be sold under the existing 2023 REMS; and issue an interim final rule with immediate effect, declaring that FDA's approval of GenBioPro's ANDA shall remain effective pending public comments and any further judicial review of the *AHM* Order. Letter from Evan Masingill, Chief Exec. Officer, GenBioPro, Inc., to the Honorable Robert M. Califf, M.D., Comm'r, FDA (Apr. 13, 2023) ("April 13 Letter") (Exhibit D).

87. To date, FDA has not responded to either GenBioPro's April 9 Letter or April 13 Letter.

88. On April 14, 2023, Danco and FDA filed applications in the U.S. Supreme Court to stay the *AHM* Order and *AHM* Fifth Circuit Order. In its application, FDA stated that the "orders would immediately render all extant doses of mifepristone misbranded," and "[t]he generic version of the drug would cease to be approved altogether." Appl. to Stay at 4, *FDA et al. v. All. for Hippocratic Med. et al.*, No. 22A902 (U.S. Apr. 14, 2023). FDA Principal Deputy Commissioner Janet Woodcock, M.D., submitted a declaration in support of the application, stating that: "I

understand that if the District Court and Fifth Circuit orders go into effect, FDA's approval of Mifepristone Tablets, 200 mg, will be stayed"; that "[i]n the absence of a stay, when the administrative stay expires, [Danco and GenBioPro's] drug products immediately would become misbranded and thus unlawful to introduce in interstate commerce"; that "[a]s a result of the courts' orders, Mifepristone Tablets, 200 mg, will be misbranded because FDA's approval of the generic application will be stayed"; that "[a] new approval [for Mifepristone Tablets, 200 mg] would be required unless the District Court's stay of the approval is lifted;" and that "the [Fifth Circuit's] order will result in Mifeprex being misbranded overnight and will stay the approval of the generic product (issued in 2019) altogether." Decl. of Janet Woodcock, M.D., in Supp. of Appl. to Stay, ¶¶ 10, 15, 16, *FDA et al. v. All. for Hippocratic Med. et al.*, No. 22A902 (U.S. Apr. 14, 2023) ("Woodcock Decl.").

89. On April 18, 2023, FDA filed a reply in support of its application to the Supreme Court to stay the *AHM* Order and *AHM* Fifth Circuit Order. Reply in Supp. of App. to Stay, *FDA et al.*, No. 22A902 (U.S. Apr. 18, 2023). The reply reiterated that under the *AHM* Fifth Circuit Order, "the generic version of [mifepristone] would lose its approval altogether." *Id.* at 22; *see also id.* at 1 ("The generic version of the drug, which accounts for most of the market, would cease to be approved altogether.").

90. Through the above-described series of statements describing their position, including in filings and a declaration to the United States Supreme Court, FDA and HHS confirmed that they have made a final policy decision with respect to GenBioPro's ANDA approval.[4] FDA and HHS have decided that they will characterize GenBioPro's mifepristone as "misbranded" and

[4] Defendants have also confirmed that interpretation in public statements. *See, e.g.*, @HHS_Spox, Twitter (Apr. 9, 2023, 5:30 PM).

characterize GenBioPro as "without an effective drug approval" for generic mifepristone—even though Secretary Becerra has not made the imminent hazard finding required by statute and GenBioPro is not a party to the *AHM* action. Opp. to Mot. to Dismiss at 5, *All. for Hippocratic Med.*, No. 23-10362 (5th Cir. Apr. 12, 2023); Woodcock Decl. ¶ 10. That determination—the "FDA Decision"—denies GenBioPro any process before depriving it of its statutorily and constitutionally protected ANDA rights.

F. The Devastating Effects of Suspension Outside FDA Procedure

91. HHS and FDA's procedures for suspending drug approvals are far more than regulatory formalities. They are critical to protecting the constitutionally recognized property and liberty interests of NDA and ANDA holders like GenBioPro in their approved applications.

92. Suspension is an extreme regulatory measure designed to protect the public following emergence of concrete scientific and medical evidence that a drug presents an "imminent hazard to the public health." 21 U.S.C. § 355(e); *see* 21 C.F.R. § 2.5(a).

93. Suspension of approvals outside of FDA and HHS's express procedures disrupts the evidence-based mandate of FDA and undermines public confidence in FDA's approval of drugs by incorrectly suggesting that FDA approval is not grounded in scientific principles or by implying that FDA misinterpreted those scientific principles in such a way that a drug must be immediately pulled from the market.

94. In addition to the severe harm to GenBioPro's commercial viability from suspension of its ANDA, catastrophic harm also results to members of the public, including doctors and patients, who have developed extensive reliance interests in the approval and availability of GenBioPro's mifepristone. In particular, mifepristone is often cheaper than procedural abortion. Accordingly, the ability to terminate a pregnancy by medication facilitates essential care in cases when external barriers such as limited clinical access, cost, transportation,

time limitations, or privacy concerns might otherwise preclude patients from receiving the care they require.

95. Suspension of mifepristone precludes GenBioPro from pursuing its core business of distributing safe and effective drugs to communities that need them.

G. Legal Consequences of the FDA Decision

96. Given the extreme urgency of the current environment, the FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone—despite FDA failing to follow legally required procedures for suspending approvals—is a discrete action subject to review. The FDA Decision determines GenBioPro's rights and obligations concerning its ANDA, and gives rise to legal consequences—the threat of severe criminal penalties and civil enforcement. That threat in turn presents a risk of potential termination of GenBioPro's relationships with suppliers, distributors and customers, as well as the need for possible returns and/or recalls, even if the *AHM* Order and *AHM* Fifth Circuit Order are later vacated or reversed.

97. The FDA Decision is erroneous and unlawful. The FDCA grants exclusive authority over suspensions of NDAs and ANDAs to HHS and FDA. The duties and procedures the FDCA establishes for suspensions—a finding of imminent hazard by the Secretary and opportunity for an expedited post-suspension hearing—are not subject to waiver under any circumstance. Nor is the validity or enforceability of those procedures challenged in the *AHM* litigation.

98. By deciding to characterize GenBioPro's mifepristone ANDA approval as "misbranded," and GenBioPro as "without an effective drug approval" for mifepristone, without adhering to statutory suspension procedures (or, indeed, procedures of any kind), Defendants have taken arbitrary and capricious action in violation of the APA, the FDCA, and the Fifth Amendment

to the U.S. Constitution, which requires Defendants to grant GenBioPro adequate process before removing GenBioPro's protected property and liberty interests in its ANDA approval.

99. FDA and HHS's erroneous and unlawful determination to ignore statutory and regulatory procedures and violate GenBioPro's due process rights by characterizing GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone causes GenBioPro imminent, catastrophic, and irreparable harm.

100. GenBioPro faces a credible, serious threat of FDCA enforcement if it attempts to continue producing and marketing mifepristone. With the specter of criminal prosecution looming, GenBioPro may be obligated to undertake recalls, cancel contracted manufacturing and hold or destroy perishable inventory. And because of the FDA Decision and the enforcement risk and uncertainty it has created, GenBioPro is suffering irreparable financial and reputational harm, severely threatening its core business model and commercial viability.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Administrative Procedure Act and All Writs Act (Declaratory/Injunctive Relief – FDA's Action is Arbitrary and Capricious and Not in Accordance with Law, in Excess of Statutory Jurisdiction, and Without Observance of Procedure Required By Law Under 5 U.S.C. § 706(2)(A), (C), (D))

101. Plaintiff realleges and incorporates by reference all preceding paragraphs in this Complaint.

102. Congress has mandated that to suspend approval of an ANDA, the HHS Secretary must make a finding that "there is an imminent hazard to the public health." 21 U.S.C. § 355(e).

103. Under FDA regulations, "an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to

prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held." 21 C.F.R. § 2.5(a).

104. FDA has implemented Congress's directions through regulations establishing a multi-step regime for suspensions that appropriately respects the statutory and constitutional rights of approval holders. *See id.* §§ 314.150(a)(1), 314.153(a)(1).

105. Contrary to this statutory and regulatory regime, FDA and HHS have determined that FDA will characterize its approval of GenBioPro's ANDA as "without … effect[]"—even though Secretary Becerra has made no imminent hazard finding.

106. The FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" is erroneous and unlawful.

107. The determination that FDA and HHS will not follow suspension procedures with regard to GenBioPro's ANDA approval is contrary to the mandatory requirements set forth in 21 U.S.C. § 355(e).

108. The determination that FDA and HHS will not follow suspension procedures with regard to GenBioPro's ANDA approval is also contrary to the requirements set forth in FDA's regulations, including 21 C.F.R. §§ 2.5, 314.150, and 314.153.

109. The erroneous and unlawful FDA Decision is final agency action subject to judicial review.

110. The FDA Decision marks the consummation of the agency's decisionmaking process on the status of GenBioPro's ANDA. GenBioPro's rights and obligations have been determined: FDA considers GenBioPro to be "without an effective drug approval" to market and sell generic mifepristone. Legal consequences—grave financial risk and the threat of severe criminal penalties and civil enforcement—flow from FDA's determination.

111. The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D).

112. The Court is also authorized by the All Writs Act to issue orders necessary to preserve its jurisdiction to review Defendants' actions, including emergency equitable relief to maintain the status quo pending judicial review.

113. The FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone, despite the lack of an "imminent hazard" finding by Defendant Secretary Becerra, is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," and "without observance of procedure required by law." 5 U.S.C § 706(2)(A), (C), (D).

114. Under Section 706(2)(A), (C), and (D) of the APA, this Court should hold unlawful and set aside the erroneous and unlawful FDA Decision and bar Defendants from characterizing GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone unless and until Defendant Secretary Becerra makes an "imminent hazard" finding on the factual bases required by law and provides GenBioPro with the opportunity for an expedited post-suspension hearing.

SECOND CLAIM FOR RELIEF

Fifth Amendment, Administrative Procedure Act, and All Writs Act (Declaratory/Injunctive Relief – Fifth Amendment Due Process Protections, Enforceable Through 5 U.S.C. § 706(2)(B), Require FDA to Follow Statutory Suspension Procedures)

115. Plaintiff realleges and incorporates by reference all preceding paragraphs in this Complaint.

116. FDA's decision to grant GenBioPro's ANDA for mifepristone vested a property interest in GenBioPro within the meaning of the Due Process Clause of the Fifth Amendment to the U.S. Constitution.

117. FDA's decision to grant GenBioPro's ANDA for mifepristone vested a liberty interest in GenBioPro within the meaning of the Due Process Clause of the Fifth Amendment to the U.S. Constitution.

118. In approving GenBioPro's mifepristone ANDA, FDA granted GenBioPro a license to market its drug lawfully in interstate commerce. *See* 21 U.S.C. § 355(a) (marketing in interstate commerce prohibited until approval granted). Under the FDCA and implementing regulations, approval of an ANDA cannot be suspended without a finding by the HHS Secretary of an imminent hazard to public health and an opportunity for an expedited post-suspension hearing. *Id.* § 355(e); 21 C.F.R. §§ 314.150(a)(1), 314.153(a)(1). These procedures are constitutionally required to afford adequate process to approval holders before removal of their protected interests.

119. With the FDA Decision, Defendants have determined that FDA will characterize GenBioPro's mifepristone as "misbranded," and GenBioPro as "without an effective drug approval" for generic mifepristone, despite the lack of an imminent hazard finding by Defendant Secretary Becerra or any opportunity for an expedited post-suspension hearing.

120. The FDA Decision to characterize GenBioPro's mifepristone as "misbranded," and GenBioPro as "without an effective drug approval" for generic mifepristone, without an imminent hazard finding by Defendant Secretary Becerra and opportunity for an expedited post-suspension hearing, is contrary to the requirements set forth in 21 U.S.C. § 355(e).

121. The FDA Decision that Defendants will characterize GenBioPro's mifepristone as "misbranded," and GenBioPro as "without an effective drug approval" for generic mifepristone,

without an imminent hazard finding by Defendant Secretary Becerra and opportunity for a post-suspension hearing is also contrary to the requirements set forth in FDA's regulations, including 21 C.F.R. §§ 2.5, 314.150, and 314.153.

122. The erroneous and unlawful FDA Decision is final agency action subject to judicial review.

123. The FDA Decision marks the consummation of the agency's decisionmaking process on the status of GenBioPro's ANDA. GenBioPro's rights and obligations have been determined: FDA considers GenBioPro's mifepristone as "misbranded" and GenBioPro to be "without an effective drug approval" to market and sell generic mifepristone. Legal consequences—grave financial risk and the threat of severe criminal penalties and civil enforcement—flow from FDA's determination.

124. The Court is also authorized by the All Writs Act to issue orders necessary to preserve its jurisdiction to review FDA's actions, including emergency equitable relief to maintain the status quo pending judicial review.

125. The FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone, without required statutory and regulatory procedures, deprives GenBioPro of its property and liberty interests in its ANDA approval without due process.

126. GenBioPro's core business is providing drugs used for medication abortion. GenBioPro exclusively manufactures and markets mifepristone and misoprostol.

127. The FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone, without due process,

severely threatens GenBioPro's ability to pursue its core business of facilitating safe and effective medication abortion.

128. The FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone, without an imminent hazard finding or opportunity for an expedited post-suspension hearing, violates GenBioPro's Fifth Amendment due process right to a hearing in connection with a deprivation of its protected property and liberty interests.

129. The Administrative Procedure Act requires courts to "hold unlawful and set aside agency action" that is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

130. Under the Fifth Amendment and Section 706(2)(B) of the APA, this Court should hold unlawful and set aside the erroneous FDA Decision and bar Defendants from characterizing GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" without required process.

THIRD CLAIM FOR RELIEF

Declaratory Judgment Act
(Declaratory/Injunctive Relief for Pre-Enforcement Review – Enforcing the FDCA's Misbranded or Unapproved Drugs Prohibitions Against GenBioPro Would Violate GenBioPro's Constitutional Due Process Rights under the Fifth Amendment)

131. Plaintiff realleges and incorporates by reference all preceding paragraphs in this Complaint.

132. Absent FDA enforcement discretion, the FDCA prohibits the introduction into interstate commerce of misbranded drugs and drugs that lack an approved NDA or ANDA. 21 U.S.C. §§ 331(a), (d), 352, 355(a). Unlawful distribution of a misbranded or unapproved drug is subject to criminal prosecution and punishable by incarceration and fines. *Id.* §§ 331, 333. FDA

and the Department of Justice may also pursue civil enforcement through injunctions and seizure actions. *Id.* §§ 332, 334.

133. In the wake of the *AHM* Order and the *AHM* Fifth Circuit Order, the FDA Decision to characterize GenBioPro's mifepristone as "misbranded," and GenBioPro as "without an effective drug approval" for generic mifepristone, has created an untenable situation for GenBioPro. Defendants have only worsened the conditions GenBioPro faces by refusing to provide assurances to GenBioPro, whether in a response to GenBioPro's April 9 Letter or April 13 Letter, an interim final rule, a non-enforcement order, or other mechanism, that Defendants will not enforce the FDCA's misbranded and unapproved drug bans against GenBioPro or its agents, partners, and customers.

134. GenBioPro's core business is providing drugs used for medication abortion. GenBioPro exclusively manufactures and markets mifepristone and misoprostol.

135. GenBioPro has no desire to cease production and distribution of mifepristone pursuant to its approved ANDA. That intended course of conduct is affected with a constitutional interest—GenBioPro's protected property and liberty interests in its approval. If that interest is removed without adequate process, GenBioPro faces a severe threat to its ability to pursue its core business of facilitating safe and effective medication abortion.

136. No constitutionally adequate procedure has been afforded to GenBioPro for the suspension of its ANDA.

137. Nonetheless, as a result of the FDA Decision and Defendants' refusal to provide assurances of non-enforcement to GenBioPro, or to issue an interim final rule, non-enforcement order, or other statement, GenBioPro faces a credible and serious threat of prosecution and civil enforcement if it continues to distribute its protected conduct.

138. That threat exists because HHS and FDA are acting as if GenBioPro's mifepristone is "misbranded" and GenBioPro is "without an effective drug approval" for generic mifepristone, without Secretary Becerra having made the "imminent hazard" finding required by statute for suspension and without providing GenBioPro an opportunity for an expedited post-suspension hearing. 21 U.S.C. § 355(e).

139. Irreparable and catastrophic harm would result to GenBioPro from enforcement actions premised on a constitutionally inadequate deprivation of GenBioPro's protected property and liberty interests in its ANDA approval.

140. To prevent that harm from occurring, this Court should: (1) conduct pre-enforcement review of the FDA Decision; (2) declare that Defendants may not suspend the approval of GenBioPro's mifepristone ANDA without the procedures required by statute and regulation and compelled by the Fifth Amendment; and (3) enjoin Defendants from enforcing the FDCA's prohibition on unapproved and misbranded drugs against GenBioPro and its agents, partners, and customers unless and until Defendant Secretary Becerra makes an imminent hazard finding with respect to GenBioPro's mifepristone and provides an opportunity for an expedited post-suspension hearing.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests a judgment in its favor against Defendants as follows:

A. Declare that FDA and HHS are required to follow the prescribed statutory and regulatory procedures for any suspension of GenBioPro's approved ANDA for mifepristone;

B. Declare that the FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone is erroneous and unlawful;

C. Declare that GenBioPro's generic mifepristone is not misbranded or unapproved under the FDCA unless and until Defendants follow the statutory and regulatory procedures required for suspension of approval for GenBioPro's mifepristone ANDA;

D. Declare that Defendants may not lawfully bring an enforcement action against GenBioPro for distribution of misbranded or unapproved drugs without first following the statutory and regulatory procedures for suspension of approval for GenBioPro's mifepristone ANDA;

E. Vacate and set aside the FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone without due process;

F. Stay the FDA Decision to characterize GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone pursuant to 5 U.S.C. § 705, until and unless FDA provides GenBioPro with adequate process;

G. Enjoin Defendants from characterizing GenBioPro's mifepristone as "misbranded" and GenBioPro as "without an effective drug approval" for generic mifepristone without first following the procedures required by 21 U.S.C. § 355(e), as implemented by 21 C.F.R. §§ 2.5, 314.150 and 314.153;

H. Enjoin Defendants from bringing an enforcement action for misbranded or unapproved drugs against GenBioPro, or its agents, manufacturers, distributors or customers, for manufacturing, importing, or shipping mifepristone or any component for the manufacture thereof, pursuant to the 2023 REMS, unless and

until Defendant Secretary Becerra makes an "imminent hazard" finding and provides an opportunity for an expedited post-suspension hearing;

I. Grant such other and further relief as the Court may deem appropriate, including any temporary relief to preserve the status quo.

Dated: April 19, 2023

Respectfully submitted,

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/s/ Samuel I. Ferenc

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**Pro hac vice motion forthcoming*

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