UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF MISSISSIPPI
NORTHERN DIVISION

GENBIOPRO, INC.,

Plaintiff,

v. Civil Action No. 3:20-cv-652-HTW-LRA

DR. THOMAS DOBBS, State Health Officer of the Mississippi Department of Health, in his official capacity,

Defendant.

COMPLAINT

Plaintiff GenBioPro, Inc. ("GBP"), by its undersigned counsel, hereby brings this Complaint against Defendant Dr. Thomas Dobbs, State Health Officer of the Mississippi Department of Health, in his official capacity and states and alleges as follows:

I. INTRODUCTION

1. Mississippi's laws restricting the use of the Food and Drug Administration's ("FDA") approved drug mifepristone conflict with federal law and are therefore preempted. The FDA, after exhaustive review and re-review, balanced patient safety and access in approving use of mifepristone for termination of early pregnancies, subject to a risk management plan known as a Risk Evaluation and Mitigation Strategy, or "REMS." First approved as a safe and effective medication in 2000 (with GBP's generic version approved in April 2019), the FDA has reiterated that adverse events associated with mifepristone are "exceedingly rare," and the drug is safer than either continuing a pregnancy (which can cause any number of health issues) or other methods for terminating an unwanted pregnancy.

2. As mandated by Congress, the FDA considered whether there were any patient risks that should be mitigated through use of a REMS. This consideration includes ensuring that any REMS restrictions "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)" and should be designed to "minimize the burden on the health care delivery system." Federal Food, Drug & Cosmetic Act of 1938 ("FDCA") §§ 355-1(f)(2)(C), (C)(ii), (D), 21 U.S.C. § 301. Under that express authority granted by Congress, the FDA imposed restrictions on who can prescribe mifepristone, where it can be dispensed, and what information must be given to patients – all to ensure patient safety without unduly burdening access.

3. Contrary to these federal authorities, Mississippi has imposed a number of ***additional*** requirements before mifepristone can be dispensed in the state, severely burdening GBP's ability to provide, and patients' ability to obtain, mifepristone. In so doing, Mississippi has improperly displaced the FDA's judgment concerning the necessary precautions, counseling requirements, patient qualification requirements, and patient safety protections for safe use of mifepristone. These state-imposed requirements upset the balance that the FDA struck between risk mitigation and ensuring access to a safe and effective medication. As an example, under the FDA's regimen, a woman can receive mifepristone from a nurse practitioner (with certain qualifications) in a nearby medical clinic or office, and then take the medication in the privacy and comfort of her own home, following up with her health care provider 7 to 14 days later (which need not be an in-person visit). By contrast, that same woman in Mississippi would need to travel to the sole licensed abortion facility in the state (in Jackson) in order to have an initial counseling and ultrasound appointment. This appointment is required to be with a physician, and is followed by a 24-hour wait, thus necessitating either spending the night in Jackson or making an additional

trip back to the clinic the next day to be seen again by a physician. At the second visit, the patient must physically ingest the mifepristone in the physician's presence, and then return again to Jackson to see that physician 7 to 14 days later. Such restrictions contravene federal law, are thus unconstitutional under the Supremacy Clause of the United States Constitution, and are preempted.

4. By this action, GBP seeks to provide the women of Mississippi with access to mifepristone as permitted by federal law, through permanent injunctive relief and declaratory judgment setting aside as unconstitutional Mississippi's laws and regulations that restrict or prevent the administration of a drug approved by the FDA as safe and effective when used in accordance with the FDA's approved label and REMS.

II. JURISDICTION AND VENUE

5. Jurisdiction is proper under 28 U.S.C. § 1331 because this action arises under the laws of the United States, and 28 U.S.C. § 2201 in that there exists between GBP and the Defendant an actual, justiciable controversy as to which GBP requires a declaration of its rights by this Court as well as permanent injunctive relief to prohibit the Defendant from violating federal laws and regulations protected under the United States Constitution.

6. Venue is proper in the Southern District of Mississippi pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to this action occurred in the District, including Defendant's decision to implement the policies at issue in this action and because, upon information and belief, Defendant is located in this judicial district.

7. GBP has standing to bring the present lawsuit because Defendant's actions have caused GBP actual injury, which is redressable through the specific relief requested herein. As a pharmaceutical company marketing and selling mifepristone through interstate commerce pursuant to its approval by the FDA, GBP's operations fall within the zone of interests to be

protected by the dormant Commerce Clause of the United States Constitution, as well as general federal preemption principles.

8. This case is ripe for adjudication. As further discussed below, the enforcement of Mississippi's restrictions on the prescription and provision of mifepristone results in an ongoing and concrete invasion of GBP's legally protected interests under federal law.

9. This Court has authority to grant declaratory and injunctive relief pursuant to 28 U.S.C. §§ 2201–2202, and the inherent equitable powers of this Court.

10. There exists an actual and justiciable controversy between Plaintiff and Defendant requiring resolution by this Court. Plaintiff has no adequate remedy at law.

III. PARTIES

11. **Plaintiff GenBioPro, Inc.** is a Nevada corporation with its principal place of business located at 651 Lindell Road, Suite D1041 (P.O. Box 32011), Las Vegas, Nevada, 89103. GBP markets and sells generic mifepristone – a drug that blocks the hormone progesterone, which is needed for a pregnancy to continue – for which it holds an approved Abbreviated New Drug Application, No. 091178.

12. **Defendant Thomas E. Dobbs III, M.D., M.P.H.,** is the State Health Officer of the Mississippi Department of Health. Dr. Dobbs maintains an office at the Mississippi State Department of Health Central Office, 570 East Woodrow Wilson Drive, O-400, Jackson, Mississippi, 39216. Dr. Dobbs is responsible for supervising and directing all activities of the Department of Health. Miss. Code Ann. §§ 41-3-5.1, 41-3-15(1)(c). Such activities include the licensing and regulating of abortion facilities in accordance with Mississippi law. Miss. Code Ann. § 41-75-1. Dr. Dobbs is being sued in his official capacity.

IV. THE NATURE OF THE CASE

A. What is Mifepristone?

13. The current FDA-approved regimen for the medical termination of early pregnancy involves two medications: (1) *mifepristone*, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) *misoprostol*, which causes uterine contractions that expel the pregnancy from the uterus.[1] The FDA has approved the use of this regimen through 70 days of pregnancy with specific labeling and approved conditions of use under both the labeling and mifepristone REMS program.

14. Mifepristone was first approved for the medical termination of early pregnancy in France and China in 1988, in the United Kingdom in 1991, in Sweden in 1992, and in numerous other European countries throughout the 1990s. In 1996, a new drug application ("NDA") was sponsored for mifepristone in the United States under the brand name Mifeprex, for use in combination with misoprostol for the medical termination of early pregnancy. The FDA approved the NDA in 2000 and Danco Laboratories, L.L.C. ("Danco") began marketing and selling Mifeprex in the United States in November of that year.

15. Plaintiff GBP submitted an abbreviated new drug application ("ANDA") for its product, Mifepristone tablets, a generic version of Mifeprex, to the FDA on February 3, 2009. The FDA approved GBP's ANDA on April 11, 2019.[2]

---

[1] U.S. FOOD & DRUG ADMIN., *Mifeprex (mifepristone) Information* (Feb. 5, 2018), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[2] U.S. FOOD & DRUG ADMIN, ANDA Approval letter for Mifepristone Tablets, 200 mg, ANDA No. 091178 (Apr. 11, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/091178Orig1s000ltr.pdf.

16. Mifepristone is currently the only medication approved in the United States for the medical termination of a pregnancy. Plaintiff's Mifepristone tablets are the only FDA-approved generic version of the medication for this indication.

B. The Federal Regulatory Scheme for Prescription Drugs

1. The United States Food and Drug Administration's Authority to Regulate Prescription Drugs

17. Congress has granted the FDA, through the FDCA, the authority to assess the safety and efficacy of prescription drugs, balance the risks and benefits of drug therapies to the public health, and approve them for marketing and sale in the United States. 21 U.S.C., ch. 9. The FDA approves prescription drugs and determines appropriate conditions for their safe and effective use after conducting a comprehensive and thorough review of available scientific evidence and a careful balancing of the risks and benefits to public safety.

18. The FDA's federally-mandated role is to assess the benefits of a proposed drug alongside its risks, approving only those drugs that strike an appropriate balance between the two, while providing the best guidance to healthcare providers and patients on the safety precautions and risks of a drug to ensure its safe and effective use. This

> "[b]enefit-risk assessment is the foundation for [the] FDA's regulatory review of human drugs and biologics. These assessments capture the Agency's evidence, uncertainties, and reasoning used to arrive at its final determination for specific regulatory decisions."[3]

19. In assessing and approving prescription drugs for sale and marketing in the United States, the FDA's role is not simply to rubber stamp requests for drug approvals. Rather, the FDA conducts a comprehensive and holistic assessment, weighing the risks and benefits of certain drugs

[3] U.S. FOOD & DRUG ADMIN., *Enhancing Benefit-Risk Assessment in Regulatory Decision-Making* (Mar. 20, 2018), https://www.fda.gov/industry/prescription-drug-user-fee-amendments/enhancing-benefit-risk-assessment-regulatory-decision-making.

and other medical technologies in order to strike the right balance between access to drug therapies on the one hand and the public's safety on the other. Carefully and comprehensively weighing the risks of a drug and crafting a detailed risk mitigation plan, when necessary, is the key to achieving the balance at the heart of the FDA's public health mission.

20. Congress has also given the FDA additional powers to place extra protections around the administration of certain drugs to ensure patient safety when necessary. In 2007, the FDCA was amended to establish the FDA's authority to impose a REMS, a "required risk management plan that can include one or more elements to ensure that the benefits of a drug outweigh its risks."[4] The REMS statutory scheme is discussed further in Sections IV.B.3–4, *infra*.

2. The FDA's Extensive Approval Process for New Drugs

21. Congress has vested the FDA with responsibility for reviewing and approving all new prescription drugs (and their generic equivalents) sold in the United States. To that end, the FDCA requires all new prescription drugs to obtain FDA approval under an NDA before they can enter the marketplace. 21 U.S.C. §§ 355(a), (b).[5]

22. To receive approval, drug manufacturers must provide extensive evidence that their drug is safe and effective. *See* 21 U.S.C. § 355(b). To establish safety and effectiveness, an NDA must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." *Id.* § 355(b)(1).

---

[4] U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. FOOD & DRUG ADMIN., *REMS: FDA's Application of Statutory Factors in Determining When a REMS Is Necessary, Guidance for Industry* 2 (Apr. 2019), https://www.fda.gov/media/100307/download (footnote omitted).

[5] The Further Consolidated Appropriations Act, H.R. 1865, 116th Cong. § 610 (2020), https://www.congress.gov/116/plaws/publ94/PLAW-116publ94.pdf, made amendments to the REMS that aim to make it easier for generic products to come to market. These recent changes do not impact the present matter.

23. Upon receipt of an NDA, the FDA is charged with performing a thorough analysis of the drug's safety and effectiveness – a process that requires the agency to carefully balance the benefits and risks to patients. *Id*. §§ 355(c), (d). The FDA will approve an NDA only when all necessary data are submitted or referenced to establish the product's safety and effectiveness. *Id*. And the FDA will refuse to approve an NDA if it finds that the application and the data presented to support the application do not establish the safety and effectiveness of the product. *Id*. § 355(d); Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.125.

24. All drugs have some ability to cause adverse effects. Thus, the FDA's safety assessment of a drug is determined by whether its benefits outweigh its risks. As the FDA notes, "[b]enefit-risk assessment is the foundation for FDA's regulatory review of human drugs and biologics,"[6] and this assessment is made after careful and comprehensive review process:

> [F]or a drug to be approved for marketing, FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This assessment is informed by an extensive body of evidence about the drug's safety and efficacy submitted by an applicant in a . . . (NDA) or Biologics Licensing Application (BLA). This assessment is also informed by a number of other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the postmarket setting; and whether risk management tools are necessary to manage specific risks.[7]

25. As a part of its assessment, the FDA considers "[s]trategies for managing risks," which include "an FDA-approved drug label . . . describ[ing] the drug's benefits and risks, and

---

[6] U.S. FOOD & DRUG ADMIN., *Benefit-Risk Assessment in Drug Regulatory Decision-Making: Draft PDUFA VI Implementation Plan (FY 2018–2020)* 2 (Mar. 30, 2018), https://www.fda.gov/media/112570/download (footnote omitted).

[7] *Id*. at 3.

how the risks can be detected and managed. [For some drugs], more effort is needed to manage risks. In these cases, a drug maker may need to implement a . . . (REMS)."[8]

26. Based on this review, the FDA either: (1) approves the drug; (2) informs the sponsor that the drug is likely to be approved once certain deficiencies in the NDA are resolved; or (3) indicates that approval cannot be obtained without substantial additional data.

27. The FDA follows a similar process in evaluating a supplemental NDA, in which a drug sponsor requests approval to make changes to the label of a previously approved drug or to market the drug for a new indication, as was done for mifepristone in 2016.

28. Under the 1984 Hatch–Waxman Amendments to the FDCA, a company wishing to market the generic version of a previously approved drug may bypass the burdensome NDA process and obtain FDA approval to market the generic version by submitting an ANDA. 21 U.S.C. § 355(j)(2)(A). The ANDA process provides for the approval of a generic drug if the applicant can show its product's "bioequivalence" to the earlier-approved NDA drug and show that its product meets both applicable product specifications and quality requirements, without repeating the clinical efficacy studies required for the initial NDA approval.[9] 21 U.S.C. § 355(j)(8).

3. The Risk Evaluation and Mitigation Strategy Statute

29. In 2007, when Congress amended the FDCA with the FDA Amendments Act, it added a new section 505-1 (codified as amended at 21 U.S.C. § 355-1), authorizing the Secretary

---

[8] U.S. FOOD & DRUG ADMIN., *Development & Approval Process | Drugs* (Oct. 28, 2019), https://www.fda.gov/drugs/developmentApprovalProcess/default.htm.

[9] At its most simply stated, bioequivalence means that the drug is comparable in "dosage form, strength, route of administration, quality, performance characteristics, and intended use" as the NDA drug. U.S. FOOD & DRUG ADMIN., FDA, *Abbreviated New Drug Application (ANDA)* (May 22, 2019), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda.

of Health and Human Services ("HHS"), in consultation with the FDA's Office of New Drugs and the Office of Surveillance and Epidemiology, to impose a REMS if "necessary to ensure that the benefits of the drug outweigh [its] risks . . . ." *Id.* § 355-1(a)(1). Congress mandated clear and complete authority to the Secretary to ensure FDA appropriately balances a drug's benefits against its "serious risks" when imposing REMS requirements. *Id.*

30. To determine whether a REMS is necessary, the Secretary must consider six factors: (1) "[t]he estimated size of the population likely to use the drug involved," (2) "[t]he seriousness of the disease or condition that is to be treated with the drug," (3) "[t]he expected benefit of the drug with respect to such disease or condition," (4) "[t]he expected or actual duration of treatment with the drug," (5) "[t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence [*i.e.*, frequency] of such events in the population likely to use the drug," and (6) "[w]hether the drug is a new molecular entity." *Id.* §§ 355-1(a)(1)(A)–(F).

31. A REMS may include any or all of the following: a medication guide and/or patient package insert; a communication plan; and elements to assure safe usage (*i.e.*, "ETASU"), such as a restricted distribution scheme or special requirements for the administration of the drug. *Id.* §§ 355-1(e)–(f).

32. ETASU are the most restrictive and burdensome type of REMS. Congress imposed several additional requirements to ensure that, even for drugs requiring ETASU, the FDA appropriately balances such a drug's benefits against its "serious risks." The ETASU requirements must "be commensurate with the specific serious risk[s]" listed in the drug's labeling, and may "not be unduly burdensome on patient access to the drug, considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved

areas)." *Id.* §§ 355-1(f)(2)(A), (C), (C)(ii). In addition, "to the extent practicable, so as to minimize the burden on the health care delivery system," ETASU must "conform with elements to assure safe use for other drugs with similar, serious risks." *Id.* §§ 355-1(f)(2)(D), (D)(i).

33. A REMS is also subject to periodic review and assessment to ensure the FDA's balancing of a drug's risks and benefits reflects the most up to date information. *See id.* § 355-1(d). A modification or removal of a REMS may be initiated by a "responsible person" (*i.e.*, the drug's sponsor) or by the Secretary of HHS, who may "require a responsible person to submit a proposed modification to the strategy." *Id.* §§ 355-1(g)(4)(A), (B). In addition, the HHS Secretary must "periodically evaluate" the ETASU "to assess whether the elements (i) assure safe use of the drug; (ii) are not unduly burdensome on patient access to the drug; and (iii) to the extent practicable, minimize the burden on the health care delivery system," *id.* § 355-1(f)(5)(B), and based on this evaluation, the FDA must modify ETASU as appropriate, *id.* § 355-1(f)(5)(C).

4. The FDA Ensures Safe Use of Mifepristone Labeling and REMS Process

a) *The Current Mifepristone Regimen*

34. Mifepristone, as approved by the FDA, is safe. Between 2000 and 2018, over 3.7 million women in the United States used mifepristone to end an early pregnancy. According to the FDA, this medication "has been increasingly used as its efficacy and safety have become well-established by both research and experience, and serious complications have proven to be extremely rare."[10] The FDA observed in March 2016 that serious adverse events following

[10] U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, *Application Number: 020687Orig1s020: Medical Review(s)* ("*2016 Medical Review*") 12 (Mar. 29, 2016) (citation omitted) (attached hereto as Exhibit A), *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

mifepristone use are "exceedingly rare" and "the numbers of these adverse events appear to be stable or decreased over time."[11] The risks of using mifepristone are estimated to be fourteen times lower than the risks women face by carrying a pregnancy to term.

35. The FDA's April 11, 2019 approval of GBP's ANDA reflects the FDA's determination that GBP's product, Mifepristone tablets, 200 mg, is therapeutically equivalent to Mifeprex and can be safely substituted for Mifeprex. Like Mifeprex, the approved generic product is indicated for the medical termination of intrauterine pregnancy through 70 days gestation. GBP's Mifepristone tablets are subject to the same requirements and restrictions as Mifeprex, including the current label and REMS, and can be safely substituted for Mifeprex.[12]

36. Under the FDA-approved mifepristone/misoprostol regimen, only a certified healthcare provider may prescribe Mifepristone tablets. After prescription, on Day One, a patient initiates a medicated abortion by taking one 200 mg tablet of mifepristone in a single oral dose. Then, 24–48 hours later, she takes four 200 mcg tablets of misoprostol buccally (*i.e.*, by placing in the area between the cheek and the gums). The FDA label does not specify where a patient should be located when she takes either doses of medication. Most patients will expel the pregnancy within 2 to 24 hours after taking the misoprostol. A patient is instructed to follow up with her health care provider approximately 7 to 14 days later to confirm that the termination of the pregnancy was successful, but the FDA label does not require that this follow-up evaluation occur in-person.

37. Under the current REMS (which applies to both the brand name Mifeprex and Plaintiff GBP's generic Mifepristone tablets):

---

[11] *Id*., Ex. A, at 47.

[12] GBP's Mifepristone tablets are the only generic, FDA-approved medication for pregnancy termination.

a. Mifepristone must be ordered, prescribed and dispensed by or under the supervision of a healthcare provider who prescribes and who meets certain qualifications;

b. Healthcare providers who wish to prescribe Mifepristone must complete a Prescriber Agreement Form attesting to their qualifications prior to ordering and dispensing Mifepristone;

c. Mifepristone may only be dispensed in clinics, medical offices, and hospitals by or under the supervision of a certified healthcare provider;

d. The healthcare provider must obtain a signed Patient Agreement Form before dispensing Mifepristone, give the patient a copy, and keep a copy of the signed agreement in the patient's chart;

e. Healthcare providers who prescribe Mifepristone are required under FDA regulations to provide the patient with a copy of the Mifepristone Medication Guide (FDA-approved information for patients).[13]

38. In essence, the existing REMS requirements for mifepristone fall into three general categories: (1) *prescribers:* the restrictions that only certified healthcare providers may prescribe the medication; (2) *safe use:* restrictions on how the medication should be dispensed and administered to patients and the conditions required to address safety issues; and (3) *informed consent:* what information patients should receive about the risks of taking the medication. The mifepristone REMS program also imposes certain requirements for tracking distribution of the medication, confidentiality provisions for prescribers and patients, and recording and reporting adverse events, if any. The FDA has determined that these REMS requirements sufficiently mitigate the risks of mifepristone so as to ensure the medication's benefits outweigh its risks.

[13] U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, *NDA 020687 Mifeprex (mifepristone) Tablets, 200 mg, Antiprogestational Synthetic Steroid: Risk Evaluation and Mitigation Strategy (REMS)* (Mar. 29, 2016) (attached hereto as Exhibit B), *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf.

b) *Procedural History of Mifepristone REMS*

39. In September 2000, when the FDA granted final marketing approval for mifepristone, in combination with misoprostol, for the termination of pregnancy up to 49 days, the FDA approved the medication under Subpart H (which provides for accelerated approval), and imposed ETASU – a restricted distribution system – as a condition of approval.

40. Pursuant to the 2007 FDA Amendments Act establishing the REMS program, in March 2008 the FDA deemed mifepristone as having a REMS in effect because it already had ETASU in place under Subpart H, and mifepristone continued to be distributed subject to the same restrictions under which it was originally approved.

41. After subsequent review, the FDA issued a new REMS for mifepristone in 2011, which incorporated the same restrictions in place when the medication was initially approved: (i) a Medication Guide to be dispensed with each prescription; (ii) three types of ETASU (A, C, D – discussed below); (iii) an implementation system governing where the medication may be shipped and requirements for maintaining confidential records tracking shipments, proof of delivery, etc.; and (iv) requiring the sponsor to submit a REMS assessment to the FDA one year following initial approval and every three years thereafter.

42. The specific ETASU imposed for mifepristone under the 2008 and 2011 modifications to the mifepristone REMS program provided detailed requirements governing who may prescribe and purchase the medication.

43. ETASU A restricted those who may prescribe mifepristone to Certified Prescribers, who executed a Prescriber's Agreement agreeing to meet certain qualifications and to follow the guidelines outlined therein. Under the 2008 and 2011 REMs, certified prescribers were required to be physicians with the ability to date a pregnancy and diagnose an ectopic pregnancy; who had made plans for a patient to receive follow-up abortion care in cases of incomplete abortion or

severe bleeding, and ensured a patient's access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary; and had read and understood the prescribing information for the medication. In addition, the prescriber agreed to provide the patient with the Medication Guide and Patient Agreement, gave the patient an opportunity to read and discuss them, obtained her signature, and then signed it him or herself; notified the manufacturer of any cases of incomplete abortion, hospitalization, transfusion, or other serious event; and recorded the unique serial number on each package of Mifeprex in each patient's record.

44. ETASU C restricts where a patient may receive mifepristone. The medication may only be dispensed in certain health care settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a prescriber certified under ETASU A; it may not be dispensed through retail pharmacies or sold over the internet.

45. ETASU D ensures that patients prescribed mifepristone receive, and certify that they have received, specific safety information about the medication. Mifepristone may only be dispensed to a patient who has completed and signed a Patient Agreement form, a copy of which must be placed in her medical record, and been provided a copy of the FDA-required Medication Guide.

c) *The 2016 Mifepristone Labeling and REMS Revisions*

46. Initiated in 2015 and completed in 2016, the FDA conducted a lengthy review of the mifepristone label and REMS. As part of that review, the FDA assembled a number of internal teams to evaluate safety monitoring data collected through the REMS program and additional medical and clinical research on mifepristone.

47. As a result of this review and based on the growing body of evidence about the safety of mifepristone, the FDA revised the label to reduce the recommended dosage from three

200 mg tablets to one 200 mg tablet and removed the requirement that a patient's follow-up assessment within 7 to 14 days after taking the medication be an in-person examination.

48. The FDA also approved two changes regarding *where* the patient ingests the mifepristone and misoprostol. First, the label no longer requires that a patient take the mifepristone and misoprostol "at [her] provider's office," or under direct observation by a health care provider.[14] Although the current REMS (described above) still requires that certified healthcare providers *dispense* the medication in certain medical facilities (mifepristone is not legally available to be purchased on the internet and retail pharmacies may not dispense mifepristone), the new label does not specify where a patient must *take* the pill.[15] The label advises the healthcare provider to "discuss with the patient an appropriate location for her to be when she takes the misoprostol, taking into account that expulsion could begin within 2 hours of administration."[16] The change in this requirement was significant: it allowed a patient to self-administer both medications in the location of her choosing and reflected the FDA's determination that direct observation of medication ingestion by a medical professional was not necessary to ensure patient safety.

49. Second, the new label clarified that mifepristone is safe for use through 70 days of pregnancy (rather than the previous 49).[17] The FDA's 2016 Medical Review concluded that, based on the available scientific evidence, "[m]edical termination of pregnancies through 70 days gestation is safe and effective and should be approved."[18]

---

[14] Mifeprex Label, 2016 (attached hereto as Exhibit C), *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[15] *See id.*, Ex. C., at 3.

[16] *Id.*, Ex. C.

[17] *Id.*, Ex. C., at 2.

[18] *See* 2016 Medical Review, *supra* note 10, Ex. A, at 21.

50. As part of its 2016 labeling revision, the FDA also undertook to "assess[] the current REMS program to determine whether each Mifeprex REMS element remains necessary to ensure that the drug's benefits outweigh the risks."[19] This assessment was conducted by a multidisciplinary reviewing team and reviewed by the Commissioner of the FDA, who gave specific feedback on proposed changes to the Mifepristone REMS.[20]

51. The FDA's justifications for the 2016 label changes, including the REMS revisions, were documented in detail in at least several internal memoranda.[21] In evaluating each element of the REMS, the FDA considered "safety data gathered over the past 16 years since approval, and information about current clinical practice."[22]

52. Following this review, the FDA "determined that a REMS continues to be necessary to ensure the safe use of Mifeprex," and reauthorized the REMS program, including all of the ETASU, with several modifications.[23] Significantly, the 2016 REMS removed the previous

---

[19] U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, *Application Number: 020687Orig1s020, Supplement Approval Letter* 2 (Mar. 29, 2016) (attached hereto as Exhibit D), *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020Approv.pdf.

[20] U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, *Application Number: 020687Orig1s020, Cross Discipline Team Leader Review* ("*Cross Discipline Team Leader Review*") (Mar. 29, 2016) (attached hereto as Exhibit E), *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020CrossR.pdf.

[21] Exs. A, *2016 Medical Review*, *supra* note 10 & E, *Cross Discipline Team Leader Review*, *supra* note 20; U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, *Application Number: 020687Orig1s020, Summary Review* (Mar. 29, 2016) (attached hereto as Exhibit F) *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020SumR.pdf; U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, *Application Number: 020687Orig1s020, Risk Assessment and Risk Mitigation Review(s)* ("*2016 REMS Modification*") (Mar. 29, 2016) (attached hereto as Exhibit G), *also available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf.

[22] *2016 REMS Modification*, *supra* note 21, Ex. G, at 30 (citations omitted).

[23] *See Mifeprex (mifepristone) Info.*, *supra* note 1; *2016 REMS Modification*, *supra* note 21, Ex. G, at 8 (listing changes and discussing retention of ETASU D), 12–17 (detailing addendum to REMS modification review).

requirement that a certified prescriber of mifepristone be a physician, allowing other types of healthcare providers with prescriptive authority[24] to prescribe mifepristone, provided they abide by the remaining certified prescriber requirements in the REMS (which include the ability to accurately date a pregnancy and other relevant qualifications).[25]

C. Mississippi Laws Regulating Mifepristone Conflict with the REMS

53. The Mississippi Legislature has passed, and the Mississippi Department of Health enforces, a number of laws and regulations that restrict the administration of mifepristone, in direct conflict with FDA's conditions of approval of mifepristone.

54. In 2013, Mississippi implemented The Women's Health Defense Act of 2013 ("the 2013 Act"), codified as amended at Miss. Code Ann. §§ 41-41-101–117. The 2013 Act is aimed squarely at regulating the provision of abortion-inducing drugs in Mississippi and purports to "[p]rotect women from the dangerous and potentially deadly use of abortion-inducing drugs when administration of the drugs does not meet the standard of care; and [e]nsure that physicians meet the standard of care when giving, selling, dispensing, administering or otherwise providing or prescribing abortion-inducing drugs." *Id.* § 41-41-103(2). In so doing, the 2013 Act places strict limitations on who may prescribe and administer mifepristone and the circumstances in which they may do so. These limitations conflict with the FDA's determination of the necessary and sufficient conditions for mifepristone's safe use.

55. The 2013 Act squarely conflicts with the FDA's REMS conditions for mifepristone on all three broad categories of restrictions: prescribers, safe use, and informed consent. For

[24] Which healthcare providers have prescriptive authority varies state-by-state, and may include nurse practitioners, physicians' assistants, nurse midwives, advanced practice registered nurses, and other master's degree-level health care providers.

[25] *Cross Discipline Team Leader Review*, *supra* note 20, Ex. E.

example, the 2013 Act mandates that only a physician licensed in Mississippi may "give, sell, dispense, administer or otherwise provide or prescribe any abortion-inducing drug." *Id.* § 41-41-107(1) (the "physician only" provision). But the state-imposed restrictions go even further: Mississippi law requires additional training before a physician may prescribe abortion-inducing medication, such that not only is administration of mifepristone restricted to physicians only (already in direct conflict with the FDA-mandated standard), but not even every licensed physician in Mississippi may prescribe the medication, only those who have completed at least one year of postgraduate training in a training facility with an approved residency program and an additional year of obstetrics/gynecology residency. 15 Miss. Admin. Code § 16-1-44.1.

56. In addition to the severe prescriber restrictions, the 2013 Act requires a series of in-person interactions between physician and patient, effectively banning the remote provision of healthcare (often referred to as "telemedicine") that has become commonplace in recent years for certain types of healthcare services; telemedicine has greatly increased access to care for rural and geographically remote populations. In fact, in light of the COVID-19 pandemic, HHS has encouraged health care professionals to "adopt and use telehealth as a way to safely provide care to [] patients in appropriate situations," which includes waiving in-person requirements for medication consultation, evaluation, and prescription, even for controlled substances.[26] That same encouragement has been echoed in Mississippi where, on June 1, 2020, Defendant issued an order to health care providers stating, "telehealth should be used when possible and as appropriate for

[26] *See* U.S. HEALTH & HUMAN SERVICES, *Telehealth: Delivering Care Safely During COVID-19* (July 15, 2020), https://www.hhs.gov/coronavirus/telehealth/index.html; U.S. DEP'T OF JUSTICE, DRUG ENF'T AGENCY, *COVID-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited Aug. 19, 2020).

medical assessment and treatment."[27] Mississippi providers are "highly encouraged to utilize telemedicine . . . to avoid unnecessary clinic visits and possible [COVID-19] exposure."[28]

57. Nonetheless, even under expanded telehealth provisions and public health guidelines that dictate the need to limit unnecessary travel and in-person interactions, in Mississippi, physicians are required to physically examine a patient prior to "giving, selling, dispensing, administering or otherwise providing or prescribing the abortion-inducing drug." Miss. Code Ann. § 41-41-107(2). Once the medication is prescribed, a patient must ingest the medication "in the same room and in the physical presence of the physician who gave, sold, dispensed or otherwise provided or prescribed the drug or chemical to the patient." *Id.* § 41-41-107(3). Physicians must report the provision of any abortion-inducing medications for the purpose of inducing an abortion to the Mississippi Department of Health. *Id.* § 41-41-109.

58. Mississippi's in-person requirements continue even after a patient ingests mifepristone. The 2013 Act further requires the prescribing physician to schedule a follow-up visit with a patient approximately 14 days after administration of an abortion-inducing drug. *Id.* §§ 41-41-107(5), (6). Any physician who is unable to provide follow-up care must have a signed contract with an alternative physician who is available to provide a patient with the mandated in-person care. *Id.*

59. As Mississippi does not carve out unique provisions for medicated abortion, provision of mifepristone is subject not only to the 2013 Act governing abortion-inducing drugs, but to the full compendium of the state's abortion regulations. This has a significant impact on

---

[27] MISS. STATE DEP'T OF HEALTH, *COVID-19 State Health Officer Order for Outpatient and Inpatient Medical Services* 1 (June 1, 2020), http://www.msdh.state.ms.us/msdhsite/_static/resources/8647.pdf.

[28] MISS. TELEHEALTH ASS'N, *Telehealth Policy Updates Related to COVID-19*, https://www.mstelehealth.org/telehealth-policy-updates-related-to-covid-19/ (last visited Aug. 19, 2020).

both where a patient may be administered the mifepristone and the information a prescriber is required to present to a patient before he or she may prescribe mifepristone.

60. In addition to mandating that the drug must be ingested in the presence of a physician, Mississippi imposes severe restrictions on the physical facilities in which the drug's administration must occur. Under Mississippi law, all Mississippi facilities providing abortion care, which by definition includes administering abortion-causing drugs (mifepristone), *id*. § 41-75-1(e), must be licensed as either a Level I or Level II Abortion Facility (though the distinction between the two is unclear, as Mississippi regulations require that a Level I abortion facility "meet minimum standards for Level II abortion facilities and Minimum Standards of Operation For Ambulatory Surgical Facilities as established by the licensing agency." 15 Miss. Admin. Code § 16-1-44.1.5(9)). An abortion facility is defined as any healthcare facility that conducts ten or more abortions per calendar month in any calendar year; or, if the facility is open less than 20 calendar days per month, if the facility conducts the pro-rated equivalent of ten abortions per month if the facility were open so many days per month; or if the facility conducts 100 abortions in any calendar year regardless of the number of abortions per month. *Id*. § 16-1-44.1.5(3). Any facility wishing to administer mifepristone with any regularity is thus subject to all corresponding abortion facility licensing regulations, including the "Minimum Standards of Operation for Abortion Facilities." Miss. Code Ann. §§ 41-75-1(e), (h). Per Mississippi regulations, 15 Miss. Admin. Code § 16-1-44.28.1, the Minimum Standards of Operation for Abortion Facilities require each such facility to have:

> 1. Examination Room(s). Rooms for examination shall have a minimum floor area of 80 square feet, excluding vestibules, toilets, and closets. Room arrangement should permit at least 2 feet 8 inches clearance at each side and at the foot of the examination table. A hand-washing fixture shall be provided.

2. Procedure Room. Procedure rooms shall have a minimum floor area of 120 square feet, excluding vestibule, toilet, and closets. The minimum room dimension shall be 10 feet. A scrub sink with knee, elbow, wrist, or foot control, soap dispenser, and single service towel dispenser will be available. All finishes shall be capable of repeated cleaning.

3. Recovery Room. One or more recovery rooms containing sufficient beds for recovering patient shall be provided. Reclining type vinyl upholstered chairs may be substituted in lieu of beds. Direct visual observation of the patients shall be possible from a central vantage point, yet patients shall have a reasonable amount of privacy.

61. In addition, abortion facilities must also meet the minimum standards of operation for ambulatory surgical centers, as established by the Mississippi Department of Public Health. *Id.* § 16-1-44.1.5(9). Among voluminous requirements, ambulatory surgical centers are required to be "located in an attractive setting" and within 15 minutes travel time from a hospital which has an emergency room. *Id.* § 16-1-42.30.1. Ambulatory surgical centers have stringent construction requirements, including, for example, that all corridors used by patients be at least six feet wide and all patient rooms have, at minimum eight foot ceilings. *Id.* §§ 16-1-42.27, 16-1-42.30.

62. In addition to the extensive facility regulations, abortion facilities are required to have agreements for transportation and care in the case of patient emergency. Miss. Code Ann. §§ 41-75-1, 41-75-29.

63. In addition to the conflicting prescriber and safe use restrictions described above, Mississippi also imposes an alternate scheme related to the information a patient must receive (about the risks of the drug, specifically, and abortion, generally), before she can receive mifepristone. These requirements include an initial, in-person meeting with a physician to discuss the risks of the abortion procedure and present a patient with alternative options to abortion, a mandatory fetal ultrasound imaging and auscultation of fetal heartbeat, and a 24-hour waiting period before a patient may proceed with an abortion. Miss. Code Ann. §§ 41-41-33, 41-41-34.

64. Mississippi also requires, prior to an abortion procedure (including medication-induced abortion), that a physician offer a woman additional information and counseling, including a list of adoption agencies and "[m]aterials designed to inform the woman of the probable anatomical and physiological characteristics of the unborn child at two-week gestational increments from the time when a woman can be known to be pregnant to full term," which must include "color pictures representing the development of the child at two-week gestational increments" that "contain the dimensions of the unborn child and must be realistic." *Id.* §§ 41-41-35(1)(b).

65. These state laws and regulations conflict with the FDA's scheme for the safe and effective use of mifepristone, and are an obstacle to fulfilling the full purpose and objectives of Congress's grant of authority to a federal agency to balance the risks and benefits of and design risk mitigation strategies for the administration of prescription drugs in the United States.

D. The Impact of Mississippi's Unconstitutional Restrictions on Mifepristone

66. Defendant's actions in enforcing the state of Mississippi's laws and regulations that conflict with the FDA's requirements for the safe use of mifepristone frustrate the FDA's purpose in regulating mifepristone, upsetting the balance that the FDA has struck to protect the public safety, and causes real harm for Plaintiff GBP by hindering GBP's ability to provide mifepristone in Mississippi.

67. By implementing onerous requirements above and beyond the FDA's approved regimen, Mississippi has made it more difficult for GBP to promote and to sell mifepristone in Mississippi than it otherwise would be under the FDA-approved regimen for the medication.

68. The additional restrictions placed on the provision of mifepristone by the state of Mississippi are a burden to healthcare providers and, therefore, deter some providers from prescribing this medication. These healthcare professionals are already subject to many laws,

policies, and standards of practice, many regulated and enforced by the state of Mississippi, to ensure that they can accurately and safely understand and prescribe medications. The additional targeted restrictions on medicated abortion are not necessary to ensure the provision of healthcare services to patients in line with governing standards of care because the FDA's comprehensive approval process for prescription drugs ensures appropriate protocols for their safe and effective use.

69. On information and belief, there is only one clinic in the state of Mississippi that meets the state's requirements to prescribe mifepristone.

70. Barriers to access often lead to increased use of illicit markets (including online sales), for medications in the United States, and mifepristone is no exception. A recently published peer-reviewed study shows that states with the most restrictive access to abortion in a clinic setting have the highest rates of online requests for the medication – Mississippi is at the top of that list.[29]

71. The FDA has determined how mifepristone should be prescribed to women in the United States through the REMS, which prohibits online and retail pharmacy sales of mifepristone. The FDA has placed a red, highly visible warning – "Do Not Buy Mifeprex Over the Internet" – on its mifepristone information page, referring visitors to the FDA's consumer safety guide to buying prescription medicines online,[30] and has been cracking down on websites selling the medication online to patients in the United States. Recently, the FDA issued a warning letter to

---

[29] Abigail Aiken, et al., *Demand for Self-Managed Medication Abortion Through an Online Telemedicine Service in the United States*, 110 AM. J. PUB. HEALTH 90 (2020), HTTPS://AJPH.APHAPUBLICATIONS.ORG/DOI/PDFPLUS/10.2105/AJPH.2019.305369; *see also* Abigail Aiken, et al., *Motivations and Experiences of People Seeking Medication Abortion Online in the United States*, 50 PERSP. SEXUAL REPROD. HEALTH 157.

[30] *Mifeprex (mifepristone) Info.*, *supra* note 1.

an online pharmacy selling misbranded and unapproved medicated abortion drugs to women in the United States outside the protections of the FDA-approved REMS program.[31]

72. Notwithstanding that mifepristone is not supposed to be sold over the internet, some women are in fact buying it online – including women in Mississippi. Thus, Mississippi's unconstitutional restrictions are pushing women to buy mifepristone (or what purports to be mifepristone) outside the scope of the FDA's thoroughly evaluated and balanced risk mitigation plan, potentially increasing the risks to those women – the exact opposite of what the FDA is trying to accomplish with the REMS.

73. GBP stands to suffer substantial lost sales in Mississippi as a result of the state's conflicting regulation of abortion inducing drugs. Mississippi's restrictions hamper GBP's ability to sell and promote its product in Mississippi.

74. GBP invested substantial money and effort in the research and development of its generic mifepristone. GBP is currently the only licensed ANDA holder approved to market and sell generic mifepristone in the United States. GBP currently sells mifepristone in a number of jurisdictions in the United States.

75. Imposition of unconstitutional state law restrictions on the prescription and use of mifepristone causes, and will continue to cause, significant revenue loss to GBP. Mifepristone is GBP's only FDA-approved and marketed product.

---

[31] U.S. FOOD & DRUG ADMIN., *Warning Letter from FDA to Aidaccess.org: MARCS-CMS 575658, Re: Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce* (Mar. 8, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/aidaccessorg-575658-03082019; U.S. FOOD & DRUG ADMIN., *Warning Letter from FDA to Rablon: MARCS-CMS 1111111, Re: Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce* (Mar. 8, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/rablon-1111111-03082019.

76. In addition, Defendant's conduct, unless enjoined, will cause immediate and irreversible harm to the reputation and goodwill of mifepristone and GBP. The State of Mississippi's unnecessary regulation of mifepristone are likely to cause physicians and patients – both in Mississippi and across the country – wrongly to believe that mifepristone is not a safe and effective medication, thus adversely affecting GBP's primary product on the market.

COUNT I

(United States Constitution: Preemption)

77. GBP realleges, reasserts, and incorporates by reference herein each of the allegations contained in paragraphs 1 through 76 of the Complaint as though set forth fully herein.

78. The Supremacy Clause of the United States Constitution provides that federal laws made under the authority of the United States shall be the "supreme law of the land," the laws of any state to the contrary notwithstanding. U.S. CONST. art. VI, § 2.

79. The Supremacy Clause mandates that federal law preempts any state regulation that poses an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

80. Under the FDCA, Congress has delegated to the FDA the authority to protect and promote the public health by approving for public use "safe and effective" prescription drugs.

81. Prescription drug regulation is an arena that is inherently national in nature in that the FDA has long set uniform standards for drug regulation across all states. In 2016, the FDA reviewed and amended the labeling and REMS requirements for mifepristone and concluded that the amended restrictions were set at the appropriate level to best balance the risks and benefits of mifepristone. That decision was grounded in a careful review of the underlying science, consistent

with regulatory and statutory requirements, and falls squarely within the federal agency's realm of expertise.

82. Mississippi imposes its own state laws and regulations that conflict with the FDA's approved regimen and risk mitigation strategies for mifepristone.

83. Mississippi's conflicting state laws are an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in granting the authority to the FDA to both approve and determine the appropriate measures to mitigate the risks of prescription drugs in the United States.

84. Taken as a whole, Mississippi's conflicting state laws represent an impermissible effort by Mississippi to establish its own drug approval policy and directly regulate the availability of drugs within the state. It conflicts with the FDA's mandate under the FDCA, disregards federal policies, undermines the FDA's comprehensive regulatory scheme for nationally-effective drug approvals, and otherwise impedes the accomplishment and execution of the full purposes and objectives of federal law.

85. Mississippi's conflicting state laws also specifically undermine the FDA's assessment that mifepristone is a safe and effective product that may be distributed and safely administered in all fifty states. In so doing, it impedes the FDA's Congressional mandate to approve a range of safe treatments to promote the public health.

86. Plaintiff has no adequate remedy at law for these violations of the Supremacy Clause.

87. Mississippi's conflicting state laws cause, and will continue to cause, substantial injury to GBP unless the state restrictions are vacated and Defendant is enjoined from imposing or enforcing these restrictions.

COUNT II

(United States Constitution: Commerce Clause)

88. GBP realleges, reasserts, and incorporates by reference herein each of the allegations contained in paragraphs 1 through 87 of the Complaint, as though set forth fully herein.

89. The Commerce Clause of the United States Constitution prevents a state from taking any action which may fairly be deemed to have the effect of impeding the free flow of trade between the states.[32]

90. Mississippi's restrictions on mifepristone impose significant burdens on interstate commerce because they interfere with the FDA's national and uniform system of regulation. If Mississippi (and other states) is allowed to make its own determinations as to how the risks and benefits of prescription drugs should be weighed and whether and how they should be approved, regulated, and administered, the result will be an unworkable patchwork of state-specific regulation governing how prescription drugs are administered that would effectively eviscerate the mission of the FDA and create different (and potentially conflicting) sets of rules for deciding what constitutes safe and effective pharmaceuticals.

91. Mississippi's conflicting regulations also impose significant burdens on interstate commerce because they harm patients living in Mississippi, as well as patients residing outside of Mississippi who see health care providers in the state. Because health care providers are restricted in their ability to prescribe mifepristone to patients (regardless of their state of residence), patients across several states will experience restricted access to mifepristone thus impacting commerce beyond the borders of the state.

[32] *See Freeman v. Hewitt*, 329 U.S. 249, 252 (1946).

92. The burden imposed on interstate commerce by Mississippi's conflicting regulations is clearly excessive in relation to the purported protections touted by the state legislature. The additional restrictions on provision and use of mifepristone in Mississippi above and beyond those imposed by the FDA are excessive, especially in light of the FDA's careful and comprehensive balancing of the risks and benefits of such medication for the public health as evidenced, generally, by its approval of the drug and by the REMS process, in particular.

93. GBP has no adequate remedy at law for the violation of the Commerce Clause.

94. Mississippi's conflicting regulations will cause substantial injury to GBP unless the state restrictions are vacated and Defendant is enjoined from imposing these restrictions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the state of Mississippi's laws and regulations restricting provision and use of FDA-approved abortion-inducing drugs violate the United States Constitution;

B. Permanent injunctive relief and/or a final order enjoining the Defendant from enforcing any state law or regulation restricting the provision and use of mifepristone beyond those outlined by the FDA's 2016 REMS for mifepristone. In the alternative, permanent injunctive relief and/or a final order vacating any state law or regulation restricting the provision and use of mifepristone beyond those outlined by the FDA's 2016 REMS for mifepristone;

C. An order awarding plaintiff's costs, expenses and attorneys' fees; and/or

D. Such other and further relief as the Court deems just and appropriate.

Dated: October 9, 2010

GENBIOPRO, INC.

s/ J. Carter Thompson, Jr.

J. Carter Thompson, Jr. (MSB No. 8195)
D. Sterling Kidd (MSB No. 103670)
BAKER, DONELSON, BEARMAN,
CALDWELL & BERKOWITZ, PC
One Eastover Center
100 Vision Drive, Suite 400
Jackson, MS 39211-6391
Tel: (601) 351-2400
Fax: (601) 351-2424
cthompson@bakerdonelson.com
skidd@bakerdonelson.com

U. Gwyn Williams (*phv* forthcoming)
Allison Lukas Turner (*phv* forthcoming)
LATHAM & WATKINS LLP
200 Clarendon Street, 27th Floor
Boston, MA 02116
Tel: (617) 880-4500
gwyn.williams@lw.com
allison.turner@lw.com