No. 23-2194

IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

GENBIOPRO, INC.,
Plaintiff-Appellant,

v.

KRISTINA D. RAYNES, *in her official capacity as Prosecuting Attorney of Putnam County*, AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of West Virginia (Huntington),
No. 3:23-cv-00058, Hon. Robert C. Chambers

OPENING BRIEF OF PLAINTIFF-APPELLANT GENBIOPRO, INC.

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February 7, 2024

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 23-2194 Caption: GenBioPro, Inc. v. Kristina Raynes et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

GenBioPro, Inc.
(name of party/amicus)

who is Plaintiff-Appellant, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☑ YES ☐ NO
If yes, identify all parent corporations, including all generations of parent corporations:

Xenia Holdco, LLC

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☑NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ David C. Frederick Date: 02/07/2024

Counsel for: GenBioPro, Inc.

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INTRODUCTION

This case concerns West Virginia's laws restricting access to the drug mifepristone. These laws contravene Congress's determination that only the U.S. Food and Drug Administration ("FDA") may regulate access to that drug. They are, therefore, preempted.

Mifepristone is the first in a two-drug regimen used for early termination of pregnancy. FDA approved mifepristone in 2000 under a program that enabled the agency to regulate certain drugs closely, including how those drugs are prescribed and dispensed. Congress codified this program in the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). That statute authorized FDA to impose a "risk evaluation and mitigation strategy" ("REMS") on certain medications and deemed mifepristone already to have such a REMS in effect. Pub. L. No. 110-85, § 909(b)(1), 121 Stat. 823, 950, *reprinted at* 21 U.S.C. § 331 note. In a REMS, FDA can regulate a drug end-to-end, including how it is packaged, dispensed, prescribed, and disposed of.

The FDAAA authorizes FDA to impose additional restrictions, known as safe-use elements, on a small subset of drugs when the agency determines that additional oversight is necessary to ensure their

benefits outweigh their risks. FDA may impose only restrictions it determines are necessary to assure the drug's safe use. Restrictions "shall . . . not be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2)(C)-(D).

Since 2007, FDA has regulated mifepristone's distribution, prescribing, and dispensing under this statutory command. The FDAAA requires FDA to update mifepristone's REMS and safe-use elements to minimize burdens on patient access and the healthcare delivery system, based on the agency's periodic assessments of evolving scientific evidence and real-world use. Plaintiff-Appellant GenBioPro, which manufactures mifepristone, provides it subject to FDA's regime.

Against this backdrop of comprehensive federal regulation, West Virginia enacted the Unborn Child Protection Act ("UCPA"). The UCPA bans abortion in almost all cases, at any stage of pregnancy. W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. Physicians can lose their medical licenses if they prescribe mifepristone in violation of the UCPA, even if they do so in accordance with mifepristone's REMS. The UCPA

makes it a felony for anyone else to sell, prescribe, or dispense mifepristone, outside of the statute's narrow exceptions.

Other West Virginia laws that predate the UCPA and will take effect if a court rules the UCPA unconstitutional restrict access to mifepristone further. These laws require healthcare providers to tell patients information that contradicts mifepristone's REMS before administering the drug; for example, that mifepristone's effects may be reversible. They impose a waiting period before patients can receive mifepristone, something FDA chose not to require.

Federal law preempts West Virginia's laws. When it subjected mifepristone to a REMS with safe-use elements, Congress vested FDA with sole authority to restrict access to the drug. Congress occupied the field of regulating the prescribing and dispensing of drugs with safe-use elements by imposing a pervasive regime that demands uniformity. Congress directed FDA to balance drug safety against patient access and to minimize burdens on "patient access" to those drugs and on "the health care delivery system." 21 U.S.C. § 355-1(f)(2)(C)-(D).

West Virginia's laws destroy that balance and interfere with the role Congress reserved for FDA. To fulfill its congressional mandate,

FDA must be the sole regulator of access to mifepristone. Otherwise, the agency would be required to act against a patchwork of changing state restrictions that would prevent it from assessing whether its restrictions are unduly burdensome, as Congress commanded.

West Virginia's laws conflict with Congress and FDA's determinations about mifepristone. They make it impossible for GenBioPro to provide mifepristone in West Virginia in accordance with the REMS. They impose requirements that FDA declined to impose. And they override the determinations Congress required FDA to make about which restrictions are necessary to ensure mifepristone's safe use while minimizing burdens.

This Court should vacate the district court's opinion, reverse the challenged preemption holdings, and remand with instructions to hold West Virginia's UCPA and other restrictions invalid under the Supremacy Clause.

JURISDICTIONAL STATEMENT

The district court had subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1343(a)(3) because GenBioPro's claims present federal questions arising under the laws of the United States, including

the Supremacy Clause of the Constitution, Article VI, Clause 2; 21 U.S.C. § 355-1; and 42 U.S.C. § 1983. The court entered final judgment dismissing all claims on November 6, 2023. JA337.

GenBioPro timely filed a notice of appeal on November 9, 2023, JA338. This Court has jurisdiction to hear GenBioPro's appeal under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether West Virginia's UCPA is preempted by the FDAAA and restrictions for use imposed under FDA's statutory authority.

2. Whether West Virginia's waiting period and counseling requirement are preempted.

STATEMENT OF THE CASE

I. Federal Statutory And Regulatory Framework

A. Congress Enacted Statutes Promoting Prescription Drugs' Availability, With FDA As Gatekeeper

The history of modern drug regulation confirms Congress's intent to achieve two (at times contradictory) goals: giving patients access to necessary drug therapies while ensuring those drugs' safety. In 1938, Congress enacted the landmark Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. § 301

et seq.), following one of the most consequential mass poisonings in the 20th century.[1] The FDCA empowered FDA to prohibit manufacturers from distributing drugs FDA deemed unsafe. *Id*. § 505(a), (d)-(e), 52 Stat. at 1052-53 (codified at 21 U.S.C. § 355). Since then, Congress has amended the FDCA dozens of times, responding to public health concerns.

In the 1980s, Congress amended the FDCA to "promote the public health" by increasing drugs' availability. 21 U.S.C. § 393(b)(1); *see*, *e.g.*, Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585 (codified at 21 U.S.C. § 355) (providing abbreviated route to facilitate new drugs' approval). In 1992, it provided funding to hasten review of new drug applications. *See* Prescription Drug User Fee Act, Pub. L. No. 102-571, § 102(2), 106 Stat. 4491, 4491, *reprinted at* 21 U.S.C. § 379g note.

In 1997, Congress authorized FDA to expedite approval of drugs treating "a serious or life-threatening condition," finding that "prompt

[1] Carol Ballentine, *Sulfanilamide Disaster*, FDA Consumer (June 1981), https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf (discussing 1937 elixir sulfanilamide disaster).

approval" of "new drugs . . . is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies." Food and Drug Administration Modernization Act, Pub. L. No. 105-115, § 101(1), 111 Stat. 2296, 2298, *reprinted at* 21 U.S.C. § 379g note; *id.* § 112(a), 111 Stat. at 2309 (codified at 21 U.S.C. § 356). And in 2012, Congress required FDA to mitigate drug shortages to ensure access to FDA-approved medications. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, §§ 1001(a), 1002, 126 Stat. 993, 1100-02 (codified at 21 U.S.C. §§ 356c(g), 356c-1).

B. Congress Authorized FDA To Regulate Certain Drugs Comprehensively

In 2007, Congress enacted the FDAAA to protect access to necessary therapies. That statute "enhance[d] [FDA's] postmarket authorities" to regulate how certain drugs move through the market after their approval. FDAAA pmbl., 121 Stat. at 823.

1. Because all drugs carry some risks, FDA may approve a drug only if it determines that its benefits outweigh those risks. JA308 (¶ 34). In the FDAAA, Congress authorized FDA to impose a REMS on drugs "associated with a serious adverse drug experience." 21 U.S.C. § 355-1(b)(4). Imposing that REMS permits FDA to ensure

that "the benefits of the drug outweigh [its] risks" and approve the drug, expanding access to essential medications. *Id.* A REMS may require manufacturers to include medication guides for patients and to employ special packaging to ensure patients use the drug safely, among other safety features. *Id.* § 355-1(e).

2. In section 505-1(f) of the FDAAA, codified at 21 U.S.C. § 355-1(f), Congress imposed an even more comprehensive regime on a small subset of drugs FDA determines it can approve only with a REMS containing *additional* postmarketing "elements to assure safe use." *Id.* § 355-1(f)(2). Safe-use elements are detailed safety measures regulating every aspect of a drug, including how it is prescribed, distributed, and dispensed. Examples include:

- requiring manufacturers to certify healthcare providers and pharmacies before they can prescribe or dispense the drug[2];
- requiring healthcare providers to tell patients specific information about the drug[3];

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[2] *REMS Single Shared System for Mifepristone 200 mg* at 1-3, FDA (Mar. 2023) ("2023 Mifepristone REMS"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf.

[3] *Ambrisentan Shared System REMS Program* at 2, FDA (June 2021) ("Ambrisentan REMS"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Ambrisentan_Shared_System_2021_06_08_REMS_Full.pdf.

- limiting the dosages providers may prescribe and pharmacies may dispense[4];
- requiring pharmacies to pass a drug-specific questionnaire before dispensing it[5]; and
- requiring patients:
  - to obtain lab results or complete written examinations before and during treatment[6];
  - to be monitored during and after treatment[7];
  - to use specified forms of contraception while taking the drug[8];
  - to refrain from donating blood or sperm while taking the drug[9]; and
  - to dispose of leftover medication in specific ways.[10]

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[4] *Lenalidomide REMS Program* at 2-3, 8, FDA (Mar. 2023) ("Lenalidomide REMS"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Lenalidomide_2023_03_24_REMS_Full.pdf.

[5] *Id.* at 7, 137-39.

[6] Ambrisentan REMS, *supra* note 3, at 3-4; *Isotretinoin (iPLEDGE®) Shared System REMS Program* at 2-3, FDA (Oct. 2023) ("Isotretinoin REMS"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Isotretinoin_2023_10_03_REMS_Full.pdf.

[7] *SPRAVATO (esketamine) REMS Program* at 1-2, FDA (Jan. 2022), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Spravato_2022_01_03_REMS_Full.pdf.

[8] Isotretinoin REMS, *supra* note 6, at 2, 46; Ambrisentan REMS, *supra* note 3, at 3, 20, 25.

[9] Lenalidomide REMS, *supra* note 4, at 3, 6-7.

[10] *Id.* at 4.

Only drugs subject to REMS with safe-use elements are regulated so comprehensively.

3. When it authorized FDA to regulate how a drug is packaged, prescribed, dispensed, and taken, Congress enacted provisions protecting patients' access to these drugs. FDA may impose safe-use elements only after determining that a drug requires them to mitigate a "specific serious risk." 21 U.S.C. § 355-1(f)(1)(A).

Congress directed FDA to "[a]ssur[e] access and minimiz[e] burden" when imposing safe-use elements. *Id.* § 355-1(f)(2). It mandated that any restrictions "shall" not be "unduly burdensome" on "patient access" and must "minimize the burden on the health care delivery system" to "the extent practicable." *Id.* § 355-1(f)(2)(C)-(D). Congress required FDA's assessment of the burden on patient access to "consider[] in particular" three categories of patients:

> (i) patients with serious or life-threatening diseases or conditions;
>
> (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and
>
> (iii) patients with functional limitations.

Id. § 355-1(f)(2)(C).

The FDAAA mandates that FDA "shall" evaluate safe-use elements periodically. FDA must "assess" whether they are "unduly burdensome on patient access to the drug" and whether they practically "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(5)(B). After making that assessment, the agency "shall" modify the safe-use elements "as appropriate," *id.* § 355-1(f)(5)(C)(ii); and "shall promulgate regulations for how a physician may provide the drug," *id.* § 355-1(f)(6). Congress required that any certification necessary for healthcare providers to prescribe the drug "shall be available to any willing provider from a frontier area," and any certification for a pharmacy, practitioner, or healthcare center to dispense the drug "shall be available." *Id.* § 355-1(f)(3)(A), (B).

C. FDA Regulates Mifepristone's Prescribing And Dispensing

For more than 20 years, FDA has regulated mifepristone with safe-use elements.[11]

[11] Medication abortion, as opposed to surgical abortion, refers to using drugs to terminate a pregnancy. JA299 (¶ 2).

1. FDA approved branded mifepristone in 2000 for termination of pregnancy up to 49 days' gestation[12] and determined that "postmarketing restrictions . . . [we]re needed to assure [its] safe use." 21 C.F.R. § 314.520(a). FDA required the drug to be prescribed and dispensed to patients by (or under the supervision of) a qualified physician, not by pharmacies. JA19 (¶ 5).

That regime prevailed until 2007, when Congress ratified and augmented it by enacting the FDAAA. The FDAAA specified that mifepristone and 15 other drugs FDA already had approved with safe-use elements would be "deemed to have in effect an approved [REMS]." FDAAA § 909(b)(1), 121 Stat. at 950-51. Senators discussed the fact that the statute would require mifepristone to be distributed under a REMS. *See*, *e.g.*, 153 Cong. Rec. S5759, S5765 (daily ed. May 9, 2007) (statement of Sen. Coburn); 153 Cong. Rec. S5444, S5469 (daily ed. May 2, 2007) (statement of Sen. DeMint). FDA later identified those 16 drugs by name in the Federal Register. *See* Identification of Drug and

[12] This is sometimes called mifepristone's "indication," referring to the medical condition the drug is FDA approved to treat. *See* Letter from Ctr. for Drug Evaluation & Rsch., FDA, to S. Arnold, Vice President, Population Council at 1 (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf.

Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313, 16314 (Mar. 27, 2008).

Since 2007, FDA has regulated mifepristone with a REMS containing safe-use elements. As the FDAAA requires, the agency evaluates and updates the restrictions regularly in light of its assessment of evolving scientific evidence, real-world use, and other "data deemed appropriate by the Secretary" of Health and Human Services. 21 U.S.C. § 355-1(b)(3); *see* JA301-302 (¶ 9)

2. "FDA has continually eased restrictions on access to mifepristone," JA97, citing the medication's strong safety record. In 2021, FDA eliminated the requirement that mifepristone be dispensed in-person, to "render the REMS less burdensome to healthcare providers and patients."[13] Mifepristone's 2023 REMS enables patients to receive mifepristone through certified pharmacies and by mail.[14]

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[13] Letter from P. Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., FDA, to D. Harrison, Exec. Dir., Am. Ass'n of Pro-Life Obstetricians & Gynecologists at 6 (Dec. 16, 2021), https://www.regulations.gov/document/FDA-2019-P-1534-0016.

[14] *See* 2023 Mifepristone REMS, *supra* note 2, at 1; JA317 (¶ 66).

Mifepristone's current safe-use elements include:

- a Prescriber Agreement Form requiring providers to review the Prescribing Information, possess certain qualifications, and review a Patient Agreement Form with patients;
- a Patient Agreement Form requiring patients to confirm that they will take both mifepristone and misoprostol, have been informed of certain risks of the medication, and should follow up with their healthcare provider within two weeks; and
- a Pharmacy Agreement Form requiring pharmacy representatives to certify that their pharmacy can meet certain shipping, dispensing, and record-keeping requirements, including dispensing mifepristone within four days of receiving a prescription.[15]

II. West Virginia's Restrictions On Mifepristone

In September 2022, West Virginia enacted the UCPA, prohibiting abortion in almost all cases, at any stage of pregnancy. W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8; JA302 (¶ 11). It does not exempt abortions induced by taking mifepristone in accordance with the REMS.

1. The UCPA states that "[a]n abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional: (1) The

[15] 2023 Mifepristone REMS, *supra* note 2, at 6-13.

embryo or fetus is nonviable; (2) The pregnancy is ectopic; or (3) A medical emergency exists." W. Va. Code § 16-2R-3(a); JA318 (¶¶ 69-70). The statute contains an exception for a pregnancy that results from rape or incest that has been reported to law enforcement at least 48 hours before the abortion, if the patient is within the first eight weeks of pregnancy. W. Va. Code § 16-2R-3(b).

The law subjects physicians who perform abortions to loss of their professional license. *Id.* § 16-2R-7. It makes it a felony punishable by imprisonment for any other "person" to induce an abortion. *Id.* § 61-2-8(a). It imposes criminal penalties on some healthcare providers eligible to prescribe mifepristone under the REMS, such as registered nurses, if they prescribe mifepristone to induce an abortion. *Id.* § 16-2R-2 (defining "[l]icensed medical professional" as "a person licensed under § 30-3-1 *et seq.*, or § 30-14-1 *et seq.*, of this code," which does not include advanced practice registered nurses licensed under Chapter 30, Article 7, or physician assistants licensed under Chapter 30, Article 3E); JA318-319 (¶ 71).

The UCPA also prohibits "attempt[ing]" to perform or induce an abortion outside of the statute's narrow exceptions. W. Va. Code § 16-

2R-3(a). It defines an "[a]ttempt to perform or induce an abortion" as an act "that, under the circumstances as the person so acting . . . believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion." *Id.* § 16-2R-2. Under this definition, healthcare providers not defined as "[l]icensed medical professional[s]," such as pharmacists, could be held liable for attempt if they provide mifepristone in accordance with the REMS. *Id.* (defining "[l]icensed medical professional" to exclude pharmacists, who are licensed under Chapter 30, Article 5 of the West Virginia Code); *id.* § 61-2-8(a) (providing criminal penalties for "[a]ny person other than a licensed medical professional" who "attempts to perform or induce an abortion").

2. West Virginia also banned healthcare providers from prescribing mifepristone by telemedicine. *Id.* §§ 30-3-13a(g)(5), 30-1-26(b)(9).[16]

3. Before the UCPA took effect, West Virginia restricted access to mifepristone in two additional ways. First, it required healthcare providers to communicate particular information to patients when

[16] These telemedicine provisions are not at issue in this appeal.

prescribing mifepristone. Providers had to tell patients that "it may be possible to counteract the intended effects of a mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug," *id.* § 16-2I-2(a)(4)(A); and that "the father, if his identity can be determined, is liable to assist in the support of her child," *id.* § 16-2I-2(b)(2). Providers had to "list agencies and entities which offer alternatives to abortion." *Id.* § 16-2I-2(b)(4) (collectively, West Virginia's "counseling requirement").

Second, West Virginia required healthcare providers to obtain patients' "informed consent" at least 24 hours before taking mifepristone. That entailed delivering the information outlined in section 16-2I-2 to patients and requiring them to sign a form affirming that they had been "informed of [the] opportunity to view the ultrasound image" of the fetus. *Id.* § 16-2I-2(c)(3) (West Virginia's "waiting period").

The waiting period and counseling requirement have "no[] effect[]" while the UCPA is in force but become "immediately" operational if the statute is struck down. *Id.* § 16-2R-9.

4. In 2019, GenBioPro received FDA approval to sell generic mifepristone. It is the only U.S. company licensed to do so and has sold more than 850,000 units of the drug throughout the United States. JA299-300 (¶ 3). The UCPA, waiting period, and counseling requirement, however, make it impossible for GenBioPro to provide mifepristone in West Virginia for its FDA-approved use in accordance with mifepristone's REMS, as it does in other states. JA303-304 (¶ 16), JA322 (¶ 77).

Major national pharmacy chains that operate stores in West Virginia stated publicly that they intend to sell mifepristone now that the REMS permits retail pharmacies to dispense it. JA322 (¶ 78). HoneyBee Health, which ships prescription drugs nationwide, also would provide mifepristone in the State. JA322 (¶ 78). But the UCPA blocks GenBioPro from providing mifepristone in West Virginia through these healthcare distribution mechanisms by criminalizing any "substantial step in a course of conduct intended to culminate in an abortion" falling outside of the law's narrow exceptions. W. Va. Code § 16-2R-2.

III. Procedural History

In January 2023, GenBioPro sued, alleging that federal law preempts the UCPA and the State's other restrictions on mifepristone. JA303-304 (¶¶ 15-16).[17] These laws, and the threat of their enforcement, cause GenBioPro economic injury in the form of lost sales, customers, and revenue. JA322 (¶ 79). GenBioPro sought equitable and declaratory relief enjoining Appellees from enforcing West Virginia's unconstitutional laws. JA306 (¶ 26).

1. The district court held that GenBioPro adequately alleged standing and a cognizable injury in the form of lost business opportunities. JA103-106.

2. On August 24, 2023, the district court granted Appellees' motions to dismiss in substantial part. JA254-289. At the outset, it found the major questions doctrine inapplicable, because FDA regulates mifepristone "pursuant to an explicit grant of authority as to a single prescription medication." JA261-262.

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[17] This brief will cite GenBioPro's First Amended Complaint, JA299-331, except where noted. GenBioPro's First Amended Complaint does not challenge West Virginia's ban on prescribing mifepristone via telemedicine.

The court held that the UCPA was not preempted. It applied a "presumption against preemption," reasoning that states historically regulated "health and safety," and "regulating abortion" and "medical professionals" are matters of health and safety subject to state police power. JA264-266.

The court found no field preemption. It defined the field as "health, medicine, and medical licensure," and held it was one in which states traditionally regulated. JA275-277.

The court found no conflict preemption, with one exception described below. It held that the FDAAA's provisions requiring FDA to minimize the burden on patient access limited only FDA's *own* restrictions. JA266-268. It reasoned that, when Congress enacted the FDAAA, a right to terminate early pregnancy was constitutionally protected. Therefore, it was implausible to infer that Congress meant to preempt "state abortion law" that "would have been unconstitutional at the time." JA269.

The court also held that the UCPA regulates only "licensed medical professionals," not GenBioPro. JA271. But even if GenBioPro could assert the interests of healthcare providers, the court found no

conflict, because the REMS "specif[ies] the *methods* by which mifepristone may be prescribed," whereas the UCPA "instructs" providers in West Virginia "to only perform abortions when certain extrinsic criteria are present." JA272 (emphasis added).

The court held that another challenged restriction, West Virginia's ban on prescribing mifepristone via telemedicine, W. Va. Code §§ 30-3-13a(g)(5), 30-1-26(b)(9), conflicts with the REMS, which "reflects a determination by the FDA that when mifepristone is prescribed, it may be prescribed via telemedicine." JA277. It held that Congress "allocated to the FDA" authority to determine "the manner in which mifepristone may be prescribed." JA278. The court observed that West Virginia's waiting period and counseling requirement "might be likewise preempted by direct conflict with the REMS" but declined to rule on these restrictions because they would go into effect only if the court struck down the UCPA. JA278.

3. GenBioPro amended its complaint to facilitate entry of a final order. The First Amended Complaint does not challenge West Virginia's telemedicine ban. JA293-296, JA299-331. The district court

entered final judgment on November 6, 2023. JA337. GenBioPro timely appealed. JA338.

SUMMARY OF ARGUMENT

I. Congress preempted West Virginia's UCPA, waiting period, and counseling requirement.

A. In the FDAAA, Congress occupied the limited field of restrictions on access to drugs subject to a REMS with safe-use elements. The FDAAA's pervasive regime regulating these drugs end-to-end evinces Congress's intent to displace state law in this area. That regime vests FDA alone with authority to determine which patients may receive mifepristone, and where, when, and how the drug is prescribed and dispensed.

Congress's dominant interest in subjecting these drugs to uniform regulation demonstrates its preemptive intent. Because the FDAAA directs FDA to balance safety against access to mifepristone, it leaves no room for state restrictions. West Virginia's laws encroach on this field by imposing additional burdens on patients' access and on the healthcare delivery system, rendering impossible a uniform FDA scheme governing access to the drug.

B. West Virginia's laws conflict with mifepristone's REMS with safe-use elements. They make providing mifepristone in the State practically impossible. The UCPA subjects GenBioPro and its customers to criminal penalties if they provide mifepristone for its FDA-approved use. That law, like the State's mandatory waiting period and counseling requirement, interferes with Congress's goal in passing the FDAAA: to ensure patients' safe access to drugs like mifepristone, with minimal burden.

West Virginia imposes restrictions that FDA determined did not assure patient safety while minimizing burdens on access and on the healthcare delivery system. The UCPA is the most restrictive form of regulation; it bars virtually all patients from access to mifepristone. FDA chose not to restrict mifepristone to certain patient groups.

West Virginia's waiting period requires patients to wait 24 hours before taking mifepristone. FDA chose not to impose a waiting period. West Virginia's counseling requirement requires healthcare providers to tell patients information that contradicts information in the REMS's Patient Agreement Form.

II. The district court's holding that the FDAAA does not preempt West Virginia's restrictions on mifepristone rests on three errors.

A. The court misidentified the regulatory field. It failed to recognize that Congress occupied the narrow field of regulating access to REMS drugs subject to safe-use elements.

B. The court mistakenly held that the FDAAA constrains *FDA's* regulation of mifepristone but permits states to restrict access to the drug. That approach impermissibly allows states to impose restrictions when Congress vested FDA with authority to balance safety against burdens on patients and the healthcare delivery system.

The court erroneously concluded that the UCPA regulates only licensed medical professionals, not GenBioPro. But that statute regulates every person or company in West Virginia that takes a substantial step intending to culminate in an abortion.

C. The court applied a presumption against preemption, reasoning that the UCPA regulates in an arena of traditional state authority — health and safety. But regulating access to REMS drugs with safe-use elements is an exclusively federal domain.

STANDARD OF REVIEW

The Court reviews the district court's grant of a motion to dismiss for failure to state a claim de novo. *Bonds v. Leavitt*, 629 F.3d 369, 385 (4th Cir. 2011). The Court "must accept as true all of the factual allegations contained in the complaint" and draw reasonable inferences in favor of Plaintiff-Appellant. *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 188 (4th Cir. 2007) (cleaned up).

ARGUMENT

I. CONGRESS PREEMPTED WEST VIRGINIA'S RESTRICTIONS ON MIFEPRISTONE

The Supremacy Clause makes the laws of the United States "the supreme Law of the Land." U.S. Const. art. VI, cl. 2. "Federal preemption of state law is the result of that basic structural guarantee." *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 761 (4th Cir. 2018).

Congress can preempt state law by occupying a regulatory field, "leav[ing] no room for the States to impose different or stricter . . . requirements." *United States v. Locke*, 529 U.S. 89, 110 (2000) (cleaned up). In addition, "state laws that conflict with federal law are 'without effect.'" *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013) (citation omitted). State laws are preempted to the extent

they impede the attainment of Congress's objectives. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873 (2000).

West Virginia's restrictions on mifepristone are preempted under those doctrines.

A. Congress Occupied The Field Of Regulating Access To REMS Drugs With Safe-Use Elements

Congress demonstrates an "intent to displace state law altogether" when it creates "a framework of regulation so pervasive that Congress left no room for the States to supplement it." *Arizona v. United States*, 567 U.S. 387, 399 (2012) (cleaned up); *see Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 157 (1978) (same). This intent is evident where Congress imposes a "comprehensive scheme of federal control." *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624, 629 (1973).

Congress also can occupy a field "where there is a federal interest so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399 (cleaned up); *see Ray*, 435 U.S. at 157 (same). To assess whether federal interests dominate, courts examine whether Congress vested "exclusive authority" in a federal agency to regulate in a particular field. *Ray*, 435 U.S. at 159. A statute emphasizing the mandatory

nature of the agency's obligation to determine which restrictions are "necessary" "indicates . . . that Congress intended uniform national standards" to govern the field. *Id.* at 161, 163. So does a statute vesting a federal agency with exclusive authority "to balance a number of considerations" in exercising regulatory power. *Id.* at 177.

Each of these factors is present here.

1. Congress established pervasive regulation of access to drugs with safe-use elements

When Congress "'regulat[es] so pervasively that there is no room left for the states to supplement federal law,'" it has occupied that field. *United States v. South Carolina*, 720 F.3d 518, 528 (4th Cir. 2013) (citation omitted). Statutes setting forth "detailed and comprehensive regulations" preempt state regulation. *Ramah Navajo Sch. Bd., Inc. v. Bureau of Revenue of N.M.*, 458 U.S. 832, 840 (1982).

In the FDAAA, "Congress has legislated comprehensively" with respect to drugs subject to a REMS with safe-use elements, "leaving no room for the States to supplement federal law." *PPL EnergyPlus, LLC v. Nazarian*, 753 F.3d 467, 474 (4th Cir. 2014) (cleaned up), *aff'd sub nom. Hughes v. Talen Energy Mktg., LLC*, 578 U.S. 150 (2016); *cf. Ramah*, 458 U.S. at 841-42 (regulatory scheme that articulates detailed

"direction and supervision provided by the Federal Government . . . le[ft] no room for the additional burden" state sought to impose).

Section 355-1 dictates what FDA must do in imposing a REMS. If the Secretary (or specified "division directors") determines, after reviewing enumerated factors, that a REMS "is necessary to ensure that the benefits of [a] drug outweigh the risks of the drug," a drug manufacturer "shall" submit a proposed REMS to the Secretary. 21 U.S.C. § 355-1(a)(1), (2), (4). The Secretary may require a REMS to include additional features if he makes specified determinations as to each one. *Id.* § 355-1(c), (e). A REMS may include a medication guide, patient inserts, a communication plan, packaging requirements, disposal requirements, and safe-use elements. *Id.* § 355-1(e), (f).

Congress requires the Secretary to make specific determinations before imposing safe-use elements. The Secretary must determine that the drug "can be approved only if, or would be withdrawn unless" the safe-use elements are required, and "other elements" described in the statute "are not sufficient." *Id.* § 355-1(f)(1)(B). The elements must be "necessary to assure safe use of the drug." *Id.*

Safe-use elements "shall" "be commensurate with the" drug's specific "serious risk" while not "be[ing] unduly burdensome on patient access to the drug." *Id.* § 355-1(f)(2)(A), (C). They "shall" be designed "to minimize the burden on the health care delivery system" "to the extent practicable." *Id.* § 355-1(f)(2)(D). In designing these elements, the Secretary "shall . . . seek input from patients, physicians, pharmacists, and other health care providers about how" safe-use elements "may be standardized" to minimize those burdens. *Id.* § 355-1(f)(5)(A).

Once FDA imposes safe-use elements, the agency "shall" reevaluate them "periodically" "to assess" whether they are "unduly burdensome on patient access" and "the health care delivery system." *Id.* § 355-1(f)(5)(B). FDA "shall" "seek input from patients" and other participants in the healthcare delivery system to ensure safe-use elements are not "unduly burdensome on patient access" and "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(5)(A). The agency "shall" — "considering such input and evaluations" — modify those elements "as appropriate." *Id.* § 355-1(f)(5)(C). In short,

Congress told FDA which determinations to make and how to make them.

A REMS with safe-use elements governs every aspect of the drug — the who, when, where, and how. For mifepristone, FDA regulates *which* patients may receive the drug and *how*, *from whom* patients may receive a prescription and *how*, and *where* the drug is dispensed. Patients must sign the Patient Agreement Form confirming that they will take mifepristone as directed.[18] Healthcare providers must meet specific eligibility criteria and become specially certified to prescribe mifepristone.[19] Pharmacies, too, must meet eligibility criteria and be specially certified to dispense mifepristone.[20] GenBioPro, the manufacturer, must make these certifications available to providers and pharmacies and ensure that those providers and pharmacies comply with the REMS. *Id.* § 355-1(f)(3)(B).[21] By vesting such

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[18] 2023 Mifepristone REMS, *supra* note 2, at 10.

[19] *Id.* at 6-9.

[20] *Id.* at 11-13.

[21] REMS for other safe-use drugs are similarly detailed. For example, to become certified to prescribe Aveed, a drug treating hormonal imbalances, providers must ensure their primary healthcare setting is enrolled in the REMS, participate in an educational program, and successfully complete a knowledge assessment. *Risk Evaluation*

"pervasive control" in FDA, Congress left "no room for" "state and local control." *Lockheed*, 411 U.S. at 633, 638.

2. Congress has a dominant federal interest in regulating access to REMS drugs with safe-use elements

a. When a "federal interest" is "dominant," "the federal system will be assumed to preclude enforcement of state laws on the same subject." *Arizona*, 567 U.S. at 399 (cleaned up). The federal government has a dominant interest when it must maintain uniform regulatory standards to create workable policy. *Cf. Campbell v. Hussey*, 368 U.S. 297, 300-01 (1961) ("Under the federal law" governing tobacco labeling "there can be but one 'official' standard — one that is 'uniform' and that eliminates all confusion . . . . ").

Thus, for immigration policy to be workable, the federal government alone must "maintain[] a comprehensive and unified system to keep track of aliens within the Nation's borders." *Arizona*, 567 U.S. at 401-02. Similarly, to achieve "a uniform and exclusive system of federal regulation" of aircraft noise, federal law required the

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and Mitigation Strategy (REMS) Document at 2, FDA (May 2022), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Aveed_2022_05_26_REMS_Full.pdf.

Federal Aviation Administration to consider "particularized standards": assess specific data, consult with agencies, and evaluate the safety and economic effects of a regulation. *Lockheed*, 411 U.S. at 632, 639. Congress thereby preempted state regulation — after all, "[p]lanes do not wander about in the sky like vagrant clouds" but "move only by federal permission," "under an intricate system of federal commands." *Id.* at 633-34.

Applying these principles here requires the same conclusion. Regulating access to prescription drugs with postmarketing restrictions is a federal function. REMS drugs with safe-use elements do not appear on the market, and are not made available or unavailable, according to the vagaries of state or local law. FDA has had sole authority to approve prescription drugs for marketing in interstate commerce since the inception of modern drug regulation. *See* 21 U.S.C. § 355-1(a).[22] Drugs with safe-use elements can be approved

[22] Nor have states banned prescription drugs that FDA approved; a court found that the rare state law attempting to do so would be preempted. *See Zogenix, Inc. v. Baker*, 2015 WL 1206354, at *4 (D. Mass. Mar. 17, 2015) (denying motion to dismiss a preemption challenge to a Massachusetts law purporting to ban an FDA-approved drug).

only after FDA makes a series of determinations, including that any restrictions minimize the burdens Congress specified. *Id.* § 355-1(f)(2)(C)-(D). Such drugs may be packaged, prescribed, dispensed, and disposed of only under a comprehensive federal regulatory mechanism. *See id.* § 355-1(e)(4), (f).

"The moment" a drug like this enters the market, "it is caught up in an elaborate and detailed system of controls." *Lockheed*, 411 U.S. at 634 (cleaned up); *see also Ray*, 435 U.S. at 166 n.15 (such statutes demonstrate that Congress considered the subject a "matter[] for national attention," with preemptive effect).

This system is national in reach and character. In requiring FDA to minimize burdens on patient access, Congress identified patient groups by nationally applicable criteria: those in "rural or medically underserved areas," and those with "serious or life-threatening diseases or conditions." 21 U.S.C. § 355-1(f)(2)(C)(i)-(ii). Similarly, Congress ordered FDA to consider the burden on the national "health care delivery system" in calibrating restrictions on access. *Id.* § 355-1(f)(2)(D). These determinations cannot vary by locality, nor can restrictions on access.

It is impossible for FDA to fulfill its requirement to assess whether a given REMS unduly burdens patients if FDA also has to consider a multitude of inconsistent and conflicting state rules. A patchwork of changing state restrictions would prevent FDA from ensuring that restrictions do not unnecessarily burden the healthcare delivery system and are "compatible with established distribution, procurement, and dispensing systems for drugs." *Id.* Yet Congress required FDA to make these assessments and update them periodically. *Id.* § 355-1(f)(5)(B).

b. Congress signals its intent to preclude state regulation in a field where it "mandate[s] federal rules on the subjects or matters there specified, demanding uniformity." *Locke*, 529 U.S. at 110; *see also Ray*, 435 U.S. at 163, 166 (Congress mandated uniform federal rules on tanker design, construction, and other topics, preempting state regulation). In *Ray*, the Court emphasized the mandatory nature of the obligation Congress imposed on the Secretary of Transportation, who "'shall establish' such rules and regulations as may be necessary with respect to the design, construction, and operation of the covered vessels." 435 U.S. at 161. Where Congress "did not leave" a federal

agency "to act at large but provided . . . particularized standards" dictating the factors the agency must "consider," state restrictions have no role. *Lockheed*, 411 U.S. at 632.

Congress's use of "shall" throughout section 355-1 indicates that it vested exclusive authority in FDA to regulate access to drugs with safe-use elements. *See Maine Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1320 (2020) ("shall" denotes "mandatory language"). When FDA subjects a drug to safe-use elements, it "shall" periodically reevaluate them, 21 U.S.C. § 355-1(f)(5)(B), and "shall" modify those elements "as appropriate," *id.* § 355-1(f)(5)(C)(ii). Restrictions may "not be unduly burdensome on patient access to the drug" and must "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(C)-(D). The regime's mandatory character "dictates that the federal judgment" about whether, when, and how to restrict access to these drugs "prevail[s] over the contrary state judgment." *Ray*, 435 U.S. at 165.

c. Congress demonstrates its "anticipat[ion] that there would be a single decisionmaker" in the field by directing a federal agency to "balance a number of considerations" when it "promulgates limitations."

Id. at 177. When a statute "vest[s]" "pervasive control" in federal agencies and "requires a delicate balance between safety and" another value, it "leave[s] no room" for state "controls." *Lockheed*, 411 U.S. at 638.

This Court applied that principle in holding that Congress preempted a state program to subsidize a power plant's participation in the federally regulated wholesale energy market. *PPL EnergyPlus*, 753 F.3d at 474-76. The Court reasoned that "the federal markets are the product of a finely-wrought scheme that attempts to achieve a variety of different aims" and that "the federal scheme is carefully calibrated to protect a host of competing interests." *Id.* at 473. Such a regime "leaves no room either for direct state regulation of the prices of interstate wholesales of energy, or for state regulations which would indirectly achieve the same result." *Id.* at 475 (cleaned up).

The FDAAA is precisely such a statute. Congress established the "competing interests" FDA must consider and told the agency how to balance them. *PPL EnergyPlus*, 753 F.3d at 473. FDA "shall" consider whether restrictions "unduly" burden patient access to the drug. 21 U.S.C. § 355-1(f)(2)(C). It must "minimize" burdens on the

healthcare delivery system "to the extent practicable." *Id.* § 355-1(f)(2)(D). The Secretary "shall . . . seek input" from stakeholders to ensure patient access and the healthcare delivery system are not "unduly burden[ed]" and modify any restrictions accordingly. *Id.* § 355-1(f)(5). FDA must seek such input before requiring safe-use elements and when assessing them periodically and must factor this input into the nationally applicable REMS elements. *Id.*

In weighing those burdens, FDA must "consider[] in particular" the impact on particular categories of patients. *Id.* § 355-1(f)(2)(C); *supra* p.10. "[T]o the extent practicable," FDA must "conform" the safe-use elements to "drugs with similar, serious risks" and ensure restrictions are "designed to be compatible with established distribution, procurement, and dispensing systems," "so as to minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(D). The scheme is "carefully calibrated to protect a host of competing interests," *PPL EnergyPlus*, 753 F.3d at 473, precluding states from altering the balance of burdens. Permitting states to enact post-hoc rules on REMS drugs with safe-use elements makes FDA balancing of interests impossible.

The FDAAA's legislative history confirms Congress's intent to grant FDA alone authority "to ensure that the balance between the benefit and the risk remains in equilibrium" so that "patients have access to life-saving and life-improving medications." 153 Cong. Rec. H10595 (daily ed. Sept. 19, 2007) (statement of Rep. Barton). Congressional representatives expressed concern that state regulation could undermine FDA's careful balancing and "potentially adversely affect public health."[23] Others worried it would be "counterproductive to public health for States to impose different REMS requirements than those imposed by the FDA"[24] and stressed that allowing state regulation in this area could "be confusing to consumers."[25]

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[23] *Discussion Drafts Concerning Prescription Drug User Fee Act Reauthorization, Medical Device User Fee and Modernization Act Reauthorization, Drug Safety, and Certain Pediatric Pharmaceutical and Device Legislation: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. 54 (2007) (statement of Rep. John Sullivan).

[24] *Id.* at 50 (statement of Rep. Joseph R. Pitts).

[25] *Id.* at 54 (statement of Rep. John Sullivan).

3. Pervasive and uniform federal regulation leaves no room for West Virginia to restrict access to mifepristone

West Virginia's restrictions encroach on the limited field of regulating REMS drugs with safe-use elements. These laws strike a different balance than FDA's. They restrict patients' access to mifepristone; impose different judgments on whether and how healthcare providers may prescribe the drug; and penalize pharmacies for dispensing it under federally permissive rules. Such state interference burdens patients and the healthcare system and destroys FDA's uniform regulation.

First, West Virginia's laws impose severe burdens on patients' access to mifepristone. The UCPA prevents virtually all REMS-eligible patients from receiving the drug. W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8. A patient must have a nonviable pregnancy or be experiencing a "medical emergency," as narrowly defined by the UCPA, or the pregnancy must result from a reported rape or incest (but only if it is within the first eight weeks of gestation). *Id.* § 16-2R-3.

West Virginia's remaining restrictions constrain patients' access and dictate how providers may prescribe mifepristone. They impose a

waiting period before patients may receive a prescription and require providers to relay specific information to dissuade patients from seeking abortion care. *See supra* pp.16-17.

Federal safe-use elements for mifepristone do not contain those restrictions. Eligible patients must only sign a Patient Agreement Form stating that they "will take mifepristone on Day 1," followed by "misoprostol tablets 24 to 48 hours after," and that their healthcare provider has counseled them "regarding the risk of serious complications associated with mifepristone" (e.g., heavy bleeding and infection).[26]

West Virginia also imposes burdens, not found in the REMS, on the healthcare delivery system. The UCPA subjects doctors to loss of their license when they prescribe mifepristone for its FDA-approved use: abortion. W. Va. Code § 16-2R-7. Other licensed healthcare providers face criminal penalties for providing mifepristone in accordance with the REMS. *Id.* § 61-2-8(a).[27] The UCPA burdens

[26] 2023 Mifepristone REMS, *supra* note 2, at 4, 10.

[27] West Virginia allows clinicians such as advanced practice registered nurses and physician assistants to prescribe drugs and diagnose patients, making them eligible to prescribe mifepristone under the 2023 REMS. 2023 Mifepristone REMS, *supra* note 2, at 8;

pharmacies, which cannot provide mifepristone despite being allowed to under the REMS. *Id.*; *supra* p.18. And the statute imposes burdens on GenBioPro, which cannot provide the drug in accordance with the REMS. *See* W. Va. Code § 16-2R-1 *et seq.*; *id.* § 61-2-8; JA322 (¶ 77).

As implemented by FDA, mifepristone's REMS imposes significant burdens on entities in the healthcare supply chain. *See supra* pp.14, 30. (requiring GenBioPro to certify healthcare providers and pharmacists to prescribe or dispense mifepristone). But these burdens are entirely different from those West Virginia imposes.

Section 355-1(f) permits only FDA to impose requirements on REMS drugs with safe-use elements. Such rules must minimize the burden on the healthcare delivery system. By preventing nearly all patients from obtaining mifepristone and subjecting healthcare providers, including pharmacists, to criminal and other severe penalties, the UCPA *maximizes* the burden. The UCPA thus disrupts

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W. Va. Code §§ 30-3E-1, 30-3E-12 (physician assistants); *id.* §§ 30-7-1, 30-7-15b(a) (advanced practice registered nurses); *see supra* pp.15-16 (UCPA subjects advanced practice registered nurses and physician assistants to criminal penalties for prescribing mifepristone to most patients).

the federal "balance of statutory objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

B. West Virginia's Restrictions Impermissibly Interfere With FDA's Required Determinations

State restrictions are "naturally preempted to the extent of any conflict with a federal statute." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citations omitted). Conflict preemption occurs "when compliance with both state and federal law is impossible, or when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress.'" *Locke*, 529 U.S. at 109 (citations omitted). A state law obstructs congressional objectives when it inhibits the "execution of the federal [regulatory] system and interfere[s] with the discretion entrusted to federal . . . officials." *South Carolina*, 720 F.3d at 530.

1. West Virginia's laws make it impossible for GenBioPro to provide mifepristone in accordance with the REMS

State law is preempted "where it is impossible for a private party to comply with both state and federal requirements." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990). A party that manufactures a product subject to conflicting federal and state regulation is not

expected to "pull[]" its product "from the market" or "stop selling" to avoid such a conflict. *Bartlett*, 570 U.S. at 475, 487 n.3 (cleaned up). Moreover, when federal regulations "are drawn not only to bar what they prohibit but to allow what they permit," those federal laws preempt "inconsisten[t]" state law on the same subject matter. *Crosby*, 530 U.S. at 380.

It is impossible for GenBioPro to comply with both mifepristone's REMS and the UCPA without ceasing sales in West Virginia for all intents and purposes. The FDAAA "deemed" mifepristone "to have in effect an approved" REMS in 2007. *Supra* pp.12-13. FDA has updated mifepristone's REMS with safe-use elements over time in response to new data, pursuant to its statutory obligations, to impose only those burdens on access necessary to assure the drug's safe use. 21 U.S.C. § 355-1(f)(2). *Supra* pp.13-14. GenBioPro provides mifepristone for its FDA-approved use in accordance with these detailed requirements. JA299-300 (¶ 3), JA322 (¶ 77). It certifies healthcare providers to prescribe mifepristone and certifies pharmacies to dispense it.[28]

[28] 2023 Mifepristone REMS, *supra* note 2, at 1-3.

The UCPA prohibits GenBioPro from conducting its normal business in West Virginia. It bans the medication's use in virtually all circumstances for which it is approved, with highly circumscribed exceptions, and it subjects GenBioPro to potential criminal sanctions for providing it. *See* W. Va. Code § 61-2-8 (criminalizing "[a]ny person . . . who . . . performs, induces, or *attempts* to perform or induce an abortion") (emphasis added); *id.* § 2-2-10(a)(9) (defining "Person" to include "corporations"); *id.* § 16-2R-2 (an "[a]ttempt to perform or induce an abortion" is "an act . . . that . . . constitutes a substantial step in a course of conduct intended to culminate in an abortion"). GenBioPro can comply with both federal and state law only by "pull[ing]" its product "from the market" in West Virginia — something the law does not require. *Bartlett*, 570 U.S. at 475, 487 n.3.

2. West Virginia's laws interfere with the balance Congress and FDA struck

a. A state law that "stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in passing a federal statute is conflict preempted. *South Carolina*, 720 F.3d at 533 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

The FDAAA's preamble states its objective: to expand access to life-saving drugs that would not be available to patients but for FDA's "enhance[d]" "postmarket authorit[y]." FDAAA pmbl., 121 Stat. at 823; *see* 21 U.S.C. § 355-1(f). The statute authorizes FDA to "[p]rovid[e] safe access for patients to drugs with known serious risks that would otherwise be unavailable" by imposing safe-use elements. 21 U.S.C. § 355-1(f). Any restrictions must "[a]ssur[e] access and minimiz[e] burden" on patient access and the healthcare delivery system. *Id.* § 355-1(f)(2). Legislative history confirms the FDAAA's focus on expanding access to covered medication. *Supra* p.38. And Congress "deemed" mifepristone to have in effect a REMS assuring patient access to the drug. FDAAA § 909(b)(1), 121 Stat. at 950-51.

West Virginia's laws thwart this purpose. They impose severe burdens on patients' access to mifepristone and on the healthcare system. *See supra* pp.14-17, 44. This undermines Congress's objectives.

b. "When Congress charges an agency with balancing competing objectives, it intends the agency to use its reasoned judgment to weigh the relevant considerations and determine how best to prioritize between these objectives" — "[a]llowing state law to impose a

different standard permits a re-balancing of those considerations." *Farina v. Nokia Inc.*, 625 F.3d 97, 123-24 (3d Cir. 2010) (holding lawsuits challenging federal standards on radio frequency emissions conflict-preempted).

Accordingly, state laws that "upset the careful balance struck by Congress" in a scheme of federal regulation are preempted. *Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982); *see Buckman*, 531 U.S. at 348 (state laws that "skew[]" a "delicate balance of statutory objectives" are preempted); *OpenRisk, LLC v. Microstrategy Servs. Corp.*, 876 F.3d 518, 523 (4th Cir. 2017) (holding "states may not upset" the "balance" that "Congress . . . struck . . . between the free flow of ideas in the public domain, on the one hand, and the protection of certain forms of intellectual property, on the other"). Even a state law that shares the same objective as the federal regime is preempted if "it interferes with the methods by which the federal statute was designed to reach this goal." *International Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987); *Columbia Venture, LLC v. Dewberry & Davis, LLC*, 604 F.3d 824, 830 (4th Cir. 2010) (same).

These principles require finding that West Virginia's restrictions conflict with the FDAAA. In the FDAAA, Congress established a balance between access and burden. *Supra* pp.33-34. West Virginia's laws upset this balance. They "dramatically increase" burdens on patient access and on the healthcare delivery system. *Buckman*, 531 U.S. at 350; *supra* pp.14-17, 44. They also interfere with Congress's methods, requiring FDA to review data, 21 U.S.C. § 355-1(b)(3); confer with stakeholders, *id.* § 355-1(f)(5); and reassess restrictions to ensure they continue to comply with section 355-1's mandate, *id.* § 355-1(f)(5)(B). *See supra* pp.28-30.

The UCPA and other restrictions do not complement or supplement the FDAAA's objectives. They contradict them, leading to a "clash" between Congress's direction that FDA reduce burdens on access to mifepristone and on the healthcare entities that deliver it, and West Virginia's restrictions on access and its imposition of criminal sanctions on participants in that healthcare delivery system. *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1329 (Fed. Cir. 2017) (quoting *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964)).

c. Courts find conflict preemption when a federal agency "has promulgated its own requirement on the subject or has decided that no such requirement should be imposed at all." *Locke*, 529 U.S. at 110 (applying conflict preemption analysis to part of statute). State law "limit[ing] the availability of an option the [federal agency] considered essential to" ensure its objectives is preempted. *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 156 (1982). When a state and federal law "cannot move freely within the orbit of their respective purposes without infringing upon one another," the state law must yield. *Hill v. Fla. ex rel. Watson*, 325 U.S. 538, 543 (1945) (cleaned up).

The UCPA conflicts with mifepristone's REMS by imposing restrictions FDA determined were unnecessary to assure safety while minimizing burdens. 21 U.S.C. § 355-1(f). The FDAAA requires FDA to determine the situations in which mifepristone is accessible; the agency determines when mifepristone may be safely administered to patients with "serious or life-threatening . . . conditions," including pregnancy. *Id.* § 355-1(f)(2)(C)(i).[29] FDA fulfilled that mandate by determining

[29] *See* Letter from J. Woodcock, FDA, to D. Harrison, Am. Ass'n of Pro Life Obstetricians & Gynecologists at 4 n.6 (Mar. 29, 2016) (pregnancy entails a risk of death "approximately 14 times higher" than

patients should be able to access mifepristone through specially certified prescribers and pharmacies.

In other REMS containing safe-use elements, FDA required patients to demonstrate eligibility for the drug by meeting certain diagnostic criteria.[30] FDA decided not to impose such restrictions for mifepristone. *Cf. id.* § 355-1(f)(3)(D) (permitting FDA to restrict dispensing to certain patients). This reflects FDA's determination that such a limitation would unduly burden patient access and the healthcare system. The UCPA conflicts with this decision, barring access to mifepristone for all patients except those meeting specified, seldom-satisfied criteria. W. Va. Code § 16-2R-3.

The UCPA also requires providers to apply different criteria in prescribing mifepristone to patients than those FDA imposed. Under the REMS, a provider who obtains the necessary certification agrees to review the Patient Agreement Form with the patient, "fully explain[]"

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that "associated with legal abortion"), https://downloads.regulations.gov/FDA-2002-P-0364-0002/attachment_1.pdf.

[30] Isotretinoin's REMS, for example, requires patients who can become pregnant to take a pregnancy test before being prescribed the drug and requires all patients to answer drug-specific "[c]omprehension [q]uestions." Isotretinoin REMS, *supra* note 6, at 2.

the risks of the treatment regimen, and answer "any questions the patient may have prior to receiving mifepristone."[31]

The UCPA adds a threshold requirement: before a patient can receive mifepristone, the prescriber must assess whether the patient carries a nonviable fetus, is experiencing a medical emergency, or carries a pregnancy of fewer than eight weeks' gestation that resulted from rape or incest that has been reported to law enforcement at least two days prior. *See id.* § 16-2R-3(a)-(b). Only patients satisfying this inquiry can receive mifepristone in West Virginia. But this threshold requirement is not part of the Patient Agreement Form; it is not found in the REMS at all.

By imposing restrictions that FDA did not determine were necessary to assure safety, the UCPA "limit[s] the availability of" mifepristone that "the [federal agency] consider[ed] essential to" meet its statutory goals. *de la Cuesta*, 458 U.S. at 156.

d. West Virginia's counseling requirement and waiting period, which will go into effect if the UCPA is ruled unlawful, likewise conflict with mifepristone's safe-use elements. W. Va. Code § 16-2I-2.

[31] 2023 Mifepristone REMS, *supra* note 2, at 1-2, 6.

The REMS's Patient Agreement Form specifies that patients understand they will take both "mifepristone and misoprostol to end [their] pregnancy."[32] The Prescriber Agreement requires only that a physician review the Patient Agreement Form, "fully explain[]" the "risks of the mifepristone treatment regimen," answer any "questions the patient may have," and ensure the patient receives and signs the form.[33] West Virginia requires healthcare providers to communicate the opposite — they must inform patients that "it may be possible to counteract the intended effects of . . . mifepristone . . . by taking" misoprostol. *Id.* § 16-2I-2(a)(4)(A). West Virginia thus requires providers to tell patients information inconsistent with the REMS.

As for the waiting period, West Virginia requires healthcare providers to wait 24 hours before prescribing mifepristone. *Id.* § 16-2I-2. FDA chose not to impose a waiting period for mifepristone, as it has for other drugs; for example, Isotretinoin's REMS requires patients to take a pregnancy test and then wait at least 19 days before beginning

[32] 2023 Mifepristone REMS, *supra* note 2, at 10.

[33] *Id.* at 1-2, 6.

treatment.[34] FDA's decision not to impose a waiting period for mifepristone reflects its determination that a waiting period is unnecessary and would not assure access while minimizing the burdens on patients and the healthcare delivery system. 21 U.S.C. § 355-1(f).

II. THE DISTRICT COURT ERRED IN HOLDING THAT THE FDAAA DOES NOT PREEMPT WEST VIRGINIA'S RESTRICTIONS ON MIFEPRISTONE

A. The District Court Erred In Analyzing Field Preemption

1. The district court misidentified the regulatory field

The court incorrectly identified the regulatory field. It began by acknowledging the scope of GenBioPro's argument: that Congress occupied the field "specifically as to drugs subject to a REMS which include[s]" safe-use elements. JA274. But it proceeded to analyze a vastly different field, several orders of magnitude broader: "health, medicine, and medical licensure," a "traditional area[] of state authority." JA275. The court relied on the *Wyeth* line of cases to hold that state action is not preempted "in the field of healthcare or medicine." JA275 (discussing *Wyeth v. Levine*, 555 U.S. 555, 581 (2009),

[34] Isotretinoin REMS, *supra* note 6, at 1-2.

and *Bartlett*, 570 U.S. at 486-87). And it predicted that the Supreme Court would not treat "the REMS provision" differently from other parts of the FDCA. JA275-276.

That conclusion errs. "[A]lthough the term 'field preemption' suggests a broad scope, the scope of a field deemed preempted by federal law may be narrowly defined." *Abdullah v. American Airlines, Inc.*, 181 F.3d 363, 367 (3d Cir. 1999). Congress can preempt state law by determining that certain aspects of regulation are too important to federal objectives to permit state intrusion, while preserving a delineated role for states. Here, by analyzing the field too broadly, the court ignored the many instances in which the federal government has carved out limited areas of a larger field for exclusive federal regulation.

Time and again, Congress occupied limited fields within the broader arena of health and safety, as it did here. *See*, *e.g.*, *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992) (safety standards for workers handling hazardous waste); *English*, 496 U.S. at 83 (nuclear safety).

Locke illustrates how Congress carves out a sub-field for exclusive regulation. There, the Supreme Court held that federal law preempted

state regulation of oil tanker design and operation, even as it preserved states' role in regulating liability for oil spills. *Locke*, 529 U.S. at 99-100, 108. A savings clause in one federal law "preserve[d]" that "important role" for states. *Id.* at 105-06. But another law provided for "national" regulation of oil tanker design and operation. *Id.* at 110. Federal rules in that limited field "demanded national uniformity." *Id.* at 103. Congress thus "circumscribe[d] its regulation and occup[ied] only a limited field." *Kelly v. Washington ex rel. Foss Co.*, 302 U.S. 1, 10 (1937) (federal law preempted state regulation of steam vessels but not state laws regulating tugboats).

Other instances in which Congress occupied a narrowly drawn field include: claims concerning defective locomotive design within state tort claims, *see Kurns v. Railroad Friction Prods. Corp.*, 565 U.S. 625, 637 (2012); regulation of aircraft noise within state noise-control regulations, *see Lockheed*, 411 U.S. at 638; tobacco labeling requirements within general state regulation of goods and services, *see Campbell*, 368 U.S. at 300-01; and the siting of liquefied natural gas facilities within local zoning regulations, *see AES Sparrows Point LNG, LLC v. Smith*, 470 F. Supp. 2d 586, 599-600 (D. Md. 2007).

Regulation of drugs with safe-use elements is one such limited field. *See supra* pp.27-31 (Congress occupied field of regulating drugs with safe-use elements by imposing pervasive regulation in area with dominant federal interest). The district court erred in failing to consider this regime's preemptive effect.

2. The district court misconstrued cases addressing state tort claims to define the field

The court erred in relying on *Wyeth* and *Bartlett* for the proposition that "the FDCA does not preempt state action in the field of healthcare or medicine" absent a conflict. JA275-276. As an initial matter, those cases involved conflict preemption, not field preemption. They concerned states' authority to provide remedies through tort law that parallel federal misbranding duties. *See Wyeth*, 555 U.S. at 571 (discussing manufacturer's duty to "ensur[e] that its warnings remain adequate as long as the drug is on the market").

Neither case addresses directly whether states may encroach on the field of regulating access to drugs subject to REMS with safe-use elements. *Bartlett* supports GenBioPro's conflict preemption argument. *See supra* pp.42-44. And unlike the state tort remedies in *Wyeth*, the UCPA does not parallel federal requirements; it purports to override

FDA's determinations. *See supra* p.47. The court failed to consider how the UCPA differs, in nature and object, from state tort suits.

If anything, *Wyeth* supports the position that Congress occupied the limited field of regulating drugs with safe-use elements. In *Wyeth*, the Court held that "common-law tort suits" function "as a complementary form of drug regulation," because FDA had "limited resources to monitor the [then] 11,000 drugs on the market." 555 U.S. at 578. By contrast, for the 64 drugs subject to REMS with safe-use elements today, Congress determined that *FDA* must monitor changing science and reassess those drugs' safety regulations to minimize specified burdens. *See supra* pp.29-30. The court erred in failing to recognize that Congress made this limited field an exclusively federal domain.

In this respect, the scheme is similar to Congress's assumption of exclusive authority to develop "occupational health and safety standards," even as the federal Occupational Safety and Health Act preserves state tort liability. *Pedraza v. Shell Oil Co.*, 942 F.2d 48, 52 (1st Cir. 1991) (cleaned up). Congress likewise reserved the field of nuclear safety for exclusive federal regulation, carving out "state tort

laws that traditionally have been available." *English*, 496 U.S. at 83 (emphasis omitted). As in those cases, Congress's preservation of (non-conflicting) state law remedies in one part of a statute does not diminish the preemptive effect of Congress and FDA's comprehensive federal regime governing mifepristone.

3. The district court erroneously distinguished the savings clause in *Locke* and misconstrued the FDCA's 1962 savings clause

The court erred in distinguishing *United States v. Locke* on the ground that it involved "an area of federal concern," in supposed contrast to the UCPA occupying an area of longstanding *state* regulation. JA276 (discussing *Locke*, 529 U.S. at 99-100). The court distinguished the savings clause addressed in *Locke* from one added to the FDCA via the 1962 Amendments.[35] Recognizing that the former did not prevent Congress from occupying "a particular sub-field of an area of historical federal concern," the court nonetheless held that the

[35] This clause states: "Nothing in the amendments made by this Act . . . shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (codified at 21 U.S.C. § 301).

savings clause *Locke* addressed is narrower than the FDCA's. JA277. It based this distinction on "the historical state police powers implicated, and the fact Congress included express preemption provisions in a different amendment to the FDCA." JA277 (citing *Wyeth*, 555 U.S. at 567).

This analysis was error. First, states traditionally did not restrict access to FDA-approved medications subject to safe-use elements. *See infra* pp.71-72. The court failed to recognize that the "particular sub-field" of end-to-end regulations on access to safe-use drugs is an "area of historical federal concern," like oil tanker design. JA277. Indeed, such drugs are a creation of federal law — they are, by definition, drugs that "can be approved only if, or would be withdrawn unless, such elements are required as part of . . . [a REMS]." 21 U.S.C. § 355-1(f)(1)(A).

Second, the 1962 FDCA savings clause does not authorize states to impose restrictions on drugs with REMS featuring safe-use elements. A savings clause does not give states license "to impose additional unique substantive regulation" on the preempted field (here, restrictions on access to prescription drugs regulated with safe-use elements). *Locke*, 529 U.S. at 106; *cf. Morales v. Trans World Airlines,*

Inc., 504 U.S. 374, 385 (1992) (holding that Congress does not "undermine" a "carefully drawn statute through a general saving clause") (quoting *Ouellette*, 479 U.S. at 494). And Congress's inclusion of an express preemption clause in another part of the FDCA cannot be read to extend state authority to regulate in a historically federal arena.

Nor could the 1962 savings clause confer such power on states; it was enacted decades before the FDAAA created the federal regime allowing such drugs to come to market. The clause instead preserves state authority to afford tort remedies to injured parties for violations of duties that parallel drug manufacturers' duties under federal law. *Wyeth*, 555 U.S. at 575, 567; *supra* pp.55-57. The court failed to recognize that *Wyeth* discussed the FDCA's savings clause only in the context of such state tort suits. 555 U.S. at 567-68.

B. The District Court Erred In Analyzing Conflict Preemption

States are preempted from enforcing rules that "run counter to an exercise of federal authority," and "[federal] regulations are to be given pre-emptive effect over conflicting state laws." *Locke*, 529 U.S. at 109-10. The district court disregarded that constitutional command.

1. The district court erred in holding that the FDAAA does not constrain state regulation

The court held that the FDAAA's provisions on "ensuring access and minimizing undue burden" are "plainly a limitation on the FDA's *own restrictions* on a drug, rather than a command that FDA assure access for all patients." JA268. This conclusion misreads the statute, whose words must be "read in their context and with a view to their place in the overall statutory scheme." *National Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007) (cleaned up). "[R]easonable statutory interpretation must account for both the specific context in which language is used and the broader context of the statute as a whole." *Utility Air Regul. Grp. v. EPA*, 573 U.S. 302, 321 (2014) (cleaned up).

In the FDAAA, Congress authorized FDA to approve drugs "associated with a serious adverse drug experience" — drugs that otherwise would not be available under the normal regime. 21 U.S.C. § 355-1(f)(1)(A). Imposing a REMS with safe-use elements is what enables FDA to do so, expanding access to essential therapies. *Id.* § 355-1(a)(1). But FDA must ensure that any restrictions it imposes are not "unduly burdensome on patient access." *Id.* § 355-1(f)(5)(B), (C).

In this context, allowing states to impose burdens on patients and on the healthcare system interferes with the authority Congress vested in FDA to make determinations about undue burden. *See Ouellette*, 479 U.S. at 494-95 (preemption warranted when state laws interfere with "complex decisions" Congress entrusted to agency); *see also supra* pp.33-34. It would not make sense to say the federal government must be careful not to burden access while allowing states to do so. *Cf. American Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 513 (1981) ("[W]e should not 'impute to Congress a purpose to paralyze with one hand what it sought to promote with the other.'") (citation omitted).

2. The district court overstated the relevance of *Casey* and *Dobbs*

The court held that the UCPA does not pose an obstacle to Congress's objectives because, when Congress passed the FDAAA, the UCPA would have violated *Planned Parenthood of Southeast Pennsylvania v. Casey*, 505 U.S. 833 (1992). JA268-269. It held Congress did not intend "to preempt state abortion restrictions which would have been unconstitutional at the time." JA269.

However, the FDAAA's preemptive scope does not depend on patients' then-enshrined right to obtain an abortion. The FDAAA

mandated a uniform system of regulation for a small subset of drugs like mifepristone, with FDA as the sole regulator. In fulfilling that mandate, Congress directed FDA to minimize burdens on the healthcare delivery system. *See supra* pp.28-29; 21 U.S.C. § 355-1(f)(2)(D). Neither *Casey* nor *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022) (overturning *Casey*), addressed burdens on that system. And Congress directed FDA to maximize patient access to these drugs, to the extent practicable. 21 U.S.C. § 355-1(f)(2)(C). *Dobbs* did not and could not alter or supersede Congress's determination in the FDAAA that FDA must ensure drugs like mifepristone are accessible.

The court ignored basic principles of statutory construction in surmising what members of Congress were thinking when they enacted the FDAAA, without citing legislative history. *E.g.*, JA268. The starting point is "the plain text of the provision." *Navy Fed. Credit Union v. LTD Fin. Servs., LP*, 972 F.3d 344, 356 (4th Cir. 2020) (citing *Marx v. General Revenue Corp.*, 568 U.S. 371, 376 (2013)). Here, that text instructs FDA to minimize burdens on patients' access to mifepristone, irrespective of *Casey*. *Bostock v. Clayton Cnty.*, 140 S. Ct.

1731, 1738 (2020) ("[O]nly the words on the page constitute the law adopted by Congress.").

The court further erred in reasoning that *Dobbs* "made it clear that regulating abortion is a matter of health and safety upon which States may appropriately exercise their police power." JA265. *Dobbs* did not purport to alter the federal government's role in regulating mifepristone and other drugs subject to the strictures of a REMS with safe-use elements under the FDAAA. Rather, it held that "authority to regulate abortion must be returned to the people and their elected representatives." 597 U.S. at 292. Those representatives include Congress, which entrusted FDA with regulating certain drugs, including medications indicated for medication abortion.

3. The district court drew an untenable distinction between regulating "when" and "how" patients receive mifepristone

The court held that state and federal law do not conflict because the UCPA limits "*when* an abortion may be performed, without touching *how* medication abortion is to be performed," while "[t]he mifepristone REMS only concern themselves with the latter." JA273; *see* JA272, JA273 n.12 (characterizing UCPA as "a restriction on the

incidence of abortion" and REMS as merely "logistical safety standards"). This distinction does not bear scrutiny.

First, the REMS are not just "logistical." JA273 n.12; *see supra* pp.8-11, 30. They are comprehensive, postmarket rules governing a drug's approval, prescribing, distribution, dispensing, packaging, accessibility to certain patient groups, and even disposal.[36]

Second, mifepristone's REMS governs not only "how" patients may obtain mifepristone, but which patients may access it, where, and under what circumstances. *See supra* pp.8-11, 30. West Virginia's restrictions, too, regulate "how" medication abortion occurs. Like the REMS, they delineate who can obtain mifepristone, when they may do so, what providers must tell patients prior to providing mifepristone, and what forms patients must sign to obtain the drug. They regulate in the same arena as the REMS and "run[] smack into the [FDA's] regulations." *National Meat Ass'n v. Harris*, 565 U.S. 452, 467 (2012).

[36] *See*, *e.g.*, 2023 Mifepristone REMS, *supra* note 2, at 6-9 (listing requirements for healthcare providers to become certified to prescribe mifepristone and instructing how to dispense the medication); *id.* at 11-13 (instructing pharmacists dispensing mifepristone and requiring pharmacists to track medication shipments).

The court correctly recognized that the FDAAA preempted West Virginia's telemedicine ban by "dictat[ing] the manner in which mifepristone may be prescribed." JA278. FDA permitted healthcare providers to use telemedicine to prescribe mifepristone, but West Virginia did not, resulting in "impossibility preemption." JA278.

The court misunderstood that, similarly, under the UCPA, practitioners, pharmacies, and other participants in the healthcare delivery system cannot "comply with both the access determination made by the FDA and the access determination made by West Virginia," which bans mifepristone in almost all circumstances. JA278; *see supra* pp.42-44.

4. The district court misread which entities the UCPA regulates

The court erred in holding that GenBioPro "is not regulated by the UCPA *at all*" and that the UCPA regulates only "licensed medical professionals." JA270-271. On the contrary, the UCPA makes it impossible for GenBioPro to provide mifepristone in accordance with the REMS, other than to "stop selling" it in almost all circumstances. *Bartlett*, 570 U.S. at 487 n.3; *see supra* pp.42-44.

First, the UCPA regulates *anyone* who performs an abortion. "[L]icensed medical professional[s]" face professional penalties for violating the law, and any *other* "person" who does so commits a felony. W. Va. Code §§ 16-2R-7, 61-2-8(a); *see supra* p.15 (explaining that UCPA subjects advanced practice registered nurses and physician assistants to criminal penalties for prescribing mifepristone to most patients).

Furthermore, the UCPA regulates GenBioPro directly through section 16-2R-2's sweeping definition of "[a]ttempt to perform or induce an abortion." *See supra* pp.15-16. That includes any act that "constitutes a substantial step in a course of conduct intended to culminate in an abortion," arguably including selling mifepristone to providers and pharmacies. W. Va. Code § 16-2R-2.

The phrase "unless in the reasonable medical judgment of a licensed medical professional" in section 16-2R-3(a) does not limit the core prohibition to such professionals. It merely prohibits anyone from performing an abortion and limits the prohibition's *exception* to the judgment of a licensed medical professional.

Even if the UCPA regulated only prescribers, and not GenBioPro, this would not save the state law from preemption. In *Engine*

Manufacturers Ass'n v. South Coast Air Quality Management District, the Supreme Court held that "a standard is a standard" for purposes of determining whether it conflicts with a federal rule, "even when not enforced through manufacturer-directed regulation." 541 U.S. 246, 254 (2004).

In *National Meat*, the Court held that California could not avoid preemption of state manufacturing standards by framing its law as a sales ban. 565 U.S. at 464. To hold otherwise "would make a mockery of the [Act's] preemption provision." *Id.* Similarly, the Court rejected North Carolina's attempt to "evade" preemption by adopting a "creative statutory interpretation" at "odds with the [state] statute's intended operation and effect." *Wos v. E.M.A. ex rel. Johnson*, 568 U.S. 627, 636 (2013); *see also PPL EnergyPlus*, 753 F.3d at 476 ("[S]tates are barred from relying on mere formal distinctions in an attempt to evade preemption.") (cleaned up).

Although GenBioPro can avoid this conflict (and associated risk of criminal penalties) by not providing mifepristone in West Virginia, the "ability to stop selling does not turn impossibility into possibility." *Bartlett*, 570 U.S. at 487 n.3. Indeed, the court recognized this and

rejected Appellees' argument that "GenBioPro may simply choose to stop selling mifepristone in West Virginia," JA271 n.10 (citing *Bartlett*, 570 U.S. at 488), but erred in holding that the UCPA does not regulate GenBioPro in the first place.

5. Neither *Virginia Uranium* nor *National Meat* supports the district court's preemption holding

The court highlighted two cases in analyzing conflict preemption; neither supports its conclusion.

a. The district court erroneously read *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894 (2019), as holding that a state may "disallow uranium mining" because such mining is "an area of authority traditionally left to the States." JA273. The Supreme Court said no such thing. There, uranium mining companies sued to enjoin a Virginia law banning uranium mining on private land as preempted by the federal Atomic Energy Act. In a fractured opinion, the Court found no preemption because "[t]he Federal Government does not regulate conventional uranium mining on private land." 139 S. Ct. at 1910 (Ginsburg, J., concurring in judgment) (citation omitted); *see id.* at 1900 (plurality op. of Gorsuch, J.) (same).

The Atomic Energy Act addresses only what happens to uranium "*after*" it is removed from the earth and is silent on regulating mining, unless that mining occurs on federal land. *Id.* at 1901-02. Thus, "the activity Virginia's law regulates . . . isn't one [federal law] has ever addressed." *Id.* at 1904. In contrast, federal law regulates mifepristone's availability to patients from manufacturing to prescription and dispensing.

b. The district court relied on *National Meat*, but that case supports reversal. *See* JA273. *National Meat* concerned the preemptive effect of the Federal Meat Inspection Act, which regulates all aspects of "slaughterhouses' handling and treatment of nonambulatory pigs from the moment of their delivery through the end of the meat production process." 565 U.S. at 468. It thus preempted a state law dictating what slaughterhouses must do when pigs cannot stand on their own. Likewise, here, FDA may regulate all aspects of drugs subject to a REMS with safe-use elements, from their manufacture, to prescription, to dispensing, to use, to disposal. *See supra* pp.8-11. State law cannot intrude.

The court cited dicta in *National Meat* discussing "Circuit decisions upholding state bans on slaughtering horses." 565 U.S. at 467; JA273 n.11. The Supreme Court described those state bans as "work[ing] at a remove from" the arena federal law governed, because the bans prevent horses from being in slaughterhouses at all. 565 U.S. at 467. But the federal statute there did not impose a mandate to minimize burdens on access to horsemeat, and horse-slaughter bans only incidentally relate to the federal meat inspection statute.

The UCPA, by contrast, conflicts with FDA's mandate to ensure restrictions on REMS drugs with safe-use elements preserve "patient access." 21 U.S.C. § 355-1(f)(2)(C). The FDAAA requires FDA to ensure mifepristone is as accessible as it determines is (safely) possible to patients with "serious or life-threatening . . . conditions," including pregnancy. *Id.* § 355-1(f)(2)(C)(i). Dicta in *National Meat* therefore is inapt.

C. The District Court Erred In Applying A Presumption Against Preemption

A presumption against preemption applies to arenas "which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (cleaned up); *see Zimmerman v. Novartis Pharms. Corp.*, 889 F. Supp. 2d 757,

766 (D. Md. 2012). No such presumption applies here, and the district court erred in holding otherwise based on its misidentification of the challenged arena as "health, medicine, and medical licensure." JA275.

1. States do not traditionally restrict access to drugs with safe-use elements

The district court erred by applying a presumption against preemption in an arena "traditionally regulated by the federal government." *South Carolina*, 720 F.3d at 529. Such a presumption does not apply when, as here, "there has been a history of significant federal presence" and "considerable federal interest[s]" are at stake. *Locke*, 529 U.S. at 90-91, 94. "Although health care in general is an area of traditional state regulation," when a "dispute concerns" matters "that arise from a federal law," "'distinctly federal interests are involved.'" *Bell v. Blue Cross & Blue Shield of Okla.*, 823 F.3d 1198, 1201-02 (8th Cir. 2016) (quoting *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 696 (2006)).

Federal, not state, law governs access to FDA-approved drugs subject to safe-use elements. While states regulate aspects of medical and pharmacy practice with regulations of general applicability, like licensing standards, they do not approve drugs or impose REMS. Even

when "responsibility for regulating" a broad arena "remains primarily with the States," "the Constitution does not erect a firewall around" that arena, and Congress may preempt state law by "validly legislating pursuant to its Article I powers." *Haaland v. Brackeen*, 599 U.S. 255, 276-77 (2023).

The court failed to recognize that the UCPA is unlike state tort remedies that parallel federal duties. It departs from traditional state regulation by prohibiting access to an FDA-approved drug subject to its own detailed set of restrictions. *See supra* pp.46-47. In that situation, no presumption against preemption applies. *See Amgen*, 877 F.3d at 1327 ("[N]o presumption . . . applies" because biosimilar patent litigation "is hardly a field which the States have traditionally occupied.") (cleaned up).

2. No presumption applies because the FDAAA's regulatory regime is comprehensive

Finally, no presumption against preemption applies when federal law propounds comprehensive regulation. *See Kelly*, 302 U.S. at 4; *Ray*, 435 U.S. at 166 n.15.[37] The FDAAA's end-to-end regulation of

[37] In any event, the district court pointed to no case rejecting preemption based solely on such a presumption. *Cf. Zimmerman*, 889

mifepristone and other drugs with safe-use elements is highly reticulated. *See supra* pp.27-31. In the context of such a detailed regime, it is inappropriate to begin with a presumption against preemption, rather than giving the federal regulatory regime full, national force. *See Locke*, 529 U.S. at 103 (discussing "longstanding rule that the enactment of a uniform federal scheme displaces state law").

CONCLUSION

The district court's judgment should be reversed.

STATEMENT REGARDING ORAL ARGUMENT

Plaintiff-Appellant respectfully requests oral argument.

F. Supp. 2d at 772 (describing the presumption as "hardly outcome-determinative").

February 7, 2024

Respectfully submitted,

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 23-2194 **Caption:** GenBioPro, Inc. v. Kristina Raynes et al.

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(s) David C. Frederick

Party Name GenBioPro, Inc.

Dated: Feb. 7, 2024

CERTIFICATE OF SERVICE

I hereby certify that, on February 7, 2024, I electronically filed the foregoing Brief for Plaintiff-Appellant GenBioPro, Inc. with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit using the appellate CM/ECF system.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ David C. Frederick
David C. Frederick

STATUTORY ADDENDUM

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U.S. Constitution, Article VI, Clause 2
(Supremacy Clause)

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, pmbl., 121 Stat. 823, 823

An Act

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

Food and Drug Administration Amendments Act of 2007,
Pub. L. No. 110-85, § 909, 121 Stat. 823, 950-51,
***reprinted at* 21 U.S.C. § 331 note**

SEC. 909. EFFECTIVE DATE AND APPLICABILITY.

(a) EFFECTIVE DATE.—This subtitle takes effect 180 days after the date of the enactment of this Act.

(b) DRUGS DEEMED TO HAVE RISK EVALUATION AND MITIGATION STRATEGIES.—

(1) IN GENERAL.—A drug that was approved before the effective date of this Act is, in accordance with paragraph (2), deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (as added by section 901) (referred to in this section as the "Act") if there are in effect on the effective date of this Act elements to assure safe use—

(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or

(B) otherwise agreed to by the applicant and the Secretary for such drug.

(2) ELEMENTS OF STRATEGY; ENFORCEMENT.—The approved risk evaluation and mitigation strategy in effect for a drug under paragraph (1)—

(A) is deemed to consist of the timetable required under section 505–1(d) and any additional elements under subsections (e) and (f) of such section in effect for such drug on the effective date of this Act; and

(B) is subject to enforcement by the Secretary to the same extent as any other risk evaluation and mitigation strategy under section 505–1 of the Act, except that sections 303(f)(4) and 502(y) and (z) of the Act (as added by section 902) shall not apply to such strategy before the Secretary has completed review of, and acted on, the first assessment of such strategy under such section 505–1.

(3) SUBMISSION.—Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect under paragraph (1) shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.

21 U.S.C. § 355-1.
Risk evaluation and mitigation strategies

(a) Submission of proposed strategy

(1) Initial approval

If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

(A) The estimated size of the population likely to use the drug involved.

(B) The seriousness of the disease or condition that is to be treated with the drug.

(C) The expected benefit of the drug with respect to such disease or condition.

(D) The expected or actual duration of treatment with the drug.

(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

(F) Whether the drug is a new molecular entity.

(2) Postapproval requirement

(A) In general

If the Secretary has approved a covered application (including an application approved before the effective date of this section) and did not when approving the application require a

risk evaluation and mitigation strategy under paragraph (1), the Secretary, in consultation with the offices described in paragraph (1), may subsequently require such a strategy for the drug involved (including when acting on a supplemental application seeking approval of a new indication for use of the drug) if the Secretary becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug.

(B) Submission of proposed strategy

Not later than 120 days after the Secretary notifies the holder of an approved covered application that the Secretary has made a determination under subparagraph (A) with respect to the drug involved, or within such other reasonable time as the Secretary requires to protect the public health, the holder shall submit to the Secretary a proposed risk evaluation and mitigation strategy.

(3) Abbreviated new drug applications

The applicability of this section to an application under section 355(j) of this title is subject to subsection (i).

(4) Non-delegation

Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(b) Definitions

For purposes of this section:

(1) Adverse drug experience

The term "adverse drug experience" means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including—

(A) an adverse event occurring in the course of the use of the drug in professional practice;

(B) an adverse event occurring from an overdose of the drug, whether accidental or intentional;

(C) an adverse event occurring from abuse of the drug;

(D) an adverse event occurring from withdrawal of the drug; and

(E) any failure of expected pharmacological action of the drug, which may include reduced effectiveness under the conditions of use prescribed in the labeling of such drug, but which may not include reduced effectiveness that is in accordance with such labeling.

(2) Covered application

The term "covered application" means an application referred to in section 355(p)(1)(A) of this title.

(3) New safety information

The term "new safety information", with respect to a drug, means information derived from a clinical trial, an adverse event report, a postapproval study (including a study under section 355(o)(3) of this title), or peer-reviewed biomedical literature; data derived from the postmarket risk identification and analysis system under section 355(k) of this title; or other scientific data deemed appropriate by the Secretary about—

(A) a serious risk or an unexpected serious risk associated with use of the drug that the Secretary has become aware of (that may be based on a new analysis of existing information) since the drug was approved, since the risk evaluation and mitigation strategy was required, or since the last assessment of the approved risk evaluation and mitigation strategy for the drug; or

(B) the effectiveness of the approved risk evaluation and mitigation strategy for the drug obtained since the last assessment of such strategy.

(4) Serious adverse drug experience

The term "serious adverse drug experience" is an adverse drug experience that—

(A) results in—

(i) death;

(ii) an adverse drug experience that places the patient at immediate risk of death from the adverse drug experience as it occurred (not including an adverse drug experience that might have caused death had it occurred in a more severe form);

(iii) inpatient hospitalization or prolongation of existing hospitalization;

(iv) a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or

(v) a congenital anomaly or birth defect; or

(B) based on appropriate medical judgment, may jeopardize the patient and may require a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(5) Serious risk

The term "serious risk" means a risk of a serious adverse drug experience.

(6) Signal of a serious risk

The term "signal of a serious risk" means information related to a serious adverse drug experience associated with use of a drug and derived from—

(A) a clinical trial;

(B) adverse event reports;

(C) a postapproval study, including a study under section 355(o)(3) of this title;

(D) peer-reviewed biomedical literature;

(E) data derived from the postmarket risk identification and analysis system under section 355(k)(4) of this title; or

(F) other scientific data deemed appropriate by the Secretary.

(7) Responsible person

The term "responsible person" means the person submitting a covered application or the holder of the approved such application.

(8) Unexpected serious risk

The term "unexpected serious risk" means a serious adverse drug experience that is not listed in the labeling of a drug, or that may be symptomatically and pathophysiologically related to an adverse drug experience identified in the labeling, but differs from such adverse drug experience because of greater severity, specificity, or prevalence.

(c) Contents

A proposed risk evaluation and mitigation strategy under subsection (a) shall—

(1) include the timetable required under subsection (d); and

(2) to the extent required by the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, include additional elements described in subsections (e) and (f).

(d) Minimal strategy

For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy that—

(1) includes an assessment, by the date that is 18 months after the strategy is initially approved;

(2) includes an assessment by the date that is 3 years after the strategy is initially approved;

(3) includes an assessment in the seventh year after the strategy is so approved; and

(4) subject to paragraphs (1), (2), and (3)—

(A) is at a frequency specified in the strategy;

(B) is increased or reduced in frequency as necessary as provided for in subsection (g)(4)(A); and

(C) is eliminated after the 3-year period described in paragraph (1) if the Secretary determines that serious risks of the drug have been adequately identified and assessed and are being adequately managed.

(e) Additional potential elements of strategy

(1) In general

The Secretary, in consultation with the offices described in subsection (c)(2), may under such subsection require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to each element involved.

(2) Medication Guide; patient package insert

The risk evaluation and mitigation strategy for a drug may require that, as applicable, the responsible person develop for distribution to each patient when the drug is dispensed—

(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

(B) a patient package insert, if the Secretary determines that such insert may help mitigate a serious risk of the drug.

(3) Communication plan

The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy (including under this paragraph). Such plan may include—

(A) sending letters to health care providers;

(B) disseminating information about the elements of the risk evaluation and mitigation strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests)

(C) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use; or

(D) disseminating information to health care providers about drug formulations or properties, including information about the limitations or patient care implications of such formulations or properties, and how such formulations or properties may be related to serious adverse drug events associated with use of the drug.

(4) Packaging and disposal

The Secretary may require a risk evaluation mitigation strategy for a drug for which there is a serious risk of an adverse drug experience described in subparagraph (B) or (C) of subsection (b)(1), taking into consideration the factors described in subparagraphs (C) and (D) of subsection (f)(2) and in consultation with other relevant Federal agencies with authorities over drug disposal packaging, which may include requiring that—

(A) the drug be made available for dispensing to certain patients in unit dose packaging, packaging that provides a set duration, or another packaging system that the Secretary determines may mitigate such serious risk; or

(B) the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system if the Secretary determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available.

(f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable

(1) Allowing safe access to drugs with known serious risks

The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

(A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

(B) for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

(2) Assuring access and minimizing burden

Such elements to assure safe use under paragraph (1) shall—

(A) be commensurate with the specific serious risk listed in the labeling of the drug;

(B) within 30 days of the date on which any element under paragraph (1) is imposed, be posted publicly by the Secretary with an explanation of how such elements will mitigate the observed safety risk;

(C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular—

(i) patients with serious or life-threatening diseases or conditions;

(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); and

(iii) patients with functional limitations; and

(D) to the extent practicable, so as to minimize the burden on the health care delivery system—

(i) conform with elements to assure safe use for other drugs with similar, serious risks; and

(ii) be designed to be compatible with established distribution, procurement, and dispensing systems for drugs.

(3) Elements to assure safe use

The elements to assure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

(A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);

(B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);

(C) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

(E) each patient using the drug be subject to certain monitoring; or

(F) each patient using the drug be enrolled in a registry.

(4) Implementation system

The elements to assure safe use under paragraph (1) that are described in subparagraphs (B), (C), and (D) of paragraph (3) may include a system through which the applicant is able to take reasonable steps to—

(A) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

(B) work to improve implementation of such elements by such persons.

(5) Evaluation of elements to assure safe use

The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) or other advisory committee of the Food and Drug Administration, shall--

(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be--

(i) unduly burdensome on patient access to the drug; and

(ii) to the extent practicable, minimize the burden on the health care delivery system;

(B) periodically evaluate, for 1 or more drugs, the elements to assure safe use of such drug 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; and

(C) considering such input and evaluations--

(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

(ii) modify elements under this subsection for 1 or more drugs as appropriate.

(6) Additional mechanisms to assure access

The mechanisms under section 360bbb of this title to provide for expanded access for patients with serious or life-threatening diseases or conditions may be used to provide access for patients

with a serious or life-threatening disease or condition, the treatment of which is not an approved use for the drug, to a drug that is subject to elements to assure safe use under this subsection. The Secretary shall promulgate regulations for how a physician may provide the drug under the mechanisms of section 360bbb of this title.

(7) Repealed. Pub. L. 113-5, Title III, § 302(c)(1), Mar. 13, 2013, 127 Stat. 185

(8) Limitation

No holder of an approved covered application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) of this title or to prevent application of such element under subsection (i)(1)(B) to a drug that is the subject of an abbreviated new drug application.

(g) Assessment and modification of approved strategy

(1) Voluntary assessments

After the approval of a risk evaluation and mitigation strategy under subsection (a), the responsible person involved may, subject to paragraph (2), submit to the Secretary an assessment of the approved strategy for the drug involved at any time.

(2) Required assessments

A responsible person shall submit an assessment of the approved risk evaluation and mitigation strategy for a drug—

(A) when submitting a supplemental application for a new indication for use under section 355(b) of this title or under section 262 of Title 42, unless the drug is not subject to section 353(b) of this title and the risk evaluation and mitigation strategy for the drug includes only the timetable under subsection (d);

(B) when required by the strategy, as provided for in such timetable under subsection (d);

(C) within a time period to be determined by the Secretary, if the Secretary, in consultation with the offices described in subsection (c)(2), determines that an assessment is needed to evaluate whether the approved strategy should be modified to--

(i) ensure the benefits of the drug outweigh the risks of the drug; or

(ii) minimize the burden on the health care delivery system of complying with the strategy.

(3) Requirements for assessments

An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include, with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified.

(4) Modification

(A) On initiative of responsible person

After the approval of a risk evaluation and mitigation strategy by the Secretary, the responsible person may, at any time, submit to the Secretary a proposal to modify the approved strategy. Such proposal may propose the addition, modification, or removal of any goal or element of the approved strategy and shall include an adequate rationale to support such proposed addition, modification, or removal of any goal or element of the strategy.

(B) On initiative of Secretary

After the approval of a risk evaluation and mitigation strategy by the Secretary, the Secretary may, at any time, require a responsible person to submit a proposed modification to the strategy within 120 days or within such reasonable time as the Secretary specifies, if the Secretary, in consultation with the offices described in subsection (c)(2),

determines that 1 or more goals or elements should be added, modified, or removed from the approved strategy to—

(i) ensure the benefits of the drug outweigh the risks of the drug;

(ii) minimize the burden on the health care delivery system of complying with the strategy; or

(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 355(j) of this title, and the applicable listed drug.

(h) Review of proposed strategies; review of assessments and modifications of approved strategies

(1) In general

The Secretary, in consultation with the offices described in subsection (c)(2), shall promptly review each proposed risk evaluation and mitigation strategy for a drug submitted under subsection (a) and each assessment of and proposed modification to an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g), and, if necessary, promptly initiate discussions with the responsible person about such proposed strategy, assessment, or modification.

(2) Action

(A) In general

(i) Timeframe

Unless the dispute resolution process described under paragraph (3) or (4) applies, and, except as provided in clause (ii) or clause (iii) below, the Secretary, in consultation with the offices described in subsection (c)(2), shall review and act on the proposed risk evaluation and mitigation strategy for a drug or any proposed modification to any required strategy within

180 days of receipt of the proposed strategy or modification.

(ii) Minor modifications

The Secretary shall review and act on a proposed minor modification, as defined by the Secretary in guidance, within 60 days of receipt of such modification.

(iii) REMS modification due to safety labeling changes

Not later than 60 days after the Secretary receives a proposed modification to an approved risk evaluation and mitigation strategy to conform the strategy to approved safety labeling changes, including safety labeling changes initiated by the responsible person in accordance with FDA regulatory requirements, or to a safety labeling change that the Secretary has directed the holder of the application to make pursuant to section 355(o)(4) of this title, the Secretary shall review and act on such proposed modification to the approved strategy.

(iv) Guidance

The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.

(B) Inaction

An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided under subparagraph (A).

(C) Public availability

Upon acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary

shall make publicly available an action letter describing the actions taken by the Secretary under such subparagraph (A).

(3) Dispute resolution at initial approval

If a proposed risk evaluation and mitigation strategy is submitted under subsection (a)(1) in an application for initial approval of a drug and there is a dispute about the strategy, the responsible person shall use the major dispute resolution procedures as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(4) Dispute resolution in all other cases

(A) Request for review

(i) In general

The responsible person may, after the sponsor is required to make a submission under subsection (a)(2) or (g), request in writing that a dispute about the strategy be reviewed by the Drug Safety Oversight Board under subsection (j), except that the determination of the Secretary to require a risk evaluation and mitigation strategy is not subject to review under this paragraph. The preceding sentence does not prohibit review under this paragraph of the particular elements of such a strategy.

(ii) Scheduling

Upon receipt of a request under clause (i), the Secretary shall schedule the dispute involved for review under subparagraph (B) and, not later than 5 business days of scheduling the dispute for review, shall publish by posting on the Internet or otherwise a notice that the dispute will be reviewed by the Drug Safety Oversight Board.

(B) Scheduling review

If a responsible person requests review under subparagraph (A), the Secretary—

(i) shall schedule the dispute for review at 1 of the next 2 regular meetings of the Drug Safety Oversight Board, whichever meeting date is more practicable; or

(ii) may convene a special meeting of the Drug Safety Oversight Board to review the matter more promptly, including to meet an action deadline on an application (including a supplemental application).

(C) Agreement after discussion or administrative appeals

(i) Further discussion or administrative appeals

A request for review under subparagraph (A) shall not preclude further discussions to reach agreement on the risk evaluation and mitigation strategy, and such a request shall not preclude the use of administrative appeals within the Food and Drug Administration to reach agreement on the strategy, including appeals as described in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007 for procedural or scientific matters involving the review of human drug applications and supplemental applications that cannot be resolved at the divisional level. At the time a review has been scheduled under subparagraph (B) and notice of such review has been posted, the responsible person shall either withdraw the request under subparagraph (A) or terminate the use of such administrative appeals.

(ii) Agreement terminates dispute resolution

At any time before a decision and order is issued under subparagraph (G), the Secretary (in consultation with the offices described in subsection (c)(2)) and the responsible person may reach an agreement on the risk evaluation and mitigation strategy through further

discussion or administrative appeals, terminating the dispute resolution process, and the Secretary shall issue an action letter or order, as appropriate, that describes the strategy.

(D) Meeting of the Board

At a meeting of the Drug Safety Oversight Board described in subparagraph (B), the Board shall—

(i) hear from both parties via written or oral presentation; and

(ii) review the dispute.

(E) Record of proceedings

The Secretary shall ensure that the proceedings of any such meeting are recorded, transcribed, and made public within 90 days of the meeting. The Secretary shall redact the transcript to protect any trade secrets and other information that is exempted from disclosure under section 552 of Title 5 or section 552a of Title 5.

(F) Recommendation of the Board

Not later than 5 days after any such meeting, the Drug Safety Oversight Board shall provide a written recommendation on resolving the dispute to the Secretary. Not later than 5 days after the Board provides such written recommendation to the Secretary, the Secretary shall make the recommendation available to the public.

(G) Action by the Secretary

(i) Action letter

With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall issue an action letter that resolves the dispute not later than the later of—

(I) the action deadline for the action letter on the application; or

(II) 7 days after receiving the recommendation of the Drug Safety Oversight Board.

(ii) Order

With respect to an assessment of an approved risk evaluation and mitigation strategy under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2), the Secretary shall issue an order, which shall be made public, that resolves the dispute not later than 7 days after receiving the recommendation of the Drug Safety Oversight Board.

(H) Inaction

An approved risk evaluation and mitigation strategy shall remain in effect until the Secretary acts, if the Secretary fails to act as provided for under subparagraph (G).

(I) Effect on action deadline

With respect to a proposal or assessment referred to in paragraph (1), the Secretary shall be considered to have met the action deadline for the action letter on the application if the responsible person requests the dispute resolution process described in this paragraph and if the Secretary has complied with the timing requirements of scheduling review by the Drug Safety Oversight Board, providing a written recommendation, and issuing an action letter under subparagraphs (B), (F), and (G), respectively.

(J) Disqualification

No individual who is an employee of the Food and Drug Administration and who reviews a drug or who participated in an administrative appeal under subparagraph (C)(i) with respect to such drug may serve on the Drug Safety Oversight Board at a meeting under subparagraph (D) to review a dispute about the risk evaluation and mitigation strategy for such drug.

(K) Additional expertise

The Drug Safety Oversight Board may add members with relevant expertise from the Food and Drug Administration, including the Office of Pediatrics, the Office of Women's Health, or the Office of Rare Diseases, or from other Federal public health or health care agencies, for a meeting under subparagraph (D) of the Drug Safety Oversight Board.

(5) Use of advisory committees

The Secretary may convene a meeting of 1 or more advisory committees of the Food and Drug Administration to—

(A) review a concern about the safety of a drug or class of drugs, including before an assessment of the risk evaluation and mitigation strategy or strategies of such drug or drugs is required to be submitted under subparagraph (B) or (C) of subsection (g)(2);

(B) review the risk evaluation and mitigation strategy or strategies of a drug or group of drugs; or

(C) review a dispute under paragraph (3) or (4).

(6) Process for addressing drug class effects

(A) In general

When a concern about a serious risk of a drug may be related to the pharmacological class of the drug, the Secretary, in consultation with the offices described in subsection (c)(2), may defer assessments of the approved risk evaluation and mitigation strategies for such drugs until the Secretary has convened 1 or more public meetings to consider possible responses to such concern.

(B) Notice

If the Secretary defers an assessment under subparagraph (A), the Secretary shall—

(i) give notice of the deferral to the holder of the approved covered application not later than 5 days after the deferral;

(ii) publish the deferral in the Federal Register; and

(iii) give notice to the public of any public meetings to be convened under subparagraph (A), including a description of the deferral.

(C) Public meetings

Such public meetings may include—

(i) 1 or more meetings of the responsible person for such drugs;

(ii) 1 or more meetings of 1 or more advisory committees of the Food and Drug Administration, as provided for under paragraph (6); or

(iii) 1 or more workshops of scientific experts and other stakeholders.

(D) Action

After considering the discussions from any meetings under subparagraph (A), the Secretary may—

(i) announce in the Federal Register a planned regulatory action, including a modification to each risk evaluation and mitigation strategy, for drugs in the pharmacological class;

(ii) seek public comment about such action; and

(iii) after seeking such comment, issue an order addressing such regulatory action.

(7) International coordination

The Secretary, in consultation with the offices described in subsection (c)(2), may coordinate the timetable for submission of assessments under subsection (d), or a study or clinical trial under

section 355(o)(3) of this title, with efforts to identify and assess the serious risks of such drug by the marketing authorities of other countries whose drug approval and risk management processes the Secretary deems comparable to the drug approval and risk management processes of the United States. If the Secretary takes action to coordinate such timetable, the Secretary shall give notice to the responsible person.

(8) Effect

Use of the processes described in paragraphs (6) and (7) shall not be the sole source of delay of action on an application or a supplement to an application for a drug.

(i) Abbreviated new drug applications

(1) In general

A drug that is the subject of an abbreviated new drug application under section 355(j) of this title is subject to only the following elements of the risk evaluation and mitigation strategy required under subsection (a) for the applicable listed drug:

(A) A Medication Guide or patient package insert, if required under subsection (e) for the applicable listed drug.

(B) A packaging or disposal requirement, if required under subsection (e)(4) for the applicable listed drug.

(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 355(j) of this title may use—

(I) a single, shared system with the listed drug under subsection (f); or

(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

(ii) The Secretary may require a drug that is the subject of an application under section 355(j) of this title and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).

(2) Action by Secretary

For an applicable listed drug for which a drug is approved under section 355(j) of this title, the Secretary—

(A) shall undertake any communication plan to health care providers required under subsection (e)(3) for the applicable listed drug;

(B) shall permit packaging systems and safe disposal packaging or safe disposal systems that are different from those required for the applicable listed drug under subsection (e)(4); and

(C) shall inform the responsible person for the drug that is so approved if the risk evaluation and mitigation strategy for the applicable listed drug is modified.

(3) Shared REMS

If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 355(j) of this title, the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 355(j) or 355(b) of this title that references the same listed drug.

(j) Drug Safety Oversight Board

(1) In general

There is established a Drug Safety Oversight Board.

(2) Composition; meetings

The Drug Safety Oversight Board shall—

(A) be composed of scientists and health care practitioners appointed by the Secretary, each of whom is an employee of the Federal Government;

(B) include representatives from offices throughout the Food and Drug Administration, including the offices responsible for postapproval safety of drugs;

(C) include at least 1 representative each from the National Institutes of Health and the Department of Health and Human Services (other than the Food and Drug Administration);

(D) include such representatives as the Secretary shall designate from other appropriate agencies that wish to provide representatives; and

(E) meet at least monthly to provide oversight and advice to the Secretary on the management of important drug safety issues.

(k) Waiver in public health emergencies

The Secretary may waive any requirement of this section with respect to a qualified countermeasure (as defined in section 247d-6a(a)(2) of Title 42) to which a requirement under this section has been applied, if the Secretary determines that such waiver is required to mitigate the effects of, or reduce the severity of, the circumstances under which—

(1) a determination described in subparagraph (A), (B), or (C) of section 360bbb-3(b)(1) of this title has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(2) the identification of a material threat described in subparagraph (D) of section 360bbb-3(b)(1) of this title has been made pursuant to section 247d-6b of Title 42.

(l) Provision of samples not a violation of strategy

The provision of samples of a covered product to an eligible product developer (as those terms are defined in section 355-2(a) of this title) shall not be considered a violation of the requirements of any risk evaluation and mitigation strategy that may be in place under this section for such drug.

(m) Separate REMS

When used in this section, the term "different, comparable aspect of the elements to assure safe use" means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 355(j) of this title that uses different methods or operational means than the strategy required under subsection (a) for the applicable listed drug, or other application under section 355(j) of this title with the same such listed drug, but achieves the same level of safety as such strategy.

W. Va. Code § 16-2I-2.
Informed consent

An abortion may not be performed in this state except with the voluntary and informed consent of the female upon whom the abortion is to be performed. Except in the case of a medical emergency, consent to an abortion is voluntary and informed if, and only if:

(a) The female is told the following, by telephone or in person, by the physician or the licensed medical professional to whom the responsibility has been delegated by the physician who is to perform the abortion at least 24 hours before the abortion:

(1) The particular medical risks associated with the particular abortion procedure to be employed, including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility;

(2) The probable gestational age of the embryo or fetus at the time the abortion is to be performed;

(3) The medical risks associated with carrying her child to term; and

(4) If a chemical abortion involving the two-drug process of mifepristone is initiated and then a prostaglandin such as misoprostol is planned to be used at a later time, the female shall be informed that:

(A) Some suggest that it may be possible to counteract the intended effects of a mifepristone chemical abortion by taking progesterone if the female changes her mind, before taking the second drug, but this process has not been approved by the Food and Drug Administration.

(B) After the first drug involved in the two-drug process is dispensed in a mifepristone chemical abortion, the physician or agent of the physician shall provide written medical discharge instructions to the pregnant female which shall include the statement:

"If you change your mind and decide to try to counteract the intended effects of a mifepristone chemical abortion, if the second pill has not been taken, please consult with your physician.

(i) You might experience a complete abortion without ever taking misoprostol;

(ii) You might experience a missed abortion, which means the fetus is no longer viable, but the fetus did not leave your body; or

(iii) It is possible that your pregnancy may continue; and

(iv) You should consult with your physician."

(C) The female shall certify, as part of the informed consent process for any medical procedure, that she has been informed about the above possibilities regarding a chemical abortion.

(D) Notwithstanding any law to the contrary, a physician acting in conformity with the informed consent provisions of this section relating to the possibility of counteracting the intended effects of a chemical abortion, or a physician prescribing a non-Food and Drug Administration approved drug therapy to counteract a chemical abortion is not liable for any loss, damage, physical injury, or death arising from any information provided by the physician related to counteracting the intended effects of a chemical abortion or arising from prescribing a non-Food and Drug Administration approved drug therapy to counteract a chemical abortion.

The information required by this subsection may be provided by telephone without conducting a physical examination or tests of the patient, in which case the information required to be provided may be based on facts supplied by the female to the physician or other licensed health care professional to whom the responsibility has been delegated by the physician and whatever other relevant information is reasonably

available to the physician or other licensed health care professional to whom the responsibility has been delegated by the physician. It may not be provided by a tape recording, but must be provided during a consultation in which the physician or licensed health care professional to whom the responsibility has been delegated by the physician is able to ask questions of the female and the female is able to ask questions of the physician or the licensed health care professional to whom the responsibility has been delegated by the physician.

If a physical examination, tests or the availability of other information to the physician or other licensed health care professional to whom the responsibility has been delegated by the physician subsequently indicate, in the medical judgment of the physician or the licensed health care professional to whom the responsibility has been delegated by the physician, a revision of the information previously supplied to the patient, that revised information may be communicated to the patient at any time before the performance of the abortion procedure.

Nothing in this section may be construed to preclude provision of required information in a language understood by the patient through a translator.

(b) The female is informed, by telephone or in person, by the physician who is to perform the abortion, or by an agent of the physician, at least 24 hours before the abortion procedure:

(1) That medical assistance benefits may be available for prenatal care, childbirth, and neonatal care through governmental or private entities;

(2) That the father, if his identity can be determined, is liable to assist in the support of her child based upon his ability to pay even in instances in which the father has offered to pay for the abortion;

(3) That she has the right to review the printed materials described in § 16-2I-3 of this code, that these materials are available on a state-sponsored website and the website address; and

(4) That the female will be presented with a form which she will be required to execute prior to the abortion procedure that is available pursuant to § 16-2I-3 of this code, and that the form to be presented will inform her of the opportunity to view the ultrasound image and her right to view or decline to view the ultrasound image, if an ultrasound is performed.

The physician or an agent of the physician shall orally inform the female that the materials have been provided by the State of West Virginia and that they describe the embryo or fetus and list agencies and entities which offer alternatives to abortion.

If the female chooses to view the materials other than on the website, then they shall either be provided to her at least 24 hours before the abortion or mailed to her at least 72 hours before the abortion by first class mail in an unmarked envelope.

The information required by this subsection may be provided by a tape recording if provision is made to record or otherwise register specifically whether the female does or does not choose to have the printed materials given or mailed to her.

(c) The form required pursuant to subdivision (b)(4) of this section shall include the following information:

(1) It is a female's decision whether or not to undergo any ultrasound imaging procedure in consultation with her health care provider;

(2) If an ultrasound is performed in conjunction with the performance of an abortion procedure, the female has the right to view or to decline to view the image; and

(3) That the female has been previously informed of her opportunity to view the ultrasound image and her right to view or

decline to view the ultrasound image. The female shall certify her choice on this form prior to the abortion procedure being performed.

The female shall certify in writing, before the abortion, that the information described in subsections (a) and (b) of this section has been provided to her and that she has been informed of her opportunity to review the information referred to in subdivision (b)(3) of this section.

Before performing the abortion procedure, the physician who is to perform the abortion or the physician's agent shall obtain a copy of the executed certification required by the provisions of subsections (b) and (c) of this section.

W. Va. Code § 16-2R-1.
Legislative findings

The Legislature finds that the State of West Virginia has a legitimate interest in protecting unborn lives and prohibiting abortions in West Virginia except in the circumstances set forth in this article.

W. Va. Code § 16-2R-2.
Definitions

The definitions set forth in this section are controlling for purposes of this article and of this code, irrespective of terms used in medical coding, notations, or billing documents. For purposes of this article:

"Abortion" means the use of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a patient known to be pregnant and with intent to cause the death and expulsion or removal of an embryo or a fetus. This term does not include the terms "intrauterine fetal demise" or "stillbirth" or "miscarriage" as defined in this section.

"Attempt to perform or induce an abortion" means an act or the omission of an act that, under the circumstances as the person so acting or omitting to act believes them to be, constitutes a substantial step in a course of conduct intended to culminate in an abortion.

"Born alive" means the complete expulsion or extraction of the fetus, at any stage of development, who after such expulsion or extraction breathes or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, regardless of whether the umbilical cord has been cut, and regardless of whether the expulsion or extraction occurs as a result of natural or induced labor, cesarean section, or induced abortion.

"Commissioner" means the Commissioner of the Bureau for Public Health of the West Virginia Department of Health and Human Resources.

"Contraception" or "contraceptive" means the prevention of pregnancy by interfering with the process of ovulation, fertilization, or implantation.

"Ectopic" means a fertilized egg which is developing outside the uterus, or a fertilized egg is developing within parts of the uterus where it cannot be viable, including a cervical, cornual, or cesarean section scar implantations.

"Embryo" means the developing human from the time of fertilization until the end of the eighth week of gestation.

"Fertilization" means the fusion of a human spermatozoon with a human ovum.

"Fetal tissue research" means tissue or cells obtained from a dead embryo or fetus after a miscarriage, abortion, or intrauterine fetal demise.

"Fetus" means the developing human in the postembryonic period from nine weeks after fertilization until birth.

"Licensed medical professional" means a person licensed under § 30-3-1 *et seq*., or § 30-14-1 *et seq*., of this code.

"Implantation" means when a fertilized egg has attached to the lining of the wall of the uterus.

"Intrauterine fetal demise" or "stillbirth" means the unintended or spontaneous loss of a fetus after the 19th week of pregnancy.

"In vitro fertilization" means a procedure or procedures intended to improve fertility or prevent genetic problems and assist with conception.

"Medical emergency" means a condition or circumstance that so complicates the medical condition of a patient as to necessitate an abortion to avert serious risk of the patient's death or serious risk of substantial life-threatening physical impairment of a major bodily function, not including psychological or emotional conditions. This term includes a circumstance in which it is necessary to terminate a pregnancy of one or more fetuses to preserve the life of another fetus or fetuses. A condition is not deemed a medical emergency if based on a claim or diagnosis that the patient intends or may engage in conduct which results in the patient's death or in substantial and irreversible physical impairment of a major bodily function.

"Miscarriage" means the unintended or spontaneous loss of an embryo or a fetus before the 20th week of pregnancy. This term includes the medical terms "spontaneous abortion," "missed abortion," and "incomplete abortion".

"Nonviable" means an embryo or a fetus has a lethal anomaly which renders it incompatible with life outside of the uterus.

"Partial-birth abortion" means an abortion performed on a live fetus after partial vaginal delivery.

"Pregnancy" means the period of gestation after which a fertilized egg has implanted in the wall of a uterus.

"Reasonable medical judgment" means a medical judgment that would be made by a licensed medical professional who is knowledgeable about the case and the treatment possibilities with respect to the medical conditions involved.

"Unemancipated minor" means a person younger than 18 years of age who is not, or has not been, married or judicially emancipated.

W. Va. Code § 16-2R-3.
Prohibition to perform an abortion

(a) An abortion may not be performed or induced or be attempted to be performed or induced unless in the reasonable medical judgment of a licensed medical professional:

(1) The embryo or fetus is nonviable;

(2) The pregnancy is ectopic; or

(3) A medical emergency exists.

(b) The prohibition set forth in subsection (a) of this section shall not apply to an adult within the first 8 weeks of pregnancy if the pregnancy is the result of sexual assault, as defined in § 61-8B-1 *et seq*. of this code, or incest, as defined in § 61-8-12 of this code, and at least 48 hours prior to the abortion the patient has reported the sexual assault or incest to a law enforcement agency having jurisdiction to investigate the complaint and provided the report to the licensed medical professional performing the abortion.

(c) The prohibition set forth in subsection (a) of this section shall not apply to a minor or an incompetent or incapacitated adult within the first 14 weeks of pregnancy if the pregnancy is the result of sexual assault, as defined in § 61-8B-1 *et seq*. of this code, or incest, as defined in § 61-8-12 of this code, and at least 48 hours prior to the abortion the patient has:

(1) A report of the sexual assault or incest has been made to law enforcement having jurisdiction to investigate the complaint; or

(2) The patient has obtained medical treatment for the sexual assault or incest or any injury related to the sexual assault or incest from a licensed medical professional or in a hospital, as defined in § 16-5B-1 of this code, which is licensed by the Office of Health Facility Licensure and Certification of the West Virginia Department of Health and Human Resources: *Provided*, That the licensed medical professional or hospital, as defined in § 16-5B-1 of this code, which is licensed by the Office of Health Facility

Licensure and Certification of the West Virginia Department of Health and Human Resources, and which performed or provided such medical treatment may not perform or provide the abortion arising from such sexual assault or incest.

(d) In all cases where a report of sexual assault or incest against a minor is made pursuant this subsection (c), the agency or person to whom the report is made shall report the sexual assault or incest to the Child Abuse and Neglect Investigations Unit of the West Virginia State Police within 48 hours.

(e) An abortion performed pursuant to this section may not use the partial birth abortion procedure.

(f) A surgical abortion performed or induced or attempted to be performed or induced pursuant to this section shall be in a hospital, as defined in § 16-5B-1 of this code, which is licensed by the Office of Health Facility Licensure and Certification of the West Virginia Department of Health and Human Resources.

(g) An abortion performed or induced or attempted to be performed or induced shall be performed by a licensed medical professional who has West Virginia hospital privileges.

W. Va. Code § 16-2R-4.
Not considered an abortion

(a) Abortion does not include:

(1) A miscarriage;

(2) An intrauterine fetal demise or stillbirth;

(3) The use of existing established cell lines derived from aborted human embryos or fetuses;

(4) Medical treatment provided to a patient by a licensed medical professional that results in the accidental or unintentional injury or death of an embryo or a fetus;

(5) In vitro fertilization;

(6) Human fetal tissue research, when performed in accordance with Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) and 45 C.F.R. 46.204 and 46.206; or

(7) The prescription, sale, transfer, or use of contraceptive devices, instruments, medicines, or drugs.

(b) This article does not prevent the prescription, sale, or transfer of intrauterine contraceptive devices, other contraceptive devices, or other generally medically accepted contraceptive devices, instruments, medicines, or drugs for a patient who is not known to be pregnant and for whom the contraceptive devices, instruments, medicines, or drugs are prescribed, sold, or transferred solely for contraceptive purposes and not for the purpose of inducing or causing the termination of a known pregnancy.

W. Va. Code § 16-2R-5.
Requirements when an abortion is performed on an unemancipated minor

(a) If an abortion is performed on an unemancipated minor under the circumstances set forth in § 16-2R-3(a) of this code, the licensed medical professional or his or her agent shall provide notice to the parent, guardian, or custodian of the unemancipated minor within 48 hours after the abortion is performed:

> **(1)** Directly, in person, or by telephone to the parent, guardian, or custodian of the unemancipated minor; or
>
> **(2)** By certified mail addressed to the parent, guardian, or custodian of the unemancipated minor at their usual place of residence, return receipt requested. The delivery shall be sent restricted delivery assuring that the letter is delivered only to the addressee. Time of delivery shall be deemed occur at 12:00 p.m. on the next day on which regular mail delivery takes place.

(b) If an abortion is performed on an unemancipated minor under the circumstances set forth in § 16-2R-3(c) of this code, the licensed medical professional may not perform an abortion until notice of the pending abortion as required by this section is complete.

> **(1)** A licensed medical professional or his or her agent may personally give notice directly, in person, or by telephone to the parent, guardian, or custodian of the unemancipated minor. Upon delivery of the notice, 48 hours shall pass until the abortion may be performed.
>
> **(2)** A licensed medical professional or his or her agent may provide notice by certified mail addressed to the parent, guardian, or custodian of the unemancipated minor at their usual place of residence, return receipt requested. The delivery shall be sent restricted delivery assuring that the letter is delivered only to the addressee. Time of delivery shall be deemed to occur at 12:00 p.m. on the next day on which regular mail delivery takes place. Forty-

eight hours shall pass from the date and time of presumed delivery until the abortion may be performed.

(3) Notice may be waived if the person entitled to notice certifies in writing that he or she has been notified. Notice is waived if the certified mail is refused.

(4) An unemancipated minor who objects to the notice being given to a parent, guardian, or custodian may petition for a waiver of the notice to the circuit court of the county in which the unemancipated minor resides. The petition shall be filed under seal.

(5) The petition is not required to be in any specific form and shall be sufficient if it fairly sets forth the facts and circumstances of the matter, but at a minimum shall contain the following information:

(A) The age and educational level of the unemancipated minor;

(B) The county in which the unemancipated minor resides; and

(C) A brief statement of the unemancipated minor's reason or reasons for the desired waiver of notification of the parent, guardian, or custodian of such unemancipated minor.

(6) A petition may not be dismissed nor may any hearing thereon be refused because of any actual or perceived defect in the form of the petition.

(7) The Supreme Court of Appeals is requested to prepare suggested form petitions and accompanying instructions and shall make the same available to the clerks of the circuit courts. The clerks shall make the form petitions and instructions available in the clerk's office.

(8) The proceedings held pursuant to this subsection shall be confidential and the court shall conduct the proceedings in camera. The court shall inform the unemancipated minor of her right to be represented by counsel. If the unemancipated minor desires the

services of an attorney, an attorney shall be appointed to represent her, if the unemancipated minor advises the court under oath or affidavit that she is financially unable to retain counsel.

(9) The court shall conduct a hearing upon the petition forthwith, but may not exceed the next succeeding judicial day. The court shall render its decision immediately and enter its written order not later than 24 hours. All testimony, documents, evidence, petition, orders entered thereon and all records relating to the matter shall be sealed by the clerk and shall not be opened to any person except upon order of the court upon a showing of good cause.

(10) Notice as required by this subsection (b) shall be ordered waived by the court if the court finds either:

(A) That the unemancipated minor is sufficiently mature and informed to make the decision to proceed with the abortion independently and without the notification or involvement of her parent, guardian, or custodian; or

(B) That notification to the person or persons to whom notification would otherwise be required would not be in the best interest of the unemancipated minor.

(11) A confidential appeal to the Supreme Court of Appeals shall be available to any unemancipated minor to whom a court denies a petition under this subsection. An order authorizing an abortion without notification is not appealable.

(12) Filing fees are not required in any proceeding under this subsection.

W. Va. Code § 16-2R-6.
Reporting by licensed medical professionals regarding abortion

Any abortion performed or induced in this state is subject to the reporting requirements of § 16-5-22.

W. Va. Code § 16-2R-7.
Licensure action

A licensed medical professional who knowingly and willfully performs, induces, or attempts to perform or induce an abortion, with the intent to violate the provisions of § 16-2R-3 of this code, is subject to disciplinary action by his or her applicable licensing board. If the licensing board finds that the licensed medical professional has knowingly and willfully performed, induced, or attempted to perform or induce an abortion, with the intent to violate the provisions of § 16-2R-3 of this code, the licensing board shall revoke medical professional's license.

W. Va. Code § 16-2R-8.
Protection of aborted fetuses born alive

(a) Whenever a licensed medical professional performs or induces, or attempts to perform or induce an abortion and the child is born alive, the licensed medical professional shall:

(1) Exercise the same degree of reasonable medical judgment to preserve the life and health of the child in the same manner as the licensed medical professional would render to any child alive at birth of the same gestational age;

(2) Ensure that the child is immediately transported and admitted to an appropriate medical facility.

(b) Any licensed medical professional who knowingly and willfully violates subsection (a) of this section shall be considered to have breached the standard of care owed to patients and is subject to discipline from the appropriate licensure board for such conduct, including but not limited to loss of professional license to practice.

(c) Any person, not subject to subsection (a) of this section, who knowingly and willfully violates subsection (a) of this section is guilty of the unauthorized practice of medicine in violation of § 30-3-13 of this code and, upon conviction thereof, is subject to the penalties contained in that section: Provided, That the provisions of this subsection (c) enacted during the third extraordinary session of the Legislature, 2022, shall be effective 90 days from passage.

(d) In addition to the penalties referenced in this section, a patient may seek any remedy otherwise available to the patient by applicable law.

(e) This section shall not be construed to subject any patient upon whom an abortion is performed or induced or attempted to be performed or induced to a criminal penalty for any violation of this section as a principal, accessory or accomplice, conspirator, or aider and abettor.

W. Va. Code § 16-2R-9.
Severability

Severability as provided in § 2-2-10(b)(7) of this code is applicable to this article: *Provided,* That if this entire article is judicially determined to be unconstitutional, then the provisions of § 16-2F-1 *et seq.*, § 16-2I-1 *et seq.*, 16-2M-1 *et seq.*, § 16-2O-1, § 16-2P-1, § 16-2Q-1, and § 33-42-8 of this code shall become immediately effective: *Provided, however,* That if a provision or provisions of § 16-2R-1 *et seq.* of this code are judicially determined to be unconstitutional, then the provisions of § 16-2F-9, § 16-2I-9, § 16-2M-7, § 16-2O-1(e), § 16-2P-1(d), § 16-2Q-1(m), and § 33-42-8(d) of this code are not effective.

W. Va. Code § 61-2-8.
Abortion; penalty

(a) Any person other than a licensed medical professional, as defined in § 16-2R-2 of this code, who knowingly and willfully performs, induces, or attempts to perform or induce an abortion, as defined in § 16-2R-2 of this code, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than three nor more than 10 years.

(b) A person who was formerly a licensed medical professional, as defined in § 16-2R-2 of this code and whose license has been revoked pursuant to the provisions of § 16-2R-7 of this code, and who knowingly and willfully performs, induces, or attempts to perform or induce a subsequent abortion, is guilty of a felony and, upon conviction thereof, shall be imprisoned in a state correctional facility for a determinate sentence of not less than three nor more than 10 years.

(c) This section shall not be construed to subject any pregnant female upon whom an abortion is performed or induced or attempted to be performed or induced to a criminal penalty for any violation of this section as a principal, accessory, accomplice, conspirator, or aider and abettor.

(d) The amendments to this section enacted during the third extraordinary session of the Legislature, 2022, shall be effective 90 days from passage.

21 C.F.R. § 314.520.
Approval with restrictions to assure safe use.

(a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:

(1) Distribution restricted to certain facilities or physicians with special training or experience; or

(2) Distribution conditioned on the performance of specified medical procedures.

(b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product.

Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (Mar. 27, 2008).

Federal Register / Vol. 73, No. 60 / Thursday, March 27, 2008 / Notices 16313

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0174]

Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to notify holders of certain prescription new drug and biological license applications that they will be deemed to have in effect an approved risk evaluation and mitigation strategy (REMS) under the Food and Drug Administration Amendments Act of 2007 (FDAAA). Holders of applications deemed to have in effect an approved REMS are required to submit a proposed REMS to FDA.

DATES: Submit proposed REMSs to FDA by September 21, 2008.

ADDRESSES: Written communications regarding the applicability of this notice to a specific product should be identified with Docket Number FDA–2008–N–0174 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic communications to *http://www.regulations.gov*. Information about FDA implementation of FDAAA is available on the Internet at *http://www.fda.gov/oc/initiatives/advance/fdaaa.html*.

FOR FURTHER INFORMATION CONTACT: Mary Dempsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4326, Silver Spring, MD 20993–0002, 301–796–0147.

SUPPLEMENTARY INFORMATION:

I. Introduction

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Title IX, subtitle A, section 901 of FDAAA created new section 505–1 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355–1). Section 505–1(a) of the act authorizes FDA to require persons submitting certain applications[1] to submit and implement a REMS if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug and informs the holder of the application for the drug of the determination. Section 909 of FDAAA provides that Title IX, subtitle A takes effect 180 days after its enactment, which is March 25, 2008.

FDAAA also contains REMS requirements for drug and biological products approved before the effective date of Title IX, subtitle A. Section 909(b)(1) of FDAAA specifies that a ''drug that was approved before the effective date of this Act is * * * deemed to have in effect an approved risk evaluation and mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act * * * if there are in effect on the effective date of this Act elements to assure safe use—(A) required under section 314.520 or section 601.42 of title 21, Code of Federal Regulations; or (B) otherwise agreed to by the applicant and the Secretary [of Health and Human Services] for such drug.''

Section 909(b)(3) of FDAAA states: ''Not later than 180 days after the effective date of this Act, the holder of an approved application for which a risk evaluation and mitigation strategy is deemed to be in effect * * * shall submit to the Secretary a proposed risk evaluation and mitigation strategy. Such proposed strategy is subject to section 505–1 of the Act as if included in such application at the time of submission of the application to the Secretary.''[2]

Section 909(b)(2) of FDAAA states that a REMS for a drug deemed to have a REMS consists of the timetable required under section 505–1(d) of the act and any additional elements under section 505–1(e) and (f) of the act in effect for the drug on the effective date of FDAAA.

The purpose of this notice is to identify those drugs that FDA has determined will be deemed to have in effect an approved REMS and to notify holders of applications for such drugs that they are required to submit a proposed REMS by September 21, 2008. FDA is developing guidance on the preferred content and format of a proposed REMS required to be submitted under section 909(b) of FDAAA and will issue it as soon as possible.

II. List of Drug and Biological Products Deemed to Have a REMS

Drug and biological products deemed to have in effect an approved REMS are those that on March 25, 2008 (the effective date of Title IX, subtitle A of FDAAA), had in effect ''elements to assure safe use.'' ''Elements to assure safe use'' include the following: (1) Health care providers who prescribe the drug have particular training or experience, or are specially certified; (2) pharmacies, practitioners, or health care settings that dispense the drug are specially certified; (3) the drug is dispensed to patients only in certain health care settings, such as hospitals; (4) the drug is dispensed to patients with evidence or other documentation of safe use conditions, such as laboratory test results; (5) each patient using the drug is subject to certain monitoring; or (6) each patient using the drug is enrolled in a registry (see section 505–1(f)(3) of the act).

Some applications approved before the effective date of FDAAA Title IX, subtitle A contain these elements to assure safe use.[3] Some of these applications were approved under § 314.520 (21 CFR 314.520) or § 601.42 (21 CFR 601.42). Others were not approved under part 314, subpart H or part 601, subpart E, but still contain elements to assure safe use that were agreed to by the applicant and the Secretary for such drug. Since 2005, these elements typically appeared in approved risk minimization action plans (RiskMAPs) (see the guidance for industry entitled ''Development and Use of Risk Minimization Action Plans'' (70 FR 15866, March 29, 2005)).

FDA has reviewed its records to identify applications that were approved before the effective date of Title IX of FDAAA with elements to assure safe use and has identified the drug and biological products listed in table 1 of this document as those that will be deemed to have in effect an approved REMS.

[1] Section 505(p)(1) of the act (21 U.S.C. 355(p)(1)) states that section 505–1 of the act applies to applications for prescription drugs approved under section 505(b) or (j) of the act and applications approved under section 351 of the Public Health Service Act (42 U.S.C. 262).

[2] Title IX, subtitle A of FDAAA, which includes section 909, takes effect March 25, 2008; 180 days after that date is September 21, 2008.

[3] These plans sometimes contain other elements to minimize risk such as a Medication Guide (21 CFR part 208) or a communication/educational plan for health care providers or patients. A drug will not be deemed to have a REMS if it has only a Medication Guide, patient package insert, and/or communication plan (see section 505–1(e)(2) and (e)(3) of the act).

TABLE 1.—PRODUCTS DEEMED TO HAVE IN EFFECT AN APPROVED REMS

Generic or Proper Name	Brand Name	Application Number[1]	Date of Approval[2]
Abarelix	Plenaxis[3]	NDA 21–320	11/25/2003
Alosetron	Lotronex	NDA 21–107	02/09/2000
Ambrisentan	Letairis	NDA 22–081	06/15/2007
Bosentan	Tracleer	NDA 21–290	11/20/2001
Clozapine	Clozaril Fazaclo ODT	NDA 19–758 ANDA 74–949 ANDA 75–417 ANDA 75–713 ANDA 75–162 ANDA 76–809 NDA 21–590	09/26/1989 11/26/97 5/27/99 11/15/02 4/26/05 12/16/05 02/09/2004
Dofetilide	Tikosyn	NDA 20–931	10/01/1999
Eculizumab	Soliris	BLA 125166	03/16/2007
Fentanyl PCA	Ionsys[3]	NDA 21–338	05/22/2006
Fentanyl citrate	Actiq	NDA 20–747	11/04/1998
Isotretinoin	Accutane Amnesteem Claravis Sotret	NDA 18–662 ANDA 75–945 ANDA 76–135 ANDA 76–356 ANDA 76–041 ANDA 76–503	05/07/1982 11/2002 04/2003 04/2003 12/2002 06/2003
Lenalidomide	Revlimid	NDA 21–880	12/27/2005
Mifepristone	Mifeprex	NDA 20–687	09/28/2000
Natalizumab	Tysabri	BLA 125104	11/23/2004
Small pox (Vaccinia) Vaccine, Live	ACAM2000	BLA 125158	08/31/2007
Sodium oxybate	Xyrem	NDA 21–196	07/17/2002
Thalidomide	Thalomid	NDA 20–785 NDA 21–430	07/16/1998

[1] New drug application (NDA), abbreviated new drug application (ANDA), biologics license application (BLA).
[2] The original date of approval of the drug. FDA may have required elements to assure safe use at a later date.
[3] Product is not currently marketed in the United States.

FDA is further asking members of the public to please notify the agency if they are aware of applications that have not been identified in this document and that they believe should be deemed to have in effect an approved REMS. Please provide the information to Mary Dempsey, Risk Management Coordinator (see the **FOR FURTHER INFORMATION CONTACT** section of this document).

Any application holder that believes its product identified in this notice should not be on the list of drug or biological products that will be deemed to have in effect an approved REMS should submit a letter identified with Docket Number FDA–2008–N–0174 to the Division of Dockets Management (see **ADDRESSES**) stating why the application holder believes its product was improperly identified in this notice. FDA will notify the application holder within 30 days of receipt of the letter of its determination.

Dated: March 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–6201 Filed 3–26–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200mg* (Mar. 2023)

Initial Shared System REMS approval: 04/2019
Most Recent Modification: 03/2023

Mifepristone Tablets, 200 mg
Progestin Antagonist

RISK EVALUATION AND MITIGATION STRATEGY (REMS)
SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200 MG

I. GOAL

The goal of the REMS for mifepristone is to mitigate the risk of serious complications associated with mifepristone by:

a) Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS Program.

b) Ensuring that mifepristone is only dispensed by or under the supervision of certified prescribers, or by certified pharmacies on prescriptions issued by certified prescribers.

c) Informing patients about the risk of serious complications associated with mifepristone.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Healthcare providers who prescribe mifepristone must be specially certified.
   a. To become specially certified to prescribe mifepristone, healthcare providers must:
      i. Review the Prescribing Information for mifepristone.
      ii. Complete a *Prescriber Agreement Form*. By signing[1] a *Prescriber Agreement Form*, prescribers agree that:
         1) They have the following qualifications:
            a) Ability to assess the duration of pregnancy accurately
            b) Ability to diagnose ectopic pregnancies
            c) Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
         2) They will follow the guidelines for use of mifepristone (see b.i-vii below).
   b. As a condition of certification, prescribers must follow the guidelines for use of mifepristone described below:
      i. Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
      ii. Ensure that the healthcare provider and patient sign the *Patient Agreement Form.*

[1] In this REMS, the terms “sign” and “signature” include electronic signatures.

iii. Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.

iv. Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.

v. Ensure that any deaths are reported to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of mifepristone that was dispensed to the patient.

vi. If mifepristone will be dispensed by a certified pharmacy:

1) Provide the certified pharmacy a signed *Prescriber Agreement Form*.

2) Assess appropriateness of dispensing mifepristone when contacted by a certified pharmacy about patients who will receive mifepristone more than 4 calendar days after the prescription was received by the certified pharmacy.

3) Obtain the NDC and lot number of the package of mifepristone the patient received in the event the prescriber becomes aware of the death of the patient.

vii. The certified prescriber who dispenses mifepristone or who supervises the dispensing of mifepristone must:

1) Provide an authorized distributor with a signed *Prescriber Agreement Form*.

2) Ensure that the NDC and lot number from each package of mifepristone dispensed are recorded in the patient's record.

3) Ensure that healthcare providers under their supervision follow guidelines i.-v.

c. Mifepristone Sponsors must:

i. Ensure that healthcare providers who prescribe their mifepristone are specially certified in accordance with the requirements described above and de-certify healthcare providers who do not maintain compliance with certification requirements.

ii. Ensure prescribers previously certified in the Mifepristone REMS Program complete the new *Prescriber Agreement Form*:

1) Within 120 days after approval of this modification, for those previously certified prescribers submitting prescriptions to certified pharmacies.

2) Within one year after approval of this modification, if previously certified and ordering from an authorized distributor.

iii. Ensure that healthcare providers can complete the certification process by email or fax to an authorized distributor and/or certified pharmacy.

iv. Provide the Prescribing Information and their *Prescriber Agreement Form* to healthcare providers who inquire about how to become certified.

v. Ensure annually with each certified prescriber that their locations for receiving mifepristone are up to date.

The following materials are part of the Mifepristone REMS Program:

- *Prescriber Agreement Form for Danco Laboratories, LLC*
- *Prescriber Agreement Form for GenBioPro, Inc.*
- *Patient Agreement Form*

2. Pharmacies that dispense mifepristone must be specially certified
   a. To become specially certified to dispense mifepristone, pharmacies must:
      i. Be able to receive *Prescriber Agreement Forms* by email and fax.
      ii. Be able to ship mifepristone using a shipping service that provides tracking information.
      iii. Designate an authorized representative to carry out the certification process on behalf of the pharmacy.
      iv. Ensure the authorized representative oversees implementation and compliance with the Mifepristone REMS Program by doing the following:
         1) Review the Prescribing Information for mifepristone.
         2) Complete a *Pharmacy Agreement Form*. By signing a *Pharmacy Agreement Form*, the authorized representative agrees that the pharmacy will put processes and procedures in place to ensure the following requirements are completed:
            a) Verify that the prescriber is certified by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with the pharmacy.
            b) Dispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in c) below.
            c) Confirm with the prescriber the appropriateness of dispensing mifepristone for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
            d) Record in the patient's record the NDC and lot number from each package of mifepristone dispensed.
            e) Track and verify receipt of each shipment of mifepristone.
            f) Dispense mifepristone in its package as supplied by the Mifepristone Sponsor.
            g) Report any patient deaths to the prescriber, including the NDC and lot number from the package of mifepristone dispensed to the patient, and remind the prescriber of their obligation to report the deaths to the Mifepristone Sponsor that provided the mifepristone. Notify the Mifepristone Sponsor that provided the dispensed mifepristone that the pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
            h) Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
            i) Maintain records of *Prescriber Agreement Forms*.
            j) Maintain records of dispensing and shipping.
            k) Maintain records of all processes and procedures including compliance with those processes and procedures.
            l) Maintain the identity of the patient and prescriber as confidential, including limiting access to patient and prescriber identity only to those personnel necessary to dispense mifepristone in accordance with the Mifepristone REMS Program requirements, or as necessary for payment and/or insurance purposes..
            m) Train all relevant staff on the Mifepristone REMS Program requirements.

n) Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

b. Mifepristone Sponsors must:

i. Ensure that pharmacies are specially certified in accordance with the requirements described above and de-certify pharmacies that do not maintain compliance with certification requirements.

ii. Ensure that pharmacies can complete the certification process by email and fax to an authorized distributor.

i. Verify annually that the name and contact information for the pharmacy's authorized representative corresponds to that of the current designated authorized representative for the certified pharmacy, and if different, require the pharmacy to recertify with the new authorized representative.

The following materials are part of the Mifepristone REMS Program:

- *Pharmacy Agreement Form for Danco Laboratories, LLC*
- *Pharmacy Agreement Form for GenBioPro, Inc.*

3. Mifepristone must be dispensed to patients with evidence or other documentation of safe use conditions as ensured by the certified prescriber in signing the *Prescriber Agreement Form.*

a. The patient must sign a *Patient Agreement Form* indicating that the patient has:

i. Received, read and been provided a copy of the *Patient Agreement Form*.

ii. Received counseling from the healthcare provider regarding the risk of serious complications associated with mifepristone.

B. Implementation System

1. Mifepristone Sponsors must ensure that their mifepristone is only distributed to certified prescribers and certified pharmacies by:

a. Ensuring that distributors who distribute their mifepristone comply with the program requirements for distributors.

i. The distributors must put processes and procedures in place to:

1) Complete the certification process upon receipt of a *Prescriber Agreement Form* or *Pharmacy Agreement Form*.

2) Notify healthcare providers and pharmacies when they have been certified by the Mifepristone REMS Program.

3) Ship mifepristone only to certified pharmacies or locations identified by certified prescribers.

4) Not ship mifepristone to pharmacies or prescribers who become de-certified from the Mifepristone REMS Program.

5) Provide the Prescribing Information and their Prescriber Agreement Form to healthcare providers who (1) attempt to order mifepristone and are not yet certified, or (2) inquire about how to become certified.

ii. Put processes and procedures in place to maintain a distribution system that is secure,

confidential and follows all processes and procedures, including those for storage, handling, shipping, tracking package serial numbers, NDC and lot numbers, proof of delivery and controlled returns of mifepristone.

iii. Train all relevant staff on the Mifepristone REMS Program requirements.

iv. Comply with audits by Mifepristone Sponsors or a third party acting on behalf of Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed for the Mifepristone REMS Program. In addition, distributors must maintain appropriate documentation and make it available for audits.

b. Ensuring that distributors maintain secure and confidential distribution records of all shipments of mifepristone.

2. Mifepristone Sponsors must monitor their distribution data to ensure compliance with the Mifepristone REMS Program.

3. Mifepristone Sponsors must ensure that adequate records are maintained to demonstrate that the Mifepristone REMS Program requirements have been met, including, but not limited to records of mifepristone distribution; certification of prescribers and pharmacies; and audits of pharmacies and distributors. These records must be readily available for FDA inspections.

4. Mifepristone Sponsors must audit their new distributors within 90 calendar days and annually thereafter after the distributor is authorized to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their distributor compliance if noncompliance is identified.

5. Mifepristone Sponsors must audit their certified pharmacies within 180 calendar days after the pharmacy places its first order of mifepristone, and annually thereafter audit certified pharmacies that have ordered mifepristone in the previous 12 months, to ensure that all processes and procedures are in place and functioning to support the requirements of the Mifepristone REMS Program. Mifepristone Sponsors will take steps to address their pharmacy compliance if noncompliance is identified.

6. Mifepristone Sponsors must take reasonable steps to improve implementation of and compliance with the requirements of the Mifepristone REMS Program based on monitoring and assessment of the Mifepristone REMS Program.

7. Mifepristone Sponsors must report to FDA any death associated with mifepristone whether or not considered drug-related, as soon as possible but no later than 15 calendar days from the initial receipt of the information by the Mifepristone Sponsor. This requirement does not affect the sponsors' other reporting and follow-up requirements under FDA regulations.

C. Timetable for Submission of Assessments

The NDA Sponsor must submit REMS assessments to FDA one year from the date of the approval of the modified REMS (01/03/2023) and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 90 calendar days before the submission date for that assessment. The NDA Sponsor must submit each assessment so that it will be received by the FDA on or before the due date.

MIFEPREX® (Mifepristone) Tablets, 200 mg

PRESCRIBER AGREEMENT FORM

Mifeprex* (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To ***become a certified prescriber***, you must:

- **If you submit Mifeprex prescriptions for dispensing from certified pharmacies**:
  - Submit this form to each certified pharmacy to which you intend to submit Mifeprex prescriptions. The form must be received by the certified pharmacy before any prescriptions are dispensed by that pharmacy.
- **If you order Mifeprex for dispensing by you or healthcare providers under your supervision:**
  - Submit this form to the distributor. This form must be received by the distributor before the first order will be shipped to the healthcare setting.
  - Healthcare settings, such as medical offices, clinics, and hospitals, where Mifeprex will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

Prescriber Agreement: By signing this form, you agree that you meet the qualifications below and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS Program. You also understand that if the guidelines below are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.

Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-877-4 EARLY OPTION (1-877-432-7596 toll-free), or by visiting www.earlyoptionpill.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
- Ensure the healthcare provider and patient sign the *Patient Agreement Form*.
- Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.
- Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.
- Ensure that any deaths of patients who received Mifeprex are reported to Danco Laboratories, LLC, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of Mifeprex that was dispensed to the patient.

Ensure that healthcare providers under your supervision follow the guidelines listed above.

- If Mifeprex will be dispensed through a certified pharmacy:
  - Assess appropriateness of dispensing Mifeprex when contacted by a certified pharmacy about patients who will receive Mifeprex more than 4 calendar days after the prescription was received by the certified pharmacy.
  - Obtain the NDC and lot number of the package of Mifeprex the patient received in the event the prescriber becomes aware of the death of a patient.
- If Mifeprex will be dispensed by you or by healthcare providers under your supervision:
  - Ensure the NDC and lot number from each package of Mifeprex are recorded in the patient's record.

I understand that a certified pharmacy may dispense mifepristone made by a different manufacturer than that stated on this Prescriber Agreement Form.

Print Name: _____ Title: _____

Signature: _____ Date: _____

Medical License # _____ State _____

NPI # _____

Practice Name(s): _____

Practice Setting Address: _____

_____

Email: _____ Phone: _____ Preferred __ email __ phone

Return completed form to Mifeprex@dancodistributor.com or fax to 1-866-227-3343.

Approved 03/2023

Mifepristone Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

To ***become a certified prescriber***, you must:

- **If you submit mifepristone prescriptions for dispensing from certified pharmacies**:
  - Submit this form to each certified pharmacy to which you intend to submit mifepristone prescriptions. The form must be received by the certified pharmacy before any prescriptions are dispensed by that pharmacy.
- **If you order mifepristone for dispensing by you or healthcare providers under your supervision:**
  - Submit this form to the distributor. This form must be received by the distributor before the first order will be shipped to the healthcare setting.
  - Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

Prescriber Agreement: By signing this form, you agree that you meet the qualifications below and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS Program. You also understand that if the guidelines below are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.

Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-855-MIFE-INFO (1-855—643-3463 toll-free), or by visiting www.MifeInfo.com.

In addition to meeting these qualifications, you also agree to follow these guidelines for use:

- Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
- Ensure the healthcare provider and patient sign the *Patient Agreement Form*.
- Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.
- Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.
- Ensure that any deaths of patients who received mifepristone are reported to GenBioPro, Inc., identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of mifepristone that was dispensed to the patient.

Ensure that healthcare providers under your supervision follow the guidelines listed above.

- If mifepristone will be dispensed through a certified pharmacy:
  - Assess appropriateness of dispensing mifepristone when contacted by a certified pharmacy about patients who will receive mifepristone more than 4 calendar days after the prescription was received by the certified pharmacy.
  - Obtain the NDC and lot number of the package of mifepristone the patient received in the event the prescriber becomes aware of the death of a patient.
- If mifepristone will be dispensed by you or by healthcare providers under your supervision:
  - Ensure the NDC and lot number from each package of mifepristone are recorded in the patient's record.

I understand that a certified pharmacy may dispense mifepristone made by a different manufacturer than that stated on this Prescriber Agreement Form.

Print Name: _____ Title: _____

Signature: _____ Date: _____

Medical License # _____ State _____

NPI # _____

Practice Name(s): _____

Practice Setting Address: _____

_____

Email: _____ Phone: _____ Preferred __ email __ phone

Return completed form to **RxAgreements@GenBioPro.com** or fax to 1-877-239-8036

Approved 03/2023 GBP-PA-01

PATIENT AGREEMENT FORM Mifepristone Tablets, 200 mg

Healthcare Providers: *Counsel the patient on the risks of mifepristone. Both you and the patient must provide a written or electronic signature on this form.*

Patient Agreement:

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my healthcare provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
   - **a.** I will take mifepristone on Day 1.
   - **b.** I will take the misoprostol tablets 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
   - heavy bleeding
   - infection
4. I will contact the clinic/office/provider right away if in the days after treatment I have:
   - a fever of 100.4°F or higher that lasts for more than four hours
   - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
   - severe stomach area (abdominal) pain or discomfort, or I am “feeling sick,” including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol
     — these symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

   My healthcare provider has told me that these symptoms listed above could require emergency care. If I cannot reach the clinic/office/provider right away, my healthcare provider has told me who to call and what to do.
5. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
6. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
7. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
8. I have the MEDICATION GUIDE for mifepristone.
9. My healthcare provider has answered all my questions.

Patient Signature: _____ **Patient Name** (print): _____ **Date**: _____

Provider Signature: _____ **Provider Name** (print): _____ **Date**: _____

Patient Agreement Forms may be provided, completed, signed, and transmitted in paper or electronically.

01/2023

MIFEPREX®(Mifepristone) Tablets, 200mg

PHARMACY AGREEMENT FORM

Pharmacies must designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Mifepristone REMS Program on behalf of the pharmacy.

Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

By signing this form, as the Authorized Representative I certify that:

- Each location of my pharmacy that will dispense Mifeprex is able to receive *Prescriber Agreement Forms* by email and fax.
- Each location of my pharmacy that will dispense Mifeprex is able to ship Mifeprex using a shipping service that provides tracking information.
- I have read and understood the Prescribing Information for Mifeprex. The Prescribing Information is available by calling 1-877-4 EARLY OPTION (1-877-432-7596 toll-free) or online at www.earlyoptionpill.com; and
- Each location of my pharmacy that will dispense Mifeprex will put processes and procedures in place to ensure the following requirements are completed. I also understand that if my pharmacy does not complete these requirements, the distributor may stop accepting Mifeprex orders.
  - Verify that the prescriber is certified in the Mifepristone REMS Program by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with your pharmacy.
  - Dispense Mifeprex such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in the following bullet.
  - Confirm with the prescriber the appropriateness of dispensing Mifeprex for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
  - Record in the patient's record the NDC and lot number from each package of Mifeprex dispensed.
  - Track and verify receipt of each shipment of Mifeprex.
  - Dispense mifepristone in its package as supplied by Danco Laboratories, LLC.
  - Report any patient deaths to the prescriber, including the NDC and lot number from the package of Mifeprex dispensed to the patient, and remind the prescriber of their obligation to report the deaths to Danco Laboratories, LLC. Notify Danco that your pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
  - Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
  - Maintain records of *Prescriber Agreement Forms*, dispensing and shipping, and all processes and procedures including compliance with those processes and procedures.
  - Maintain the identity of Mifeprex patients and prescribers as confidential and protected from disclosure except to the extent necessary for dispensing under this REMS or as necessary for payment and/or insurance.
  - Train all relevant staff on the Mifepristone REMS Program requirements.
  - Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

Any new authorized representative must complete and submit the *Pharmacy Agreement Form*.

Authorized Representative Name: _____ Title: _____

DANCO
Support • Progress • Options

P.O. Box 4816-New York, NY 10185
1-877-4-EARLY-OPTION (1-877-432-7596) www.earlyoptionpill.com

Signature: _____ Date: _____

Email: _____ Phone: _____ Preferred __ email __ phone

Pharmacy Name: _____

Pharmacy Address: _____

Return completed form to Mifeprex@dancodistributor.com or fax to 1-866-227-3343.

PHARMACY AGREEMENT FORM **Mifepristone Tablets, 200 mg**

Pharmacies must designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Mifepristone REMS Program on behalf of the pharmacy.

Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

By signing this form, as the Authorized Representative I certify that:

- Each location of my pharmacy that will dispense mifepristone is able to receive *Prescriber Agreement Forms* by email and fax.
- Each location of my pharmacy that will dispense mifepristone is able to ship mifepristone using a shipping service that provides tracking information.
- I have read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-855-MIFE-INFO (1-855-643-3463 toll-free) or online at www.MifeInfo.com; and
- Each location of my pharmacy that will dispense mifepristone will put processes and procedures in place to ensure the following requirements are completed. I also understand that if my pharmacy does not complete these requirements, the distributor may stop accepting mifepristone orders.
    - Verify that the prescriber is certified in the Mifepristone REMS Program by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with your pharmacy.
    - Dispense mifepristone such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in the following bullet.
    - Confirm with the prescriber the appropriateness of dispensing mifepristone for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
    - Record in the patient's record the NDC and lot number from each package of mifepristone dispensed.
    - Track and verify receipt of each shipment of mifepristone.
    - Dispense mifepristone in its package as supplied by GenBioPro, Inc.
    - Report any patient deaths to the prescriber, including the NDC and lot number from the package of mifepristone dispensed to the patient, and remind the prescriber of their obligation to report the deaths to GenBioPro, Inc. Notify GenBioPro that your pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
    - Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.
    - Maintain records of *Prescriber Agreement Forms*, dispensing and shipping, all processes and procedures including compliance with those processes and procedures.
    - Maintain the identity of mifepristone patients and prescribers as confidential and protected from disclosure except to the extent necessary for dispensing under this REMS or as necessary for payment and/or insurance purposes.
    - Train all relevant staff on the Mifepristone REMS Program requirements.
    - Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

Any new authorized representative must complete and submit the *Pharmacy Agreement Form*.

Authorized Representative Name: _____ Title: _____

Signature: _____ Date: _____

Email: _____ Phone: _____ Preferred __ email __ phone

Pharmacy Name: _____

Pharmacy Address: _____

Return completed form to **RxAgreements@GenBioPro.com** or fax to **1-877-239-8036.**

153 Cong. Rec. S5444 (daily ed. May 2, 2007).
(excerpts)

The objective of these al-Qaida attacks is to reignite the sectarian violence in Baghdad and breaking support for the war here at home. That was the goal of al-Zarqawi, whom we were fortunate to be able to take out of the fight, and that is the fight now of the remaining al-Qaida extremists in Iraq. General Petraeus explained it this way:

Iraq is, in fact, the central front of al-Qaida's global campaign.

It just boggles my mind, Mr. President, for some of us to stand here on the floor and say we ought to withdraw our troops from Iraq when, in fact, al-Qaida—the enemy that hit innocent Americans and killed 3,000 of them on September 11, 2001—considers Iraq to be the central front in their campaign against the West. Al-Qaida's role makes the conflict in Iraq far more complex than a simple fight between Iraqis. Many also belong to the same terrorist network, as I said, that attacked us on September 11, 2001. Were we to leave prematurely, were we to leave a power vacuum in Iraq, al-Qaida would no doubt, as they did in Afghanistan earlier, use that power vacuum as an opportunity to regroup, to plan, to train, to recruit, and then to export additional terrorist attacks against the United States here on this continent.

We need to give our troops all of the equipment and training and protection they need to prevail. Without a war funding bill, the military has to take money from some other account—notably, the Air Force or Navy—just in order to make sure the Army has the resources they need, so the troops can have the equipment they need, so they can rotate back on a timely basis and come home to the loving arms of their families, to repair existing equipment. And worst of all, in one sense, failing to send this money on a timely basis to the military hurts the military families who are waiting behind, anxious, as we all understand, for the welfare and safety of their loved ones. Our troops and their families deserve better.

So I hope that after the last 86 days, which have been characterized by political theater and gamesmanship, where some have been more focused on the 2008 election and trying to find ways to gain political advantage, I hope Republicans and Democrats, the legislative branch and executive branch, can come together and do what we should have done months ago—get the funds to the troops as soon as possible, without the surrender deadline, without tying the hands of our military commanders and making their opportunity for success impossible, and without the porkbarrel spending that demeans the noble sacrifice of these brave men and women.

Mr. President, I yield the floor and yield back our remaining time.

I suggest the absence of a quorum.

The ACTING PRESIDENT pro tempore. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. COCHRAN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. WEBB). Without objection, it is so ordered.

Mr. KENNEDY. Mr. President, we yield back all morning business time.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The assistant legislative clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Landrieu amendment No. 1004, to require the Food and Drug Administration to permit the sale of baby turtles as pets so long as the seller uses proven methods to effectively treat salmonella.

Dorgan amendment No. 990, to provide for the importation of prescription drugs.

AMENDMENT NO. 1010 TO AMENDMENT NO. 990

(Purpose: To protect the health and safety of the public)

Mr. COCHRAN. Mr. President, I send an amendment to the desk and ask that it be stated.

The PRESIDING OFFICER. The clerk will report.

The assistant legislative clerk read as follows:

The Senator from Mississippi [Mr. COCHRAN], for himself, Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ, proposes an amendment numbered 1010 to amendment 990.

At the end of the amendment, add the following:

SEC. ___. PROTECTION OF HEALTH AND SAFETY.

This title, and the amendments made by this title, shall become effective only if the Secretary of Health and Human Services certifies to Congress that the implementation of this title (and amendments) will—

(1) pose no additional risk to the public's health and safety; and

(2) result in a significant reduction in the cost of covered products to the American consumer.

The PRESIDING OFFICER. The Senator from Mississippi.

Mr. COCHRAN. Mr. President, I am offering this amendment for myself, as well as for these cosponsors: Mr. CARPER, Mr. NELSON of Nebraska, Mr. HATCH, Mr. BENNETT, Mr. ENZI, Mr. BURR, and Mr. MENENDEZ. This is an amendment to the amendment proposed by Mr. DORGAN.

Improving the health and quality of life for Americans is very important to all of us, and access to safe and effective prescription drugs is a major step in accomplishing these goals. With recent scientific advances, a number of medical therapies have been made available to treat and, in some cases, to cure diseases. We want Americans to continue to have access to safe and effective drugs that are approved by the Food and Drug Administration.

But we must not create opportunities for potentially dangerous drug products from foreign countries to reach the American consumer. For example, counterfeit products, those that have been tampered with or those of unknown origin, should not be brought into this country. I am concerned that allowing the importation of prescription drugs would allow such risks to become more likely.

The amendment proposed by the Senator from North Dakota will put in jeopardy the process we now have to ensure the safety of prescription medications and protect the health of the American people.

I am offering this second-degree amendment to require the Secretary of Health and Human Services to certify that the importation of drug products will not pose additional risks to Americans and will, indeed, lower costs to consumers.

If, as some argue, a policy of importation is safe and will reduce costs, this amendment should not be a problem.

We have debated this issue before on several previous occasions. For example, during the consideration of annual appropriations bills for the Department of Agriculture, the Food and Drug Administration, and related agencies, when considering the Greater Access to Pharmaceuticals Act, and even during the debate and passage of the Medicare Modernization Act of 2003, a similar amendment to require the safety of imported drugs was considered and unanimously approved each time.

In all these instances, the Senate has adopted this amendment by a unanimous vote. The safety of the American consumer must be our No. 1 priority. These safeguards should also be applied to this proposal.

We should be certain that any change we make in the law does not result in less protection in terms of the safety of the drugs supplied to the American people and will, indeed, make prescription drugs more affordable. Liberalization of protections that are designed to keep unsafe drugs out of this country, especially considering the terrorist threats we face now, should occur only if the necessary safeguards are in place. This amendment will ensure that the concerns of the last two administrations regarding safety and cost-effectiveness are addressed prior to the implementation of this proposal.

Counterfeiting of drugs has become a more common practice throughout the world, and the transshipment of these counterfeit products through Canada is one of the most serious dangers we face. The Canadian Government itself has said that drug products shipped to

site you are purchasing from is an FDA-approved supplier.

So this reimportation bill is essentially going to create an atmosphere where those Internet pharmacies are going to become basically the ''wild west'' of supplying drugs in this country, and you are going to see people going on to these Internet pharmacy sites and purchasing drugs they think are being represented as an American-approved drug that has been reimported—and is at a lower price—but may actually be a totally adulterated drug which will do significant harm to you.

We have seen instances of that already—dramatic instances. Case after case has been reported of people being significantly harmed and in some instances dying as a result of buying pharmaceuticals off the Internet that turned out not to be what they were represented to be from international sites.

So at a minimum, this reimportation proposal, which has received significant support in the past because it has a motherhood name on it—even though it might be actually creating significant problems for children and for other people in this country as a result of the risk it puts people at—at a minimum, this proposal should be subject to creating some sort of a regime where FDA has the ability to monitor and to approve and to make available to the public the knowledge that Internet pharmaceutical sites have been approved by the FDA. That is what my amendment does. It tries to address that.

So we should not move forward precipitously in the way that is proposed by the Senator from North Dakota. We should not be supporting this simply because it has a nice name on it and because he can hold up two bottles which are the same drug but costs differently in a managed economy in Canada and a market economy here in the United States. We should, rather, set up a structure where FDA can be sure that when you buy that pharmaceutical product through an Internet site that is international or from a Canadian pharmacy, that you are getting what they claim you are getting, so when you take that drug, you benefit from it and are not harmed by it.

This all, however, gets to a bigger issue. Probably, there is not time right now to go into it in depth. But the bigger issue is, where do pharmaceutical products come from? Where do all these amazing products, the biologic products that are saving lives in this country and are creating such a much better lifestyle come from? Remember, they do not come from trees, and they are not grown in North Dakota in the sugar beet fields. They are developed through processes which involve years—years of investigation and research.

The average pharmaceutical product in this country takes 12 years and $800 million to bring to the market. Think about that: 12 years and $800 million before you can produce a product Americans can take. That is a pharmaceutical product. If you are getting in the biologics area, which is a much more complicated area, it takes even longer. It is even more complex, and in many instances it is even more expensive.

It is these products that are changing the life expectancy of people and making the quality of life of people so much better. We have basically gone from a medical regime in this Nation where invasive action was always the first call, was always the first event, where you basically went under the surgical knife, to a regime where you are given pharmaceuticals or biologics to try to address a very serious illness. It is a huge step, an exponential step in the direction of better health care and a better lifestyle for Americans and for the world.

Where are these products developed? Well, they are developed here in the United States. Why are they developed here in the United States? Why are almost all the major pharmaceutical breakthroughs and all the biologic breakthroughs coming in the United States? Because we have a market system which allows people to take the risks to develop those products.

We do not fix prices, as they do in Canada or in England, at a rate that is so low that nobody would be willing to invest in developing that product because the return on that investment is too low. We allow people who make the investment, who take the risk, who put the 12 years in, who invest $800 million, to get a reasonable return on their investment and on their effort. As a result, we have the explosion in advances in technology, in medical technology, in biologics, and in pharmaceuticals.

It is a result of the fact that people who want to take that risk, and who have the ability to pursue that type of opportunity to make life better for people by creating these pharmaceutical products and these biologic products, have the capacity to get resources to do it. It is called capital markets.

Now, capital does not flow for goodwill. People do not invest in things because it makes them feel good, in most instances. People invest where they are going to get the best return on the dollars they invest, or a reasonable return on the dollars they invest. So we have to maintain an atmosphere in this country where people are willing to put money—cash, capital resources—into the investment and research and development of pharmaceutical and biological and device products.

But if you listen to the other side of the aisle, almost every proposal they come forward with seems to be of the view that these products are grown in some wheatfield in North Dakota, that they do not take any effort, that they do not require any capital, they do not require any expertise, research, or time. All they require is to be price fixed, to be limited in their ability to be distributed relative to the price that is charged.

Time and again, the other side of the aisle has come forward with proposals which basically undermine the incentive for capital to flow into these research areas. Believe me, if capital is disincentivized from going into these areas because they do not get a reasonable return, they will go somewhere else—they will go into developing software, into gaming, into whatever it is that happens to give them a reasonable return, into investing in some other country's activities in some area.

Capital does not flow out of goodwill into pharmaceutical production, into biologic production, into device production. It flows into those accounts because they expect a reasonable return.

Now, sure, the countries of Canada, England, and the European common market, to some degree, are living off of the fact that we give people a reasonable return on our pharmaceuticals and biologics in this country. That is absolutely true, and it is reasonably disgraceful. In fact, in Canada, they threaten to take people's patents away if they don't—they basically capture American patents if they don't sell these drugs at a price which nobody would have invested in them in the first place to produce them were the price fixed at that level. But that is their policy.

Now, we could subscribe to that policy, which is what the other side of the aisle wants us to do. They proposed it in Medicare negotiations, they proposed it now and passed it here in the child drug review. They proposed it in this reimportation, and they proposed it in the negotiated language relative to Medicare, and in biologic generics. In all of these areas they are basically saying: Well, drugs must appear in the marketplace. We don't have to be concerned with the fact of getting capital into the investment exercise. We don't have to be concerned with the fact that it takes years and years to research these products and hundreds of millions of dollars to bring them to the market, they just appear. We can basically, for lack of a better term, kill the goose that is laying the drug or the biologic or the pharmaceutical or the device that is saving people and not worry about it.

Well, that is not true. If you were to follow all of the proposals from the other side of the aisle, or even a significant amount of them, we would see investment in this area start to dry up. We would see a contraction of the production of pharmaceuticals that save lives, of biologics that save lives, of devices that save lives. We would see fewer and fewer of those coming to the American people and to the world because people wouldn't invest in that activity any longer, or the investments would be significantly curtailed because money would flow in other directions.

This concept of the marketplace totally escapes the other side of the aisle. This concept that drugs have to actually have some flow of capital behind them to be produced because it takes so long to get them to the market, and it takes so much money to actually research them—and that is especially true in biologics and equally true in devices. It totally escapes the other side of the aisle. Their idea is, we have a good line, we have a motherhood statement, let's let people go buy the drugs somewhere else at a price that is fixed at which nobody would have ever produced the drug in the first place if that was the price. Let's negotiate so we have a regime of price setting at the Federal level, which basically eliminates the capacity for that drug to be competitive.

Let's create a biologic generic which basically wipes out the capacity of the true biologic to actually come to the market and be successful. Let's create an atmosphere where testing on children of the drugs will basically not have a fiscal return which will make it worthwhile to test them on children. Let's do all of those things in the name of the motherhood language of getting a better price for drugs for Americans, ignoring the fact that what you are actually going to end up doing is dramatically limiting the number of drugs coming to the market for Americans, and therefore significantly impacting the quality of life of Americans and our ability to advance the dramatic and revolutionary activity that we are seeing in bringing biologics to the marketplace, which are basically curing and have the potential to cure diseases which have been extraordinarily threatening to the American population for so long.

It makes no sense, if you look at the substance of the issue, what they are proposing. It is totally inconsistent. They are saying they are doing this to help people. What they are actually ending up doing is harming not only the people of today who won't be able to get the drugs because they won't be produced but people in the future because the drugs won't be brought to the market. There is a blindness to the fact that market forces are at work. I guess it is just a function of the fact that you want to get out a good press release, so you are going to send it out. Of course, anybody who takes the position I just outlined is immediately demagogued, and the pejorative tool of the drug industry is thrown out there.

Well, I am hardly that, since I was one of the few people in this Chamber who actually aggressively opposed and tried to stop the Medicare Part D Program, which was the biggest windfall the drug industry ever got and which was voted for by many of my colleagues on the other side of the aisle and which ended up putting an $8 trillion bill which is unpaid for onto our children's future.

More importantly, the reason I take the position I take is because I believe very strongly that America should not give up its lead in one of the industries where it is at the cutting edge and where it is producing jobs and where it is producing the intellectual capital that is going to keep us a vibrant, strong economy. In addition, we should not give up an industry or undermine an industry and geniuses and creative individuals who are producing products which are saving lives and are giving people a better livelihood. So I am not going to sign on to these various jingoistic proposals which are brought to the floor for the purposes of putting out good press releases about how I did this or that for motherhood at the expense of undermining the quality of care for future generations by basically limiting dramatically the ability of people to get capital who want to be creative, who want to invest, and who want to do research in the area of producing biologic products, pharmaceutical products, and medical devices.

That is why I take the position I take, to say nothing of the fact that if you start haphazardly importing products from the Internet and from countries such as Canada, as strong as Canada is, without any FDA oversight or approval of those products, you are going to harm a lot of people at the end of the day. A lot of people are going to be hurt, and some people are going to die as a result of buying products which have not gone through FDA approval and which are not subject to FDA oversight because they are bought from a pharmacy or a provider in Canada, and that product may have come out of India or it may have come out of Afghanistan. It may have come out of Pakistan. It may be adulterated, and it may kill. The same can be said by a factor of 10 relative to purchasing on Internet pharmacies.

So there are some big issues at play. There are big issues at play relative to the future of the health of Americans on the issue of importation, on the issue of negotiation and Medicare, on the issue of biologic generics, and on the issue of making sure that children are adequately tested relative to the application of drugs which are brought to the market. There are big issues relative to safety and big issues relative to whether this country remains on the cutting edge of producing products that help people and give them a better lifestyle with a biological, pharmaceutical, or medical device. We shouldn't just pass these proposals willy-nilly for the sake of putting out a nice press release.

Mr. President, I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from South Carolina is recognized.

Mr. DEMINT. Mr. President, I ask unanimous consent that the pending amendment be set aside.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

AMENDMENT NO. 1018

Mr. DEMINT. Mr. President, I have an amendment at the desk and ask for its immediate consideration.

The ACTING PRESIDENT pro tempore. The clerk will report the amendment.

The legislative clerk read as follows:

The Senator from South Carolina [Mr. DEMINT] proposes an amendment numbered 1018.

Mr. DEMINT. Mr. President, I ask unanimous consent that the reading of the amendment be dispensed with.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

The amendment is as follows:

(Purpose: To amend the notification provision with respect to drugs deemed to have risk evaluation and mitigation strategies)

In section 214(b)(3)(B) of the bill, insert '', except with respect to the drug Mifeprex (mifepristone), such assessment shall be submitted 6 months after the applicant is so notified'' before the period at the end.

Mr. DEMINT. Mr. President, my amendment calls for the Food and Drug Administration to conduct an assessment of the risk evaluation and mitigation strategy, which we refer to as REMS, for Mifeprex, commonly known as RU–486, within 7 months of the effective date of this legislation.

According to the legislation before us, any drug that is currently on the market with restrictions on its distribution or use, which includes RU–486, would be required to have a risk evaluation and mitigation strategy. This means that RU–486 would be subject to periodic assessment of how well the risk management plan, including its restrictions, is working. Unfortunately, the bill does not establish a deadline for the risk evaluation for RU–486.

The current RU–486 abortion regimen was approved by the Food and Drug Administration in September of 2000. Since that time, the regimen has been linked to the deaths of seven women, including three Americans. The public has learned since November of 2004, through the release of documents by the FDA through a Freedom of Information Act request, that over 1,000 additional women have experienced adverse effects from the RU–486 regimen, including 9 life-threatening incidences, 232 hospitalizations, 116 blood transfusions, and 88 cases of infection. It should be noted this dangerous drug is attacking young, healthy women.

I also want to point out the approval process for RU–486 was highly irregular in the first place. The drug regimen was approved under FDA subpart H, which is a regulation that applies to certain new drugs used for treating serious or life-threatening illnesses. While certain conditions may arise during pregnancy that are dangerous, pregnancy itself is hardly a serious or life-threatening illness.

The RU–486 regimen actually requires the use of two drugs: RU–486, which kills the child, and misoprostol,

which causes the uterus to expel the dead baby. G.D. Searle, the manufacturer of misoprostol, never sought to have its drug approved by the FDA for abortions. Nevertheless, the FDA, in what appears to be an unprecedented decision, mandated that misoprostol be used for unapproved ''off-label'' use in an abortion regimen along with RU–486.

Finally, the FDA approved the RU–486 regimen based on data submitted from clinical trials in which there was no control group comparison. This directly violates Federal law and appears to be unprecedented as well.

In my opinion, the FDA has not done enough to curb the use of this deadly drug, and for far too long the FDA has put politics ahead of science and ahead of women's health. When the Clinton administration expedited the approval process for RU–486 in the final days of its tenure, many medical professionals expressed serious concerns about the FDA's rush to bring RU–486 to market. Since then, the statistics have proven these concerns to be well-founded.

The legislation we are considering today has everything to do with drug safety. Yet we have a drug on the market that has killed several women and injured many others. My amendment simply sets a 7-month deadline for the FDA to assess the risk evaluation and mitigation strategy for RU–486. Given all the adverse events associated with this drug, this is the least we can do.

This is not an abortion issue, it is a women's health issue. Even those who support abortion agree there are serious problems with this drug. Let me read several quotes from abortion supporters which were part of a New York Times story that ran last year: ''None of these women should be dying; it's shocking,'' said Dr. Peter Bours, an abortion provider in Portland, OR, who is rethinking whether to offer pill-based or medical abortions.

Dr. Warren Hern, an abortion provider in Denver, said the latest reports demonstrated that abortions by RU–486, or Mifeprex, were far riskier than the surgical ones. ''I think surgery should be the procedure of choice,'' Dr. Hern said. ''Pills,'' he said, ''are a lousy way to perform an abortion.''

I quote again from another source: ''The complications associated with RU–486 far exceed the complications of surgical abortion,'' said Dr. Damon Stutes. He is an abortion provider in Reno, NV. He refuses to offer pill-based abortions.

Dr. Stutes, whose clinic has been bombed, said he was uneasy about agreeing with abortion proponents on anything. But the truth is the truth, he said.

Another quote:

> One needs to tell patients that the medical procedure, even though it seems more natural, may be more likely to result in death.

That is Dr. Phillip G. Stubblefield, a professor of obstetrics and gynecology at Boston University.

It is clear that even the supporters of abortion believe this drug is dangerous. It also appears that even the leader of the abortion industry—Planned Parenthood—supports actions by the FDA to further examine the safety of the drug. Dr. Vanessa Cullins, vice president for Medical Affairs at Planned Parenthood, told the San Francisco Chronicle:

> We are glad there will be continuing investigations by the FDA. We will work with the CDC, the FDA, and academicians to figure this out.

The FDA needs to quickly complete its risk evaluation on RU–486. That is what my amendment guarantees. I urge my colleagues to support it. I understand that Senator KENNEDY will accept a voice vote on this. I look forward to supporting it, along with all of my colleagues.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from North Dakota is recognized.

AMENDMENT NO. 990

Mr. DORGAN. Mr. President, I have listened to some of the debate on the floor of the Senate in opposition to the amendment I have offered with many colleagues dealing with the reimportation of prescription drugs. Especially entertaining was to hear the Senator from New Hampshire, Mr. GREGG, describe North Dakota wheatfields. The Senate is a place of fascinating and interesting debate. I expect we will have more of that in the coming hours, leading up to a vote tomorrow on a cloture motion on this amendment.

The continued and insistent reference to this amendment posing safety risks, or risks of unsafe prescription drugs, is at odds with everything we know to be the case. I described Dr. David Kessler, and I suggested if anybody knows a more important, better informed expert than Dr. David Kessler, who was head of the FDA for nearly 8 years, tell me his or her name. I described the statement that Dr. David Kessler made that says this will make the prescription drug supply safer. In fact, the regime of safety we have put into this amendment is appropriate, important, and will mean that we will be able to allow reimportation without a safety risk.

Despite the evidence, we continue to hear this issue. I was thinking, as I was listening to this a while ago, about the Lincoln-Douglas debates, when Lincoln became enormously exasperated at one point and he said to Douglas: Tell me, how many legs does a horse have?

Douglas said: Well, four, of course.

Lincoln said: Now, if you were to call the tail of a horse a leg, then how many legs would a horse have?

Douglas said: Well, five.

Lincoln said: You see, that is where you are wrong. Just because you call the tail a leg doesn't make it a leg at all.

The same principle holds true now on the floor of the Senate. You can say what you want, but that doesn't make it true. Safety issues? That doesn't exist in the amendment we are talking about. This will make the drug supply safer. While I am speaking of Lincoln and Douglas, let me say something else that Lincoln said, which has always been interesting to me. He was describing his opponent's arguments. He said: Your argument is as thin as the homeopathic soup made from boiling the shadow of a pigeon that has been starved to death.

Wasn't Abraham Lincoln wonderful? That description can still exist for some of the arguments we are hearing these days on some of these issues.

I hope my colleague was not serious a few moments ago when he said this is an amendment that is not worthy and is put out by a bunch of people who want to put out press releases and aren't concerned about the safety of the drug supply. My colleague surely doesn't mean to say that Senators GRASSLEY, MCCAIN, SNOWE, and COLLINS on his side and Senators KENNEDY, STABENOW, BROWN, and so many on our side—the 33 Senators who have come to a serious issue with a thoughtful proposal—did so because they want a press release. My colleague knows better than that. He perhaps ought to tell the Senate he knows better than that.

I respect those who disagree with this amendment. I hope they will respect as well our determination to correct something we see as a serious problem. When my colleague says we don't want to give up our lead, describing our lead in pharmaceuticals and the development of prescription drugs, I don't want to give that up. Let me tell you another lead we don't want to give up; that is, the lead in providing the highest prices in the world to the American consumer who needs prescription drugs. That is a lead we ought to relinquish right now. I wonder if my colleague would agree with that.

Mr. President, this is an interesting debate, a useful debate. It will conclude tomorrow with the vote. My colleague from Michigan, Senator STABENOW, has gone across the bridge that connects our two countries, taken busloads of senior citizens and has been involved in this issue for many years, believing that we ought to insist on fair pricing for prescription drugs for the American people. I am pleased that she was one of the people who helped put together the bill introduced by 33 Senators, and I am pleased that she is a strong advocate for the amendment that we have added to this piece of underlying legislation.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Michigan is recognized.

Ms. STABENOW. Mr. President, I rise to support the amendment we have put together, led by the Senator from North Dakota. I thank him for his passionate leadership and advocacy and the way he is able to speak in very commonsense terms about what this is all about. What we are talking about is common sense. We are talking about whether we have the most competition

153 Cong. Rec. S5759 (daily ed. May 9, 2007).
(excerpts)

gallon standard of 25 miles today to 35 miles in a 10-year period, this would unquestionably be a great accomplishment.

Attached to this legislation is also very important consumer protection legislation that provides the Federal Trade Commission the tools it needs to protect consumers against price gouging. With our current statutes, the FTC has the ability to investigate certain cases on the basis of antitrust laws, which are based on whether we think oil companies are colluding to set prices. What we really have to question is whether the companies may be conducting activities that actually take supply offline and thereby decrease the supply, leading to shortages at the pump. Therefore we need to give the FTC the authority it needs through this legislation and make sure consumers are protected.

This legislation, as part of a package, was passed unanimously out of the Commerce, Science, and Transportation Committee yesterday. It was the result of a bipartisan effort, led by the work of the chairman, Senator INOUYE, and the ranking member, Senator STEVENS. Unfortunately certain provision did not make it into the final version of this bill, however I firmly believe that it is a historic and important piece of bipartisan legislation that will come to the Senate floor for all of us to discuss.

Just recently, the Energy and Natural Resources Committee passed another very positive landmark legislation which relates to setting a higher mandate on biofuels. In the last Energy bill we were able to pass, we stipulated that we should have a goal of producing 7½ billion gallons of biofuel a year by 2012. Both the President and the Congress are trying to achieve a higher goal. In this legislation, that sets the goal that by 2022, we would actually have a mandate of having 36 billion gallons of alternative fuel produced in this country. I firmly believe that this is a realistic goal and an achievable mandate for us, and that it will aid in starting mass-production of alternative fuels in this country.

In addition, that legislation had money for what we call a biofuels infrastructure—how we do actually get this product out to the consumer and to the corridors of transportation so the public does not have to worry about where they can fill up their cars. Thanks in part to this legislation we will have the infrastructure to do that.

In the Commerce Committee, we also produced legislation focusing on flex-fuel cars so that, by 2015, 80 percent of the cars being driven on our roads will be flex-fueled. These are vehicles that could either use gasoline or an alternative fuel.

We have also passed legislation now for studying plug-in hybrids and making sure the plug-in hybrid research continues to move ahead.

In the Energy bill, we also included language about carbon sequestration, making sure we move ahead so carbon sequestration becomes a reality. Again, this is an important issue and it is a very important bill to my colleagues in various parts of the country in which we have an ample supply of coal. I commend Senators DOMENICI and BINGAMAN for working so closely together. That legislation also was passed in a bipartisan effort. It is a great compliment to those two distinguished Senators who worked so closely on the last Energy bill to yet produce another Energy bill.

We are in a position to make a very positive impact on what I think is one of the biggest challenges we face, getting off our overdependence on foreign oil and providing sources of cleaner energy. We are well poised to take up that debate here on the Senate floor with this landmark bipartisan legislation out of two different committees.

We will have a lot of work to do across the aisle. We still have great opportunities to see legislation out of those other four committees I mentioned that will contribute to this energy package. But we should embrace the opportunity the President laid out in his State of the Union Address when he said that he wanted to make sure we had a higher fuel efficiency standard and that we also set a higher renewable fuel standard, and that is exactly what we are doing now.

I personally think we should also set a renewable standard for the amount of electricity we use from our electricity grid to further reduce our dependence on fossil fuel. These are topics that will be debated. I am sure later in the year we will have an important debate about climate change. But for now we are making great progress. I hope my colleagues will focus on the fact that this energy bill gives us another opportunity to work together here on the Senate floor and put real energy solutions before the American public.

Right now, with gas prices reaching $4, Americans want to know we are going to have an aggressive policy, not only giving them consumer protections but better planning for the future so our economy can benefit from alternative sources of fuel.

I yield the floor.

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will resume consideration of S. 1082, which the clerk will report.

The bill clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

Pending:

Brown (for Grassley) amendment No. 1039, to clarify the authority of the Office of Surveillance and Epidemiology with respect to postmarket drug safety pursuant to recommendations by the Institute of Medicine.

Brown (for Grassley) amendment No. 998, to provide for the application of stronger civil penalties for violations of approved risk evaluation and mitigation strategies.

Brown (for Durbin/Bingaman) amendment No. 1034, to reduce financial conflict of interest in FDA Advisory Panels.

The PRESIDING OFFICER. Under the previous order, there will be 60 minutes for debate currently on the bill and remaining amendments, with 10 minutes under the control of the Senator from Iowa, Mr. GRASSLEY or his designee, 5 minutes under the control of the Senator from Illinois, Mr. DURBIN or his designee, and the remaining time equally divided between the chairman and ranking member or their designees.

The Senator from Massachusetts is recognized.

Mr. KENNEDY. Madam President, I yield myself 6 minutes of our time.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KENNEDY. Madam President, we will see later this morning the successful conclusion of this legislation. We have some important matters to consider, which we will do in a very short period of time. But as we are coming into the closing time for this amendment, I think it is appropriate that we review very quickly what this legislation does and what it does not do.

I am a strong believer in this legislation, which has strong bipartisan support. I am enormously grateful to Senator ENZI and Members on our side of the aisle as well as those on the other side for all of their help and assistance in getting us to the point where we are ready to take final action on something that makes a major difference to families in America. We ensure the safety of our prescription drug system and also are making very important progress in the safety of our food supply.

This is, in an important way, breakthrough legislation. I will review quickly what this does and then come back to the amendments that are before the Senate and how we think the Senate should dispose of them; why this legislation is urgent, why it is extremely important, and why the American people deserve the best.

Very quickly, again, there is strong emphasis on safer food and safer medicines for families in this country. We spelled out at the earlier part of our presentations the effective systems we have supported to make sure we are going to have the safest prescription drug program in the world, using different kinds of modern technologies and also modern surveillance systems for monitoring postmarketing safety. This will ensure in the future we are going to have the safest prescription drug program in the world. We will have safer medicines.

We will also have safer food for families and pets. I think all Americans have been alarmed, as they should have

amendment offered by Senators DURBIN and BINGAMAN would have made great improvements to the recruitment of qualified advisory committee members. The amendment would have required the FDA to conduct aggressive outreach to professional medical and scientific societies to help with recruitment for advisory committees, especially ones with the greatest number of vacancies. Those are important policy goals and ones that I fully support.

However, I voted against the amendment because I was concerned about the impact a hard and fast limit of one waiver per committee meeting would have on timely access to drugs and new drug information. Specifically, the Pediatric Advisory Committee, a standing FDA advisory committee which relies on experts with specific expertise in pediatric issues, is an important component of the Best Pharmaceuticals for Children Act program. I was concerned that setting an arbitrary limit on the number of waivers per committee meeting would further complicate an already small pool of qualified individuals in fields such as pediatrics.

I am disappointed that an agreement on the amendment was not reached between the bill managers and sponsors of the amendment so that the Senate bill could contain the important provisions dealing with recruitment and outreach. It is my hope that we can find a way to address these issues in the conference with the House.

Taken as a whole, the underlying legislation is vital to our nation's children as well as consumers needing timely access to safe and effective drugs. Therefore, it is essential that the House act quickly so that we can send a conference report to the President in the coming months. I urge the House to pass all of the major provisions contained in S. 1082. I support this legislation and look forward to continuing to work with my colleagues on both sides of the aisle and in both Chambers so that we can send this legislation to the President for his signature.

Mr. KENNEDY. Madam President, I would like to take some time to talk about some issues that I haven't spent a great deal of time describing to the Senate about S. 1082, the Food and Drug Administration Revitalization Act.

First, I thank Senator ROBERTS and Senator HARKIN for working with Senator ENZI and me and with many members of the committee on the important issue of direct-to-consumer, or DTC, advertising.

We have worked together to accomplish our common goal—a constitutionally sound, effective, workable way to see that DTC ads provide accurate information to patients about the drugs they are taking.

Some have advocated a ban on such advertising altogether, but Senator ENZI and I rejected that approach since it failed to meet the constitutional test. Instead, we included a more measured provision in our legislation that allows FDA to impose a moratorium in extraordinary circumstances where needed to protect public health.

During our committee's consideration of this issue, Senator ROBERTS brought up his concerns that even this limited provision fell afoul of recent Supreme Court decisions on free speech. Senator HARKIN raised his strong interest in seeing that these DTC ads include strong, effective safety information that is clearly and prominently presented to consumers in a way that does not gloss over important information. Senator ENZI and I committed to work with Senator ROBERTS to see that any provision on DTC met the constitutional threshold, and we agreed to work with Senator HARKIN to make certain that it provided strong safety information to consumers. The result of our discussions is an amendment that our two colleagues offered. It is a true bipartisan compromise, worked out by two Senators committed to making real progress on an important issue, and I am pleased to support the amendment.

Instead of the moratorium included in our original bill, the Roberts-Harkin amendment puts in place strong safety disclosures for DTC ads, coupled with effective enforcement. Under current law, safety disclosures can be an afterthought—a rushed disclaimer read by an announcer at the conclusion of a TV ad while distracting images help gloss over the important information provided. Our proposal requires safety announcements to be presented in a manner that is clear and conspicuous without distracting imagery.

We also give FDA the authority to require safety disclosures in DTC ads if the risk profile of the drug requires them. Senator ROBERTS had a concern that this authority not be used indiscriminately, so we have made clear that the required disclosure must pertain to a specific identified risk.

We have made important improvements in FDA's ability to enforce the requirement to provide clear and accurate information to consumers.

For advertisements, as in so many other areas, FDA's enforcement tools are now limited. Although FDA does have the capacity under current law to remove a drug from the market for misleading ads, that authority is not often used and rightly so, since it punishes patients for the transgressions of the manufacturers. Since removing a drug from the market is an empty threat, FDA is often left with little option but to make polite requests to companies to change their ads. Under the Roberts-Harkin amendment, FDA will have the ability to levy fines of up to $150,000 for false or misleading ads.

It is unacceptable for patients to be put at risk by inaccurate ads. The Roberts-Harkin amendment makes certain that FDA will have the ability to see that this does not occur, in a way that is clearly consistent with the Constitution.

The amendment is a victory for bipartisan common sense on a difficult issue.

I would also like to address the affect of title II of this bill. Generally speaking, title II grants the FDA new authority to conduct postapproval safety surveillance activity in order to improve drug safety.

In enacting title II, we do not intend to alter existing State law duties imposed on the holder of an approved drug application to obtain and disclose information regarding drug safety hazards either before or after the drug receives FDA approval or labeling. Nor are we expressing a belief that the regulatory scheme embodied in the bill is comprehensive enough to preempt the field or every aspect of State law. FDA's approved label has always been understood to be the minimum requirement necessary for approval. In providing the FDA with new tools and enhanced authority to determine drug safety, we do not intend to convert this minimum requirement into a maximum.

As the Institute of Medicine and others have found, the FDA's past performance has been inadequate. While we fully expect substantial improvement as a result of the enactment of this bill, we cannot and do not expect the FDA or this new process to identify every drug-specific safety concern before a drug manufacturer becomes aware or should have become aware of such concerns. Nor are the bill's requirements that holders disclose certain safety information to the Government intended to substitute for the disclosure requirements that may be required under State law.

I would also like to focus on another aspect of our legislation, the Reagan-Udall Foundation.

During the discussions that led to consideration of this bill, we heard time and again that there was a major need for better research tools to aid FDA in evaluating the safety of drugs and help researchers move through the long process of developing drugs more effectively. Every day that a new medicine is needlessly delayed is another day that a patient does not receive a treatment that could well mean the difference between health and continued illness. If new research tools and better ways to evaluate the safety and effectiveness of drugs could be developed, patients will benefit from quicker drug development. If current procedures can be made more effective, then the cost of developing new drugs will drop.

One area where scientists can make real progress is developing new cell lines and new genetic techniques for testing drugs that reduce the need for costly forms of testing.

The Reagan-Udall Foundation sets up a way to develop these new tools—not so they can help just one researcher or one company, but so they can help the entire research enterprise. New ways to test drugs for effectiveness and safety

will bring new advances to patients quicker and more smoothly. Through the Reagan-Udall Foundation, they will be available to the FDA and to the entire research enterprise. This new foundation is not many pages in a long bill, but it is an important component to help get needed medicines to patients as quickly as safety will allow.

I also wish to mention another critical aspect of our legislation—its registry of clinical trials.

This provision serves two essential purposes. First, it allows patients who want to enroll in those trials an accessible and central Internet site to find out which trials are being conducted and whether they might be eligible.

This provision builds on an existing provision of law to create a clinical trials site, but report after report has shown that the requirement to list trials has not been complied with. Our legislation puts more force in the requirement to list trials so that patients will benefit.

Listing trials is important for patient access—but reporting results is critical for safety. Our legislation requires that the results of trials be reported. No longer will companies be able to hide the outcome of a trial that did not turn out the way they hoped.

Examples of this kind of abuse are shocking. The manufacturer of the antidepressant drug Paxil conducted five clinical trials of the drug in adolescents and children, yet published only one study whose mixed results it deemed positive. The company sat on two major studies for up to 4 years, although the results of one were divulged by a whistleblower and all of the studies were submitted to the FDA when the company sought approval for new uses of Paxil. At that time it became apparent that Paxil was no more effective than a placebo in treating adolescent depression.

Under the bill, these kinds of abuses will not be permitted, since clinical trials will have to be reported—no matter what the result.

Senator ENZI, Senator DODD and many others in the committee worked hard to get this provision right. We require immediate listing of all publicly available data and require a negotiated rulemaking, backed by the full authority of statute to develop the precise requirements for other results information to be included.

I would like to thank my colleagues for considering these comments as they relate to S. 1082, and I urge my colleagues to support the bill.

Mr. COBURN. Madam President, as we debate the important issue of drug safety, I want to address the safety of one drug in particular: RU–486 or mifepristone. This drug was approved in 2000 under a special pathway, subpart H drug approval that is reserved for drugs that treat severe or life-threatening illnesses. Subpart H approvals generally require a special ''restricted distribution'' approval process. Unfortunately some drugs, RU–486 for example, approved under subpart H have caused serious adverse health events in women.

Every drug approved under Subpart H is listed on the Food and Drug Administration's Web site. The vast majority of drugs listed combat HIV or specific types of cancer. One governs the use of thalidomide in treating leprosy. These drugs are supposed to relate to the treatment of life-threatening illnesses.

One example of a subpart H approval makes a mockery of the regulatory process by an expedited approval of two extremely risky drugs for abortions. Pregnancy is not an illness and certainly not one that is life-threatening in the first 7 weeks, unless it is a tubal or ectopic pregnancy in which case RU–486 abortions are absolutely contraindicated.

RU–486 was inappropriately approved in 2000. RU–486 was approved using special ''subpart H'' regulations to address problems for ''certain new drug products that have been studied for their safety and effectiveness in treating serious or life-threatening illnesses . . .'' and under restricted distribution conditions due to serious hazards presented by the drug; for example, severe hemorrhage and ectopic pregnancies. This was an inappropriate approval of RU–486 as pregnancy is not normally a life-threatening condition. Today many health care providers do not follow the limited distribution requirements of RU–486's approval.

RU–486 has put women's lives at risk. To date there have been six North American deaths related to the use of the RU–486 abortion regimen: five Americans and one Canadian have died from septic shock stemming from infection by the anaerobic bacteria Clostridium sordellii. Five other international deaths have been related to RU–486.

RU–486 causes serious safety issues. More than 1,000 adverse event reports—232 hospitalizations, 116 blood transfusions, and 88 cases of infection—have been submitted regarding RU–486 and are significant because they confirm that large numbers of mifepristone patients require surgical intervention for infection, hemorrhage, complications from ectopic pregnancy, and incomplete abortions. While lives have been lost from the use of RU–486, not a single case has been documented where RU–486 has been used to save a woman's life.

RU–486 is not always effective and when it is not the consequences are dire. I recently learned of a woman who was given RU–486 after she had a seizure. Her physicians assumed that the seizure was life-threatening to the baby she was carrying and gave her RU–486 for a therapeutic abortion.

RU–486 was not effective in her case and the woman carried the baby to term. When the baby was born at a low birth weight, it also suffered from failure to thrive. That baby has had three subsequent brain surgeries due to hydrocephalus. The baby also suffers from idiopathic lymphocytocholitis—an inflammatory disease of the colon, which is extremely rare in children. It is clear that RU–486 not only is unsafe in women, but it is also not completely effective. And when it is not effective, the results are devastating.

I appreciate the desire to effect safer drugs through this bill. Senator KENNEDY and Senator ENZI have done a great deal of work in designing the REMS scheme for certain drugs to ensure that they can be safely and effectively used.

Under the risk evaluation and mitigation system, REMS, provisions of this drug safety bill, a drug that has previously been approved under subpart H is deemed to have a REMS. Every REMS is subject to a periodic review. Therefore, RU–486 is deemed to have a REMS and is subject to periodic review.

I am pleased that the amendment offered by Senator DEMINT was accepted by the full Senate. Senator DEMINT's amendment sets a ''date certain'' REMS assessment for RU–486 to properly evaluate its drug safety risks in women. Women in this country deserve to know the safety risks associated with RU–486.

The PRESIDING OFFICER. Who yields time? The Senator from Illinois.

AMENDMENT NO. 1034

Mr. DURBIN. Madam President, I have an amendment pending and scheduled for a vote this morning on the conflict of interest provision. I believe I have 5 minutes to speak to it.

The PRESIDING OFFICER. The Senator does have 5 minutes.

Mr. DURBIN. I ask the chairman and ranking member if this a convenient time to raise the issue?

Thank you very much.

Yesterday I proposed this amendment with Senator BINGAMAN. The Food and Drug Administration Advisory Committees make important decisions, life-and-death decisions. They decide whether the drugs and medical devices which are going to be used in America are safe and effective. In other words, if a person in America has a prescription from a doctor and takes this drug, is it going to be good for their health, or bad?

This is a critical situation. If they make the wrong decision, if the advisory committee turns a dangerous drug loose on the market, it can have terrible consequences, so these committees literally have life-and-death decisions in their hands on approving drugs, on deciding what the warning labels say, deciding what you have to say in advertising. There might be a danger in these drugs. These advisory committees are the juries of scientific experts who have to make these calls. That is one of the most important decisions of our Government.

They are not just life-and-death decisions, they are decisions involving millions and millions of dollars. Drug companies spend a fortune over a long period of time trying to bring a drug to

market. They would hope this will be a drug very popular and profitable for them and their shareholders. That is a natural inclination of a business. So the advisory committee not only decides the safety and efficacy of the product, it makes a decision which has a direct impact worth millions of dollars to the drug companies involved.

Do you know what we found out? We found out over the last 10 years many people sitting on these advisory committees, those who are actually sitting on the so-called juries and deciding the fate of these drugs, have a conflict of interest. Some of them were already receiving, from the companies that make the drugs, tens of thousands of dollars in consulting fees and speaking fees. It turns out they are on the payroll, some of them, of the very companies on which they are being asked to stand in judgment. That is a conflict of interest which people cannot accept and I cannot accept.

The Food and Drug Administration argues that there are so few experts that we have to sometimes turn to those who have a conflict of interest; there is no place else to go. So occasionally we have to put a waiver in and allow someone to sit on an advisory committee panel who frankly has a financial interest in the company they are making a decision about.

That worries me. Because if you are going to have truly objective jurisdictions, that are right for the consumers of America, that approve drugs or disapprove them on the merits, not because of some inclination or prejudice which you might bring to the table, you don't need these conflicts of interest.

So basically what Senator BINGAMAN and I have said is: Let's strengthen the conflict-of-interest provisions on advisory committees. Let's make certain that there is confidence in the process. We know what happened with Vioxx. There were 10 people sitting on the advisory committee who had a financial conflict of interest. Had they been removed from the deliberation, the panel would not have recommended they go back on the market, endangering the health of thousands of Americans.

How can you ever justify that kind of conflict of interest? Our language tightens it. What we are trying to do is to make sure the Food and Drug Administration, with this amendment, limits the number of waivers to one per each advisory committee meeting, allows advisory committees to receive information from guest experts who have a financial conflict but prevents those experts from participating in the deliberations.

They can come in and express their point of view and then leave the room before the deliberation and the vote take place. And also strengthen the provisions to increase the outreach for new experts. The Food and Drug Administration has to do a better job of cultivating this new cadre of trustworthy experts who can serve on these advisory committees.

We have 125 medical schools in this country, 90 schools of pharmacy, 40 schools of public health. If the FDA is more aggressive in filling the slots on the advisory committees, we can remove this shadow of doubt which is over this process.

Now, some will argue: Well, the FDA has come forward with draft guidance to improve this. This is draft guidance. They are suggestions. This is law. This tells them they will have to follow the law to avoid these conflicts of interest. This is not an idea that Senator BINGAMAN and I bring to the table without support.

I ask unanimous consent, Madam President, to have printed in the RECORD with my remarks letters from the Consumers Union, the Union of Concerned Scientists, and a broader letter from 11 different organization that support this amendment, that would reduce and eliminate the conflicts of interest when it comes to approving new drugs and medical devices. What is at stake is the integrity of the Food and Drug Administration, the integrity of the process, and making certain we can say, with a straight face to American consumers, the products that are coming to the market, the life-and-death decisions that are being made that bring them to the market are being made by people who do not have a financial conflict of interest with these devices. I urge my colleagues to support the Durbin-Bingaman amendment.

I ask unanimous consent these letters be printed in the RECORD after my remarks.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

CONSUMERS UNION,
May 8, 2007.

DEAR SENATOR, Consumers Union, the nonprofit, independent publisher of Consumer Reports, urges you to support the Durbin-Bingaman amendment to S. 1082, the Food and Drug Administration Revitalization Act. This amendment will help ensure that FDA advisory committees responsible for assessing a drug's safety are not inappropriately influenced by scientists or others with financial ties to the affected drug company.

A recent national survey by Consumer Reports National Research Center found that Americans are extremely concerned about the pharmaceutical industry's influence on the drug safety process, as well as financial conflicts on FDA advisory boards.

Sixty percent of those surveyed disapproved of allowing doctors and scientists with a conflicting financial interest to participate on advisory boards. And 84 percent of consumers agree that drug companies have too much influence over the government officials who regulate them.

This amendment would make it more difficult for the FDA to issue financial conflicts of interest waivers to the scientific experts who serve on its advisory committees. The Durbin-Bingaman amendment would: limit the number of waivers to one per advisory committee meeting; establish a specific process to allow experts with a financial conflict to present information to an advisory committee, while not permitting them to deliberate or vote with the committee; and enhance the FDA's outreach activities for identifying non-conflicted experts to participate in advisory committees.

The integrity of the FDA advisory process is vital to ensuring that decisions by federal policymakers benefit the public, and not the agendas of any special interest.

Please support the Durbin-Bingaman amendment to S. 1082. If you have any questions, please contact Bill Vaughan.

Sincerely,

BILL VAUGHAN,
Senior Policy Analyst.

MAY 8, 2007.

DEAR SENATOR: The Union of Concerned Scientists strongly urges you to support the Durbin-Bingaman amendment to the FDA Revitalization Act, S. 1082. This amendment will help ensure that the Food and Drug Agency's assessment of the safety and efficacy of drugs is not inappropriately influenced by scientists with ties to the drug companies affected by an FDA approval decision.

This amendment would make it more difficult for the FDA to issue financial conflicts of interest waivers to the scientific experts who serve on its 30-plus advisory committees.

Conflicts of interest can have serious consequences for drug safety. For example, ten of the 32 scientists on the February 2005 advisory committee that considered the safety of Cox-2 inhibitors, including Vioxx, had ties to the drug companies that made the products. The scientists voted to permit the companies to continue marketing the drugs, even though Vioxx had already been withdrawn from the market and had been implicated in tens of thousands of deaths.

The Durbin-Bingaman amendment would: limit the number of waivers to one per advisory committee meeting; establish a specific process to allow experts with a financial conflict to present information to an advisory committee, while not permitting them to deliberate or vote with the committee; and enhance the FDA's outreach activities for identifying non-conflicted experts to participate in advisory committees.

The integrity of science is vital to ensuring that decisions by federal policymakers benefit the public, and not the agendas of any special interest. We at the Union of Concerned Scientists are working to ensure that federal scientists, and those who advise federal agencies, are free to do their work without interference. This amendment will be a constructive step in addressing the pervasive problem of political interference in government science.

For all these reasons, we believe that the Durbin-Bingaman amendment merits your support. Please call our Washington Representative Celia Wexler if you'd like more information on either S. 1082 or the amendment.

Sincerely,

DR. FRANCESCA GRIFO,
Director, Scientific Integrity Program,
Union of Concerned Scientists.

APRIL 30, 2007.

Senator JEFF BINGAMAN,
Washington, DC.

DEAR SENATOR BINGAMAN: We, the undersigned organizations, give our wholehearted support to the amendment to S. 1082 that you plan to offer next week that would limit the number of conflict of interest waivers allowed on Food and Drug Administration advisory committees. This amendment would end the vast majority of conflicts of interest while insuring that the FDA has access to the best advice that this nation has to offer.

The amendment would: require the FDA to engage in greater efforts to find experts without conflicts of interest to serve on its

153 Cong. Rec. H10551 (daily ed. Sept. 19, 2007).
(excerpts)

□ 1445

Mr. RUPPERSBERGER changed his vote from ''yea'' to ''nay.''

So the motion to recommit was rejected.

The result of the vote was announced as above recorded.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and the Speaker pro tempore announced that the ayes appeared to have it.

Mr. PRICE of Georgia. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. This will be a 5-minute vote.

The vote was taken by electronic device, and there were—yeas 312, nays 110, not voting 10, as follows:

[Roll No. 884]

YEAS—312

Abercrombie
Ackerman
Alexander
Altmire
Andrews
Arcuri
Baca
Baird
Baldwin
Barrow
Bean
Becerra
Berkley
Berman
Bilirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blumenauer
Blunt
Bono
Boozman
Boren
Boswell
Boucher
Boyd (FL)
Boyda (KS)
Brady (PA)
Braley (IA)
Brown (SC)
Brown, Corrine
Brown-Waite, Ginny
Buchanan
Butterfield
Calvert
Cantor
Capito
Capps
Capuano
Cardoza
Carnahan
Carson
Castor
Chandler
Clarke
Clay
Cleaver
Clyburn
Coble
Cohen
Conyers
Cooper
Costa
Costello
Courtney
Cramer
Crenshaw
Crowley
Cuellar
Cummings
Davis (AL)
Davis (CA)
Davis (IL)
Davis (KY)
Davis, Lincoln
Davis, Tom
DeFazio
DeGette
DeLauro
Dent
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Donnelly
Doyle
Edwards
Ellison
Ellsworth
Emanuel
Emerson
Engel
English (PA)
Eshoo
Etheridge
Farr
Fattah
Ferguson
Filner
Fortenberry
Fossella
Frank (MA)
Frelinghuysen
Gallegly
Gerlach
Giffords
Gilchrest
Gillibrand
Gonzalez
Gordon
Graves
Green, Al
Green, Gene
Grijalva
Gutierrez
Hall (NY)
Hall (TX)
Hare
Harman
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Hayes
Herseth Sandlin
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Hinchey
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Holt
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Hooley
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Hulshof
Hunter
Inslee
Israel
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Jones (NC)
Jones (OH)
Kagen
Kanjorski
Kaptur
Keller
Kennedy
Kildee
Kilpatrick
Kind
King (NY)
Kirk
Klein (FL)
Knollenberg
Kucinich
Kuhl (NY)
Lampson
Langevin
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Larsen (WA)
Larson (CT)
Latham
LaTourette
Lee
Levin
Lewis (GA)
Lewis (KY)
Lipinski
LoBiondo
Loebsack
Lofgren, Zoe
Lowey
Lynch
Mahoney (FL)
Maloney (NY)
Markey
Matheson
Matsui
McCarthy (NY)
McCollum (MN)
McCotter
McDermott
McGovern
McHenry
McIntyre
McNerney
McNulty
Meek (FL)
Meeks (NY)
Melancon
Mica
Michaud
Miller (MI)
Miller (NC)
Miller, Gary
Mitchell
Mollohan
Moore (KS)
Moore (WI)
Moran (KS)
Moran (VA)
Murphy (CT)
Murphy, Patrick
Murphy, Tim
Murtha
Nadler
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Neal (MA)
Nunes
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Pallone
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Pastor
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Peterson (MN)
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Price (NC)
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Reynolds
Richardson
Rodriguez
Rogers (KY)
Rogers (MI)
Ros-Lehtinen
Ross
Rothman
Roybal-Allard
Ruppersberger
Rush
Ryan (OH)
Salazar
Sánchez, Linda T.
Sanchez, Loretta
Sarbanes
Saxton
Schakowsky
Schiff
Schmidt
Schwartz
Scott (GA)
Scott (VA)
Serrano
Sessions
Sestak
Shays
Shea-Porter
Sherman
Shimkus
Shuler
Sires
Skelton
Slaughter
Smith (NJ)
Smith (WA)
Snyder
Solis
Space
Spratt
Stark
Stearns
Stupak
Sutton
Tanner
Tauscher
Taylor
Terry
Thompson (CA)
Thompson (MS)
Thornberry
Tiahrt
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Tierney
Towns
Turner
Udall (CO)
Udall (NM)
Upton
Van Hollen
Velázquez
Visclosky
Walberg
Walsh (NY)
Walz (MN)
Wasserman Schultz
Waters
Watson
Watt
Waxman
Weiner
Welch (VT)
Weller
Wexler
Whitfield
Wilson (NM)
Wilson (OH)
Wolf
Woolsey
Wu
Wynn
Yarmuth
Young (AK)
Young (FL)

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Aderholt
Akin
Bachmann
Bachus
Baker
Barrett (SC)
Bartlett (MD)
Barton (TX)
Berry
Biggert
Bilbray
Blackburn
Bonner
Boustany
Brady (TX)
Broun (GA)
Burgess
Burton (IN)
Buyer
Camp (MI)
Campbell (CA)
Cannon
Carter
Castle
Chabot
Cole (OK)
Conaway
Culberson
Davis, David
Deal (GA)
Doolittle
Drake
Dreier
Duncan
Ehlers
Everett
Fallin
Feeney
Flake
Forbes
Foxx
Franks (AZ)
Garrett (NJ)
Gingrey
Gohmert
Goode
Goodlatte
Granger
Hastings (WA)
Heller
Hensarling
Herger
Hoekstra
Inglis (SC)
Issa
Johnson (IL)
Johnson, Sam
Jordan
King (IA)
Kingston
Kline (MN)
LaHood
Lamborn
Lewis (CA)
Linder
Lucas
Lungren, Daniel E.
Mack
Manzullo
Marchant
Marshall
McCarthy (CA)
McCaul (TX)
McCrery
McKeon
McMorris Rodgers
Miller (FL)
Musgrave
Myrick
Neugebauer
Paul
Pearce
Pence
Peterson (PA)
Petri
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Poe
Price (GA)
Radanovich
Rogers (AL)
Rohrabacher
Roskam
Royce
Ryan (WI)
Sali
Sensenbrenner
Shadegg
Shuster
Simpson
Smith (NE)
Smith (TX)
Souder
Sullivan
Tancredo
Walden (OR)
Wamp
Weldon (FL)
Westmoreland
Wicker
Wilson (SC)

NOT VOTING—10

Allen
Boehner
Carney
Cubin
Davis, Jo Ann
Delahunt
Jindal
Johnson (GA)
McHugh
Miller, George

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore (during the vote). Members are advised that 2 minutes are remaining in this vote.

□ 1454

So the bill was passed.

The result of the vote was announced as above recorded.

A motion to reconsider was laid on the table.

AUTHORIZING THE CLERK TO MAKE CORRECTIONS IN ENGROSSMENT OF H.R. 2761, TERRORISM RISK INSURANCE REVISION AND EXTENSION ACT OF 2007

Mr. FRANK of Massachusetts. Mr. Speaker, I ask unanimous consent that in the engrossment of H.R. 2761, the Clerk be authorized to correct section numbers, punctuation, cross-references, and to make such other technical and conforming changes as may be necessary to accurately reflect the actions of the House.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Massachusetts?

There was no objection.

REMOVAL OF NAME OF MEMBER AS COSPONSOR OF H.R. 1644

Mr. ANDREWS. Mr. Speaker, I ask unanimous consent that the gentleman from Wisconsin's (Mr. RYAN) name be removed as a cosponsor of H.R. 1644. Our staff inadvertently, mistakenly added his name.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, the Chair will postpone further proceedings today on motions to suspend the rules on which a recorded vote or the yeas and nays are ordered, or on which the vote is objected to under clause 6 of rule XX.

Record votes on postponed questions will be taken later today.

FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007

Mr. DINGELL. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3580) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to enhance the postmarket authorities of the Food and Drug Administration with respect to the safety of drugs, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3580

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food and Drug Administration Amendments Act of 2007''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

section 920, is further amended by adding at the end the following:

''(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

''(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

''(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

''(ii) the application submitted under subsection (b) for such non-racemic drug—

''(I) includes full reports of new clinical investigations (other than bioavailability studies)—

''(aa) necessary for the approval of the application under subsections (c) and (d); and

''(bb) conducted or sponsored by the applicant; and

''(II) does not rely on any investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

''(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

''(i) in a therapeutic category in which the approved racemic drug has been approved; or

''(ii) for which any other enantiomer of the racemic drug has been approved.

''(2) LIMITATION.—

''(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

''(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

''(3) DEFINITION.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'therapeutic category' means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

''(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

''(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, 2012.''.

SEC. 1114. REPORT.

Not later than January 1, 2012, the Comptroller General of the United States shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines whether and how this subtitle has—

(1) encouraged the development of new antibiotics and other drugs; and

(2) prevented or delayed timely generic drug entry into the market.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. DINGELL) and the gentleman from Texas (Mr. BARTON) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan.

GENERAL LEAVE

Mr. DINGELL. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and to include extraneous matter on the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. DINGELL. Mr. Speaker, I yield myself 3 minutes.

Mr. Speaker, I rise today to express strong support for H.R. 3580, the Food and Drug Administration Amendments Act of 2007. This is excellent legislation. It contains needed reforms to strengthen the safety of our Nation's drug, device, and food supply.

I want to pay a word of compliment to my Republican colleagues and say that we have come to a compromise which I believe is satisfactory in the broad public interest and is an excellent piece of legislation. And I want to commend my friend Mr. BARTON and our Republican colleagues for having worked with us well on this matter.

On July 11, 2007, the House passed H.R. 2900, the Food and Drug Administration Amendments, by a bipartisan vote of 403–16. The bill was hailed by all as a strong bill that would improve the lives of Americans by ensuring that drugs and devices are reviewed in a competent and in a timely fashion.

Earlier this year the Senate passed a similar bill. Since July, bipartisan meetings have been held frequently between the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor, and Pensions to reconcile the differences between the two bills.

This bill includes two very different user-fee programs, both vital to the timely approval of lifesaving drugs and devices. The legislation would significantly improve our postmarket safety programs, thereby preventing many of the drug and device injuries and deaths that occur today. It fills an important gap in therapies available to one of our most vulnerable and important patient groups: our children. Finally, I note that the period of market exclusivity in the pediatric studies remains 6 months, as in current law.

I want to thank all the members of the committee who have worked hard on this bill. They have endured long hours to ensure that this bill would be completed before the expiration of the two user-fee programs at the end of this month. And I want to pay particular tribute to the staff on both sides for their outstanding labors.

Mr. Speaker, I want to point out that if this bill does not pass in the time limits which are imposed upon us by the September 30 expiration of this statute, we will have significant problems here that we may not be able to address because, I would point out, that failure to do so will leave us with a situation where we are going to find that RIF notices will be going out at Food and Drug and the ability to approve new drugs will all of a sudden come to a screeching and unfortunate halt.

□ 1500

I urge my friends and colleagues to support this legislation; it is a good piece of legislation, it has the support of all who have worked with it, and I would commend it to the attention and the kindness of my colleagues.

Mr. Speaker, I reserve the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I yield myself such time as I may consume.

(Mr. BARTON of Texas asked and was given permission to revise and extend his remarks.)

Mr. BARTON of Texas. Mr. Speaker, most of us are too young to remember, but in the early days of the movies there was a series of movies based on the ''Perils of Pauline.'' Pauline was a heroine who always got tied to the railroad track, and just as the train was bearing down on her the hero would come out and rescue her for another adventure in the next movie reel.

Well, this bill before us has kind of experienced the Perils of Pauline. It started out in a tremendous positive bipartisan spirit here in the House. Chairman DINGELL and Subcommittee Chairman PALLONE on the majority and Mr. DEAL and myself on the minority side and our colleagues in the rank-and-file worked together. We reported a bill, and I don't remember how many votes it got on the House floor, but I believe it was over 400. It got over to the other body, and they modified it in some ways that were somewhat different than the House bill. The negotiations broke down, and it looked for a while this week that the Food and Drug Administration was going to have to send out reduction in force notices to over 2,000 employees at the Food and Drug Administration. But thanks to the tremendous leadership of Chairman DINGELL and Subcommittee Chairman PALLONE and the help of people like Congressman WAXMAN and others on the majority side, we've been able to come back together and create a unified House position and work with our friends in the other body. And they've accepted the compromise that's before us to say that here, at 3 o'clock on Wednesday afternoon, we're going to rescue Pauline and pass the PDUFA, I hope by unanimous consent on the suspension calendar, the PDUFA reauthorization bill, and lots of good things are going to happen.

I am honored to be the ranking member on the Energy and Commerce Committee, along with Subcommittee

Ranking Member DEAL, who has worked with the majority to put this compromise together.

I want to stress the sensitivity of completing the reauthorization of the Prescription Drug User Fee Program and the Medical Device User Fee Program right now. As I said earlier, if we were not to have done that by the end of this week, over 2,000 employees at the FDA would probably have received a reduction in force notice sometime next week or the week after. These are dedicated experts who are responsible for reviewing and approving new drugs, biologics and medical devices. If we were to lose those individuals, we would probably never get them back. That would have severe negative repercussions for everybody in this country.

The legislation before us will promote advancement in pediatric therapies both for pharmaceuticals and for medical devices. The Pediatric Rule and the Best Pharmaceuticals for Children Act have helped to fill a void in pediatric medicine. Prior to these acts, many children were not getting the best treatment because the information was simply not available to determine how a drug would act on them. Drugs do perform differently in different patients, which is especially true when that patient is a child. These acts have begun to provide physicians the information they need to make the best decisions for their pediatric patients. These two acts work together to ensure that accurate, timely pediatric use information is developed to ensure the best medical outcomes for the Nation's children.

The bill preserves the 6-month incentive that companies receive to do additional testing in pediatric populations. I want to emphasize that. The bill before us preserves the 6-month pediatric exclusivity provision in current law, and I think that's a real accomplishment. Chairman DINGELL should be commended for his leadership on that effort. I was glad to support him in that insistence on that particular provision. I would also like to thank Congresswoman ANNA ESHOO for her work on that provision.

Finally, the legislation addresses the issue of drug safety. No drug is completely safe. All drugs have some risk. The goal of the Food and Drug Administration is to ensure that the benefits of the drug outweigh any potential risks and ensure that patients have access to life-saving and life-improving medications.

The legislation before us today strives to ensure that the FDA has the authority to monitor drugs to ensure that the balance between the benefit and the risk remains in equilibrium. The FDA will now have the authority to require that drug sponsors conduct postmarket clinical trials. The FDA will now have the authority to require that a drug make a label change. The FDA will also now have the authority to impose additional requirements on a drug in the form of a risk evaluation and mitigation strategy when it is needed to ensure that a drug's benefits outweigh its risk.

Mr. Speaker, this bill is a bipartisan compromise that does strengthen the FDA, it will improve children's health, and it will reauthorize programs that are essential to ensuring that patients have timely access to drugs and medical devices.

Before I reserve the balance of my time, I again want to thank Chairman DINGELL, Subcommittee Chairman PALLONE, Ranking Member DEAL, and all the rank-and-file members. I also want to especially thank Ryan Long on the minority staff, the gentleman that is sitting to my left. He stayed up all last night working on these final nuances. I shouldn't say this, but I'm told that he has the same clothes on today that he had on yesterday because he has worked so hard on this bill. We do want to give him special commendation. And I would urge that he take the appropriate hygienic provisions as soon as possible.

With that, Mr. Speaker, I reserve the balance of my time.

Mr. DINGELL. Mr. Speaker, I ask unanimous consent that I be permitted to yield the remainder of my time to the distinguished gentleman from New Jersey (Mr. PALLONE), the chairman of the subcommittee, and that he be permitted to control the time.

The SPEAKER pro tempore. Without objection, the gentleman from New Jersey is recognized.

There was no objection.

Mr. PALLONE. Thank you, Mr. Speaker, and I yield myself such time as I may consume.

Mr. Speaker, this is an important day for American consumers. Thanks to the legislation the House is about to pass, the Food and Drug Administration will have the financial resources and authorities necessary to ensure patients have timely access to safe and effective therapies.

First and foremost, this bill is about drug safety. In order to empower the FDA to protect the public from harmful drugs, we are giving the agency new authority to compel important labeling changes. This is a significant improvement over current policy, where FDA must haggle with drug companies and protracted negotiations that put patients and consumers at risk.

Under this bill, FDA will also be better equipped to force drug manufacturers to fulfill their responsibility to the American public and complete postmarket study commitments which are critical to ensuring a drug is safe.

In addition to these important new authorities, this bill authorizes the collection of $225 million in new user fees, a significant increase in the amount of funds dedicated for the use of drug safety activities.

The FDA Revitalization Act also provides for commonsense improvements to our Nation's food safety system, such as more stringent ingredient and labeling standards, establishment of an adulterated food registry, and improvements in public notifications.

Patients will be happy to know that the bill before us also requires greater transparency of drug makers by calling for clinical trials to be registered in a database monitored by the National Institutes of Health, along with basic results data. As we saw with the case of Avandia, making this information available to patients, providers and researchers is critical to uncovering potential harmful effects of a drug. And under this legislation, the public will also have greater access to internal documents that FDA used in its review of a drug application.

We also secure FDA scientists' right to publish by requiring the Secretary to establish clear policies on the timely clearance of articles written by FDA employees.

And finally, Mr. Speaker, this bill would make significant progress in reducing the number of conflicted experts who serve on advisory committees.

Mr. Speaker, I'm proud to say that this bill reauthorizes two very important programs for our Nation's children, the Best Pharmaceuticals for Children Act and the Pediatric Research and Equity Act. These programs have been crucial in the successful cultivation of important research used by doctors and parents to better determine what kinds of drug therapy is safest and most appropriate for a child patient.

In addition to the two existing programs, we're creating a new program that would help provide device manufacturers with greater incentives to conduct research and development of pediatric devices. Combined, these three bills will strengthen the research being done on pediatric uses of drugs and devices, and will make sure that our Nation's children have access to the medicines and therapies they need to grow up healthy and strong.

And finally, this bill reauthorizes two critically important user fee agreements with respect to prescription drugs and medical devices. These programs provide FDA with the necessary resources to review applications in a timely manner so patients who rely on new and improved drugs and devices don't have to go without. In addition to reauthorizing these existing user fee programs, this bill would establish a new user fee for the specific purpose of reviewing direct-to-consumer advertising.

I just want to commend Mr. DINGELL, our ranking member Mr. BARTON, Mr. DEAL, and all of the members here, Mr. WAXMAN, Ms. ESHOO, Mr. MARKEY. Their leadership on these issues has been unwavering. It is to their credit that we have a bill on the floor today.

This is a great victory for American consumers that will make tremendous strides in empowering the FDA and restoring public confidence in its ability to protect the public health, and I would urge my colleagues to vigorously support it.

Mr. Speaker, I reserve the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I would ask unanimous consent that the balance of the time on the minority side be yielded to Mr. NATHAN DEAL, the ranking member of the Health Subcommittee, for him to use and control as he sees fit.

The SPEAKER pro tempore. Without objection, the gentleman from Georgia is recognized.

There was no objection.

Mr. DEAL of Georgia. Thank you, Mr. Speaker.

I want to, first of all, thank Chairman DINGELL and Chairman PALLONE for working in a bipartisan fashion on this very important piece of legislation.

As we all know, the work of the FDA is vital to the health and safety of the citizens of this country, and especially legislation such as this that enhances their ability to deal with the questions of drug safety and the monitoring capabilities and the continuing programs that are so vital both to the drugs and to medical devices which require review and approval by the FDA.

The user fee programs that are being reauthorized by this legislation are very important to fulfilling their role in meeting their personnel needs to achieve a timely review of drugs and medical devices, and I believe that Congress should not and cannot afford to delay further action on this package. Certainly to do so would require FDA to begin to scale back their personnel, and none of us want to see that happen.

Moreover, patients demand and deserve to know that the medications they are taking are safe and effective, and that the FDA has adequate resources, both pre- and postmarket, in order to ensure that the safety of the Nation's drug supply is intact.

This legislation makes sensible bipartisan strides in that direction and balances the need to bring new life-saving medications to market, and at the same time provide the necessary protections for patient safety.

Like all compromises, there was a necessary give-and-take from all sides to bring this bill to the floor today. I think it is through the responsible work of the leadership of our committee of Energy and Commerce and through the processes that the committee has followed that we were able to accomplish that on this very significant piece of legislation.

I would urge my colleagues to vote in favor of the bill and hope that our colleagues across the rotunda would do likewise so that we can present a bill to the desk of the President for his signature which will keep this vital program and functions of FDA going forward and will not allow it to expire.

Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield 3 minutes to the gentleman from California who has been a leader on this issue for so many years.

Mr. WAXMAN. Mr. Speaker, the legislation we are considering provides FDA with critical tools the agency has been desperately lacking in its efforts to protect the American public from unsafe drugs. This legislation will provide FDA with the ability to require companies to update their drug label with new information, and FDA won't have to haggle with companies to get them to make those changes.

It also says, in giving FDA this labeling change authority, Congress is making it clear that we do not intend to impact a drug company's responsibility to promptly update its label with safety information on its own accord.

The legislation also gives FDA the authority to require companies to conduct postmarket studies and clinical trials of drugs. And it creates a mandatory clinical trial registry and results database to increase the transparency of those trials.

□ 1515

Mr. Speaker, before we break our arms trying to pat ourselves on the back, I want to express my deep disappointment that today we are walking away from a critical opportunity to make some reasonable adjustments to the windfall profits that drug companies receive for conducting pediatric studies under the Best Pharmaceuticals for Children Act. This is not about whether those pediatric studies should be done. We all agree about that. They are being done now. There is no question they will continue to be done. But if we were to cut back slightly on the term of exclusivity for only the blockbuster drugs, that would make a great deal of difference to people who are paying the high cost for pharmaceuticals.

In my view, we lost that opportunity, and it is going to hurt a lot of our consumers. In my view, there is simply no justification for rewarding companies with incentives that are so far in excess of the actual cost of doing the studies themselves.

I am also deeply disturbed the legislation fails to remove the sunset on FDA's authority to require pediatric studies under the Pediatric Research and Equity Act. There is absolutely no reason Congress needs to keep revisiting this commonsense measure that allows FDA to get essential information about whether new therapies are safe and effective for children.

So although I am pleased that today will provide FDA with important new authorities and resources, I must express my deep regret that we fail to take this opportunity to help individuals, businesses, State governments and insurers who pay the bill for the higher prices that result when generic competition is delayed for these expensive blockbuster drugs. I think it is a shame. We are talking about drugs of $5 billion in sales a year. If they spend a couple million dollars for their studies, they are being overreimbursed at the consumer's expense.

Mr. DEAL of Georgia. Mr. Speaker, I have no other requested time and would be prepared to close whenever the gentleman from New Jersey is prepared.

Mr. PALLONE. Mr. Speaker, I yield 2½ minutes to the gentleman from Massachusetts who, again, had quite a bit to do with this legislation, particularly on the safety provisions.

Mr. MARKEY. First of all, I want to commend you, Mr. Chairman, and Chairman DINGELL, your staffs, Mr. WAXMAN, Ranking Member BARTON and Mr. DEAL, all the Members on the Republican side for the product that is here, all of the staff which has worked on it for so long. My own staff, Kate Bazinsky, who is sitting right here, just was married 2 months ago, this has definitely affected those first 2 months of marriage, the incredible negotiations that have taken place to reach this point, along with Mark Bayer who was working on the privacy parts of this legislation with your staffs. I congratulate everyone.

I am pleased that the final bill before us today retains the core drug safety and clinical trial provisions from the bill that Congressman WAXMAN and I introduced in March, which will improve transparency at the FDA and make drugs safer. Although I had hoped the sunset would be removed from the pediatric rule and less exclusivity given to blockbuster products under the pediatric incentive program, this bill is a historic achievement which will make drugs and medical devices safer for consumers around the world.

The past several years have been marked by drug scandal after drug scandal, Vioxx, Ketek, Paxil and Avandia. These drugs have harmed families across the country and come to symbolize the urgent need for reform at the FDA. Taking drugs should not be a game of RX roulette, and yet the FDA's current system is broken, and thousands of American families have been harmed by drugs with dangerous side effects.

Today, the House is responding to those failures. The bill is a victory for consumers and for patients. The bill will empower the FDA with important new authorities to mandate label changes and require postmarket studies. However, these new FDA authorities do not change the responsibility of companies to maintain drug labels and warn the public about risk.

For the first time ever, the FDA will have the power to impose civil monetary penalties on companies that fail to conduct required postmarket studies. It will also establish a new postmarket risk identification and analysis system to identify harmful side effects without compromising patient privacy.

Since 2004, I have been fighting for a mandatory clinical trial registry and results database which will ensure that the public has accurate and complete information about drugs and devices.

Discussion Drafts Concerning Prescription Drug User Fee Act Reauthorization, Medical Device User Fee and Modernization Act Reauthorization, Drug Safety, and Certain Pediatric Pharmaceutical and Device Legislation:
***Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (2007).**
(excerpts)

DISCUSSION DRAFTS CONCERNING PRESCRIPTION DRUG USER FEE ACT REAUTHORIZATION, MEDICAL DEVICE USER FEE AND MODERNIZATION ACT REAUTHORIZATION, DRUG SAFETY, AND CERTAIN PEDIATRIC PHARMACEUTICAL AND DEVICE LEGISLATION

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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gram ends up being a good alternative for them. Do you think that this is set up so that it lessens the FDA's inspection authority under the law? It relates back to what I was asking before and you said you have to get back to me, but I want to probe in this area to see how far we have come since the 2002 legislation became law.

Mr. LUTTER. We believe that with the recommendations for change in our MDUFMA proposal, it would not lessen at all the FDA's authority. The key question is efficient use of resources that we have and an ability to allocate them with respect to risks that we believe are important. What we have is a proposal for a third party——

Ms. ESHOO. But the participation, historically, has been low, so I am asking you what you think has worked, that the proposed legislation really enhances, the best of what we made law in 2002. There is something not working right because the participation is low.

Mr. LUTTER. We agree that the program currently has not worked. We agree with you.

Ms. ESHOO. Now, why? Why do you think so, FDA? GAO has leaned in on it. Why do you think it hasn't?

Mr. LUTTER. We think it is partly for the lack of the changes that we are making with respect to the particular——

Ms. ESHOO. Did you ever come up and ask for additional authorities or changes in this?

Mr. LUTTER. Well, the changes are ones that we are now asking for with respect to part of the MDUFMA proposal. The key concern that we have is the use of resources internally. We have spent, I think it is like $3 million over the years as part of MDUFMA, implementing the proposal. It is very little money for third party inspection and, that is, the use of our resources that aren't well spent relative to alternative ways of improving device safety.

Ms. ESHOO. Can I just get a real quick one in here regarding the sunset of PREA and the exclusivity incentive under the BPCA? Does the FDA prefer any of the provisions that are being cast about, the blockbuster provision included in the Committee Print or an extension of the 6-month exclusivity?

Mr. LUTTER. We would prefer the existing statute for its simplicity and for the high incentives that it gives for pediatric trials that provide information that benefit the children.

Ms. ESHOO. Thank you. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I didn't know what your intention was there with the other gentleman and if you wanted to have one of them answer a question, that is fine. I didn't know if that is what you were trying to do there.

Mr. LUTTER. Thank you, sir. We will figure it out.

Mr. PALLONE. All right. Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman. To follow up, just briefly on Congresswoman Wilson's question about, Dr. Lutter, has the agency done anything to date related to establishing a unique device identifier system for medical devices?

Mr. LUTTER. We are currently involved in a rulemaking process that would allow for the development of unique device identifiers and we are pursuing that expeditiously.

Mr. PITTS. Now, some claim it is not as easy to establish a UDI system for devices as it is for drugs. Can you please explain what issues make UDI for devices more complicated along with the steps that you are proposing to address those concerns?

Mr. LUTTER. I am not in a position at this time to talk about the rulemaking that is ongoing. I think with respect to the difficulties, the first question is that unlike with the drugs, there is a threshold issue of scope. Is it all medical devices or is it only a subset and what is the subset of special concern; is it implantable or does it go more broadly than that. And second, there is also a question of how the unique device identifiers should be linked to the device, itself; is it on the labeling or should it be implanted in some way on the device so that it can't be separated, even after the device is separated from its labeling. Those are questions that we will consider in the rulemaking.

Mr. PITTS. Regarding preemption, some proponents of the labeling or language, claimed that the language only has to do with provisions in the current bills before us. Would it not be counterproductive to public health for States to impose different REMS requirements than those imposed by the FDA?

Mr. LUTTER. Confusion about REMS requirements or confusion about risks of FDA-regulated products is broadly of concern to us because it undermines both the trust that we need to have with the public to communicate the risk with them in a manner that lets them take appropriate action to control and to mitigate those risks and we think that preemption language would essentially have the effect of formalizing, in Federal statute, a collection of State actions that may be contradictory to or inconsistent with FDA actions on the safety and effectiveness of FDA-regulated products.

Mr. PITTS. That is all I have. Thank you, Mr. Chairman.

Mr. PALLONE. The gentleman from Utah.

Mr. MATHESON. Mr. Chairman, I have a series of questions I am going to submit in writing. I am not, after discussion with the agency, I am pretty sure they are not ready to answer today, so I will just submit them for written response. I yield back.

Mr. PALLONE. Thank you. Mr. Rogers. He is not there? Mr. Buyer.

Mr. BUYER. Thank you. I would like to follow-up on Mr. Pitts' questions. If all this legislation is intended to strengthen your ability to give assurances to the public about the products that are in the marketplace, how is it that the provisions that are in the bill regarding preemption actually allow you to do that? If we are going to allow these State class action lawsuits to even make jurisprudence more complex, how does that help you do your job?

Mr. LUTTER. We are concerned with the preemption provision in the discussion draft, because it may actually complicate our efforts to communicate risks in a manner that people understand. And the key question is, if we have additional resources through PDUFA and an additional set of information about risk, do we also have a system that we can convey to the public the risks of and the benefits of use in FDA-regulated products? We think that the preemption position may undermine our ability to do that effectively by allowing for multiplicity of views in State jurisdictions that may be

seen as contrary to or inconsistent with the FDA statements about risks and effectiveness.

Mr. BUYER. Mr. Pitts asked you about unique device identifiers. Let us talk about your present authority as opposed to what authority you may not have that you may need for us to put in a bill. Right now you have authority to require tracking for class II and class III devices, correct?

Mr. LUTTER. Yes.

Mr. BUYER. Now, in the bill, it appears that there is a broad expansion, which would require unique device identifiers on about anything imaginable that we are going to put into the body. Now, you said you don't want to talk about your present rulemaking on the development of a present system, but it would be shocking to me that the FDA would like to create a system in a rulemaking whereby you would have—well, let me take another step back. I would think that you need to create a rule that would have tracking orders that would be issued based on risk, would it not?

Mr. LUTTER. Our focus, in general, in managing the agency is on risk and we try to be——

Mr. BUYER. So earlier, when you talked about scope and subsets of scope, you are talking about tracking devices that are going to go into the body based on the risk and the impact that failure could have, right?

Mr. LUTTER. That is correct.

Mr. BUYER. So when we want you to have that focus in that scope, how does broadening the expansion to apply to about every device imaginable going into the body help you do your job if tracking is not going to be based on assessment of the risk?

Mr. LUTTER. In general, our effort and our policy with respect to protecting and promoting public health is to emphasize the risks of greatest concern and in that sense we would be concerned about excess breadth in the design of a program to focus unique identifiers. With respect to the particular language, this is something that because we received this only last Thursday, we should probably welcome that opportunity to talk separately with your staff about the unique identifier language, because this is not an area that we have studied in this legislation in detail.

Mr. BUYER. As you are developing your regulations for your own type of tracking system, what is your timeline to complete such system?

Mr. LUTTER. We are committed to doing it expeditiously, but we do not have a timeline for completion of a final rulemaking.

Mr. BUYER. Would your counsel to us be for you to complete your work and for us to then provide the oversight with regard to your system? And then, if we have questions or have our own ideas or want to broaden its scope, it would be more prudent to modify FDA's system rather than Congress just mandating a broad expansion with no regard to the system you are presently developing?

Mr. LUTTER. Well, the present program is one that we are developing without any concern about limitations of authorities in regard. So in that sense it is one that we think is worth pursuing with existing authorities, yes.

Mr. BUYER. Yes. In other hearings FDA had witnesses come before us, and not only myself but some other members of the com-

mittee have been concerned about counterfeit drugs and their prevalence in the marketplace. So we have seen this growth of adverse events reports over the last 3 years, and I have been trying to figure out what has been the impact of the growing prevalence of counterfeit drugs on the marketplace on this increase in adverse reports. What I am learning is that it is very difficult to determine this impact, and that, really, the system itself is not set in such a manner whereby we can have such retrospective analysis of that data. So I have a couple of recommendations that you can do on your own that we don't have to put into law, so I want you to please take these back to the FDA, and I think we can be helpful to each other.

What I am learning also, from the current MedWatch adverse events reporting, on the reporting form itself—is anybody going to write this down? Alright, because I don't want to waste my breath here, otherwise I will put it in the law. It includes a line that calls for name, strength and then manufacturer, and that information is all in that one line. My recommendation would be that the manufacturer be given a separate space on the form so whenever the healthcare provider completes the MedWatch form, we get the correct name of the manufacturer, because what I am also—and I know you are saying, Steve, that is up to the clinicians—but what is happening out there is that the clinicians are putting the name of the manufacturer, and sometimes it is a generic product and they mistakingly put the name of the original manufacturer. So if we give it a separate line, we are actually saying that we hope the clinician stops and gives it some good thought and actually pulls the manufacturer that is from the drug label itself.

Number 2 is you would also have a separate line that would have the addition of the purchase location of the medication. Now, earlier at one of the other hearings I had said, are we going to have to require doctors to start asking their patients where are they obtaining their drugs, because many of them are either running off to Canada or they run off to an Internet or they go to an Internet site and they are pulling them down from many different sources.

So we have docs out there that are struggling. We have internists and they give their script to their patient, but then we have no idea where the patient then is obtaining the drug and they come back and the doc thinks that the drug which they are prescribing is supposed to get the effect but they are not. He is puzzled. He then switches drugs. So I am trying to figure out how we get to that next follow-on step as we are trying to deal with these counterfeit drugs. These are actions that you can take on your own and I wish you would consider them.

Mr. LUTTER. Thank you very much for sharing them.

Mr. BUYER. Right.

Mr. LUTTER. I made careful note and we will discuss them internally.

Mr. BUYER. All right. Thank you very much. I yield back.

Mr. PALLONE. Thank you. Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. Dr. Lutter, I wanted to go back to the subject that Congresswoman Capps raised and that was the New York Times article yesterday. You did not see it?

Mr. LUTTER. I had an opportunity to glance at it only.

Ms. SCHAKOWSKY. OK. Mr. Chairman, I would like to have it included in the record, if I could.

Mr. PALLONE. Without objection, so ordered.

Ms. SCHAKOWSKY. Well, let us talk about the substance of it rather than maybe the specific issue. I will just quote. "The increasing number of FDA drug safety officers who say they have been punished or ignored after uncovering dangerous popular medicines." They talk about this one particular woman and the drug Avandia, but they give a number of other examples. Dr. Andrew Mossholder, in 2003, who discovered antidepressants led some children to become suicidal and the findings—Dr. Mossholder was prevented from speaking to an advisory committee about his analysis. Then Dr. David Ross, in 2006, very concerned about serious illness and death from patients taking the antibiotic Ketek. Is that Ketek? And Dr. Ross met with agency officials and pleaded with them to take action and nothing happened. It ends with a quote from someone still at the FDA, saying that people in this former office of Dr. Johann-Liang were very demoralized. There is a feeling of fear.

Obviously, that is of concern, I think, to us as representing the interests of consumers, if people who do report problems that they have found are being suppressed or even feel the need to leave the agency. This particular issue, this culture that seems to be at the FDA, I think, shows the need for transparency, and there was the inclusion in the Senate version of this bill an action package that would provide the public with documents related to a drug's approval, including a scientific explanation of the risk-to-benefit ratio and a summary review of any disputes and how they were resolved during the approval.

So what I am asking you is, in your experience, is there a culture of, let us say, bullying and intimidation and do you agree that allowing FDA scientists to give voice to their concerns and decisions is an integral piece of the scientific process?

Mr. LUTTER. In my experience, I am unaware of bullying at FDA and I think it would be appalling to me personally and to the FDA leadership, including the leadership of the Center for Drugs and the Center for Biologics and the Center for Medical Devices. We take these concerns expressed in the public very, very seriously.

Ms. SCHAKOWSKY. Well, are you saying, then, that the individuals that are cited in this article are misrepresenting the situation at the agency?

Mr. LUTTER. I am unfamiliar with the specifics of their cases. I do not know the facts about their cases.

Ms. SCHAKOWSKY. Well, what happens when something like this comes to light?

Mr. LUTTER. Let me tell you the commitments that have been made by the FDA leadership to address culture. The Institute of Medicine last fall issued a report that we had asked for, which was openly critical of the agency's ability to address scientific dissent. We responded in a report of our own, the future of drug safety that we issued in late January 2007. At that press conference, Dr. Gaulson and Dr. von Eschenbach made open personal commitments to welcome a diversity of scientific views as well as diversity

of individuals throughout the agency and to a personal responsibility for ensuring that dissent would not be punished.

Ms. SCHAKOWSKY. Well, let me just ask you this. There is a 2006 survey of FDA scientists done by the Union of Concerned Scientists, which found that 40 percent of scientists said they could not publicly express "concerns about public health without fear of retaliation." Are you saying that Dr. von Eschenbach's response is something new that is being done in response to the criticism or that that has always been the policy and that what you are saying is there never was this culture of retaliation?

Mr. LUTTER. I don't know whether there was a culture of retaliation. There is surely a culture of controversy and we acknowledge that, and that has had adverse effects on morale and effectiveness and we are concerned about that. But the key question is, A, we recognize that, and then B, we have laid out, in our response to the IOM report, a whole collection of actions, including personal commitments by the FDA leadership and the leadership of the relevant centers for medical products to ensure that the diversity is not in any way suppressed, is surely not punished, and does not result in any bullying or suppression of scientific views.

Mr. PALLONE. We have to move on. Thank you. Mr. Sullivan.

Mr. SULLIVAN. Thank you, Mr. Chairman. And thank you for being here. A lot of the questions I was going to ask have already been asked and there were other members that were talking about preemption, and you talked about that as well. One thing I would like to talk about is wouldn't you think that conflicting State labeling requirements for drugs, wouldn't that be confusing to consumers and potentially adversely affect public health? For example, if a grandmother was living in Nebraska and visiting her children in Oklahoma and had to get her prescription filled there and had a different notice on the labeling couldn't that be detrimental?

Mr. LUTTER. Conflicting, inconsistent and even contradictory statements about the benefits and the effectiveness and the risk of medical products is surely of concern. How can people figure out what they should be doing if there is not a single voice? The best approach to ensuring safety of medical products is to ensure that there is a single authoritative voice which, through a process of developing the best available scientific information, and evaluating that in a timely and effective manner, can be conveyed to everybody as an authoritative statement, and we believe that is our job. We believe that is our job as a regulatory agency. We have responsibility for regulating the safety and effectiveness of medical products, devices and drugs and biologics. We have been asked to do that by Congress and the American public and we think that if those messages that we convey to the pubic are seen as inconsistent with other authoritative sources, then confusing may result to the detriment of public health.

Mr. SULLIVAN. So you would say that different State labeling would be very confusing and bad to public health?

Mr. LUTTER. If it is seen as inconsistent and incompatible with ours. If we say something and a different statement is made by a State authority, then surely consumers may be confused.

Mr. SULLIVAN. Wouldn't you agree that different labeling would be detrimental to public health?

Mr. LUTTER. Yes.
Mr. SULLIVAN. Thank you.
Mr. PALLONE. Finished? Ms. Solis.
Ms. SOLIS. Thank you, Mr. Chairman. My question is for the director.
Has the FDA ever evaluated whether any of its mechanisms for warning the public, for instance, changes in labeling, are effective in terms of raising awareness for safety issues with products? And are there any plans to evaluate how FDA communicates with the pubic and how effective such measures are and if you have ever looked at that? And then lastly, what kinds of evaluation tools do you have for, say, consumers that don't speak English, whose primary language is something other than English?
Mr. LUTTER. We take very seriously our responsibilities to communicate the information about risks and effectiveness. We recently instituted, in this regard, a new committee on risk communication. Its function is to advise FDA about how to communicate the risks and the benefits of medical products and other FDA-regulated products as well. This committee was first initiated in response to the recommendations of the Institute of Medicine that I alluded to earlier. We anticipate that it will be up and running to have public meetings in the early part of next year. And we are currently soliciting, publicly, nominations from interested experts and people with responsibilities for communication to serve on that advisory committee. One of its functions will be to look at the effectiveness of our efforts generally. This is, we think, an area that is important and could be greatly strengthened by work of this committee.
Ms. SOLIS. And what about reaching out to groups that its primary language is not English? How do you communicate with them?
Mr. LUTTER. We do have a plain English program at FDA. We have a variety of outreach efforts that run through the Office of External Relations to representatives of minority groups and people for whom English is not the primary language.
Ms. SOLIS. Has that been evaluated?
Mr. LUTTER. The effectiveness of that has not been separately independently evaluated.
Ms. SOLIS. That probably should be looked at, because of course there are degrees of education with different groups from different backgrounds and I would even say English, in terms of just the type of individuals that may have no more than an eighth grade education and may not—labeling obviously has to be simplified in some format; but to find also different groups, Asian as well as Hispanic, that may not be fluent in English to have appropriate culturally competently appropriate language that is made available to them, because that could even be misconstrued and obviously lead to abuses.
Mr. LUTTER. We would be very happy to take that suggestion into advisement as a topic for the advisory committee when it has its first meetings next year.
Mr. SOLIS. And I would hope, just as a follow-up, too, I know that sometimes we often talk about the Internet and put posting information to the public. But by and large, the Hispanic community