**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**HUNTINGTON DIVISION**

**GENBIOPRO, INC.,**

***Plaintiff*,**

**v.**

**MARK A. SORSAIA*, in his official capacity as Prosecuting Attorney of Putnam County*** **AND PATRICK MORRISEY*, in his official capacity as Attorney General of West Virginia*,**

***Defendants.***

**Civil Action No.: 3:23-cv-00058**
**(Hon. Robert C. Chambers)**

**PLAINTIFF'S OPPOSITION TO DEFENDANT PATRICK MORRISEY'S MOTION TO DISMISS**

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## INTRODUCTION AND BACKGROUND

West Virginia has unlawfully attempted to ban a drug that Congress required the U.S. Food and Drug Administration ("FDA") to regulate as part of a comprehensive scheme that assures access to the drug for its approved indication. States cannot deny patients access to mifepristone (Mifepristone Tablets, 200 mg), because Congress authorized only FDA to restrict patients' access to this drug.

GenBioPro is the only U.S. manufacturer of generic mifepristone, one drug in a two-drug regimen for medication abortion. FDA approved mifepristone in 2000 as a safe and effective method to terminate a pregnancy. At that time, FDA imposed postmarket restrictions on how mifepristone could be dispensed and administered (known as "elements to assure safe use"), including requiring qualified physicians to supervise its provision and limiting where patients could take it. Compl. ¶¶ 36-39. Medication abortion, which allows patients to terminate a pregnancy at home, has grown as a share of overall elective abortions in recent years.

In 2007, Congress enacted the Food and Drug Administration Amendments Act ("FDAAA"), Pub. L. No. 110-85, 121 Stat. 823, amending the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. § 301 *et seq*.). The FDAAA expanded FDA's authority to regulate certain drugs, following their approval, under a Risk Evaluation and Mitigation Strategy ("REMS"). *See* 21 U.S.C. § 355-1. In the FDAAA, Congress specifically "deemed" mifepristone and 15 other drugs FDA had approved with "elements to assure safe use" to "have in effect an approved [REMS]." § 909(b)(1), 121 Stat. at 950-51, *reprinted at* 21 U.S.C. § 331 note. For other drugs, FDA would consider whether to impose a REMS in the first instance.

Congress required FDA to ensure that any additional elements to assure safe use restricting access to a REMS drug provide "safe access for patients" while assuring its "safe use." 21 U.S.C. § 355-1(f). Restrictions may "not be unduly burdensome on patient access" and must "minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(C)-(D). Since 2007, FDA has regulated mifepristone subject to this statute, updating mifepristone's REMS in 2023 to allow patients to receive the drug from certified pharmacies. Compl. ¶ 9.

West Virginia contravened Congress's mandate by enacting laws, on topics addressed by FDA, that bar patient access to the drug. The Unborn Child Protection Act, W. Va. Code § 16-2R-1 *et seq.*, and associated penalties, *id.* § 61-2-8, (collectively, the "Criminal Abortion Ban" or "Ban"), ban abortion in almost all circumstances for which mifepristone is indicated. The Ban imposes burdens on patients' access to the drug and on the healthcare delivery system, including criminal penalties, severely constricting the market for mifepristone in West Virginia. *See* Compl. ¶ 71; Opposition To Defendant Mark A. Sorsaia's Motion To Dismiss at 11 & n.3 (Mar. 7, 2023), ECF No. 31 ("Sorsaia Opp."). Even before it took effect, West Virginia restricted access to mifepristone, limiting GenBioPro's ability to market it in the State. *See* W. Va. Code §§ 16-2I-2 (requiring a waiting period and counseling before an abortion), 30-3-13a(g)(5) (prohibiting providers from prescribing mifepristone via telemedicine); *see also id.* § 30-1-26(b)(9) (providing for a rule banning prescription of mifepristone via telemedicine) (collectively, the "Restrictions"). Because those provisions are preempted and run afoul of the dormant Commerce Clause, GenBioPro has stated legally sufficient claims.

## STANDARD OF REVIEW

In ruling on a motion to dismiss, the Court "accept[s] as true all well-pleaded facts in [the] complaint and construe[s] them in the light most favorable to the plaintiff," *Wikimedia*

*Found. v. NSA*, 857 F.3d 193, 208 (4th Cir. 2017), and denies the motion if the complaint contains enough facts "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

## ARGUMENT

### I. GENBIOPRO HAS STANDING BECAUSE WVAG CREDIBLY THREATENED TO ENFORCE THE BAN THAT CONSTRICTS ITS ABILITY TO MARKET MIFEPRISTONE IN WEST VIRGINIA

To establish standing, "a plaintiff must show (1) an 'injury in fact,' (2) a sufficient 'causal connection between the injury and the conduct complained of,' and (3) a 'likel[ihood]' that the injury 'will be redressed by a favorable decision.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157-58 (2014) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992)). GenBioPro has standing to challenge the Ban and Restrictions, which constrict its pool of customers in the State.

#### A. GenBioPro's Injuries Include Economic Harm And Threatened Enforcement

West Virginia's Ban imposes "financial harm," the "classic and paradigmatic form of injury in fact," on GenBioPro. *Md. Shall Issue, Inc. v. Hogan*, 971 F.3d 199, 210 (4th Cir. 2020)). "[L]ost business opportunities" and "the operation of a challenged statute that results in the constriction of a vendor's buyers' market plainly inflict[] an injury in fact." *Id.* at 211 (alterations and internal quotation marks omitted) (citing *Craig v. Boren*, 429 U.S. 190, 194 (1976)). The Ban and Restrictions "severely constricted the market for mifepristone statewide," Compl. ¶¶ 11-12, "mak[ing] it impossible for GenBioPro to promote and market its product in West Virginia as it does in other states," *id.* ¶ 77, and "caus[ing] significant, ongoing economic injury to GenBioPro in the form of lost sales, customers, and revenue," *id.* ¶¶ 78-79. GenBioPro would be able to provide mifepristone to more patients in West Virginia if the Ban did not

prevent Walgreens and CVS, which stated they intend to sell it, and HoneyBee Health, which ships prescription drugs nationwide, from selling it there. *Id.*

GenBioPro is independently injured because it "alleges 'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony*, 573 U.S. at 159 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). The Ban violates the Supremacy Clause, *see infra* pp. 8-22; Compl. ¶¶ 94-99, so GenBioPro's intended sales raise "a constitutional interest." *Susan B. Anthony*, 573 U.S. at 159. The threat of prosecution is "credible." *Id.* Attorney General Patrick Morrisey ("WVAG"), as the State's chief legal officer, has authority to enforce the Ban. *See* W. Va. Code § 5-3-1.[1] He signed a public letter stating his intent to stand by state law restrictions on mifepristone. Compl. ¶ 25 & n.8. The pharmacies through which GenBioPro seeks to provide mifepristone in West Virginia take such threats of state enforcement seriously.[2]

WVAG concedes (at 12-13) that West Virginia restricts sales of mifepristone for its approved indication, but argues the drug may be used off-label and "in the few situations exempt from the [Ban's] general prohibition." *See also* Amicus Brief for State Att'ys Gen. at 4 (Mar. 6, 2023), ECF No. 30 ("Amicus Br.") (arguing GenBioPro can sell the drug "off-label"). Mifepristone is indicated for medication abortion up to 70 days' gestation, without restriction as

[1] Off. of Att'y Gen. of W. Va., *Mission of the Office of the Attorney General* (stating that WVAG is "entrusted with enforcing the laws of the State," including "prosecuting and defending legal actions on behalf of the state"), https://ago.wv.gov/about/Pages/default.aspx (last visited Mar. 17, 2023).

[2] *See* Letter from Danielle Gray, Exec. Vice President, Walgreens, to Kris Kobach, Att'y Gen., Kansas (Feb. 17, 2023) (agreeing not to sell mifepristone in Kansas due to fear of prosecution), https://perma.cc/5C4Y-9XE2; Alice Miranda Ollstein, *Walgreens Won't Distribute Abortion Pills in States Where GOP AGs Object*, Politico (Mar. 2, 2023), https://www.politico.com/news/2023/03/02/walgreens-abortion-pills-00085325; *see also* Sorsaia Opp. 6-8.

to the cause of the patient's pregnancy. *See* Compl. ¶ 58. GenBioPro is therefore injured because, as WVAG does not contest, the State banned it for its FDA-approved indication.

WVAG incorrectly (at 7) casts GenBioPro's intent to provide mifepristone in West Virginia as "conjectural." GenBioPro alleges ongoing and immediate harm: limits on its ability to provide mifepristone for its approved use in West Virginia. GenBioPro *currently* provides the product throughout the United States and would do so in West Virginia if the Ban and Restrictions did not constrict its market. Compl. ¶¶ 3, 11, 74, 79, 110. Prescribers and pharmacies that stock the product in other states will not do so in West Virginia because of the Ban. *Id.* ¶ 78 & n.32; *see also* Sorsaia Opp. 5-6; *supra* p. 4 & n.2. GenBioPro is not required to demonstrate that it *previously* sold mifepristone in West Virginia, and WVAG cites no case supporting his contrary assertion.[3] *See* Mot. 7.

The cases WVAG cites (at 7) are distinguishable because the plaintiffs did not have definite plans to engage in the proscribed conduct and because their injuries were noneconomic. In *Lujan*, the individuals claiming injury had no plans to observe the endangered species in question and conceded that events unrelated to the defendant prevented them from doing so. 504 U.S. at 563-64. In contrast to *Doe v. Obama*, 631 F.3d 157, 162-63 (4th Cir. 2011), holding that parents who were "considering adopting" embryos lacked standing, but for the Ban, GenBioPro would be providing mifepristone in West Virginia, not simply "considering" that step.

**B. GenBioPro's Injuries Are Redressable And Comstock Does Not Bar Relief**

WVAG does not dispute that GenBioPro's injury is fairly traceable to the Ban, nor could he. "[W]hen a 'challenged provision[ ] . . . inhibits [a vendor's] ability to' conduct its business,

[3] If the Court believes (contrary to precedent) past sales, or any other facts are necessary, it should permit Plaintiff to amend the Complaint to allege them.

'the alleged injury is . . . traceable to the' provision at issue." *Md. Shall Issue*, 971 F.3d at 213 (quoting *Air Evac EMS, Inc. v. Cheatham*, 910 F.3d 751, 760 (4th Cir. 2018)). The Ban constrains GenBioPro from providing its product in West Virginia, limiting its potential customer base and causing it to lose "sales, customers, and revenue." *See* Compl. ¶¶ 77-79.

WVAG argues (at 8, 17, 20) that a favorable decision will not redress GenBioPro's injuries because shipping mifepristone into West Virginia violates the Comstock Act of 1873, which forbids shipping by common carrier "[e]very obscene, lewd, lascivious, indecent, filthy or vile article, matter, thing, device, or substance; and — Every article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use." 18 U.S.C. § 1461; *see id.* § 1462. For a century, courts have held that the Comstock Act does not forbid shipping products "employed by conscientious and competent physicians," such as prescription medications. *United States v. One Package*, 86 F.2d 737, 739 (2d Cir. 1936); *see New York v. Sanger*, 118 N.E. 637, 637-38 (N.Y. 1918) (holding that physicians could not be prosecuted for shipping contraception). Rather, it criminalizes shipping black-market, unregulated materials. WVAG cites no authority for his contrary interpretation.

Moreover, the Comstock Act's prohibitions on mailing "obscene, lewd, lascivious, indecent, filthy or vile" devices and substances "intended for producing abortion" are a dead letter that "have never been applied to prosecute the recipients of abortion- and contraception-related materials."[4] Reading them to prohibit shipping mifepristone would be nonsensical after Congress and FDA ratified provision of mifepristone under a REMS. *See* FDAAA § 909(b)(1), 121 Stat. at 950-51 (mifepristone among drugs "deemed to have in effect an approved

[4] Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C. slip op. at 1-2 n.3 (Dec. 23, 2022), https://www.justice.gov/d9/opinions/attachments/2023/01/03/2022-12-23_-_comstock_act_1.pdf.

[REMS]"). Mifepristone's REMS allows pharmacies to dispense it by mail. U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* at 3 (Jan. 2023) ("2023 REMS Document"); *see Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 786 n.17 (2000) ("[I]t is well established that a court can, and should, interpret the text of one statute in the light of text of surrounding statutes, even those subsequently enacted.").

WVAG's remaining standing arguments (at 7-8) fail. He argues that redressability hinges on third parties' responses, but the pharmacies through which GenBioPro intends to provide mifepristone would dispense it absent the Ban. Compl. ¶ 78; *see supra* p. 4 & n.2. And WVAG cites no support for the contention that GenBioPro insufficiently alleged it would benefit if the Ban and Restrictions were lifted.

WVAG next argues (at 8) that GenBioPro cannot challenge the waiting period and counseling requirements, W. Va. Code § 16-2I-2, because they are not operative. But those provisions, which restricted GenBioPro's market in West Virginia, remain part of the Code and will go into effect if a court strikes down any part of the Ban. *Id.* § 16-2R-9. WVAG points to *California v. Texas*, but that case involved a toothless law: an Affordable Care Act provision that carried a penalty of $0 and had "no means of enforcement." 141 S. Ct. 2104, 2114 (2021); *see* Mot. 8. Here, GenBioPro's requested relief (enjoining the Ban) will make the waiting period and counseling restrictions operative and enforceable, thereby rendering jurisdiction proper. *See Associated Indem. Corp. v. Fairchild Indus., Inc.*, 961 F.2d 32, 35 (2d Cir. 1992) ("That the liability may be contingent does not necessarily defeat jurisdiction . . . .).

**C. GenBioPro Has Third-Party Standing**

Alternatively, GenBioPro has third-party standing to challenge the Ban on behalf of the pharmacies and healthcare providers that would prescribe and dispense mifepristone in West

Virginia and are prevented from doing so because they are subject to enforcement. "[A] vendor has a sufficiently close relationship with its customers when a challenged statute prevents that entity from transacting business with them." *Md. Shall Issue*, 971 F.3d. at 216. GenBioPro meets this test for the reasons explained in the Sorsaia Opp. (at 12-14).

## II. THE FDAAA PREEMPTS WEST VIRGINIA'S BAN AND RESTRICTIONS

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*, 910 F.3d at 761. Field preemption occurs when Congress "mandate[s] federal rules on the subjects or matters there specified, demanding uniformity" and "leaves no room for the States to impose different or stricter . . . requirements." *United States v. Locke*, 529 U.S. 89, 110 (2000). In addition, "it has long been settled that state laws that conflict with federal law are 'without effect,'" *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 479-80 (2013), including 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. Finally, federal law preempts state law that "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000) (internal quotation marks omitted).

Each of these doctrines applies here. First, where FDA determines a REMS is necessary, Congress authorized only FDA to impose restrictions on a patient's access to that drug, and required FDA to balance any restrictions with patients' access to the drug. West Virginia's attempts to impose its own access restrictions encroaches on this field. Second, because FDA imposed certain elements to assure safe use on mifepristone (and declined to impose others), West Virginia's conflicting elements that alter the balance FDA struck are preempted. Finally,

Congress determined that mifepristone should have a REMS, and thus intended patients to have access to it; the Ban and Restrictions obstruct that purpose.

**A. Congress Occupied The Field Of Restrictions On Drugs Subject To A REMS**

Congress preempted state laws banning or restricting access to drugs regulated by a REMS. Once FDA determines a drug requires a REMS, state attempts to impose additional restrictions on access to the drug encroach impermissibly on the preempted field. Field preemption occurs where Congress has created 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) (alterations and internal quotation marks omitted). Where Congress mandates federal regulation "demanding uniformity," it "leaves no room for the States to impose different" regulations on the same matter. *Locke*, 529 U.S. at 110 (quoting *Ray v. Atl. Richfield Co.*, 435 U.S. 151, 168 (1978)).

The FDAAA created a pervasive framework governing the subset of drugs subject to a REMS, leaving no room for states to supplement. Historically, FDA evaluated only a drug's safety and efficacy before approving it. *See Wyeth v. Levine*, 555 U.S. 555, 574 (2009) ("Congress enacted the FDCA to bolster consumer protection against harmful products."). But Congress enacted the FDAAA to "enhance the postmarket authorities of [FDA] with respect to the safety of drugs." FDAAA pmbl., 121 Stat. at 823. Congress granted FDA "[e]nhanced [a]uthorit[y]" to implement a comprehensive scheme regulating the prescribing, dispensing, packaging, and even disposal of a subset of drugs: those requiring a REMS. *Id.*, tit. IX, 121 Stat. at 922. Only the Secretary of Health and Human Services (or specified "division directors") may determine whether a REMS "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1), (2), (4). Under the FDAAA, FDA "shall" consider an enumerated list of factors in making that determination. *Id.* § 355-1(a). If

FDA concludes a REMS is necessary, the Secretary "shall" consult with "the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug" in determining whether any "additional elements" are necessary to ensure safe access to the medication. *Id.* § 355-1(c)(2). Any such elements "shall . . . not be unduly burdensome on patient access to the drug, considering in particular [ ] patients with serious or life-threatening . . . conditions." *Id.* § 355-1(f)(2)(C).[5]

Congress thereby authorized FDA to do even more than evaluate safety and efficacy. If FDA determines that a drug requires a REMS, FDA "shall" review and act on a proposed REMS. *Id.* § 355-1(a), (h)(2). The statute authorizes FDA to take additional steps it deems necessary to maintain safety while assuring patient access to the medication, and it requires FDA avoid any requirements that would be "unduly burdensome" to "patient access."[6] Unlike drug approval and label regulation, a REMS governs a drug's approval, prescribing, distribution, dispensing, packaging, accessibility to certain patient groups, and even disposal. *See generally id.* § 355-1.

The comprehensiveness of the REMS regime evinces Congress's intent for FDA alone to control how drugs with REMS move through the market from manufacturer to patient. In 2007,

[5] FDA determined that "[p]regnancy can be a serious medical condition." Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Amin., to Donna Harrison, Executive Dir., Am. Ass'n of Pro Life Obstetricians & Gynecologists, Gene Rudd, Sr. Vice Pres., Christian Med. & Dental Ass'ns, & Penny Young Nance, CEO & Pres., Concerned Women for Am. at 4 (Mar. 29, 2016), https://downloads.regulations.gov/FDA-2002-P-0364-0002/attachment_1.pdf; *see also* Compl. ¶ 39.

[6] Those measures include regulating how manufacturers distribute the drugs, *see* 21 U.S.C. § 355-1(f)(4); who can prescribe them, *id.* § 355-1(f)(3)(A), and to whom, *id.* § 355-1(f)(3)(D); who can dispense them, *id.* § 355-1(f)(3)(B); how the drugs can be packaged and dispensed, *id.* § 355-1(e)(4), (f)(3)(C); what information prescribers must know before dispensing, *id.* § 355-1(e)(3); what information prescribers must convey to patients using the drugs, *see id.* § 355-1(e)(2); and even how patients dispose of the drugs, *see id.* § 355-1(e)(4).

Congress subjected mifepristone to this end-to-end regulation.[7] West Virginia's attempt to regulate mifepristone differently — by banning it, limiting which patients may receive it, and restricting how they access it — encroach on that comprehensive structure. *See Locke*, 529 U.S. at 111 (where statute covered "design, construction, alteration, repair, maintenance, operation, equipping, personnel qualification, and manning of tanker vessels . . . Congress has left no room for state regulation of these matters") (internal quotation marks omitted); *see also Sperry v. Fla. ex rel. Fla. Bar*, 373 U.S. 379, 385 (1963) (state may not "impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress").

WVAG does not seriously contest this issue, stating only (at 11) — without citation or argument — that GenBioPro "cannot show field preemption." WVAG thereby waived any argument that field preemption precludes enforcement of West Virginia's Ban and Restrictions. *See Moseley v. Branker*, 550 F.3d 312, 325 n.7 (4th Cir. 2008) ("As a general rule, arguments not specifically raised and addressed in opening brief . . . are deemed waived.").

**B. West Virginia's Ban Conflicts With The Restrictions FDA Imposed**

West Virginia's Ban and Restrictions also conflict with the specific restrictions FDA imposed under the FDAAA. Conflict preemption occurs where state law "limit[s] the availability of an option the [federal agency] considered essential to" ensure its objectives. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 156 (1982). In such circumstances,

[7] In the FDAAA, Congress determined that any "drug that was approved before the effective date of this Act" where FDA had imposed "elements to assure safe use" would be "deemed to have in effect an approved" REMS. FDAAA § 909(b)(1), 121 Stat. at 950-51; 21 U.S.C. § 355-1. When FDA approved branded mifepristone in 2000, it did so with several elements to assure safe use. Compl. ¶¶ 36-39. FDA had approved only 15 other drugs with elements to assure safe use by 2007. *Id.* ¶ 37 & n.10; *see also* 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) (identifying the 16 drugs that FDA noted that Congress determined would have a REMS).

"States are not permitted to use their police power to enact such a regulation." *Locke*, 529 U.S. at 110. Moreover, "[w]hen federal law forbids an action that state law requires, the state law is 'without effect.'" *Bartlett*, 570 U.S. at 486 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

Where FDA determines a REMS is necessary, Congress authorized only the Secretary to require additional elements to assure safe use, specifying the factors FDA may consider. 21 U.S.C. § 355-1(f). Elements may not be "unduly burdensome on patient access," particularly considering patients with serious conditions, including pregnancy, *supra* pp. 9-10 & n.5, and must "minimize the burden on the health care delivery system." 21 U.S.C. §§ 355-1(f)(2), (5). FDA "shall" consult with "patients, physicians, pharmacists, and other health care providers" to ensure these factors are met. *Id.* § 355-1(f)(5). Mifepristone's REMS specifies how patients may receive the drug: through certified pharmacies and prescribers. *See generally* 2023 REMS Document. FDA did not limit mifepristone's dispensing or prescribing to certain patients (beyond those for whom the drug is contraindicated, as specified on its label) or require patients to prove their pregnancy was the result of sexual assault or incest.[8] *Cf.* 21 U.S.C. § 355-1(f)(3)(D) (permitting FDA to restrict dispensing to certain patients).

[8] FDA has included similar requirements in other REMS. For example, FDA prohibits pregnant people from taking isotretinoin, a medication that treats severe acne. U.S. Food & Drug Admin., *Risk Evaluation and Mitigation Strategy (REMS) Isotretinoin (iPLEDGE®) Shared System REMS Program* at 1-2 (Oct. 2022) ("Isotretinoin REMS Document"), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Isotretinoin_2022_10_6_REMS_Full.pdf; Compl. ¶ 35. Before a patient who can get pregnant may take the drug, FDA requires that a healthcare provider "order[ ] and confirm[ ]" a "negative pregnancy test result," and "[d]ocument and submit the result to the REMS program." Isotretinoin REMS Document at 1. Prior to obtaining a prescription for a single month's supply, such a patient must correctly answer several "comprehension questions" about the drug and pledge to use two kinds of birth control while taking it for the next month. *See id.* at 2-3, 26, 69-82 (detailing possible questions).

The challenged statutes unlawfully alter the balance FDA struck and conflict with FDA's elements to assure safe use. West Virginia prohibits "perform[ing]," induc[ing]" or "attempt[ing]" to perform or induce an abortion, unless the pregnancy is within eight weeks' gestation and results from sexual assault or incest that was reported to law enforcement at least 48 hours before the procedure. W. Va. Code § 16-2R-3(b). It imposes a waiting period and mandatory counseling session, requiring healthcare providers to tell patients information that is different from (and in some cases, contradicts) the information in the Patient Agreement Form incorporated into the REMS, *see id.* § 16-2I-2; Compl. ¶ 87.[9] And it prohibits providers from prescribing mifepristone via telemedicine, W. Va. Code §§ 30-3-13a(g)(5), 30-1-26(b)(9), which FDA explicitly declined to include in the REMS. Compl. ¶ 88.

The Ban and Restrictions thus restrict patients' access to mifepristone and burden the healthcare delivery system, conflicting with Congress's determination in section 355-1 that only FDA may do so for REMS drugs. Where FDA determined that a restriction should govern how patients access a REMS drug with elements to assure safe use, it precludes contrary state restrictions. *Cf. Locke*, 529 U.S. at 110 (Congress in Title II of the Ports and Waterways Safety Act of 1972 "mandated federal rules on the subjects or matters there specified, demanding uniformity," leaving "no room for the States to impose different or stricter design requirements than those which Congress has enacted."). States' restrictions on access to REMS drugs "frustrate the congressional desire of achieving uniform" standards regulating access to these drugs. *Ray*, 435 U.S. at 168.

[9] The Patient Agreement Form in the REMS specifies that patients understand they will take both "mifepristone and misoprostol to end [their] pregnancy." Compl. ¶ 67; 2023 REMS Document at 10. In contrast, West Virginia requires healthcare providers to inform patients that "it may be possible to counteract the intended effects of . . . mifepristone . . . before taking" misoprostol." W. Va. Code § 16-2I-2(a)(4)(A).

### C. The Ban And Restrictions Interfere With Congress's Purpose

When Congress enacted the FDAAA, it determined that 16 drugs FDA had approved with elements to assure safe use should continue to be available under 21 U.S.C. § 355-1. *See supra* p. 10 & n.7. Only FDA may restrict access to those drugs. It can impose only elements to assure safe use that do not unduly burden patient access. State bans or restrictions must give way where they present an "unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Wyeth*, 555 U.S. at 563-64 (internal quotation marks omitted), by "upset[ting] the careful balance struck by Congress" when it enacted a scheme of federal regulation. *Edgar v. MITE Corp.*, 457 U.S. 624, 634 (1982). Banning access to a drug Congress earmarked for "access" frustrates Congress's purpose in doing so.

### D. WVAG Fails To Show GenBioPro Has Not Stated A Preemption Claim

WVAG (at 10-11, 17) argues that States' historic police powers are not superseded absent the clear intent of Congress. But "an 'assumption' of nonpre-emption is not triggered when the State regulates in an area where there has been a history of significant federal presence." *Locke*, 529 U.S. at 108. Congress has long regulated drugs under a national system of approval and labeling, preserving only state regulation that did not pose a "direct and positive conflict" with the federal regime. *Wyeth*, 555 U.S. at 567-68 (explaining history of federal drug regulation); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 586 (2011) (Breyer, J., dissenting) ("The pharmaceutical drug industry has been heavily regulated" by federal statute "at least since 1906," resulting in "a traditional, comprehensive regulatory regime.").

#### 1. WVAG Miscasts The Case As One About Regulating Abortion

West Virginia cannot cloak its impermissible regulation of a REMS drug by calling it a ban on abortion. Preemption is concerned with a law's "practical impact," not the "description or characterization given it by the [State] legislature." *Hughes v. Oklahoma*, 441 U.S. 322, 336

(1979) (internal quotation marks omitted). Otherwise, "state legislatures" could "nullify nearly all unwanted federal legislation by simply publishing a legislative committee report articulating some state interest or policy — other than frustration of the federal objective — that would be tangentially furthered by the proposed state law." *Perez v. Campbell*, 402 U.S. 637, 652 (1971).

It is irrelevant whether, as Amici claim (at 6-7), West Virginia's Ban has a different "purpose" in restricting access to mifepristone from Congress's purpose in making mifepristone available to patients under the REMS. "Whatever the purpose or purposes of the state law, pre-emption analysis cannot ignore the effect of the challenged state action on the pre-empted field." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 107 (1992); *see also Bartlett*, 570 U.S. at 480 ("[A]ny state law, however clearly within a State's acknowledged powers, which interferes with or is contrary to federal law, must yield."). Amici cite *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 383 (2015) (at 7), but that case does not support a conflict preemption argument. It concerned field preemption, and the Court contrasted conflict preemption cases in its analysis. 575 U.S. at 388-89. Moreover, *Oneok* concerned the field preempted by the Natural Gas Act, where the Court observed there was no "clear division between areas of state and federal authority." *Id.* at 388. By contrast, the Ban directly conflicts with, and encroaches on the field of, Congress's determination about how mifepristone must be regulated and FDA's regulation of the drug.

WVAG cannot save the Ban by noting that mifepristone can still be used off-label. Mot. 12-13; Amicus Br. 4. West Virginia bans mifepristone for its indicated use — medication abortion — in nearly all circumstances. *See supra* p. 4. WVAG's theory invites the very Supremacy Clause clash the Framers resolved in favor of federal law. Congress gave states no role in determining whether a drug requires a REMS — that is FDA's job. States may object to a REMS, *see* 21 C.F.R. § 10.30, but may not ban a REMS drug for its approved indication. Once a

REMS is in effect, a state may not add to or subtract from the requirements FDA imposed. GenBioPro's drug is approved only for medication abortion, and is subject to a REMS. Korlym, to which WVAG refers (at 18), is a different drug not subject to a REMS.[10]

Amici's discussion (at 4-6) of *Virginia Uranium, Inc. v. Warren*, 139 S. Ct. 1894 (2019), is inapt. There, federal law did not regulate uranium mining, only milling. Here, by contrast, the FDAAA establishes a regime regulating mifepristone at all stages — prescribing, distribution, and provision of the drug to patients by prescribers and pharmacies. *See supra* p. 10 & n.7. These are the very activities with which West Virginia's Ban interferes, limiting when mifepristone may be prescribed, how it may be dispensed, and whether it may be received via a certified pharmacy. *See supra* pp. 12-13. There is nothing "downstream" about the prescribing of mifepristone — that is precisely what Congress has reserved to FDA. *See supra* p. 10 & n.7 (listing statutory provisions governing prescribing and dispensing of mifepristone).

**2. WVAG Misapprehends The Relevant Congressional Purpose**

WVAG misses the point in arguing (at 5, 12-13) that West Virginia's Ban does not conflict with FDA's determinations about "safety" and "efficacy." Unlike the FDCA's approval provisions (on which WVAG erroneously relies (at 13)), the FDAAA expressly includes "patient access" among FDA's concerns. *See* 21 U.S.C. § 355-1(f)(2) (entitled "Assuring access and minimizing burden"). Congress reiterated this priority throughout the statute. *See id.* §§ 355-1(f) ("Providing safe access for patients to drugs . . . ."), 355-1(f)(1) ("Allowing safe access to

[10] *See* U.S. Dep't of Health & Hum. Servs., Approved Drug Products with Therapeutic Equivalence Evaluations § 1.2, at vii (43d ed. 2023) (defining "[p]harmaceutical equivalents" as drugs "in identical dosage forms . . . that contain identical amounts of the identical active drug ingredient), https://www.fda.gov/media/71474/download; Letter from Mary H. Parks, Dir., Div. of Metabolism & Endocrinology Prods., to Luana Staiger, Regulatory Affairs, Corcept Therapeutics at 4 (Feb. 17, 2012) ("Korlym Approval Letter") (approving Korlym and determining that "a REMS is not necessary" for the drug), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202107s000ltr.pdf.

drugs"), 355-1(f)(2)(C) (requiring restrictions to "not be unduly burdensome on patient access to the drug"). States cannot interfere with the congressional judgment to provide access to healthcare.

WVAG and Amici rely on inapposite hypotheticals. They do not (and cannot) point to any drug FDA approved for "euthanasia," much less with a REMS subject to the strictures of section 355-1. Mot. 13; Amicus Br. 17-18. FDA does not approve drugs with an indication for "assisted suicide" or lethal injection. *See* Whether the Food and Drug Administration Has Jurisdiction over Articles Intended for Use in Lawful Executions, 43 Op. O.L.C. slip op. at 1-2 (May 3, 2019) (FDA does not regulate drugs used in executions), https://www.justice.gov/d9/opinions/attachments/2019/05/14/2019-05-03-fda-juris-exec_2.pdf. Any analogy would have to begin with a drug as to which Congress mandated access and that is subject to a REMS with elements to assure safe use. WVAG has cited none.

### 3. WVAG Misapplies The Supreme Court's Preemption Case Law

WVAG's reliance on cases recognizing Congress's preservation of state law remedies is misplaced. *See also* Amicus Br. 11-14 (arguing the REMS provides a "floor" on which States may layer additional restrictions). In *Wyeth*, the Supreme Court held that the FDCA preserved state tort remedies, in which the breach of the state law duty paralleled federal misbranding standards. 555 U.S. at 572-73. A state *ban* is entirely different in this context because FDA imposed a REMS precisely to ensure safe *access* to the medication.[11] Postmarket regulation of

[11] Although "state tort and contract law long have supplied the *remedy* for anyone injured by food or medical products . . . the *prevention* of injury through safety, efficacy, and marketing regulations has a substantial history of federal power." Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 Temp. L. Rev. 95, 131 (2016); *id.* at 135 (noting that "[r]egulation of medical products is thus heavily and historically federal, with an enormous, specially-devoted federal agency").

FDA-approved medication has long been federal, *see id.* at 567-68, not a matter of "historically local concern." Mot. 15.

With a single exception, no state has tried to ban a drug subject to a REMS, and that attempt was rejected. *See Zogenix, Inc. v. Patrick*, 2014 WL 1454696 (D. Mass. Apr. 15, 2014). WVAG's attempt to distinguish *Zogenix* (at 13 n.11) fails. He argues that West Virginia does not ban mifepristone, but does not dispute that the State bans mifepristone for its indicated use in almost all circumstances, which is functionally the same thing. WVAG cites no court upholding a state ban of an FDA-approved drug under any provision in the modern era of drug regulation.

WVAG (at 16) "place[s] more weight on the [FDCA's] savings clause than those provisions can bear, either from a textual standpoint or from a consideration of the whole federal regulatory scheme." *Locke*, 529 U.S. at 105. As in *Locke*, the statute preserves states' historic "important role" in providing parallel state law remedies to protect consumers, but does not "upset the settled division of authority by allowing States to impose additional" bans or restrictions on drugs Congress and FDA have included under section 355-1. *Id.* at 106; *see also Wyeth*, 555 U.S. at 567 (FDCA saving clause permits "state common-law suits").

Congress's limitations on the restrictions *FDA* can impose under section 355-1(f) does not help WVAG's position. Congress nowhere indicated its intent to allow 50 different state "ceilings." Instead, it asserted a federal interest in establishing the balance between safety and access for drugs subject to a REMS. Where Congress intended to allow states to ban a product notwithstanding a federal regulatory regime, it made this ability explicit. *See*, *e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 439, 446 (2005) (the Federal Insecticide, Fungicide, and Rodenticide Act permitted states to "ban the sale of a pesticide" as a result of language allowing states to "regulate the sale or use of any federally registered pesticide or device in the State").

The REMS' incorporation of state law for some purposes, *see* Mot. 16-17, demonstrates FDA's deliberate rejection of the kinds of restrictions advanced by West Virginia and, in any event, does not address whether Congress intended states to be able to impose directly their own restrictions on drugs regulated under section 355-1. The statutory text answers that question against state interference. *See supra* pp. 9-10.

Finally, it is no answer to say (at 11) that GenBioPro is not required to sell mifepristone. A "stop-selling rationale" is "incompatible" with the Supreme Court's FDA "pre-emption jurisprudence." *Bartlett*, 570 U.S. at 488.

**E. *Dobbs* Does Not Alter The Preemption Analysis**

WVAG (at 9-10) and Amici (at 6-7) erroneously rely on *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). There, the Court overruled *Roe v. Wade*, 410 U.S. 113 (1973), and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), and "return[ed] the issue of abortion to the people's elected representatives," which include Congress. *Dobbs*, 142 S. Ct. at 2243. The Court did not address whether Congress and FDA's regulation of mifepristone under a REMS with elements to assure safe use preempts state bans on patients' access to the drug, as WVAG admits (at 15). Instead, it held that matters relating to abortion are subject to the normal political processes, *see Dobbs*, 142 S. Ct. at 2243, and to established legal rules, *see id.* at 2276 (overruling *Roe* and *Casey* because, *inter alia*, their holdings "require[d] courts to engineer exceptions to longstanding background rules" such as res judicata and First Amendment doctrines). Among those processes is Congress's decision to regulate access to certain drugs at the national level.

**F. The Major Questions Doctrine Is Inapplicable**

WVAG argues (at 8-9) that Congress did not grant FDA authority to "set national abortion policy." GenBioPro's Complaint does not concern "abortion policy," but Congress's

decision to establish uniform national regulation of federally approved medications, including mifepristone, for their indicated uses. In the case of mifepristone, the indicated use is medication abortion up to 70 days' gestation. Compl. ¶¶ 76, 89. Congress mandated that only FDA may determine whether to continue to subject mifepristone to a REMS and to impose elements to assure patients' safe use and access to the drug. 21 U.S.C. § 355-1(f).

**1. The FDAAA Subjects Medication Abortion To The REMS Regime**

WVAG's assertion (at 9) that the FDCA does not "mention abortion" — a predicate for his "major questions" argument — fails because Congress specifically addressed mifepristone in the FDAAA. Congress deemed that the 16 drugs with elements to assure safe use would have a REMS, mifepristone among them. FDAAA § 909(b)(1), 121 Stat. at 950-51. Mifepristone is indicated *only* for abortion.[12] By including mifepristone in the group of drugs it deemed to have a REMS, Congress addressed medication abortion.

The history of Congress's consideration of mifepristone bears out this conclusion. Before FDA approved mifepristone, Congress debated and rejected amendments to appropriations bills in 1998, 1999, and 2000 prohibiting FDA from using funds to test or approve any drug for medication abortion.[13] After FDA approved mifepristone, Congress continued to

[12] In fact, when Congress passed the FDAAA, the only FDA-approved mifepristone-based drug was branded mifepristone. FDA did not approve Korlym — the drug Amici incorrectly claim is also mifepristone — until 2012. *See* Korlym Approval Letter at 4.

[13] The proposed amendments provided that "[n]one of the funds made available in this Act may be used by the Food and Drug Administration for the testing, development, or approval (including approval of production, manufacturing, or distribution) of any drug for the chemical inducement of abortion." 144 Cong. Rec. H5089-100 (daily ed. June 24, 1998); 145 Cong. Rec. H3798-812 (daily ed. June 8, 1999); 146 Cong. Rec. H5693-709 (daily ed. July 10, 2000). Their sponsor, Senator Tom Coburn, urged: "[t]here is something terribly wrong when we ask the taxpayers of this country to spend money in a way which is designed to give the Food and Drug Administration the ability to research and approve drugs that are designed to kill unborn children." 145 Cong. Rec. at H3798 (statement of Sen. Coburn). Congress did not enact these provisions, and it ultimately included mifepristone in the FDAAA.

debate the issue before enacting the FDAAA. *See*, *e.g.*, 153 Cong. Rec. S5469-70 (daily ed. May 2, 2007) (statement of Sen. Jim DeMint) (urging greater restrictions on mifepristone).

Congress declared that the drugs in question would be deemed to have in effect a REMS with elements to assure safe use. FDAAA § 909(b)(1), 121 Stat. at 950-51. It did not delegate this determination to the agency in the first instance, but required FDA to evaluate and review the REMS going forward to ensure it did not unduly burden patient access or the healthcare system. *See* 21 U.S.C. § 355-1(f). Where Congress considered the issue and reached a statutory resolution from which it has not deviated, the major questions doctrine is not implicated.

**2. Cases In Which Congress Rejected Agency Action Are Inapposite**

The Supreme Court's decision in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022), supports GenBioPro's position. There, the U.S. Environmental Protection Agency ("EPA") used its general Clean Air Act authority over pollution emissions to require coal-burning plants to reduce production of electricity and promote alternative forms of generation. The Court held that the agency's decision wrongly sought to derive authority from an ancillary provision of a statute designed to be a "gap filler" and was contrary to the statute's text, thereby constituting a "major question[]" that Congress had never left to EPA's discretion. *Id.* at 2610. The Court stressed that: EPA's novel interpretation was different from any authority it had exercised before; EPA claimed to find "newfound power" in a mere "ancillary provision" of the Clean Air Act, which had "rarely been used in the preceding decades," and never for that purpose; and EPA was exercising authority Congress had *refused* to grant it on at least four prior occasions. *Id.* at 2610-14 (Congress had "conspicuously and repeatedly declined to enact" similar plans). Congress also had not made that "major policy decision[] itself." *Id.* at 2609.

This case presents the opposite scenario. Congress gave FDA authority to weigh the benefits and burdens of imposing barriers to accessing particular medications. Since 2007, when

Congress included mifepristone among the drugs on which only FDA can impose restrictions, and *itself* deemed that group of drugs to have a REMS, FDA has continuously and conspicuously exercised this authority to regulate mifepristone. For the same reason, the case is unlike *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014), where the agency sought expanded power without congressional authorization. Congress has not impeded FDA's determination of how to strike the balance, overruled it, or removed FDA's power to regulate access to medication abortion, and has regularly discussed and reviewed FDA's actions.[14]

*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 127 (2000), also is unlike this case. The Court there considered FDA's claim of authority to regulate cigarettes as "drug delivery devices." *See* Mot. 10. The Court stressed "Congress'[s] clear intent as expressed" in many other statutes to regulate, but not "remove [cigarettes] from the market." 529 U.S. at 143. It recounted the many times Congress refused to extend the FDCA to include regulation of tobacco products. *Id.* at 142-56. By contrast, since 2007 FDA has exercised authority Congress granted it to ensure patients' safe access to mifepristone. Congress repeatedly considered whether FDA should regulate a drug indicated only for medication abortion, but refused to remove that authority. *See supra* p. 20 n.13. Unlike in *Brown & Williamson*, where the agency used "vague language" of a "long-extant" statute that had "rarely been used" (*EPA*, 142 S. Ct. at 2610) to assert *new* authority in an area where it had previously denied regulatory competence, here FDA has consistently regulated access to mifepristone since Congress enacted the FDAAA.

[14] Members of Congress have proposed bills aimed at reversing FDA decisions about mifepristone by: adding additional consent provisions not adopted by FDA, H.R. 2010, 116th Cong. (2019); requiring patients be informed about possibility of reversing effects of mifepristone, H.R. 552, 117th Cong. (2021); banning mifepristone's provision through telehealth, H.R. 4935, 116th Cong. (2019), S. 3252, 116th Cong. (2020), H.R. 5136, 117th Cong. (2021), H.R. 626, 117th Cong. (2021); and exempting mifepristone from appropriations for telemedicine, H.R. 2112, 112th Cong. (2011) (amend. 463). None were enacted.

## III. THE BAN AND RESTRICTIONS VIOLATE THE COMMERCE CLAUSE

The Commerce Clause grants Congress the power to regulate commerce "among the several States," U.S. Const. art. I, § 8, cl. 3, "limit[ing] the power of the States to erect barriers against interstate trade," *Dennis v. Higgins*, 498 U.S. 439, 446 (1991). The Framers sought "to prevent States from engaging in economic discrimination so they would not divide into isolated, separable units." *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2093-94 (2018). The Ban and Restrictions violate the Clause by imposing an undue burden on interstate commerce, by regulating extraterritorially, and by functionally banning an article of commerce. *See* Compl. ¶¶ 17, 104, 106-110. WVAG addresses only the first allegation (at 17-19), forfeiting any objections to GenBioPro's remaining arguments. *See Hannah v. Mullins Fam. Funeral Home, LLC*, 2022 WL 194413, at *6 (S.D.W. Va. Jan. 20, 2022) (arguments "not asserted in the defendant['s] opening memorandum" are "waived").

### A. The Ban And Restrictions Unduly Burden Interstate Commerce

The Commerce Clause "confer[s] a 'right' to engage in interstate trade free from restrictive state regulation." *Dennis*, 498 U.S. at 448. West Virginia's Ban and Restrictions abridge that right by preventing GenBioPro from developing a market for its product in the State and depriving residents of access to a safe, FDA-approved medication available to other Americans. *See* Compl. ¶¶ 17, 107, 110. A state law violates the Commerce Clause when the "burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits." *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). When a statute serves a legitimate local interest, courts balance that interest against the interference with interstate commerce — including, but not limited to, the burden a statute creates by regulating "in an area where there is a

compelling need for national uniformity" in regulation. *Yamaha Motor Corp., U.S.A. v. Jim's Motorcycle, Inc.*, 401 F.3d 560, 572 (4th Cir. 2005).

A statute may violate the Clause under *Pike*'s balancing test when it "adversely affect[s] interstate commerce by subjecting activities to inconsistent regulations." *CTS Corp. v. Dynamics Corp.*, 481 U.S. 69, 88 (1987). The Supreme Court has "invalidated state laws under the dormant Commerce Clause . . . where such laws undermined a compelling need for national uniformity in regulation." *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 298 n.12 (1997); *see*, *e.g.*, *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520, 527-28 (1959) (despite state's significant interest in highway safety, state law governing mudflap length unduly burdened interstate commerce in area requiring national uniformity).

West Virginia's Ban and Restrictions regulate in an area requiring national uniformity and place an excessive burden on interstate commerce in relation to their local benefits.[15] Compl. ¶¶ 104-110. Congress authorized FDA alone to develop a uniform national system of regulation for medications it determined to require a REMS. *See supra* pp. 19-20. In implementing a REMS, FDA must balance safety and access concerns in a way that leaves no room for regulatory interference from states. *See* Compl. ¶ 17.

WVAG (at 18) argues the Ban targets a litany of "legitimate state interests," without explaining how they apply to medication abortion. The only interest the statute

[15] WVAG argues (at 20) that the dormant Commerce Clause cannot apply here because Congress has already regulated abortion-inducing medications like mifepristone via the Comstock Act. But as discussed *supra* pp. 5-7, that argument fails because the Comstock Act does not apply to prescription medications like mifepristone.

identifies, "protecting unborn lives," W. Va. Code § 16-2R-1,[16] must be weighed against the burden on West Virginians' right to access lifesaving, safe, and necessary healthcare — access that Congress prioritized in section 355-1(f). "[S]imply . . . invoking [a] legitimate state interest" does not end the inquiry. *Am. Librs. Ass'n v. Pataki*, 969 F. Supp. 160, 178 (S.D.N.Y. 1997); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 350 (1977) ("[A] finding that state legislation furthers matters of legitimate local concern, even in the health and consumer protection areas, does not end the inquiry.").

This interest, which results in forcing West Virginians to carry unwanted pregnancies until their lives are at risk, cannot overcome the burden on the national interest in access to effective medication and uniform pharmaceutical commerce. *See* Compl. ¶¶ 17, 108-110. Instead of all Americans benefiting from pharmaceutical ingenuity, West Virginia's approach forces companies to develop products based on which states they view as friendly markets. If manufacturers making drugs requiring a REMS face the prospect of 50 states overriding the federal rules governing access to their product, manufacturers will face increased regulatory costs and unresolvable complexity with deleterious effects throughout the national healthcare delivery system and the pharmaceutical market. *See id.* ¶ 17.

WVAG argues (at 18) that this Court must give "due deference" to the state legislature's analysis of the benefits and burdens of its legislation. But the Court cannot disregard the national interest in affording Americans access to safe and reliable drugs,

[16] *See Harper v. Pub. Serv. Comm'n*, 427 F. Supp. 2d 707, 713 (S.D.W. Va. 2006) (expressing skepticism about purported local benefits not "set forth in the statutory scheme"); *see also Chambers Med. Techs. of S.C., Inc. v. Bryant*, 52 F.3d 1252, 1259 (4th Cir. 1995) (courts should look to legislative statement of purpose in statutes to determine laws' local benefit).

no matter the State where they live, nor Congress's intent that FDA alone regulate, and impose restrictions on, REMS drugs. As WVAG acknowledges (at 18), "[t]he healthcare market is infamously complicated." *Colon Health Ctrs. of Am., LLC v. Hazel*, 813 F.3d 145, 159 (4th Cir. 2016). That is why drug regulation requires uniform federal regulation to be workable. *See* Compl. ¶¶ 106, 108-109. Congress did not impose national regulation on the hospital certificate of need laws at issue in *Colon Health*, but it did so for REMS drugs. West Virginia's Ban keeps patients from accessing FDA-approved, effective medication and burdens the national healthcare system,[17] creating the "economic Balkanization" that the Framers ratified the Commerce Clause to prevent. *Hughes*, 441 U.S. at 325-26; *see* Compl. ¶¶ 104, 110.

### B. The Ban And Restrictions Violate The Clause's Prohibition On States Regulating Extraterritorially And Banning An Article Of Commerce

WVAG does not address GenBioPro's allegations that the Ban and Restrictions have the "practical effect" of regulating extraterritorially and that the laws functionally ban an article of commerce — something states cannot do.[18] Compl. ¶ 104; *see id.* ¶ 17. WVAG forfeited the argument that these allegations do not state Commerce Clause claims. A "critical inquiry" under the Commerce Clause is "whether the practical effect of the regulation is to control conduct beyond the boundaries of the State," which "must be evaluated . . . by considering . . . what effect would arise if not one, but many or every, State adopted similar legislation." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989); *see* Compl. ¶ 104. If many states followed West

[17] Patients who wait until their lives are at risk to terminate a pregnancy are more likely to suffer complications that require hospital care. *See* Andrea MacDonald et al., *The Challenge of Emergency Abortion Care Following the* Dobbs *Ruling*, 328 JAMA 1691, 1691 (2022).

[18] While WVAG quotes (at 19) part of the Complaint's allegations about banning an article of commerce, he does so only in a paragraph arguing that West Virginia's statutes "do not impose a significant burden on interstate commerce" — a *Pike* undue burden argument.

Virginia, the interstate market for medications would be eviscerated by a patchwork of "inconsistent legislation." *Healy*, 491 U.S. at 337; *see* Compl. ¶ 106.

Under the Commerce Clause, "a lawful article of commerce cannot be wholly excluded from importation into a state from another state where it was manufactured or grown." *Schollenberger v. Pennsylvania*, 171 U.S. 1, 12 (1898). West Virginia's Ban does just that. Compl. ¶¶ 17, 104. Medication abortion is the *only* FDA-approved indication for GenBioPro's product. *See supra* pp. 4-5. While the Ban formally allows mifepristone to terminate a pregnancy in some situations, Compl. ¶ 69 & n.26, those situations are so rare as to be functionally nonexistent. Patients seeking to take mifepristone to terminate a pregnancy resulting from rape or incest must report their trauma to law enforcement and then wait two days before taking mifepristone (while still being within the 8-week window West Virginia purports to establish).[19] *Id.* WVAG cannot show at the pleading stage that the State's medical emergency exception will materially ameliorate the State's interference with interstate commerce. The Ban is, as Prosecuting Attorney Sorsaia acknowledges (at 4-6), a ban. Under the Commerce Clause, it is unconstitutional.

## CONCLUSION

For these reasons, the Court should deny WVAG's Motion to Dismiss in its entirety. Alternatively, Plaintiff respectfully requests leave to amend should the Court find any deficiencies in the sufficiency of its Complaint.

[19] Most people do not know they are pregnant until around five and a half weeks, and one in three learn that they are pregnant after six weeks. Univ. of Cal. S.F., *One in Three People Learn They're Pregnant Past Six Weeks' Gestation* (Nov. 10, 2021), https://www.ansirh.org/research/research/one-three-people-learn-theyre-pregnant-past-six-weeks-gestation; Amy M. Branum & Katherine A. Ahrens, *Trends in Timing of Pregnancy Awareness Among US Women*, 21 Maternal Child Health J. 715, 715-26 (Apr. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5269518/pdf/nihms842105.pdf.

Dated: March 17, 2023

Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**HUNTINGTON DIVISION**

**GENBIOPRO, INC.,**

***Plaintiff*,**

**v.**

**MARK A. SORSAIA*, in his official capacity as Prosecuting Attorney of Putnam County* AND PATRICK MORRISEY, *in his official capacity as Attorney General of West Virginia*,**

***Defendants.***

**Civil Action No.: 3:23-cv-00058**
**(Hon. Robert C. Chambers)**

## CERTIFICATE OF SERVICE

I, the undersigned, counsel for Plaintiff, GenBioPro, Inc., do hereby certify that on March 17, 2023, I electronically filed and served the foregoing **PLAINTIFF'S OPPOSITION TO DEFENDANT PATRICK MORRISEY'S MOTION TO DISMISS** with the Clerk of the Court and all parties using the CM/ECF system.

Respectfully submitted,

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* * *

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**(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.

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**Food and Drug Administration Amendments Act of 2007,**
**Pub. L. No. 110-85, 121 Stat. 823, § 909, 121 Stat. 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.

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**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.

**(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); or

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

**(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; and

(ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas); 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) 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) at least annually, 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) Waiver in public health emergencies**

The Secretary may waive any requirement of this subsection during the period described in section 247d(a) of title 42 with respect to a qualified countermeasure described under section 247d–6a(a)(2) of such title, to which a requirement under this subsection has been applied, if the Secretary has—

(A) declared a public health emergency under such section 247d; and

(B) determined that such waiver is required to mitigate the effects of, or reduce the severity of, such public health emergency.

**(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, and propose a modification to, the approved strategy for the drug involved at any time.

**(2) Required assessments**

A responsible person shall, subject to paragraph (5), submit an assessment of, and may propose a modification to, 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 new safety or effectiveness information indicates that—

(i) an element under subsection (d) or (e) should be modified or included in the strategy; or

(ii) an element under subsection (f) should be modified or included in the strategy; or

(D) within 15 days when ordered by the Secretary, in consultation with the offices described in subsection (c)(2), if the Secretary determines that there may be a cause for action by the Secretary under section 355(e) of this title.

**(3) Requirements for assessments**

An assessment under paragraph (1) or (2) of an approved risk evaluation and mitigation strategy for a drug shall include—

(A) with respect to any goal under subsection (f), an assessment of the extent to which the elements to assure safe use are meeting the goal or whether the goal or such elements should be modified;

(B) with respect to any postapproval study required under section 355(o) of this title or otherwise undertaken by the responsible person to investigate a safety issue, the status of such study, including whether any difficulties completing the study have been encountered; and

(C) with respect to any postapproval clinical trial required under section 355(o) of this title or otherwise undertaken by the responsible party to investigate a safety issue, the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 282 of title 42.

**(4) Modification**

A modification (whether an enhancement or a reduction) to the approved risk evaluation and mitigation strategy for a drug may include the addition or modification of any element under subsection (d) or the addition, modification, or removal of any element under subsection (e) or (f), such as—

(A) modifying the timetable for assessments of the strategy as provided in subsection (d)(3), including to eliminate assessments; or

(B) adding, modifying, or removing an element to assure safe use under subsection (f).

**(h) Review of proposed strategies; review of assessments 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 an approved risk evaluation and mitigation strategy for a drug submitted under subsection (g).

**(2) Discussion**

The Secretary, in consultation with the offices described in subsection (c)(2), shall initiate discussions with the responsible person for purposes of this subsection to determine a strategy not later than 60 days after any such assessment is submitted or, in the case of an assessment submitted under subsection (g)(2)(D), not later than 30 days after such assessment is submitted.

**(3) Action**

**(A) In general**

Unless the dispute resolution process described under paragraph (4) or (5) applies, the Secretary, in consultation with the offices described in subsection (c)(2), shall describe any required risk evaluation and mitigation strategy for a drug, or any modification to any required strategy—

(i) as part of the action letter on the application, when a proposed strategy is submitted under subsection (a) or a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1); or

(ii) in an order issued not later than 90 days after the date discussions of such modification begin under paragraph (2), when a modification to the strategy is proposed as part of an assessment of the strategy submitted under subsection (g)(1) or under any of subparagraphs (B) through (D) of subsection (g)(2).

**(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**

Any action letter described in subparagraph (A)(i) or order described in subparagraph (A)(ii) shall be made publicly available.

**(4) 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.

**(5) Dispute resolution in all other cases**

**(A) Request for review**

**(i) In general**

Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the responsible person may 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 recommendationof 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—

(i) has initiated the discussions described under paragraph (2) not less than 60 days before such action deadline; and

(ii) 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.

**(6) 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 any of subparagraphs (B) through (D) 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 (4) or (5).

**(7) 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.

**(8) 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.

**(9) Effect**

Use of the processes described in paragraphs (7) and (8) 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) Elements to assure safe use, if required under subsection (f) for the listed drug. A drug that is the subject of an abbreviated new drug application and the listed drug shall use a single, shared system under subsection (f). The Secretary may waive the requirement under the preceding sentence for a drug that is the subject of an abbreviated new drug application, and permit the applicant to use a different, comparable aspect of the elements to assure safe use, if the Secretary determines that—

(i) the burden of creating a single, shared system outweighs the benefit of a single, system,1 taking into consideration the impact on health care providers, patients, the applicant for the abbreviated new drug application, and the holder of the reference drug product; or

(ii) an aspect of the elements to assure safe use for the applicable listed drug is claimed by a patent that has not expired or is a method or process that, as a trade secret, is entitled to protection, and the applicant for the abbreviated new drug application certifies that it has sought a license for use of an aspect of the elements to assure safe use for the applicable listed drug and that it was unable to obtain a license.

A certification under clause (ii) shall include a description of the efforts made by the applicant for the abbreviated new drug application to obtain a license. In a case described in clause (ii), the Secretary may seek to negotiate a voluntary agreement with the owner of the patent, method, or process for a license under which the applicant for such abbreviated new drug application may use an aspect of the elements to assure safe use, if required under

subsection (f) for the applicable listed drug, that is claimed by a patent that has not expired or is a method or process that as a trade secret is entitled to protection.

**(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; and

(B) 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.

**(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.

**18 U.S.C. § 1461**
**Mailing obscene or crime-inciting matter**

Every obscene, lewd, lascivious, indecent, filthy or vile article, matter, thing, device, or substance; and—

Every article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use; and

Every article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion, or for any indecent or immoral purpose; and

Every written or printed card, letter, circular, book, pamphlet, advertisement, or notice of any kind giving information, directly or indirectly, where, or how, or from whom, or by what means any of such mentioned matters, articles, or things may be obtained or made, or where or by whom any act or operation of any kind for the procuring or producing of abortion will be done or performed, or how or by what means abortion may be produced, whether sealed or unsealed; and

Every paper, writing, advertisement, or representation that any article, instrument, substance, drug, medicine, or thing may, or can, be used or applied for producing abortion, or for any indecent or immoral purpose; and

Every description calculated to induce or incite a person to so use or apply any such article, instrument, substance, drug, medicine, or thing—

Is declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier.

Whoever knowingly uses the mails for the mailing, carriage in the mails, or delivery of anything declared by this section or section 3001(e) of title 39 to be nonmailable, or knowingly causes to be delivered by mail according to the direction thereon, or at the place at which it is directed to be delivered by the person to whom it is addressed, or knowingly takes any such thing from the mails for the purpose of circulating or disposing thereof, or of aiding in the circulation or disposition thereof, shall be fined under this title or imprisoned not more than five years, or both, for the first such offense, and shall be fined under this title or imprisoned not more than ten years, or both, for each such offense thereafter.

The term “indecent”, as used in this section includes matter of a character tending to incite arson, murder, or assassination.

**18 U.S.C. § 1462**
**Importation or transportation of obscene matters**

Whoever brings into the United States, or any place subject to the jurisdiction thereof, or knowingly uses any express company or other common carrier or interactive computer service (as defined in section 230(e)(2)[1] of the Communications Act of 1934), for carriage in interstate or foreign commerce—

(a) any obscene, lewd, lascivious, or filthy book, pamphlet, picture, motion-picture film, paper, letter, writing, print, or other matter of indecent character; or

(b) any obscene, lewd, lascivious, or filthy phonograph recording, electrical transcription, or other article or thing capable of producing sound; or

(c) any drug, medicine, article, or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use; or any written or printed card, letter, circular, book, pamphlet, advertisement, or notice of any kind giving information, directly or indirectly, where, how, or of whom, or by what means any of such mentioned articles, matters, or things may be obtained or made; or

Whoever knowingly takes or receives, from such express company or other common carrier or interactive computer service (as defined in section 230(e)(2)[1] of the Communications Act of 1934) any matter or thing the carriage or importation of which is herein made unlawful—

Shall be fined under this title or imprisoned not more than five years, or both, for the first such offense and shall be fined under this title or imprisoned not more than ten years, or both, for each such offense thereafter.

[1] See References in Text note below.

**W. Va. Code § 5-3-1**
**Written opinions and advice and other legal services;**
**expenditures by state officers, boards and commissions for legal services prohibited**

The attorney general shall give written opinions and advice upon questions of law, and shall prosecute and defend suits, actions, and other legal proceedings, and generally render and perform all other legal services, whenever required to do so, in writing, by the governor, the secretary of state, the auditor, the state superintendent of free schools, the treasurer, the commissioner of agriculture, the board of public works, the tax commissioner, the state archivist and historian, the commissioner of banking, the adjutant general, the director of the division of environmental protection, the superintendent of public safety, the state commissioner of public institutions, the commissioner of the division of highways, the commissioner of the bureau of employment programs, the public service commission, or any other state officer, board or commission, or the head of any state educational, correctional, penal or eleemosynary institution; and it is unlawful from and after the time this section becomes effective for any of the public officers, commissions, or other persons above mentioned to expend any public funds of the state of West Virginia for the purpose of paying any person, firm, or corporation for the performance of any legal services: Provided, That nothing contained in this section impairs or affects any existing valid contracts of employment for the performance of legal services heretofore made.

It is also the duty of the attorney general to render to the president of the Senate and/or the speaker of the House of Delegates a written opinion or advice upon any questions submitted to the attorney general by them or either of them whenever he or she is requested in writing so to do.

**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**

If any provision of § 16-2R-1 *et seq.* of this code is judicially determined to be unconstitutional, this entire article shall be of no force and effect and 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.

**W. Va. Code § 30-1-26**
**Telehealth practice**

(a) For the purposes of this section:

"Abortifacient" means any chemical or drug prescribed or dispensed with the intent of causing an abortion.

"Established patient" means a patient who has received professional services, face-to-face, from the physician, qualified health care professional, or another physician or qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, within the past three years.

"Health care practitioner" means a person authorized to practice under § 30-3-1 *et seq.*, § 30-3E-1 *et seq.*, § 30-4-1 *et seq.*, § 30-5-1 *et seq.*, § 30-7-1 *et seq.*, § 30-7A-1 *et seq.*, § 30-8-1 *et seq.*, § 30-10-1 *et seq.*, § 30-14-1 *et seq.*, § 30-16-1 *et seq.*, § 30-20-1 *et seq.*, § 30-20A-1 *et seq.*, § 30-21-1 *et seq.*, § 30-23-1 *et seq.*, § 30-26-1 *et seq.*, § 30-28-1 *et seq.*, § 30-30-1 *et seq.*, § 30-31-1 *et seq.*, § 30-32-1 *et seq.*, § 30-34-1 *et seq.*, § 30-35-1 *et seq.*, § 30-36-1 *et seq.*, § 30-37-1 *et seq.* and any other person licensed under this chapter that provides health care services.

"Interstate telehealth services" means the provision of telehealth services to a patient located in West Virginia by a health care practitioner located in any other state or commonwealth of the United States.

"Registration" means an authorization to practice a health profession regulated by § 30-1-1 *et seq.* of this code for the limited purpose of providing interstate telehealth services within the registrant's scope of practice.

"Telehealth services" means the use of synchronous or asynchronous telecommunications technology or audio only telephone calls by a health care practitioner to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration. The term does not include internet questionnaires, e-mail messages, or facsimile transmissions.

(b) Unless provided for by statute or legislative rule, a health care board, referred to in § 30-1-1 *et seq.* of this code, shall propose an emergency rule for legislative approval in accordance with the provisions of § 29A-3-15 *et seq.* of this code to regulate telehealth practice by a telehealth practitioner. The proposed rule shall consist of the following:

(1) The practice of the health care service occurs where the patient is located at the time the telehealth services are provided;

(2) The health care practitioner who practices telehealth shall be:

(A) Licensed in good standing in all states in which he or she is licensed and not currently under investigation or subject to an administrative complaint; and

(B) Registered as an interstate telehealth practitioner with the appropriate board in West Virginia;

(3) When the health care practitioner-patient relationship is established;

(4) The standard of care for the provision of telehealth services. The standard of care shall require that with respect to the established patient, the patient shall visit an in-person health care practitioner within 12 months of using the initial telemedicine service or the telemedicine service shall no longer be available to the patient until an in-person visit is obtained. This requirement may be suspended, in the discretion of the health care practitioner, on a case-by-case basis, and it does not to the following services: acute inpatient care, post-operative follow-up checks, behavioral medicine, addiction medicine, or palliative care;

(5) A prohibition of prescribing any controlled substance listed in Schedule II of the Uniform Controlled Substance Act, unless authorized by another section: *Provided*, That the prescribing limitations contained in this section do not apply to a physician or a member of the same group practice with an established patient;

(6) Establish the conduct of a registrant for which discipline may be imposed by the board of registration;

(7) Establish a fee, not to exceed the amount to be paid by a licensee, to be paid by the interstate telehealth practitioner registered in the state;

(8) A reference to the Board's discipline process; and

(9) A prohibition of prescribing or dispensing an abortifacient.

(c) A registration issued pursuant to the provisions of or the requirements of this section does not authorize a health care professional to practice from a physical location within this state without first obtaining appropriate licensure.

(d) By registering to provide interstate telehealth services to patients in this state, a health care practitioner is subject to:

(1) The laws regarding the profession in this state, including the state judicial system and all professional conduct rules and standards incorporated into the health care practitioner's practice act and the legislative rules of registering board; and

(2) The jurisdiction of the board with which he or she registers to provide interstate telehealth services, including such board's complaint, investigation, and hearing process.

(e) A health care professional who registers to provide interstate telehealth services pursuant to the provisions of or the requirements of this section shall immediately notify the board where he or she is registered in West Virginia and of any restrictions placed on the individual's license to practice in any state or jurisdiction.

(f) A person currently licensed in this state is not subject to registration but shall practice telehealth in accordance with the provisions of this section and the rules promulgated thereunder.

**W. Va. Code § 30-3-13a**
**Telemedicine practice; requirements; exceptions; definitions; rule-making**

(a) *Definitions*. -- For the purposes of this section:

(1) "Chronic nonmalignant pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic nonmalignant pain" does not include pain associated with a terminal condition or illness or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition or illness.

(2) "Physician" means a person licensed or registered by the West Virginia Board of Medicine to practice allopathic medicine in West Virginia.

(3) "Store and forward telemedicine" means the asynchronous computer-based communication of medical data or images from an originating location to a physician or podiatrist at another site for the purpose of diagnostic or therapeutic assistance.

(4) "Telemedicine" means the practice of medicine using tools such as electronic communication, information technology, store and forward telecommunication, audio only telephone calls, or other means of interaction between a physician or podiatrist in one location and a patient in another location, with or without an intervening health care provider.

(5) "Telemedicine technologies" means technologies and devices which enable secure communications and information exchange in the practice of telemedicine, and typically involve the application of secure real-time audio/video conferencing or similar secure video services, remote monitoring or store and forward digital image technology, or audio only telephone calls to provide or support health care delivery by replicating the interaction of a traditional in-person encounter between a physician or podiatrist and a patient.

(b) *Licensure or registration*. --

(1) The practice of medicine occurs where the patient is located at the time the telemedicine technologies are used.

(2) A physician or podiatrist who practices telemedicine must be licensed as provided in this article or registered as provided in § 30-1-1 *et seq.* of this code.

(3) This section does not apply to:

(A) An informal consultation or second opinion, at the request of a physician or podiatrist who is licensed to practice medicine or podiatry in this state:

*Provided,* That the physician or podiatrist requesting the opinion retains authority and responsibility for the patient's care; and

(B) Furnishing of medical assistance by a physician or podiatrist in case of an emergency or disaster, if no charge is made for the medical assistance.

(c) *Physician-patient or podiatrist-patient relationship through telemedicine encounter*. --

(1) A physician-patient or podiatrist-patient relationship may not be established through: Text-based communications such as e-mail, Internet questionnaires, text-based messaging, or other written forms of communication.

(2) If an existing physician-patient or podiatrist-patient relationship does not exist prior to the utilization to telemedicine technologies, or if services are rendered solely through telemedicine technologies, a physician-patient or podiatrist-patient relationship may only be established:

(A) Through the use of telemedicine technologies which incorporate interactive audio using store and forward technology, realtime videoconferencing, or similar secure video services during the initial physician-patient or podiatrist-patient encounter;

(B) For the practice of pathology and radiology, a physician-patient relationship may be established through store and forward telemedicine or other similar technologies; or

(C) Through the use of audio-only calls or conversations that occur in real time. Patient communication though audio-visual communication is preferable, if available or possible. Audio-only calls or conversations that occur in real time may be used to establish the physician-patient relationship.

(3) Once a physician-patient or podiatrist-patient relationship has been established, either through an in-person encounter or in accordance with subdivision (2) of this subsection, the physician or podiatrist may utilize any telemedicine technology that meets the standard of care and is appropriate for the patient presentation.

(d) *Telemedicine practice*. --

A physician or podiatrist using telemedicine technologies to practice medicine or podiatry shall:

(1) Verify the identity and location of the patient;

(2) Provide the patient with confirmation of the identity and qualifications of the physician or podiatrist;

(3) Provide the patient with the physical location and contact information of the physician;

(4) Establish or maintain a physician-patient or podiatrist-patient relationship that conforms to the standard of care;

(5) Determine whether telemedicine technologies are appropriate for the patient presentation for which the practice of medicine or podiatry is to be rendered;

(6) Obtain from the patient appropriate consent for the use of telemedicine technologies;

(7) Conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the patient presentation;

(8) Create and maintain health care records for the patient which justify the course of treatment and which verify compliance with the requirements of this section; and

(9) The requirements of § 30-3-13(a)(1) through § 30-3-13(a)(8) of this code do not apply to the practice of pathology or radiology medicine through store and forward telemedicine.

(e) *Standard of care*. –

The practice of medicine or podiatry provided via telemedicine technologies, including the establishment of a physician-patient or podiatrist-patient relationship and issuing a prescription via electronic means as part of a telemedicine encounter, are subject to the same standard of care, professional practice requirements and scope of practice limitations as traditional in-person physician-patient or podiatrist-patient encounters. Treatment, including issuing a prescription, based solely on an online questionnaire, does not constitute an acceptable standard of care.

(f) *Patient records*. --

The patient record established during the use of telemedicine technologies shall be accessible and documented for both the physician or podiatrist and the patient, consistent with the laws and legislative rules governing patient health care records. All laws governing the confidentiality of health care information and governing patient access to medical records shall apply to records of practice of medicine or podiatry provided through telemedicine technologies. A physician or podiatrist solely providing services using telemedicine technologies shall make documentation of the encounter easily available to the patient, and subject to the patient's consent, to any identified care provider of the patient.

(g) *Prescribing limitations*. --

(1) A physician or podiatrist who practices medicine to a patient solely through the utilization of telemedicine technologies may not prescribe to that patient any controlled substances listed in Schedule II of the Uniform Controlled Substances Act:

*Provided*, That the prescribing limitations contained in this section do not apply to a physician or a member of the same group practice with an established patient.

(2) The prescribing limitations in this subsection do not apply when a physician is providing treatment to patients who are minors, or if 18 years of age or older, who are enrolled in a primary or secondary education program and are diagnosed with intellectual or developmental disabilities, neurological disease, Attention Deficit Disorder, Autism, or a traumatic brain injury in accordance with guidelines as set forth by organizations such as the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry, or the American Academy of Pediatrics. The physician must maintain records supporting the diagnosis and the continued need of treatment.

(3) The prescribing limitations in this subsection do not apply to a hospital, excluding the emergency department, when a physician submits an order to dispense a controlled substance, listed in Schedule II of the Uniform Controlled Substances Act, to a hospital patient for immediate administration in a hospital.

(4) A physician or podiatrist may not prescribe any pain-relieving controlled substance listed in Schedule II of the Uniform Controlled Substance Act as part of a course of treatment for chronic nonmalignant pain solely based upon a telemedicine encounter: *Provided*, That the prescribing limitations contained in this section do not apply to a physician or a member of the same group practice with an established patient.

(5) A physician or health care provider may not prescribe any drug with the intent of causing an abortion. The term "abortion" has the same meaning ascribed to it in § 16-2F-2 of this code.

(h) *Exceptions*. --

This article does not prohibit the use of audio-only or text-based communications by a physician or podiatrist who is:

(1) Responding to a call for patients with whom a physician-patient or podiatrist-patient relationship has been established through an in-person encounter by the physician or podiatrist;

(2) Providing cross coverage for a physician or podiatrist who has established a physician-patient or podiatrist-patient relationship with the patient through an in-person encounter; or

(3) Providing medical assistance in the event of an emergency.

(i) *Rulemaking*. --

The West Virginia Board of Medicine and West Virginia Board of Osteopathic Medicine may propose joint rules for legislative approval in accordance with § 29A-3-1, of this code to implement standards for and limitations upon the utilization of telemedicine technologies in the practice of medicine and podiatry in this state.

(j) *Preserving traditional physician-patient or podiatrist-patient relationship*. --

Nothing in this section changes the rights, duties, privileges, responsibilities, and liabilities incident to the physician-patient or podiatrist-patient relationship, nor is it meant or intended to change in any way the personal character of the physician-patient or podiatrist-patient relationship. This section does not alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law.

**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.

**73 Fed. Reg. 16313-14 (Mar. 27, 2008)**

## 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 | NDA 19–758<br>ANDA 74–949<br>ANDA 75–417<br>ANDA 75–713<br>ANDA 75–162<br>ANDA 76–809 | 09/26/1989<br>11/26/97<br>5/27/99<br>11/15/02<br>4/26/05<br>12/16/05 |
| | Fazaclo ODT | NDA 21–590 | 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<br>Amnesteem<br>Claravis | NDA 18–662<br>ANDA 75–945<br>ANDA 76–135<br>ANDA 76–356 | 05/07/1982<br>11/2002<br>04/2003<br>04/2003 |
| | Sotret | ANDA 76–041<br>ANDA 76–503 | 12/2002<br>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<br>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* (Jan. 2023)**

Initial Shared System REMS approval: 04/2019
Most Recent Modification: 01/2023

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 (1/3/2023) 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 Setting Address: _____

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

Approved 01/2023 [Doc control ID]

PRESCRIBER AGREEMENT FORM Mifepristone Tablets, 200 mg

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. 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.

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 Setting Address: _____

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

Approved 01/2023 [Doc control ID]

# 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.**

**144 Cong. Rec. H5089-100 (daily ed. June 24, 1998)**
**(excerpts)**

United States of America

# Congressional Record

PROCEEDINGS AND DEBATES OF THE 105th CONGRESS, SECOND SESSION

Vol. 144 WASHINGTON, WEDNESDAY, JUNE 24, 1998 No. 84

# House of Representatives

The House met at 10 a.m. and was called to order by the Speaker pro tempore (Mr. BLUNT).

## DESIGNATION OF THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,
*June 24, 1998.*

I hereby designate the Honorable ROY BLUNT to act as Speaker pro tempore on this day.

NEWT GINGRICH,
*Speaker of the House of Representatives.*

## PRAYER

Rev. David S. Clift, Duck United Methodist Church, Duck, North Carolina, offered the following prayer:

Dear God, our Creator, we acknowledge Your reign over the universe and the affairs of men. You ordained that governments should lead and guide Your people.

Grant these servants wisdom as they take up the mantle of stewardship of a nation and a world.

Grant them inspiration as they endeavor to find answers, solve problems, and dream dreams.

Grant them courage so when they are right, they will be able to stand firm in spite of criticism, persecution, or resistance.

Grant them humility so that when they are wrong, they will be able to change in spite of embarrassment and pride.

Grant them understanding so that they will know when to be courageous and when to be humble.

We express our gratitude for the privilege of living in a free and wonderful land. May we rise up with sacrificial enthusiasm to fulfill the glorious task of keeping alive the hope we call America. Amen.

## THE JOURNAL

The SPEAKER pro tempore. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

## PLEDGE OF ALLEGIANCE

The SPEAKER pro tempore. Will the gentlewoman from Michigan (Ms. STABENOW) come forward and lead the House in the Pledge of Allegiance.

Ms. STABENOW led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

## MESSAGE FROM THE SENATE

A message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate had passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 4060. An act making appropriations for energy and water development for the fiscal year ending September 30, 1999, and for other purposes.

The message also announced that the Senate insists upon its amendment to the bill (H.R. 4060) "An Act making appropriations for energy and water development for the fiscal year ending September 30, 1999, and for other purposes," requests a conference with the House on the disagreeing votes of the two Houses thereon, and appoints Mr. DOMENICI, Mr. COCHRAN, Mr. GORTON, Mr. MCCONNELL, Mr. BENNETT, Mr. BURNS, Mr. CRAIG, Mr. STEVENS, Mr. REID, Mr. BYRD, Mr. HOLLINGS, Mrs. MURRAY, Mr. KOHL, Mr. DORGAN, and Mr. INOUYE, to be the conferees on the part of the Senate.

## WELCOMING REV. DAVID CLIFT OF DUCK, NORTH CAROLINA

(Mr. JONES asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. JONES. Mr. Speaker, on behalf of my colleagues, I want to thank Rev. David Clift for his opening prayer.

Reverend Clift is pastor of the Duck United Methodist Church located on the beautiful Outer Banks of North Carolina, which is in the Third Congressional District. Since coming to the Outer Banks in 1994, the Reverend has served one of the fastest growing congregations in the State.

Reverend Clift is married to Libby Aull and they have two children, Mark, who is a college student, and Elizabeth, who is in high school.

I personally know several of Reverend Clift's church members who tell me he is a dynamic preacher and is greatly appreciated by his congregation. He is often invited to speak throughout the United Methodist Conference.

Again, I would like to thank Reverend Clift for joining us today and for the work he does every day by serving our Lord and his fellow man.

## ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. The Chair will entertain 10 1-minutes on each side of the aisle.

## CONGRATULATIONS TO HEATHER WILSON UPON HER ELECTION TO CONGRESS

(Mr. SHIMKUS asked and was given permission to address the House for 1 minute and to revise and extend his remarks.)

Mr. SHIMKUS. Mr. Speaker, it is hard for this West Pointer to say, "Go

and will be able to preserve the $10 million subsidy to the private ranching interests for one more year.

Mr. BASS. Mr. Chairman, will the gentleman yield?

Mr. DEFAZIO. I yield to the gentleman from New Hampshire.

Mr. BASS. Is it not true that either of these two suggested changes can easily be corrected in the committee of conference under technical corrections? There is no need to worry if under the unfortunate circumstance we have a revote that these corrections will not obviously be made, because it is the intent of Congress to make this change.

Mr. DEFAZIO. Mr. Chairman, I reclaim my time and thank the gentleman. There are a plethora of ways that this could be fixed. The simplest way is by the insertion of the word "operations" which the chairman objected to. I am going to propose changing a number. That is one change in one number. That would fix the problem or any potential problem. If the chairman objects there, it could still be fixed in conference or with a technical correction later. That is correct. So clearly the revote, if it occurs, will be on whether or not the Members want to provide a $10 million subsidy to western cattle and ranching interests which I believe a clear majority stated yesterday they do not. That will be the vote that will be rated.

REQUEST FOR MODIFICATION TO AMENDMENT NO. 2 OFFERED BY MR. DEFAZIO

Mr. DEFAZIO. Mr. Chairman, I ask unanimous consent that the language of the original amendment be changed on line 2 to not more than $28,097,000.

The CHAIRMAN pro tempore. The Clerk will report the modification.

The Clerk read as follows:

In the matter inserted in the Bass amendment providing for "Limitation on Use of Funds" strike "$18,800,000" and insert "$28,000,000".

The CHAIRMAN pro tempore. Is there objection to the request of the gentleman from Oregon?

Mr. SKEEN. Mr. Chairman, I object.

The CHAIRMAN pro tempore. Objection is heard.

Mrs. LINDA SMITH of Washington. Mr. Chairman, I move to strike the last word.

Mr. Chairman, we are going to begin a colloquy talking about the tobacco issue. First of all I would like to say that every year since I have been in Congress, I have introduced an amendment, or cosponsored an amendment, to get rid of subsidy for the Risk Management Agency, the crop insurance section, and the net cost of this, of this program. Each year we have lost by a scratch. This year as we went into working on the agriculture bill, we also have another bill which is the tobacco bill coming up. As we have worked on that, none of the objections that I have had have lessened. But it appears that the leadership now has agreed that there will be no cost to taxpayers. They will eliminate all cost to taxpayers of this particular program in the tobacco bill which the Speaker of the House will be introducing in just a few weeks. I would like to have confirmation of that.

Ms. PRYCE of Ohio. Mr. Chairman, will the gentlewoman yield?

Mrs. LINDA SMITH of Washington. I yield to the gentlewoman from Ohio.

Ms. PRYCE of Ohio. I thank the gentlewoman from Washington for yielding for the purpose of this colloquy. I recognize the gentlewoman's longstanding role in trying to solve this program funding issue which we debate each year. I would like to take this opportunity to confirm that we on the Tobacco Task Force and in leadership share her concerns and are committed to correcting this problem as part of our efforts to craft tobacco legislation later next month in a more comprehensive way.

I have to say that I myself personally feel very strongly. I have consistently voted against the subsidy as she has. I would like to see it eliminated. I will confirm that this will be a part of the tobacco legislation.

Mrs. LINDA SMITH of Washington. I thank the gentlewoman for her comments. I want to ask one question to clarify what she just said. She is saying that the tobacco legislation will eliminate any taxpayer support for this program.

Ms. PRYCE of Ohio. That is correct.

Mr. HANSEN. Mr. Chairman, will the gentlewoman yield?

Mrs. LINDA SMITH of Washington. I yield to the gentleman from Utah.

Mr. HANSEN. I appreciate the gentlewoman yielding. As I understand it, the designee for the leadership is the gentlewoman from Ohio (Ms. PRYCE), and we appreciate the great work that we expect her to do which I am sure she will. She is very aware that myself, the gentleman from Massachusetts (Mr. MEEHAN) and the gentleman from California (Mr. WAXMAN) have a piece of legislation that we think is an excellent piece of legislation. We are not solidly in cement, but we would like some assurance from the leadership's designee that the language that we are talking about which would give protection as I see it to the small farmer who we are very concerned about would be included in any piece of legislation, whether it be an abbreviation or change of ours, or it be one that the Speaker and the task force comes up with, that we could have that assurance. I think it would make those of us on a bipartisan nature who are working on this feel much better about that if we could have that assurance at this time.

Ms. PRYCE of Ohio. If the gentlewoman will yield, the assurance that the gentleman is asking for is that this subsidy will not any longer be in existence as a result of the tobacco legislation, he has that assurance.

Mr. HANSEN. We do appreciate that. I would hope that the task force would work with us closely on many of the things that are in our legislation which I notice the Speaker of the House on television the other night, I thought he was repeating our bill as he gave his rendition on television, if I may respectfully say that.

Mr. FAZIO of California. Mr. Chairman, will the gentlewoman yield?

Mrs. LINDA SMITH of Washington. I yield to the gentleman from California.

Mr. FAZIO of California. If I could ask the gentlewoman from Ohio to comment further, it has been the assumption that a number of us who have been working on tobacco legislation have had that somehow this would be paid out of the settlement, so that the individual tobacco farmer would not be eliminated from a program that all other farmers could participate in, but that we would relieve the burden that I know a number of Members have had of public support through the general fund of the Government.

Is it contemplated that somehow the companies through the settlement would make available funds to ensure that these growers can participate in this program?

Ms. PRYCE of Ohio. That still is a very viable possibility. We will be working through the next 2 weeks of recess to further that goal. I cannot say exactly that that is how it will happen, but I can say with great assurance that it will no longer be a burden on the American taxpayer.

Mr. FAZIO of California. There may be another approach taken, if the gentlewoman will yield further, that I have not mentioned but still a way in which these growers would not be discriminated against vis-a-vis other agricultural producers?

Ms. PRYCE of Ohio. That is being explored. There are several different proposals on the table. I am sure the gentleman is aware that there are many Members on our side of the aisle that are very interested in this as well. I have been trying to work with them so that these small farmers are not cast out overnight. But it does not belong on the taxpayers' shoulders. I feel the same as the gentlewoman from Washington in that respect.

Mr. FAZIO of California. Mr. Chairman, we look forward to seeing the legislation. Obviously I hope it is a comprehensive approach to the solution to this problem but one that does not leave out the needs of legitimate tobacco farmers in this country.

Mrs. LINDA SMITH of Washington. Mr. Chairman, in conclusion I want to thank the gentlewoman from Ohio for her leadership and the assurance that the taxpayers will no longer pay this, and I will pull my amendment.

AMENDMENT OFFERED BY MR. COBURN

Mr. COBURN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. COBURN:

At the end of the bill, insert after the last section (preceding the short title) the following new section:

SEC. 739. None of the funds made available in this Act may be used by the Food and

Drug Administration for the testing, development, or approval (including approval of production, manufacturing, or distribution) of any drug for the chemical inducement of abortion.

Mrs. LOWEY. Mr. Chairman, I reserve a point of order on the gentleman's amendment.

The CHAIRMAN. The gentlewoman from New York reserves a point of order.

Mr. COBURN. Mr. Chairman, this is a bill that is intended to do a very discrete function. Number one, we should look at what the definition of the charge to the Food and Drug Administration is. Let me quote from page 96 of this bill:

"The programs of the Food and Drug Administration are designed to achieve a single overall objective, consumer protection."

Mr. Chairman, it is my contention that there is nothing associated with consumer protection in the development and securing of abortifacient drugs, that in fact this is an area far outside the charge of the Food and Drug Administration.

What does this bill not do? This bill has no effect on the development of any drug which has a purpose other than abortifacient of an implanted blastocyst. This amendment will not prohibit the FDA from conducting its legitimate oversight function, and following its guidelines to in fact follow the charge of consumer protection.

Part of the point of order that I am sure will be raised is that this is far reaching and goes outside the scope, which it does not, because it is not intended to completely block research on efficacious drugs.

The other point that I would make, that the charge of the FDA is, is to maintain surveillance over food, drugs, medical devices and electronic products to ensure that they are safe, effective and honestly labeled. The use of abortifacients supported by our tax dollars, researched by our tax dollars, approved by our tax dollars, has nothing to do with the charge of the FDA. It would seem to me that if we wanted to be honest, that this is something that totally should be ignored, is not an area of safe and effective oversight of the FDA, and, in fact, raises several other troubling questions:

Number one is we should be seeking, regardless of our position on pro-life or pro-choice, alternatives to abortion rather than making abortion easier.

Number two, we markedly oversimplify the concept of abortifacient drugs by saying that we can have a pill that will solve this problem.

□ 1245

Number 3, there is significant scientific evidence today that abortion is associated with a marked increase in the incidence of breast cancer.

Number 4, abortion drugs are often dispensed without a doctor's approval and oftentimes endanger a woman's health rather than protect her health. Twelve States already give pharmacists the authority to dispense these drugs without the aid of a physician.

Finally, if we talk about the research that has been done on the abortifacient drugs that are presently available or used in that manner, what we find is they are extremely ineffective. If my colleagues look at the studies that have been done in Brazil or in Europe on the multitude of drugs that are followed by this concept, what they will find is that 8 to 10 percent failure rate to accomplish what they were intended to do. What we find also is what has happened to the children that have been exposed to these drugs, and again let me bring this back.

What is the charge of the FDA? The charge of the Food and Drug Administration is safety, is consumer protection. Having Federal dollars spent to perfect and introduce and license and hold up a drug that takes away life goes completely opposite of the charge of the Food and Drug Administration.

Finally I would like to describe for my colleagues what happens to children who have been exposed to this. About 12 percent of the women who are exposed to the abortifacients that are out there now end up having to have an instrumented procedure. So, first of all, it fails for those 12 percent. Another 12 percent of the women do not abort. Of those 12 percent of women who do not abort, 9 percent, 8 to 9 percent, of the children are born.

The CHAIRMAN. The time of the gentleman from Oklahoma (Mr. COBURN) has expired.

(By unanimous consent, Mr. COBURN was allowed to proceed for 1 additional minute.)

Mr. COBURN. Mr. Chairman, of the 8 to 9 percent of the children that are born, 50 percent of those children, a large number, have microcephaly, which is a smaller-than-normal brain which leads to severe retardation, a large number have hydrocephaly, which means they have an inability to circulate the fluid around the brain.

So if, in fact, we want the Food and Drug Administration to be about consumer protection, then we in fact ought to ask them not to have anything to do in their charge with abortifacient drugs.

Mrs. LOWEY. Mr. Chairman, will the gentleman yield for the purpose of a question?

The CHAIRMAN. The time of the gentleman from Oklahoma (Mr. COBURN) has again expired.

(By unanimous consent, Mr. COBURN was allowed to proceed for 2 additional minutes.)

Mr. COBURN. Mr. Chairman, I yield to the gentlewoman from New York.

Mrs. LOWEY. Mr. Chairman, does the gentleman's amendment mean that if the application is submitted to FDA without the term, without the term "chemical inducement of abortion" as its stated purpose, would the amendment apply?

Mr. COBURN. The amendment would not apply to any drug that is applied to the FDA that the primary purpose is not intended to be an abortifacient. For example, there is a drug that is presently on the market called Cytotec. The gentlewoman is familiar with that drug. If that drug were being applied for now, its primary intended use is for ulcer prevention and treatment. This amendment would not preclude the application of that NDA for that drug.

Mrs. LOWEY. So, if the gentleman would clarify once more for me, if the application does not include the specific term "chemical inducement of abortion," what would the gentleman expect the department to do?

Mr. COBURN. First of all, the department is much more knowledgeable than my colleague might give them credit for. They understand what drugs are used for, and they are scientists and very good at what they do. And if, in fact, some company is making application for a drug that the primary purpose is for something that fits the charge of the FDA, consumer safety, not death, not killing, but consumer safety, then I think they have very well the ability to figure out what the purpose of that application is. And they also have to very clearly state in their NDA what the purpose is for the drug.

Mrs. LOWEY. But then, if I can further ask for clarification again, if the application is submitted to the FDA without the specific term "chemical inducement of abortion" as its stated purpose, would the amendment apply?

Mr. COBURN. Again, I would give the gentlewoman the same answer:

If somebody applies for a drug that is intended to do chemical induced abortion, and that is what they are asking for an NDA for, then it would apply. If it is not intended for that, it would not apply. And so therefore any drug that has any other use that might be beneficial and under consumer protection, the charge of the FDA, would be recognized as a legitimate NDA application.

POINT OF ORDER

Mrs. LOWEY. May I proceed, Mr. Chairman, with my point of order?

The CHAIRMAN. The gentlewoman from New York will state her point of order.

Mrs. LOWEY. Mr. Chairman, the Coburn amendment violates clause 2 of rule XXI of the Rules of the House prohibiting authorization on an appropriations bill.

Under clause 2 of rule XXI a provision is authorizing in nature if it imposes a new duty on a Federal employee.

The Coburn amendment does just this by prohibiting the Food and Drug Administration from expending any funds on an activity for which it does not have a definition. Quote: "Drug for the chemical inducement of abortion," as the Coburn amendment is written, is not a term of art that is legally recognized by the FDA.

I have a memo from the Department of Health and Human Services, and will

ask that it appear in the RECORD, stating that the term is one that is not recognized by the agency and would require interpretation. Requiring the agency to define this term unto the Coburn amendment means imposing a new duty on a Federal official.

This is clearly authorizing language.

Mr. Chairman, the memo goes on to say, and I quote: Under the statute's drug-approval scheme, sponsors propose to the Food and Drug Administration particular medical indications for which they seek to conduct research. Sponsors then seek FDA approval to market the drug for those proposed indications that the research demonstrates that the drug is safe and effective for these indication.

Since sponsors are free to propose any medical indication for their drugs and are unlikely to propose this precise language under this amendment, FDA would need to interpret each of these terms in the amendment in this context, chemical inducement and abortion, none of which are defined in the Federal Food, Drug and Cosmetic Act, and evaluate whether the proposed indication was subjected to the restriction.

I have a letter from the gentleman from California (Mr. WAXMAN) the former chairman and the ranking member of the Committee on Commerce Subcommittee on Health and the Environment, agreeing with the assessment that the Coburn amendment is authorizing in nature, and I will ask that this letter be included in the RECORD as well.

Mr. Chairman, I ask the Chair to sustain a point of order against this amendment. It is a clear violation of rule XXI, clause 2 of the Rules of the House.

One more point. The duty is they have to make a determination even if the exact words of the application are different from those in the gentleman's amendment. The FDA needs to determine the meaning of the applicant's words, and I would suggest that the gentleman from Oklahoma (Mr. COBURN) has conceded this point, and I thank the Chair, and again I ask the Chair to sustain a point of order against this amendment. It is a clear violation of rule XXI, clause 2 of the Rules of the House.

Mr. COBURN. Mr. Chairman, I would like to respond to the gentlewoman's point of order.

The CHAIRMAN. The Chair will hear the gentleman's response on the point of order.

Mr. COBURN. Mr. Chairman, this is an amendment based first on a limitation of funds. Number two, there is nothing in this amendment that requires anything additional by the FDA because every NDA that comes before the FDA today has to state the purpose for which the drug application is made. And then finally is that we would not agree to a stipulation, as the gentlewoman from New York pointed out, that would limit anybody's application for any drug and to apply this Rule of the House, we will happily concede, if we want to use the definition as she stated initially, in terms of abortifacient, if that is what she desires.

But the point is the actual functioning of the FDA, having brought drugs to the FDA, having filed NDAs, her statement is inaccurate, it does not follow the rules of the FDA, it is not a true statement to say that this will require any additional burden on the FDA.

Mr. Chairman, the FDA already requires every drug that has applied for it to state very specifically what its purpose is. If the purpose for the drug is not abortifacient, then there is no problem. If the purpose for the drug is it is, then the FDA would be limited.

This is a medical term under which the FDA already knows the definition. There is no question about what the definition is. There is no question in Federal law about what the definition is. So to confuse the issue under this rule is wrong.

Mrs. LOWEY. Mr. Chairman, may I ask the gentleman for further clarification?

The CHAIRMAN. The gentlewoman may proceed on her point of order.

Mrs. LOWEY. Mr. Chairman, I would like to ask the gentleman from Oklahoma if the application for RU-486 did not include the terms in the gentleman's amendment, how would the gentleman require the FDA to rule?

Mr. COBURN. What the gentlewoman from New York will have to tell me first to answer that is how was the RU-486 applied for.

Mrs. LOWEY. Mr. Chairman, I am asking the gentleman a question.

Mr. COBURN. The question is that the RU-486 was not applied for under that rule initially and is now.

Mrs. LOWEY. Yes, correct; or I am asking the gentleman, let us say if RU-486 did not apply for the application, would those terms expressed in the gentleman's amendment, how would the gentleman expect under his amendment the FDA to rule?

Mr. COBURN. Very easily. RU-486 is used for other things besides that. So, if they did not specify it, then that RU-486 would be approved for whatever it is specified for.

Very straightforward. Any drug that follows the guidelines of the FDA's NDA application process must state its intent. If RU-486 were applied for and it was not stated intent to accomplish what it in fact did, then it would be eligible for consideration under this rule.

The CHAIRMAN. Do other Members wish to be heard on the point of order?

Mr. WELDON of Florida. Mr. Chairman, I rise to speak in opposition to the gentlewoman's point of order, and I would just like to say that the point she is trying to make, I think, runs contrary to the whole tradition of what we do here in the House in these appropriations bills. It is the right and the prerogative of any Member to rise and put limitations or specifications on how money is going to be spent, and this man's amendment, the gentleman from Oklahoma, is very simple and straightforward.

We all know that abortion is a very controversial issue, it is controversial in this body, it is controversial with the American people, and the House of Representatives has repeatedly voted, for example, that no Federal dollars will be used for performing abortions. The so-called Hyde amendment language easily passes the House with overwhelming majorities, and I think the reason for this is obvious. Even though many Members may feel that they are personally pro-choice, they think it is totally appropriate not to be spending Federal dollars for performing abortions, and to ask that the Food and Drug Administration not use its funds for putting abortion drugs on the market I think is a very reasonable proposal.

Mr. Chairman, I would strongly recommend the Chair rule against the gentlewoman's point of order and that the gentleman's amendment be allowed to be debated and voted on according to the proceedings of the House.

□ 1300

The CHAIRMAN. Are there other Members that wish to be heard on the point of order?

Mr. WAXMAN. Mr. Chairman, I am a little confused, and I want some clarification. As I understand what the gentleman from Oklahoma (Mr. COBURN) told us, he expects the FDA to make some kind of interpretation of the primary intent of the drug.

Mr. COBURN. Mr. Chairman, if the gentleman will yield, every application made to the FDA has to have the primary intent of a drug, as the gentleman well knows. My objection to the point of order is we presented this just like every other limitation that has been placed in this Congress on the dispensing of funds, and we have followed that guidelines and made no new requirements on the part of the FDA.

Mr. WAXMAN. Mr. Chairman, reclaiming my time, I am not asking the gentleman's conclusions on the point. I was trying to find out what he would ask FDA to do if a manufacturer came in and said the primary purpose of the drug was to be abortifacient. The gentleman would argue then that his amendment would apply, is that correct?

Mr. COBURN. Yes.

Mr. WAXMAN. If the manufacturer came in and asked for approval of a drug and it did not state that it was for that purpose, then the amendment would not apply?

Mr. COBURN. That is true.

Mr. WAXMAN. Now, my point, Mr. Chairman, is that FDA has to look at these words which are not words within the context of the FDA law. The chemical inducement of abortion is a new phrase. It has no precedent in FDA's statutory authority, it has no legal definition, no statutory reference, no

regulatory guidance and no legislative history.

In other words, if this amendment were adopted, the head of the FDA would have to look at the application from a drug manufacturer. If the application said that the drug was being requested for approval for the purpose of a chemical inducement of abortion, then I would say this amendment would apply and there is no question about it.

But if the gentleman, as he stated earlier, would ask the FDA administrator to in some way make some judgment that really that is what they intend, even though they do not say it, then we are doing something beyond a limitation on the use of the funds.

Mr. COBURN. If the gentleman would yield further, the FDA makes a judgment on every drug application made to it.

The CHAIRMAN. The gentleman from California (Mr. WAXMAN) may speak on his point of order. When he is finished, the Chair will recognize other Members. There is no yielding back and forth. Is the gentleman finished?

Mr. WAXMAN. I did not realize there is no yielding back and forth.

The CHAIRMAN. There is not. If the gentleman wants to continue, he may.

Mr. WAXMAN. Mr. Chairman, if I may conclude, my point is if the FDA Commissioner has to make a judgment, then this amendment should not be permitted in order.

The CHAIRMAN. Are there other Members who wish to be heard on the point of order?

Mrs. LOWEY. Mr. Chairman, based on the gentleman's interpretation that unless the application for RU-486 contains the worlds "chemical induced abortion," the prohibition would not apply, I would withdraw my point of order.

The CHAIRMAN. The point of order is withdrawn.

Are there any Members who wish to speak on the amendment offered by the gentleman from Oklahoma (Mr. COBURN)?

Mrs. LINDA SMITH of Washington. Mr. Chairman, I move to strike the last word.

Mr. Chairman, I rise to speak in favor of this amendment. I think we need to go back to what the role of the Food and Drug Administration is, and that is the role of ensuring public safety and health, and that is by approving medically necessary drugs and devices, as well as ensuring food safety.

The amendment offered by the gentleman from Oklahoma (Mr. COBURN) is consistent with the mission of the FDA and simply bans funding for the testing, development or approval of any drug which causes a chemical abortion.

You see, women's health is really at stake. New evidence has indicated that abortions increase the chances of breast cancer. Presently breast cancer is the leading cause of cancer among middle-aged women. If protecting all members of society is the goal of the FDA, certainly we need to study this link exhaustively before we approve any drug that causes a chemical abortion. Make no mistake, the morning after pill which the FDA approved is not a contraceptive. It is an abortifacient, meaning it causes a chemical abortion.

In my home state of Washington, for example, pharmacists are permitted to dispense the "morning after" pill without a doctor's prescription. A doctor gives the general prescription to the pharmacist, the pharmacist interviews the woman, and then he decides or she decides whether or not the woman is eligible for this abortion. The protection of the doctor is then removed and the ramifications of the woman's health, whether physical or emotional, are not even discussed.

Additionally, our taxpayer dollars should not be used for the FDA to implement the abortion drug RU-486. The long-term effects of this abortive are still unknown. In U.S. clinical trials, four women nearly bled to death and required blood transfusions. Many women bled profusely and required hospitalization, and 68 percent of the women experienced such severe pain that medication was required.

It is unacceptable for the Federal Government through the vehicle of the FDA to promote a drug whose sole purpose is to destroy the life of another human being.

I think the goal of most lawmakers, whether Republican or Democrat, is to find alternatives to abortion. But with the increased accessibility of these abortion pills, unwanted pregnancies become the medical equivalent of a simple headache. Just pop a pill, and your problems all will go away. In our State it is as easy as calling the hot line number which appeared in my State paper, 1-888-NOT-2-LATE.

Mr. Chairman, in an age of increased personal responsibility, this is not a signal to be advertising to American women. It is not a signal to be advertising to American youth.

The job of the FDA is to protect and promote the health of all citizens. That includes the health of unborn children of America. The funds in the agriculture appropriation bill should not be used by the FDA to test, develop or approve any drug which substitutes abortives for self-discipline, causing abortions.

Mr. Chairman, I urge my colleagues to support the amendment offered by the gentleman from Oklahoma (Mr. COBURN).

Mrs. LOWEY. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in strong opposition to the gentleman's amendment. The Coburn amendment would stop the drug approval process in its tracks by placing unprecedented roadblocks in front of the FDA. It puts ideology ahead of science and compromises women's health.

This amendment would block final approval of a drug, RU-486, that the FDA has already declared to be safe and effective. I repeat, this amendment would block final approval of a drug that the FDA has already declared safe and effective when it is issued on approval letter for the drug.

This amendment would make FDA drug approval contingent not on science, but on politics. The FDA is charged with protecting the public's health, and they should not be subject to congressional interference.

Mr. Chairman, let us allow the FDA to do its job free from right wing intimidation. The American people do not want the Christian Coalition in charge of our Nation's drug approval process.

The amendment specifically bars the FDA from approving any drug for the chemical inducement of abortion. But what does that term mean? The FDA does not know. I have a letter here from their chief counsel that says they have no idea what it means. Doctors and scientists do not know what that phrase means either.

So in addition to stopping RU-486, this broad, vague amendment may also prohibit the development of new contraceptive methods, if you believe, as some do, that any form of hormonal contraception, like the pill, is tantamount to abortion.

What about other drugs that as a side effect may induce abortion, like many chemotherapy drugs and anti-ulcer medication? Will research be halted on these lifesaving drugs as well? This amendment may also prevent the FDA from preventing unsafe and unsupervised clinical trials.

So, Mr. Chairman, this amendment is about much more than RU-486; it is about whether the FDA will be free to test, develop and improve important medications without Congressional interference. It is about whether politics or science will govern our Nation's drug approval process. This amendment would tie the FDA's hands, rendering it absolutely helpless in its primary task to evaluate scientific data consistent with its mandate to protect the public health.

Since Roe v. Wade, unfortunately, the anti-choice minority has attempted to stymie contraceptive research and suppress advances in reproductive health. For example, there used to be 13 pharmaceutical companies engaged in contraceptive research. There are now four. Thankfully, despite the right wing's pressure tactics, scientists have made some important progress. Among the most significant is the development of RU-486.

RU-486 would make a dramatic difference in the options available to women facing unwanted pregnancies. It could make abortion, already one of the safest medical procedures performed in the United States, even safer. The drug would eliminate the need for surgery for women choosing to use it. This would present tremendous health benefits for some women.

RU-486 is also effective early in pregnancy. Women in France have been

using RU–486 for a decade, and it is also available in Sweden and Great Britain. Over 400,000 women have had abortions using RU–486. The New England Medical Journal recently published clinical trials on RU–486 confirming its acceptability and effectiveness. RU–486 is safe and effective.

Mr. Chairman, RU–486 has another significant advantage over current abortion procedures. RU–486 can be given in the privacy of a physician's office, away from clinics blockaded by protestors, away from violence, harassment and intimidation. This change would give women greater freedom and security. This is a fact that terrifies so many.

What will the radical right do when RU–486 is approved? Will it picket every doctor's office in America? Will it harass every woman in the Nation? Thankfully, it cannot, and that is why it is fighting so hard to block the approval of this drug.

The gentleman from Oklahoma (Mr. COBURN) wants to turn the clock back, back on scientific advances, back all the way to the back-alley in the days of the wire hanger, back to the days when thousands of women died every year from unsafe, illegal abortions.

Well, we have news for the gentleman from Oklahoma (Mr. COBURN). We will not go back.

The CHAIRMAN. The time of the gentlewoman from New York (Mrs. LOWEY) has expired.

(By unanimous consent, Mrs. LOWEY was allowed to proceed for 1 additional minute.)

Mrs. LOWEY. Mr. Chairman, I would say to the gentleman from Oklahoma (Mr. COBURN) that I am a mother of three and a grandmother of two, and, frankly, I am sick and tired of debating abortion on this floor in the House of Representatives. Restriction after restriction, ban after ban, amendment after amendment. Enough.

If one really wants to reduce the number of abortions, work with us to increase funds for family planning, work with us to ensure that women have access to prescription contraceptives. I have been working to prevent unwanted pregnancies, to reduce the number of abortions. We need to make abortions less necessary, not more dangerous.

Mr. Chairman, I am very sorry that this amendment is being offered to an otherwise outstanding bill. Congress should not be ordering the FDA to suppress a drug that is safe and effective. This amendment flies in the face of sound science. It puts women's health in jeopardy, it sets a dangerous precedent, and it should be defeated.

Mr. WELDON of Florida. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in strong support of the Coburn amendment. I encourage all my colleagues on both sides of the aisle to vote in support of the Coburn amendment.

As the gentlewoman from New York alluded to, the issue of abortion is very controversial. The American people are very divided on this issue, and there are many people who feel, as I do, very strongly on the sanctity of human life.

The House of Representatives and the Senate have repeatedly voted to restrict the use of Federal dollars when it comes to this issue. The best example is the Hyde amendment, which prohibits the use of Federal dollars for performing abortions.

□ 1315

We have a very simple amendment here. We ask the Food and Drug Administration not to get involved in this issue and not to get involved in administering or testing or approving drugs for the chemical inducement of abortion.

As to this issue that is being brought up that some of these drugs are safe and effective, I really want to speak to that point. As a physician, I took the Hippocratic oath. In the Hippocratic oath you do no harm. To say that these drugs are safe and effective, when in effect they are lethal for the unborn child growing in the womb of the woman, is a very deceptive and distorted use of the English language.

I would encourage all of my colleagues to seriously, those who are prolife, obviously, those who take a prolife position, but in particular those who may be personally pro-choice but may feel that it is appropriate to not be using Federal dollars for these kinds of purposes, consider that millions of Americans object to Federal dollars being used for these kinds of purposes.

I think it is a perfectly reasonable amendment. I think it is a well-thought-out amendment. I do not think there should be any confusion over there at the FDA as to what this is about, despite the claims by some that these words are somehow mysterious.

As to the claims of why there are so few pharmaceutical companies doing contraceptive research, that has nothing to do with these claims that it has some implication with those who oppose abortion. It is the trial attorneys and all the litigation. That is why there are a limited number of pharmaceutical companies doing research. It is very expensive. Then when you do put a product on the market, if anything goes wrong with those products, you get every lawyer in this country looking to draw up a lawsuit in the case.

I think this is a very good amendment. I would encourage all of my colleagues to vote yes.

Mr. WAXMAN. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in opposition to the amendment. The gentleman from Florida acted as if this were a government subsidy for some abortion procedure. We are not talking about a government subsidy, we are talking about the Food and Drug Administration reviewing an application by a manufacturer who proposes to make a drug for a specific purpose that he wants to go out and sell, which is legal.

Whether Members like abortion or not, it is legal to have abortions in this country. Why should we stop the FDA from being able to consider a drug that might be used for an abortion that would be safer than other abortion procedures? Abortion is not going to stop. It is legal. Why should we now impose our judgment, saying that the FDA cannot even look at the science of what a manufacturer presents to it?

This amendment says we cannot test the substance, we cannot learn how it works, or judge if it has benefits over other procedures. Even if it became an approved drug, we could not manufacture it. This is the kind of an amendment that bars private actions in the free market. What the FDA does is not a subsidy. The FDA scrutinizes the science. They do not make judgments as to what products are brought before them, nor should they.

This amendment is wrong. It is certainly wrong to include it in an appropriation bill, where no one has examined the implication of this language for other FDA activities.

It is going to have a chill on manufacturers who want to deal with anything that may be considered unpopular. Today it may be unpopular to have an abortifacient, but a lot of manufacturers feel it might become unpopular to develop new contraceptive drugs. The FDA may be stopped from reviewing those drugs. This is a very wrong and offensive precedent. I would strongly urge my colleagues to oppose this amendment.

Mr. HOEKSTRA. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, today I rise in support of the Coburn amendment. Last month myself and 14 of my colleagues sent a letter to the editor of the New England Journal of Medicine. We did that because we wanted to take issue with a report that they publicized.

In that report, they described the abortion drug RU–486 as "safe." This report is being cited as a landmark study by the advocates of RU–486 as proof of the safety and the effectiveness of the drug. Nothing could be further from the truth. As a matter of fact, that is a bizarre conclusion, given the facts.

The authors reported that RU–486 ". . . has been reported to be a teratogenic in humans." What does that mean? In plain English, it means the drug causes developmental malformations, or birth defects. Unfortunately, the authors mention this almost as an afterthought.

Given the possibility that this two-drug hit in RU–486 may cause birth defects unless drug-induced abortion occurs, the authors secured a commitment, they secured a commitment from all the participants to submit to a surgical abortion in the event the drugs fail.

The authors apparently sought to preempt the possibility of a participant having second thoughts after the administration of the drug, and their unborn child eventually being born with a skull deformity or some other birth defect.

There were 106 women who were administered the drugs, but they were not included in the final assessment phase of the study. The authors do not know, they do not know, whether any of these women who were administered the drug changed their minds and decided to carry their child to full term. The authors do not know whether a child or a number of children were born with a developmental malformation due to the administration of the drug, even though they stated that such a possibility may exist.

The authors claim that the two-drug regimen is effective in terminating pregnancies. This is a very selective choice of words, because what these drugs do is they are designed to kill human life. We are disappointed with the authors' insensitivity to the drug's full impact. At least 2,121 unborn children died because of the drugs administered during this study. The fact that this two-drug regimen was able to kill innocent human lives is nothing to celebrate.

We recognize the authors' intent in maintaining a narrow focus in their study, but when at least 4,242 people are involved in an experiment involving life or death, it would seem only appropriate that those executing the experiment assess the impact of the drugs on all of the study's participants, both the born and the unborn.

For these reasons, it is entirely inappropriate for the FDA to grant final approval for RU-486. For those reasons, it is also totally appropriate for my colleagues to support the Coburn amendment.

Ms. WOOLSEY. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in strong opposition to the Coburn amendment. Make no mistake about it, this amendment is one more unwarranted intrusion to tell the Food and Drug Administration how to do its job. It is also one more time when Members of Congress step up here and act like they know more than the scientists and the experts, and they are going to tell scientists what their conclusions are before they even get there. And it is one more step in the far right's campaign against a woman's right for reproductive choice.

In 1993, following my election in 1992, I led the effort to bring RU-486 under FDA. I did that so that RU-486 would be tested here in the United States to ensure its safety and its effectiveness. My action and my concern was that women in the United States have access to a safe and effective method regarding unwanted pregnancies. I only wanted them to have access when it was deemed safe by the FDA.

Mr. Chairman, this amendment would set an alarming precedent by allowing the unwarranted interference in the FDA's decision-making process. It would prevent the FDA from testing, developing, or approving any drug such as RU-486 for the chemical inducement of abortion, no matter the wishes of the women in this country.

Let us get the FDA out of politics, let us get Members of Congress out of the rights of women in their reproductive choice, and let us let the FDA determine which drugs are safe, which drugs are effective, and which drugs are good public health.

Mr. Chairman, I yield to the gentlewoman from New York (Mrs. LOWEY).

Mrs. LOWEY. I thank the gentlewoman for yielding to me, Mr. Chairman.

I would like to make a point to the gentleman. The New England Journal of Medicine and the FDA has declared this safe and effective. Again, a Member of Congress should not be making this determination.

I just wanted to make one additional point. It seems to me many of us reluctantly have been debating on this floor over and over again for the past few years about late-term abortions, and how dangerous and how inappropriate late-term abortions are.

RU-486 is effective and can be a choice of women early on in pregnancy. Again, it is the choice of a woman. It is up to the FDA to determine if it is safe. The FDA has said that it is safe and effective, as has the New England Journal of Medicine.

Mr. PITTS. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, this amendment will bring us back to the original purpose of the Food and Drug Administration. I rise to support the Coburn amendment.

As originally intended, the FDA should make their priority ensuring the safety of food and developing medically necessary drugs. We simply must provide America with a system where life-saving drugs are made available to patients in a timely and effective manner.

Mr. Chairman, when was the FDA given the task of making abortion on demand easier and more accessible? How does this action correspond with the assertion of the liberals that abortion should be a rare occurrence? Does not the FDA's current role in expediting the approval of abortifacients, which destroy lives, stand in direct contradiction to its responsibility to save them?

Mr. Chairman, abortion pills make unwanted pregnancy the medical equivalent of a headache: pop a pill and it will go away. But there are serious consequences for women. New scientific evidence has indicated that abortion may increase the risk of breast cancer. This link should be carefully examined before any new forms of abortion are approved. But we cannot ensure the safety of women if the FDA is speeding abortion pills through the approval process.

For the sake of women, we need to adopt the Coburn amendment. Just consider these facts. Ten out of the 11 studies on American women report an increased risk of breast cancer after having an induced abortion. A metaanalysis in which all worldwide data were combined, published by Dr. Joel Brind and fellow researchers, reported that an induced abortion elevates a woman's risk of developing breast cancer by 30 percent. Currently, breast cancer is the leading form of cancer among middle-aged American women.

Mr. Chairman, it is time to send a message to the FDA: Return to the business of saving lives. If they truly care about the health of our Nation's women, Members will vote for the Coburn amendment and fight to keep women alive and well.

Ms. NORTON. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise to speak against the amendment. We are constrained to come to the floor once again to send out an alert to American women that once again, one of the perennial attempts to get around Roe versus Wade and to stop abortions when they are most safe is at hand.

The Coburn amendment has grave constitutional implications. Roe versus Wade says we may not regulate abortion in the first trimester. There is a reason for that, because that is when it is safest. If anything, we want to encourage whatever abortions are to be done to be done then or not at all. RU-486 is only for early abortions, and it perhaps may be used for emergency contraception up to 72 hours after intercourse; again, at the very earliest period when abortions are performed.

□ 1330

Moreover, this method may be the only method or the safest method that some women should use. And that clearly comes under Roe vs. Wade's concern with the health of the mother. Surgical abortion obviously poses more risk, the most risk, at least as far as we know. And at least given the kind of approval that RU-486 has thus far received, we do know this, that for most of us a nonsurgical procedure is in fact preferable.

We want to say to women who need abortions, while the rest of us for other procedures will use nonsurgical procedures, we want them to repair to surgical procedures, to invasive procedures only. For abortion we make a distinction between women and men that we do not otherwise make.

Mr. Chairman, if nonsurgical abortion is available, if it is the safest method, it must be allowed. Most of us would choose nonsurgical methods if they were available. Indeed, managed care requirements today in health care often require us to use nonsurgical methods because they are the least costly.

Why would we want to deny safe, nonsurgical approaches here? Why would the government want to turn toward the most invasive form of abortion? Why should the government not

step back and say whatever method women use is something that the government is in no position to prescribe in the particular case?

Why is it not an absolute insult to women to deny them the right to choose the safest method, if any method at all must be chosen? Why is it not a risk to the health of women for whom more invasive methods would simply not be prescribed? Should we not welcome the fact that there is a choice for those women?

And why would this body want to engage in the know-nothing, nonscientific practice of, for the first time in this Chamber, saying what the FDA should approve and what it should not approve? That takes us back to the kind of ignorance I would hope this body had escaped long ago.

If this drug is safe, by denying the right to go through the approved channels we are welcoming back-channel, black market approaches to getting this drug. Surgical and invasive procedures are not preferable. Once again, we are invading the territory of a physician and his patient. Whenever we do that, we lose our way.

Let us stand back, even if we regard this as not the right way to go, and leave it to those who are in the best position to make this most personal of decisions, and that is the physician and the woman who has to decide what is safest for her.

Mr. SMITH of New Jersey. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, let me make it very clear, and I think we all more and more of us realize this, abortion is violence against children. Abortion is violence against children. It is not some benign act that benefits or nurtures. It kills babies.

Now that can be done by the hideous method that we have described called partial-birth abortion where the brains are literally sucked out of the body of a child. Or it can be done by dismemberment, by hooking up a powerful loop-shaped knife, a curette, to a suction machine 20 to 30 times more powerful than the average vacuum cleaner. Or it could be done by a myriad of chemical potions, salt solution that burns the baby to death.

The other side on this issue will defend that as choice. That is violence against children. Saline abortion is violence against children. RU–486, Mr. Chairman, is just the newest form of baby pesticide. A chemical that has no intention of nurturing, providing any benefit to the baby, just kill the baby. Make the child a deceased member of the human race.

Mr. Chairman, the FDA should be all about testing and helping to bring to market those drugs that save and nurture and heal. RU–486 does not heal, unless Members think that a baby is a disease or a wart or some other disposable appendage that has to be done away with.

The "choice" rhetoric is cheap. It denigrates human life. Unborn children are no different than my colleagues or I, except by reason of their immaturity and their developmental status in life. That is all. Nothing is added from the moment of fertilization until natural death.

When will we wake up and see that birth is an event that happens to each and every one of us. It is not the beginning of life. And an unborn child deserves at least the minimum respect of not having new drugs, new devices developed that kill them.

It is a new mouse trap. How can we better kill those kids? These are boys and girls that are being killed. Chemical abortions, RU–486, as we all know, usually has its operative effect at around the seventh week. Other chemical potions have it at other times during the pregnancy. But all of them do the same thing. They kill the baby.

Mr. Chairman, I ask my colleagues, support this very important amendment offered by the gentleman from Oklahoma (Mr. COBURN). I urge everyone to support it.

Mr. COBURN. Mr. Chairman, will the gentleman yield?

Mr. SMITH of New Jersey. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, I would like to address a couple of points that have been made. When discussing 486, the words "safe" and "effective" have been used. I want us to think about what those words mean.

Safe and effective for whom? They are not safe for women. They cause tremendous pain, tremendous discomfort, tremendous risk for blood transfusion, tremendous risk for instrumentation, and tremendous risk to the remaining fetuses and children who will be born outside of that complication.

The other thing that was said, and words tell us a whole lot, what was said is if we cannot use this medical form of abortion, it is a limitation on contraception. That was made in an earlier statement, which tells us exactly what people mean.

Abortion is a method of contraception in this country. The taking of innocent human life is used as a method of contraception. I would make two points. The Supreme Court said they did not know when life began. But we know when life ends in this country, when there is not a heartbeat and there is not a brain wave.

Well, there is a brain wave at 41 days post-conception, and there is a heartbeat at 26 days post-conception, before most women know they are pregnant. There is no question, life is present when RU–486 will be applied. Should the government be in the business be of killing unborn babies? I think not.

Ms. DELAURO. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I stand before my colleagues as a cancer survivor to strongly oppose this amendment. This amendment would not just block access and research to reproductive health drugs, although that in itself is enough reason to vote against it.

In an attempt to promote an anti-choice agenda, proponents of this amendment are risking the lives of millions of Americans, because this amendment would block the development of drugs that cure cancer and other kinds of medical treatment because some of those drugs can cause miscarriage, also known as spontaneous abortion.

Mr. Chairman, I am an ovarian cancer survivor. Millions of Americans suffer from cancer every year. Anyone who has undergone chemotherapy sessions in a desperate attempt to kill the cancer cells before they kill them knows the warnings given by the doctor. If a woman is pregnant, chemotherapy could endanger the pregnancy and induce miscarriage. I was fortunate that those circumstances did not apply to me. But if we pass this amendment, the development of new lifesaving drugs would be blocked.

If cancer patients wait while researchers draw closer and closer to a cure for cancer, this amendment would close the door in their faces. No more hope. No chance of developing a drug that could save their lives.

When I received my cancer diagnosis, it felt as if the world had stopped. The mind just cannot comprehend what is happening. And once it does sink in, all one thinks about is how am I going to beat this? What can I do to get my life back?

Let us make sure that patients who are faced with this difficult moment have access to the best science that is available; not science that is compromised by politics.

This amendment is a slap in the face to the women of America. It is a slap in the face to anyone who has survived a cancer diagnosis. It is a slap in the face to anyone who is fighting now to beat this deadly disease.

Mr. Chairman, I urge everyone in this House who cares about improving the health of Americans and the life of Americans to vote against this very dangerous amendment.

Mr. HOSTETTLER. Mr. Chairman, I move to strike the requisite number of words.

(Mr. HOSTETTLER asked and was given permission to revise and extend his remarks.)

Mr. COBURN. Mr. Chairman, will the gentleman yield?

Mr. HOSTETTLER. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, first of all let me say to the gentlewoman from Connecticut (Ms. DELAURO), I am very thankful that she is a cancer survivor. This amendment in no way whatsoever will limit any drug research.

The other reason why I know that that is the case is because I too am a cancer survivor. I am 23 years out. I would never put forth an amendment on the floor of this House that would limit that. What this amendment does is have the FDA work on drugs that save life rather than take life.

Mr. HOSTETTLER. Mr. Chairman, reclaiming my time, I rise in strong

support of this amendment from the gentleman from Oklahoma (Mr. COBURN). The Supreme Court has told us that we have to allow the killing of unborn children on demand. It has not, however, told us that government has an obligation to facilitate this service.

This amendment would help ensure that American taxpayers do not end up funding the approval of drugs that are designed to kill our unborn children. FDA's mission as it was created by this Congress should be to approve drugs that save lives, not end lives.

With all the illnesses we have to deal with, cancer, AIDS, heart disease, diabetes, the examples go on and on, why would we want to spend our hard-earned dollars on drugs designed to exterminate our most valued resource, our children?

There is a core principle at issue today: Whether the government is obligated to provide the people's money to research and test new and innovative ways to kill our children for a right pulled out of thin air by a majority of the Supreme Court.

□ 1345

Congress has the responsibility under our Constitution to ensure that the money we collect from hardworking and productive Americans is spent wisely.

Mr. Chairman, let us ensure the FDA uses America's resources to help us and not kill us.

I would simply add, Mr. Chairman, that today I have heard a lot of discussion with regard to the elevation of the science of the efficient extermination of human life almost to the extent of a virtue. I think we must be very careful in our rhetoric when we talk about that efficient extermination of human life, that we do not go to a very troubling time in our world's history, a time when Nazi Germany carried on the efficient extermination of human life. Where do we go from here with that argument? Do we go to the efficient extermination of life that cannot sustain itself, to the aged and to the infirm?

Mr. Chairman, in order that we do not start down that slippery slope or that we do not go further down that slippery slope, I urge a yes vote on this amendment.

Mrs. LOWEY. Mr. Chairman, will the gentleman yield?

Mr. HOSTETTLER. I yield to the gentlewoman from New York.

Mrs. LOWEY. Mr. Chairman, I would like to respond to the gentleman that as a Jewish woman and one who knows many survivors of the Holocaust, I personally resent the comparison of this amendment to the Holocaust and the evils of the extermination that took place during that tragic time that we have to learn from and not make comparisons that perhaps are very inappropriate.

Mr. HOSTETTLER. Mr. Chairman, I go back to the words of Jeremiah the profit, who said that he knew me in my mother's womb, and simply say that there are those of us that do believe that life does begin at conception and that we are indeed involved in the extermination of human life in this very day.

Mr. FAZIO of California. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I am sure that many who may be viewing these proceedings would be surprised to discover we are debating the agriculture appropriations bill. It has always been one of those bills that passes here with great support on a bipartisan basis. I regret very much that it today has been taken over by those who are, for want of a better term, pursuing what we call a wedge issue.

I would not be surprised that despite all the work that has been done by the gentleman from New Mexico (Mr. SKEEN) and the gentlewoman from Ohio (Ms. KAPTUR) to bring a very popular and broadly supported bill to the floor, it could well be vetoed if this language were adopted by the House today and remain in the bill through conference.

If it were somehow to become law, I believe it would be ultimately considered unconstitutional because it clearly flies in the face of the current Supreme Court view of a woman's right to choose in this country, and clearly Roe v. Wade remains the law of the land.

But I am most troubled by the fact that for the first time since the Food, Drug and Cosmetic Act was placed on the books, since 1962, in fact, we are attempting to legislate what we have until now wisely left up to a regulatory authority to decide, and that is whether a safe and effective drug should be brought to market.

Now, the gentleman from Oklahoma (Mr. COBURN) and others have said that this is an unsafe and ineffective drug. That is to be determined by the FDA. That is their charge. We would be, I think, in terrible error if we got in front of that decision and attempted to legislate it. It would be unprecedented and I think totally inappropriate.

It is a fact, however, that in France and Great Britain and Sweden, extensive clinical trials have demonstrated that it is safe and effective. But this FDA, known to the rest of the world as perhaps the bottom line gold standard for drug review systems, is being more cautious, and they should be. That is correct. It is right that they slow down this process of bringing RU-486 to the public because, in fact, they want to determine a number of things about it before it is made available to the general public.

The irony is, of course, as the gentleman from Oklahoma (Mr. COBURN) indicated in his colloquy with the gentleman from California (Mr. WAXMAN) and the gentlewoman from New York (Mrs. LOWEY) earlier on the point of order, it would be possible to bring RU-486 to the market for some other purpose. And I think it is important to point out that there are at least publicly reported uses for RU-486 that are unrelated to termination of pregnancy.

So under the interpretation we heard today and the one in which we are currently debating, we could have it on the market for other purposes and the public, should they be interested in taking it for termination of pregnancy, could well be exposed to an unsafe and ineffective product because the FDA, under this amendment, has not been allowed to make that determination to their satisfaction.

Mr. COBURN. Mr. Chairman, will the gentleman yield?

Mr. FAZIO of California. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, I would just say that we would not want any drug, no matter what its ill-use might be, if it has a positive use to ever be denied by the FDA. We know lots of drugs today that are approved by the FDA that have tremendously, terrible side effects. Thalidomide has a terrible side effect profile, but yet it has some tremendous positive benefits.

Mr. FAZIO of California. Reclaiming my time, the point I was making is that there are purposes for which RU-486 might be approved under the gentleman's interpretation that would make the public vulnerable, when it uses them to terminate a pregnancy, to the potential for the very unsafe and ineffective purposes that the gentleman ascribes to them. So I think the gentleman is being somewhat duplicitous when he indicates that he wants drugs to be made available for other purposes when in fact he may be knowingly exposing the public to problems.

I would underscore "may" because I think it is very likely that the FDA would determine otherwise and bring this to the market for a variety of purposes.

The public should have their regulatory agency, the one we all look to as the benchmark for drugs around the world, in a position to make this without a political decision made by this Congress. I would say to my colleagues that if this amendment is adopted we have opened unfortunately a new avenue to be involved in an area that we should best leave to science, to research.

We, as politicians with a variety of causes and beliefs, should not be getting in the way of what this agency has done very effectively since its founding and that is to bring scientific research to bear so that drugs can be taken when appropriate for the most safe and effective purposes.

There is no question, in my view, that for us to break the bounds that we have imposed on ourselves since 1962, to politicize this agency is to take a slippery slope we do not want to go down, even under the wedge issue arguments that we are hearing today about abortion.

I would hope that my colleagues, even those who consider themselves to be "pro-life" or "antiabortion," will

think twice about using still one more mechanism to inject this abortion debate into the deliberations of this Congress. Vote no on the Coburn amendment.

Mrs. JOHNSON of Connecticut. Mr. Chairman, I move to strike the requisite number of words.

I rise in strong opposition to this amendment. It is sobering that Saint Thomas Aquinas defined life as beginning at conception. I mention that only to remind us that this difficult issue of when life begins is an issue on which great religious leaders of the world have differed, and so it is an issue on which a Nation that believes in freedom, that enshrines freedom of religion in our Constitution, must have the courage to allow our own people individually to decide.

I am a Republican in part because I take so seriously the issue of personal responsibility. I believe each of us has the responsibility to make wise choices, to support themselves, to contribute to their fellow citizens and their communities. And I believe family planning represents personal responsibility that is indeed one's obligation as a mature, free adult, to plan the number of children they have, the spacing between them. And so I believe contraceptives in general are very important to freedom in our Nation and to the health of women and the strength of families.

The issue before us today is whether we in a free Nation will have the knowledge to use our freedom wisely and to take personal responsibility for our lives. We cannot pass this amendment and not do damage to the concept of freedom and the belief in the power of knowledge as the essential foundation for a free society.

Many drugs, including chemotherapy and anti-ulcer medications, have the side effect of inducing abortion. Under this amendment, you could not do research on something, even if that was not its primary goal, because it might have the side effect of inducing abortion.

I would remind this body that we spent months talking about fetal tissue research because people did not want to use fetal tissue for critical research that could cure critical and terribly important diseases in America, and the goal was not to ultimately use fetal tissue, the goal was to learn enough about it from the research to be able to create the artificial substances or the substitute substances that would allow us to create, to produce the drugs en masse that we learned were necessary from fetal tissue research. And the issue here is to learn enough from some of the rather crude, in the sense of their mechanism, drugs like that that is the subject of this amendment so that we can in time develop something that you take right away that does not interfere with, that is not an abortifacient in your definition because it has its effect before there is even fertilization.

But we cannot get to that point if we do not allow science to move forward and we do not get better experience. Why should I, as an American woman, be told or my daughters be told that they must take contraceptive pills months and months and months, years of their life, when I believe, if we allow the research to go forward, we can provide something that will give them a much more direct control over whether or not conception takes place at implantation and the development of a fetus.

I do want to conclude my comments by saying that wherever you block the path of science, you block the development of knowledge and you compromise the opportunity that only a free society can give you. In freedom, we depend on knowledge to empower us to make the right decisions.

I trust the women of America and the men to whom they are married to make good decisions about whether or not to use one type of contraception over another. I do not believe that it is the government's responsibility to tell our citizens how or what mechanism they should use. We do not want HMOs to do that, and I do not want the government to do that.

So I would urge defeat of this amendment because I think it cuts off essential research.

Mrs. MALONEY of New York. Mr. Chairman, I move to strike the requisite number of words, and I rise in opposition to the amendment.

Mr. COBURN. Mr. Chairman, will the gentlewoman yield?

Mrs. MALONEY of New York. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, I would just again reemphasize, nothing in this amendment limits any drug whose primary purpose is not an abortifacient. There is no limitation on any research of any other drug if its primary purpose is not that of an abortifacient.

I thank the gentlewoman for yielding to me.

Mrs. MALONEY of New York. Mr. Chairman, I yield to the gentlewoman from Connecticut (Mrs. JOHNSON).

Mrs. JOHNSON of Connecticut. Mr. Chairman, that may be the gentleman's impression now or what his intent is, but we all know how these things work in government. Frankly, it will have such a dampening effect on research that it will affect research on things that have a dual purpose or that could be perceived as having a dual purpose. That is my concern about it.

Mrs. MALONEY of New York. Reclaiming my time, Mr. Chairman, I rise in opposition to the Coburn amendment, which will prohibit the FDA from testing, developing or approving any drug that has the chemical inducement of abortion connected to it.

Last time I looked, the Supreme Court ruled that abortion was legal. However, this Congress continues to attack a woman's right to choose. This is the 85th vote against reproductive rights since the beginning of the 104th Congress or maybe I should say since the beginning of the antiwoman Congress.

□ 1400

What might surprise some people is the fact that this vote is about much more than reproductive rights. As my colleague on the other side of the aisle, the gentlewoman from Connecticut (Mrs. JOHNSON) was pointing out. It is about biomedical research.

One of the drugs targeted by this amendment is used to treat a number of conditions, among them, uterine fibroids, certain breast cancers, and endometriosis. To my gentleman friends on the other side of the aisle, it is even used to treat conditions affecting men, like glaucoma, arthritis, AIDS, lupus, and some types of burns.

Blocking research and development of safe and effective drugs in the name of abortion politics is just plain wrong. My opponents called their position on reproductive rights pro-life and their position on this bill pro-life, but this amendment and their position is anything but. I urge a "no" vote on this amendment. Science should not be compromised by politics. It would be a dampening affect on research. I urge all of my colleagues to vote "no".

Mr. ADERHOLT. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise today in support of the amendment offered by the gentleman from Oklahoma (Mr. COBURN), an amendment that could literally save the lives of countless children throughout the United States.

Abortion creates several risks for women, it is well-known. Also, abortion drugs are often dispensed without a doctor's approval. Because of the numerous possible side effects associated with abortions, these drugs should not be administered without consultation and medical follow-up with the doctor.

The Food and Drug Administration has an ethical duty not to approve a drug that will be harmful to mothers taking the drug. The research on RU-486 is insufficient in regards to long-term effects, the linkage with breast cancer and medical complications.

I commend my colleague, the gentleman from Oklahoma, for taking steps to save children and to save their mothers from these life-endangering drugs. I would encourage my colleagues to support this amendment.

Mr. MCDERMOTT. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, this is a pretty amazing debate. I was sitting over in my office listening to it, and I could not help but think that this is yet another assault on women.

I am a physician also. In 1963, before there was abortion reform, before the Rowe v. Wade was decided in the Supreme Court, I was an intern in a hospital in New York State and stood next to the bed while two women died from back-alley abortions.

We have come a long way since 1963. One of those women left six children orphaned, and the other one left eight. We said as a society, our Supreme Court said, women have a right to choose.

Yet, this Congress, I understand, the Republican Party has a problem with women voters in this country. It is very clear. They assault them over and over again. As the last speaker, the gentlewoman from New York (Mrs. MALONEY) talked about, 85 times in this session this issue has come up.

It comes up on everything. It comes up on IMF funding. We will not fund the International Monetary Fund if somebody, somewhere, somehow is doing anything related to women's rights to choose. Military women cannot use their own money to take care of this problem in a military facility when they are assigned by this government to serve overseas.

We say, if you want an abortion, I do not care what the Supreme Court says, we the Congress say you cannot have one in a military hospital, even if you pay with your own money. That is the kind of assault we have.

Here today we have a new twist on it. I think the slippery slope of where we are going is really one to consider, because when we start standing out here and saying what is good science and what is bad science, and we choose this drug over that drug, what will be next in that list?

Here we have the Food and Drug Administration says that this drug is safe. They have done the tests. They are waiting for a pharmaceutical manufacturer to step up and say we want to produce it in this country. That is the only thing that stands between this particular pharmaceutical being on the counter and not.

What this bill does is put a threat out to the pharmaceutical industry, do not step up to produce this pharmaceutical, because if you do, you are going to get the wrath of a certain segment of this society.

My view is that when we start to threaten people and do not want to listen to the science, we are going down a long slippery slope. I feel like I am in Tennessee in the middle of the Scopes trial where it is religion versus science.

We have the FDA. We asked them to look at this, and they looked at it; and we say, well, we do not like the conclusion you came up with, so we will use a little technical way of preventing it ever being put on the counter.

I heard the gentlewoman from Washington come out here and mix this whole thing up more with the drug overall, which is in the State of Washington in the State legislature. They evaluated this, and it is not pro-life. They looked at the issue and said "We will give the pharmacy board the right to deal with that issue," and they do it.

Anybody who wants, they can go to a pharmacy. If they follow a protocol and they fit the protocol under the supervision of a doctor, they can get the drug. They do not just hand it out to anybody that comes into the drug store. I went and called the pharmacy board in the State of Washington to find out what goes on.

The fact is that what we are saying here is that we want women to use whatever antiquated way we have, not to have the best that science can produce.

One of the fascinating things about the last 3½ years around here, the bigger part of the assault on women is that we put on welfare reform. We said we are going to throw people off welfare. What that has done, in at least three States there has been an increase in abortions. The very people who say they do not want abortion buy the mechanism of driving people off welfare and giving women no way to feed their kids; we are then leading to more abortions.

They do not want to do it with a pill. They want to put them through surgery. I can understand why an obstetrician might want to do that if he was in the business of doing this. But I do not hear obstetricians who are in support of a woman's right to choose coming to this House and saying "Do not give them a pill because I want to make money doing abortions." What I hear is that the pharmaceutical that is there will do it just as effectively.

Mr. DICKEY. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I yield to the gentleman from Oklahoma (Mr. COBURN).

Mr. COBURN. Mr. Chairman, the first point I would make is there are two obstetricians in this House, and neither of us would terminate a baby and take that life unless it depended on the life of the mother. There is no question. We know a lot about life. We get to see it. We get to see a lot of death. So to answer the gentleman, there are two obstetricians in this House, and we would not take the life of the baby any time unless there is a cause in the life of the mother at risk.

Number two, let us not confuse what this issue is about. This is about whether the Federal Government is going to spend money to figure out how to kill babies. That is what it is. It is not anything else. Should we be in the business of spending Federal tax dollars to facilitate the death of children? It is not any other than that. We can say it is, we can skirt around all the other issues, but this is about whether or not we are going to have an institution of this government which is charged with protecting life spend its resources to take life.

Mr. DICKEY. Mr. Chairman, I would like to say I am on this subcommittee of the Committee on Appropriations, and this issue did not come up for discussion.

We have in our laws the provision that no Federal funding will be made available for abortions, time and time again, both domestically and in foreign relations and in our appropriations for foreign countries. This is because people differ on this issue, but we mainly prohibit any Federal funding.

In this case we would have Federal funding because of an agency's decision and not because of a vote of this body. I am against that. I think abortion is wrong. That is my opinion. I think abortion is wrong. I do not think for sure that we ought to have Federal funding.

This is a way that we can avoid having this attempt for Federal funding for abortion when it is against the women of the people of America.

Ms. FURSE. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I just want to point out, first of all, while I am very much in favor of this amendment, I would like to say to the physicians who choose not to do abortions, that is their choice. But when I was a young woman, prior to Rowe v. Wade, I did not get that choice. I was not allowed to make that choice. Neither was my physician husband allowed to make the choice of whether he would provide safe and legal abortions.

I do not think we should talk so broadly about choice. It is a woman's choice and her family's choice and her physician's choice we are talking about.

This has been, in my view, the most antichoice Congress that I have ever had the sadness to witness. It is also the most antiscience amendment that I have ever witnessed. But over and above that, it is an antiwoman amendment.

Why should American women not have the right to access to the same level of science as European women or British women? Why is this Congress, a few people who have certain ideas, why are they preventing American women access to good science?

I am asking the people of this body to understand that it is time for us to step forward, to vote "no" on antichoice legislation, to vote "no" on antiscience legislation, and above all, to vote "no" on antiwoman legislation.

We are 55 percent of the population of this country. We have a right to make those choices. We do not have to give up that right that the Supreme Court has stood for, that we have fought for. We are not going back to back-room abortions. We will not do that. The women of this country will not. If there is access to good science, let American women have that access. So I ask my colleagues to vote "no". Vote for women.

Mr. PAPPAS. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I urge my colleagues to vote for the amendment of the gentleman from Oklahoma (Mr. COBURN). As he spoke very eloquently just a few moments ago, this is not about a choice for an unborn baby.

The Federal Government or those within this administration, whether it is the FDA, they have their marching

orders, no matter what their personal view is, from the administration to facilitate abortion on demand under any circumstance. That is not what the American people support. I certainly do not support that.

The gentleman from Oklahoma (Mr. COBURN) spoke a few minutes ago about how he, as a physician, would only in the case of the endangerment of the life of the mother take an unborn baby's life. If we recall what so many people throughout the history of this country have said, that we here in this body, I believe, are here to protect the vulnerable; and certainly the unborn baby in the mother's womb is among the most vulnerable that could ever exist.

I enthusiastically support the amendment of the gentleman from Oklahoma (Mr. COBURN) and certainly urge my colleagues to do the same.

Ms. PELOSI. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise today in strong opposition to the Coburn amendment. Women in America have a right to choose. I believe it is the goal of all of us in this body to reduce the number of abortions and to make abortions safe, legal, and rare. It is on the subject of safe that I would like to address my remarks.

This amendment offered by the gentleman from Oklahoma (Mr. COBURN) would prohibit the expenditure by the Food and Drug Administration of funds for testing, development or approval, including approval of production, manufacturing or distribution, of any drug for the chemical inducement of abortion.

The RU–486, the chemical, the product in question, is a nonsurgical abortion, and it is one that is also medically safe.

□ 1415

Such a ban, as the gentleman from Oklahoma is proposing, would unconstitutionally restrict the right to choose. For some women for whom surgical abortion poses risks or is otherwise inappropriate, the Coburn amendment would unconstitutionally again restrict the right to choose. For others who live far from clinics, it would preclude the possibility of receiving RU–486 in their physician's office, thus burdening again the right to choose.

This option is an effective and nonsurgical method of early abortion that has been in use since 1981. The drug was approved for use in France, Great Britain and Sweden following extensive clinical trials that determined its effectiveness and its safety.

In September 1996, the FDA issued an approval letter for early abortion, but the agency is waiting for more information about its manufacturing and labeling before giving Mifepristone final approval and allow it to be prescribed to American women outside of clinical trials.

I know this is a very difficult issue for our colleagues to deal with. We have deep commitments in our point of view as to whether a woman has a right to choose, and I certainly respect my colleagues' views on the question of abortion. But the fact is that women do have a right to choose that option, in consultation with their family, their doctors, their God, and we should not make that decision a more dangerous one for them.

Again, in the interest of making abortions in our country rare, legal but safe when necessary, I urge my colleagues to vote against the Coburn amendment. It always interests me to see over and over again in this body how many times we vote against scientific research. By going forward with this, we can learn a lot about making these processes even safer for women. As Members of Congress who represent the people of our country, we have a responsibility to do that. For that reason, I urge my colleagues once again to vote "no" on the Coburn amendment.

Mr. COBURN. Mr. Chairman, will the gentlewoman yield?

Ms. PELOSI. I yield to the gentleman from Oklahoma.

Mr. COBURN. I would just say, to do research to take life, to do research to take life somehow does not smell right in this body; to spend our dollars. I agree, nobody wins in abortion.

Ms. PELOSI. Reclaiming my time, I appreciate the gentleman's point. As a Catholic and a mother of five children myself and one who comes from a family that is not always sympathetic to my point of view on this subject, I understand and respect the gentleman's beliefs. But I will say as a Catholic that I have done some of my own research on this and the gentleman's statement implies that he knows when life begins. I think that is really a mystery to all of us. St. Augustine himself when he was asked would a fetus before 3 months, would that entity go to the judgment day and be resurrected into heaven as a person, he said, "No, because before 3 months, it isn't a person." They made him a saint. He is a saint of the church. He has a different view from some of my colleagues on when life begins. We do not know. It is a mystery. So I do not know how my colleagues on the other side of the aisle can determine that this is taking a life. I do not view it that way, and I urge my colleagues to vote "no."

Ms. KAPTUR. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I wanted to say with all due respect to the gentleman from Oklahoma who is offering this amendment, I respect his sincerity and the ferver with which he approaches this. As someone who does not support Federal funding of abortion myself, I have studied his proposal carefully. I am opposing him for three reasons, and I ask my colleagues to give me forbearance on this.

The first is, as ranking member of this particular committee, number one, this issue never came before us. We have not had one hearing, certainly not at the subcommittee level. The FDA never referenced it in its testimony. Then when we went to the full committee, this was never considered. There have been absolutely no hearings on this matter, which is a very serious scientific and medical as well as moral issue, and I think it is inappropriate to try to attach it to this agriculture bill. We have never been faced with this on this subcommittee before.

Secondly, I really do not think that at this point in the deliberations in this Committee of the Whole that we are going to make the proper, objective scientific judgment. Congress has never, and I underline, never previously legislated the approval or disapproval of any particular drug over which the FDA has responsibility for review. These decisions on the appropriateness of medical devices and medications are based in the agency solely on the scientific evidence available. None of that has been presented to any single Member here, with perhaps the exception of the author of the amendment. I do not know. But we certainly have not had the benefit of that.

Thirdly, let me say that though the laws of our country say that abortion under certain circumstances is legal, certainly when the life of the mother is at stake, if this particular pill or medication or drug would somehow alleviate pain and suffering, there is no reason that we should in those circumstances disallow the FDA, with as little testimony as we have had on this and as little experience as we have had as a subcommittee and a full committee to deal with this, which actually should be in the authorizing committee, there is no reason that we should for any single life in this country deny that family the ability to have access to that medication if they would need it. But I really do not think that that should be the debate here today.

Based on the lack of hearings in our own committee, and with respect for the chairman of our committee with a desire to try to have decent scientific evidence, full hearings on the matter, and finally not to deny any family that might find this necessary as a way to alleviate pain and suffering of the mother, I think voting for the amendment would be ill-advised at this time.

Mrs. LOWEY. Mr. Chairman, if the gentlewoman will yield, the ranking member of this committee was so eloquent and she has done such a fine job on this bill.

Mr. GALLEGLY. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I yield to the gentleman from Oklahoma.

Mr. COBURN. I thank the gentleman from California for yielding.

Mr. Chairman, I would like to make three points. Number one, we can deny medical scientific fact. We have heard that argument a lot.

Scientific fact: Life is present at least at 26 days. We will recognize that

in this country as a consequence of the logical recognition of when death is. Death is the absence of brain waves, death is the absence of a heartbeat, in all 50 States, also associated with the Federal code. We know at least life is present at 26 days. We are talking about using medicines to take life. We can deny it. But scientific fact has already proven that the heart is beating in a fetus at 26 days. Scientific fact, it has already been proven that the brain waves are functioning in a fetus at 41 days. Most women in this country have barely recognized conception by the time those two scientific facts have been made available.

Number two. This was offered to the committee. The committee chose not to put it in its mark. So it is not that we did not approach the committee, we did in good faith, attempting to put this in the committee's mark.

The gentlewoman makes a good point that there were not hearings on it. There do not need to be hearings on this issue in this country. We do not need to have a hearing, because the hearing is going to go back to the same issue, is it right to take an unborn life or not. Is it right? I mean, that is what it will all filter down to. My opinion, and that of a large number of this country and the majority of this body, is it is not right to take an unborn life. Scientific evidence now shows, without a doubt, that life is present at least at 41 days.

Ms. KAPTUR. Mr. Chairman, will the gentleman yield?

Mr. GALLEGLY. I yield to the gentlewoman from Ohio.

Ms. KAPTUR. Mr. Chairman, I just want to say for purposes of the record, this Member believes that life begins at conception. St. Augustine may not agree with me. The author of the amendment may not agree with me. We each make those decisions on our own. However, I would say to the gentleman that as far as the procedures we follow on committee, no one came to our staff, I as ranking member, and our legislative people, regarding this particular amendment. It is extremely complicated. Had I known, we would have asked for special hearings on this amendment. But I would say with all due respect to the gentleman, we were never afforded the opportunity to consider this. We did not know this was going to come up until just yesterday.

Mr. GALLEGLY. Reclaiming my time, Mr. Chairman, I would yield again to the gentleman from Oklahoma.

Mr. COBURN. To the gentlewoman from Ohio, I appreciate and I am sorry that she was not made aware of that. This was given to the committee, majority committee staff.

Finally, I too believe that life begins at conception. But I know what the Supreme Court said, is they do not know when life begins. But we know life is present at 26 days. We know it. There is no doubt about it. Science has proven that by our very definition of death in this country. We say that you are dead when you do not have brain waves and you do not have a heartbeat. If you are dead, then if you have those two things, you have got to be alive. Otherwise, the definition of death is out the window in this country.

Ms. JACKSON-LEE of Texas. Mr. Chairman, thank you for the opportunity to speak on this important issue. As an advocate for women's choice, I must strongly oppose this amendment. Mr. COBURN's amendment will prohibit the FDA from testing, developing, or approving any drug that induces an abortion. However, Mr. Chairman, this debate is not about Mifepristone or abortion. It is about the FDA's ability to test, research, and approve any drug based on sound scientific evidence. Reproductive health drugs should be subject to the FDA's strict science based requirements that any drug must meet before approval can be granted. These drugs should not be singled out simply because they are reproductive health drugs. Mifepristone, a drug which has been available to women in Europe for 20 years was found safe and effective for early medical abortion by the FDA in 1986. The search, however for an appropriate American manufacturer and distributor is being stymied by anti choice extremists whose opposition to abortion has led to a climate of intimidation and harassment. This amendment would not only prohibit development and testing of drugs to be used to provide women another safe and private reproductive choice, it also would target new contraceptive development. Mr. Chairman, I strongly oppose this amendment and I urge my colleagues to do the same.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Oklahoma (Mr. COBURN).

The question was taken; and the Chairman announced that the noes appeared to have it.

Mr. COBURN. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The CHAIRMAN. Pursuant to House Resolution 482, further proceedings on the amendment offered by the gentleman from Oklahoma (Mr. COBURN) will be postponed.

The point of no quorum is considered withdrawn.

Mr. SKEEN. Mr. Chairman, I move that the Committee do now rise.

The motion was agreed to.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. TIAHRT) having assumed the chair, Mr. LAHOOD, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee, having had under consideration the bill (H.R. 4101) making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 1999, and for other purposes, had come to no resolution thereon.

## CONFERENCE REPORT ON H.R. 2676, INTERNAL REVENUE SERVICE RESTRUCTURING AND REFORM ACT OF 1998

Mr. ARCHER submitted the following conference report and statement on the bill (H.R. 2676) to amend the Internal Revenue Code of 1986 to restructure and reform the Internal Revenue Service, and for other purposes:

CONFERENCE REPORT (H. REPT. 105–599)

The committee of conference on the disagreeing votes of the two Houses on the amendment of the Senate to the bill (H.R. 2676) to amend the Internal Revenue Code of 1986 to restructure and reform the Internal Revenue Service, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the House recede from its disagreement to the amendment of the Senate, and agree to the same with an amendment, as follows:

In lieu of the matter stricken and inserted by said amendment, insert:

***SECTION 1. SHORT TITLE; AMENDMENT OF 1986 CODE; WAIVER OF ESTIMATED TAX PENALTIES; TABLE OF CONTENTS.***

*(a) SHORT TITLE.—This Act may be cited as the "Internal Revenue Service Restructuring and Reform Act of 1998".*

*(b) AMENDMENT OF 1986 CODE.—Except as otherwise expressly provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.*

*(c) WAIVER OF ESTIMATED TAX PENALTIES.—No addition to tax shall be made under section 6654 or 6655 of the Internal Revenue Code of 1986 with respect to any underpayment of an installment required to be paid on or before the 30th day after the date of the enactment of this Act to the extent such underpayment was created or increased by any provision of this Act.*

*(d) TABLE OF CONTENTS.—The table of contents for this Act is as follows:*

**145 Cong. Rec. H3798-812 (daily ed. June 8, 1999)**
**(excerpts)**

United States of America

# Congressional Record

PROCEEDINGS AND DEBATES OF THE 106th CONGRESS, FIRST SESSION

Vol. 145 WASHINGTON, TUESDAY, JUNE 8, 1999 No. 80

# House of Representatives

The House met at 9 a.m. and was called to order by the Speaker pro tempore (Mr. GIBBONS).

## DESIGNATION OF SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,
*June 8, 1999.*

I hereby appoint the Honorable JIM GIBBONS to act as Speaker pro tempore on this day.

J. DENNIS HASTERT,
*Speaker of the House of Representatives.*

## MORNING HOUR DEBATES

The SPEAKER pro tempore. Pursuant to the order of the House of January 19, 1999, the Chair will now recognize Members from lists submitted by the majority and minority leaders for morning hour debates. The Chair will alternate recognition between the parties, with each party limited to 25 minutes, and each Member, except the majority leader, the minority leader, or the minority whip, limited to 5 minutes each, but in no event shall debate continue beyond 9:50 a.m.

The Chair recognizes the gentleman from Texas (Mr. DOGGETT) for 5 minutes.

## THE ABUSIVE TAX SHELTER SHUTDOWN ACT OF 1999

Mr. DOGGETT. Mr. Speaker, long ago, Will Rogers suggested that, "people want just taxes even more than they want lower taxes. They want to know that every man is paying his proportionate share according to his wealth."

Today, some of our worst tax inequities arise from those who use abusive tax shelters to exploit loopholes in the Tax Code. To stop these, and to make our tax system more fair and just, I am introducing the Abusive Tax Shelter Shutdown Act of 1999.

Forbes Magazine, which proudly proclaims itself "The Capitalist Tool," recently reported on, as the cover of the magazine says, what are called "Tax Shelter Hustlers: Respectable accountants are peddling dicey corporate tax loopholes." Here on the cover, we see the fellow with the fedora standing in the shadows. Unlike those supermarket tabloid stories about UFO abductions, with this particular cover, the substance inside actually lives up to the teaser on the cover. It is true that most abusive tax shelters are already against the law. The problem is that every time we shut down one, more spring up. That is not by accident because, as Forbes also reported, some of the Big 5 accounting firms actually have teams of staffers, and my guess is that most of them dress a little better than this fellow does, who are out there and have as their job to come up with one new tax shelter every single week.

Deploring what he calls the "energy, creativity and viciousness" of these so-called "shelter shops," Calvin Johnson, a professor of tax law at the University of Texas, has labeled these hustling operations "skunk works" because of the sorry odor surrounding their fouling of our tax system. The literal hustling of improper tax shelters is so commonplace that one representative of a Texas-based multinational corporation has recently indicated that he gets a cold call every day from someone hawking or hustling one of these shelters.

Some are even called black box proposals. They are kept under wraps and they are not offered to any but a select few so as to avoid public notoriety. As a partner at one national firm boasted, "A whale cannot get harpooned unless it surfaces for air."

What a whale-sized gulp of arrogance toward honest taxpayers everywhere who dutifully file our returns on April 15 and who have to make up for the taxes that the big boys dodge.

My legislation will curtail egregious behavior without impacting legitimate business deals. It will eliminate the well-justified feeling that these high rollers are cheating and gaming the system, a feeling which leads to distrust and disrespect on behalf of our taxpaying public.

This bill seeks to shut down abusive tax shelters by prohibiting loss generators. These are transactions that lack any legitimate business purpose that are ginned up just to obtain another tax loss, credit or deduction in order to dodge taxes.

The second thing the bill does is it says that a company which thinks it has a proper shelter will be required to provide complete, clear and concise disclosure, verified by a corporate officer. This does not make them forfeit their buried pirate treasure but on these complex transactions it does require them to give up the map where X marks the spot of the treasure.

These disclosure provisions were drafted based on the sound advice of tax practitioners; not the kind of practitioner that is proud to define their success by having another loophole named after them, but the thoughtful commentary of the tax section of the American Bar Association.

The third provision is directed to the penalty for tax dodging, and we tighten and increase the penalty for such tax dodging. Just getting some thick carpet, downtown lawyer to bless what the accounting department has contrived with the help of these tax shelter hustlers is no longer going to be sufficient to save a corporation from penalties if it has clearly stepped over the line with an abusive tax shelter.

These abusive tax shelters have grown and have become so extensive that some experts estimate that they account for $10 billion a year in lost

will continue our discussions because it is dangerous to broad-brush, it is indispensable that we not and that we recognize that sending signals to countries; for example, some terrorist states that have absolutely no way that they can pay, sending signals to them that they will no longer be sanctioned, that they will be in a situation where the American market will be open to them before liberation of political prisoners or free elections are held can be very destructive at this particular time.

So I thank the gentleman for yielding, and I look forward to further discussions on this issue which must not be broad-brushed and which must remain leaving to the United States the option in particular instances of not having to have recourse to military action as the only way in which the United States can act.

Mr. LATHAM. Mr. Chairman, I just want to make one point.

I do not think this would be as much of an issue if we did not use embargoes like we have in this recent administration, and talk about sanctions, they are embargoes. No one likes to use that term because in agriculture that has real connotations, has real effects.

We remember the Nixon embargo, the Carter embargo, how that devastated the agriculture. This, in fact, is what we are talking about, our embargoes, and in the last 80 years there have been 120 embargoes put forth by this country and other countries, and in fact over half of them have been put in place in the last 6½ years.

So my colleagues can see the dramatic impact this has had on agriculture in recent years, a major reason for the decline in prices today, the fact that 40 percent of the world's population today is under some type of embargo from the United States, and it is extraordinarily destructive to agriculture, to free trade and our position in the world market.

AMENDMENT OFFERED BY MR. COBURN

Mr. COBURN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. COBURN:

Insert before the short title the following new section:

SEC. . None of the funds appropriated or otherwise made available by this Act may be used by the Food and Drug Administration for the testing, development, or approval (Including approval of production, manufacturing, or distribution) of any drug for the chemical inducement of abortion.

Mr. SKEEN. Mr. Chairman, I ask unanimous consent that all debate on this amendment and all amendments thereto close in 2 hours and that the time be equally divided.

The CHAIRMAN. Is there objection to the request of the gentleman from New Mexico?

There was no objection.

The CHAIRMAN. Does the gentleman wish to designate with whom the time will be divided?

Mr. SKEEN. Mr. Chairman, no, we do not.

Mr. COBURN. Mr. Chairman, I ask unanimous consent to control one-half of the time, 1 hour, and allow the opposition to control one-half.

The CHAIRMAN. Any Member seeking to control 1 hour in opposition?

Ms. KAPTUR. Mr. Chairman, yes, we will on this side control the 1 hour in opposition.

The CHAIRMAN. The gentlewoman from Ohio (Ms. KAPTUR) will control the 1 hour in opposition. The gentleman from Oklahoma (Mr. COBURN) will control the 1 hour in favor.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, we are going to hear a lot of debate this afternoon and statements about the intended purpose of this amendment. I want to say from the outset that this amendment is not intended to have an effect on any drug used for any purpose other than that which is specifically spelled out in this amendment.

The taxpayers of the United States spend a great deal of money each year in funding the Food and Drug Administration. There is something terribly wrong when we ask the taxpayers of this country to spend money in a way which is designed to give the Food and Drug Administration the ability to research and approve drugs that are designed to kill unborn children.

Now let me say that again. The purpose of this amendment is to limit the FDA's ability to approve any drug which has its sole purpose to eliminate and terminate an unborn child.

This should not be in a debate about abortion, and I do not intend it to be. It is about how we use taxpayers' money and for what purpose should that money be used.

Abortion is legal in this country. I recognize that. But allowing a Federal agency to spend taxpayers' dollars to perfect and approve a method under which we take life to me seems totally irreconcilable with the fact that our whole country is supposed to be about the pursuit of happiness, the pursuit of freedom and the pursuit of life.

So this amendment will not block Cytotech from being used in other medicines and in other ways, it will not block RU–486 if it has an intended purpose for giving life, saving life, prolonging life. It will not stop any utilization of FDA funds in terms of that effort. Its sole purpose is to say to the FDA none of their money should be used in a manner which will enhance the taking of unborn life.

It is a very simple proposition. Whether one believes in abortion or do not, both sides of this issue believe that we have way too many abortions. None of us think that abortion is a great thing. There are not many people who have been through an abortion who think an abortion is a great thing.

So I want to move our debate not to the issue of abortion, but whether or not we can in good conscience utilize taxpayer dollars to perfect drugs to kill unborn children. That is what the debate is about. It is not about whether or not somebody can have an abortion; we all know that that is possible.

□ 1430

Regrettably so, from my viewpoint. But, rather, the debate is about protecting unborn life from unwise use of Federal taxpayer dollars.

Mr. Chairman, I reserve the balance of my time.

Ms. KAPTUR. Mr. Chairman, I rise in opposition to the amendment, and yield myself such time as I may consume.

Mr. Chairman, as the gentleman knows, on many votes we share similar values, a similar point of view, and this Member certainly does not have a voting record of supporting Federal funding for abortion. I have read carefully the gentleman's amendment. I think it is a bit different from the one the gentleman offered 1 or 2 years ago, if I recall.

I think that the wording of the gentleman's amendment has a worthy purpose. The problem is, I oppose the gentleman's amendment respectfully for three reasons. First of all, on the basis of science.

I do not think that we can really say with certainty and the kind of broad language that the gentleman has included in his amendment that you know for certain what every drug will be used for. I do not have a Ph.D. in science myself, but certainly in the area of medical science, if I think about the decade of the brain that we are now working our way through and all of the discoveries that have been made, for example, in the area of mental illness, most of them by accident; in places like France, for example, where patients were on operating tables, and in order to alleviate pain they were using certain types of pain medications, and, all of a sudden, they discovered, my gosh, why did that work to help to diminish hallucinations and other conditions relating to mental illness?

We certainly are in a period of time now where many of these medications that were by accident discovered to have application for the remediation of the symptoms of mental illness are being worked on, and medical science is at a new horizon in terms of hopefully finding answers for the millions and millions of people that suffer from those illnesses.

I think similarly to some of the lab experiments that have been done, even the discovery of the X-ray itself was an accident. They did not go in there, I think it was Mr. Roentgen, was that not the name, to actually discover x-rays, but it happened. All of a sudden we have a major technology like that that has been used around the world now because of the ability of science to probe into the unknown, but then to figure out practical applications.

I think the gentleman's desire to limit abortion is a very worthy objective, and I do not think anybody on

this side of the aisle would disagree with the objective. The problem is that you cannot really say to medical science that you are going to know for every drug or every chemical that FDA reviews, you are going to know that it would have an end result that you are talking about.

Mr. COBURN. Mr. Chairman, will the gentlewoman yield?

Ms. KAPTUR. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, perhaps the gentlewoman did not hear my first statement. There is nothing in this amendment that will limit the research of any drug in any way, in any concept, whose purpose is something other than that. So if you were to take Cytotech or RU–486 and say you want to try to use it in a different way, this does not limit that at all. When you file an application with the FDA, you give what your intended purpose is.

What this amendment says is if you bring to the FDA a drug whose only intended purpose is to induce the separation of a blastocyst from the uterine wall, that is the technical term for what it does, that they should not spend money approving that.

If you bring the same drug to the FDA and say this is something that solves a problem with the liver, or this decreases portal hypertension, even though it might have that effect of causing an inducement of abortion, it is still approved.

Let me give you some examples. There is a new hair treatment to grow hair back on the head of the gentleman from California (Mr. WAXMAN), yet it cannot be used around anyone wanting to get pregnant. Why? Because it causes severe birth defects and can in fact induce abortions. That was approved. This would not eliminate that drug from ever coming to market or the FDA spending money on it.

Ms. KAPTUR. Mr. Chairman, reclaiming my time, I guess my point is to the gentleman that scientific inquiry and the work of the FDA by its very nature probes into the unknown, and even though the gentleman says that a given drug has to state a purpose, I am saying that we do not always know, once science begins to move, all of the various applications that science might ultimately have for that substance.

So I think that one of the reasons for my opposition to the amendment is I do not think we ought to prejudge science. We ought to let the Food and Drug Administration move forward, the scientists ought to move forward. Let them do what they do best.

I would guess that most drugs have more than one application, and the chemicals that go into them. Even today, many drugs are given, prescription drugs in fact, that may have side effects or other results that even the FDA scientists have not anticipated as they begin.

The second reason I oppose the gentleman's amendment is because I really do believe that this should be within the Food and Drug Administration. I do not think that we should be making this decision on the floor. We should leave it up to the people over at FDA to decide the procedures for drug approval and so forth, and Federal law currently provides that no Federal money can be spent for abortion. That has been on the books for many, many, many years. So I think that we should let the FDA do its job.

Finally, I would say to the gentleman, with all due respect, this subcommittee of the Committee on Agriculture had absolutely no testimony on this issue. The gentleman is bringing a very important issue to the floor. I personally, as just one member of that subcommittee, would have appreciated to have the FDA testify before us, many scientists, to talk about the chemistry of what the gentleman is concerned about, to try to perfect the language of what the gentleman is trying to offer here.

We really have heard from no one in the public on this particular subcommittee. So I find it somewhat uncomfortable to try to accept the gentleman's amendment, when our subcommittee really had absolutely nothing, we did not spend one minute on this within the committee itself.

So for those three reasons, and I want to yield time to other Members to comment, on the basis of science, on the basis of the safety by having the FDA involved, and also committee procedure, I would respectfully oppose the gentleman's amendment.

Mr. Chairman, I reserve the balance of my time.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume to respond.

Mr. Chairman, again, what the gentlewoman just said is it is against the Federal law to use Federal dollars for abortion, but in fact when the FDA approves a drug whose sole purpose is to kill unborn children, that is spending Federal dollars to perform abortion. So I would counter that.

Number two, there was no intention to come before your committee on this issue. This is a well-known issue, this is well documented. There is lots written on RU–486 and Cytotech, and through this discussion I will be happy to give you all of the references in the literature on that.

Mr. Chairman, I yield 5 minutes to the gentleman from Pennsylvania (Mr. PITTS).

Mr. PITTS. Mr. Chairman, I rise today in support of the Coburn amendment's efforts to protect the lives and health of our Nation's women and unborn children.

This amendment would bar FDA's approval and development of new drugs whose primary purpose is to induce abortion. Those are called abortifacients.

Some people believe it is in the best interests of women to make all forms of abortion available to women. However, even for those who support abortion on demand, approving RU–486 is shortsighted and it is a risky approach. Scientific studies have shown a link between abortion and breast cancer. Unfortunately, many who commit abortions do not want to let women know about that risk.

Breast cancer is the leading form of cancer among middle-age American women, but we do not even want to tell women who are considering abortion of this risk.

Ten out of 11 studies on American women report an increased risk of breast cancer after having an induced abortion.

A meta-analysis in which all worldwide data were combined reported that an induced abortion elevates a woman's risk of developing breast cancer by 30 percent. How can we in good conscience approve new forms of abortion before we study the breast cancer and abortion link further and let women know of the risk?

This is the kind of investigation that should be done. This kind of information should be held in hearings before the committee. So I urge the Members to support the Coburn amendment to protect women, both born and unborn.

Ms. KAPTUR. Mr. Chairman, I yield 4½ minutes to the gentlewoman from the State of Connecticut (Ms. DELAURO).

Ms. DELAURO. Mr. Chairman, I thank the gentlewoman for yielding me time.

Mr. Chairman, I might just say to the last speaker, very quickly, that in fact the editor of the Journal of the National Cancer Institute has said that there is insufficient evidence that exists to link induced abortion and breast cancer. That is a medical opinion.

Let me move onto this amendment this afternoon. I am shocked, quite frankly, that we are going through this debate again this year after the outcry of the many medical and pharmaceutical organizations who opposed this amendment last year. It is an unprecedented invasion into the FDA's approval process.

Quite frankly, this is a place where Congress has no right to be. We are not scientists. We do not know what is best for the health of American citizens.

This amendment is intended to block research. It blocks not only drugs that are currently in the pipeline, but potential future breakthroughs in biomedical research. It is an attempt to promote an anti-choice agenda. I have respect for people who have a different view of this issue on choice than I do, but the proponents of this amendment are risking the lives of millions of Americans, because this amendment would also block the development of drugs to cure cancer, ulcers, rheumatoid arthritis, epilepsy, and other medical conditions because some of those drugs can cause a spontaneous miscarriage.

Let me read you a portion of a letter from the National Coalition of Cancer

Research that is just one of the many medical organizations that is firmly opposed to this amendment:

"Attempting to legislate any drug's approval or disapproval is inappropriate. It starts down a slippery slope of prohibiting development in certain drug categories. The comment that the ranking member of this committee made, not only does it threaten the credibility of the drug approval process, it would impede the development of pharmaceuticals to treat different diseases not related to reproduction, such as cancer. If disease or condition-specific approval is dictated by legislative action, drug researchists' efforts to develop new therapies will be stymied." By passing this, the FDA's approval process would be prevented from having the opportunity to do something about this issue.

Let me just talk to you for a second as a cancer survivor. I am a survivor of ovarian cancer; 25,500 women will contract ovarian cancer this year; one-half of them will die. Any chemotherapy drug that is taken by anyone with cancer, any chemotherapy drug has the propensity to cause a spontaneous miscarriage. Why do we take our personal philosophy about where we are on choice and try to foist it on the millions of Americans who, through no fault of their own, contract cancer or a serious illness?

□ 1445

Why would we relegate millions of women to die because we have a particular view on choice?

Mr. Chairman, it is wrong for us to prevent biomedical research. We have an obligation. We spend billions of dollars to promote what happens at the National Institutes of Health because we believe we have the obligation to cure disease in this country. Do not take an action here this afternoon that would in fact condemn millions to die because somehow we want to score a point on choice in this country.

It is wrong, it is unconscionable, and I plead with my colleagues to defeat this outrageous amendment this afternoon.

Mr. SMITH of New Jersey. Mr. Chairman, I ask unanimous consent to control the time allotted to the gentleman from Oklahoma (Mr. COBURN) during his brief absence.

The CHAIRMAN (Mr. PEASE). Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. SMITH of New Jersey. Mr. Chairman, I am happy and pleased to yield such time as she may consume to the gentlewoman from North Carolina (Mrs. MYRICK).

Mrs. MYRICK. Mr. Chairman, I think most of us agree that we would like to be seeking alternatives to abortion, rather than making abortion more accessible.

But the one issue that I wanted to speak on today is what has been shown scientifically as an increased risk of breast cancer. Supposedly there is a link between breast cancer and abortion. This should be examined much more thoroughly before any new forms are approved.

Ten out of 11 studies on American women report an increased risk of breast cancer after having an induced abortion, particularly among women with a history of breast cancer in their families. We know this is already a major problem which we are trying to effectively deal with because currently cancer is the leading form, or breast cancer is the leading form of cancer among middle-aged American women.

In the few countries in which RU–486 is available, it is strictly regulated by the government's health care systems. However, in the U.S., control of abortion drugs is more lax, and sometimes they are often dispensed without a doctor's approval, which again potentially endangers women's health.

But because of the potentially dangerous side effects of abortion, and this is not just physical, this is emotional, as well, these drugs should not be administered without consultation and medical follow-up with a doctor. So I hope we give this serious thought.

Ms. KAPTUR. Mr. Chairman, I am very pleased to yield 4 minutes to the gentlewoman from the great State of New York (Mrs. LOWEY), a member of the committee.

(Mrs. LOWEY asked and was given permission to revise and extend her remarks.)

Mrs. LOWEY. Mr. Chairman, I thank our ranking member for yielding time to me.

Before I address the overall issue, I would like to respond to my colleague, the gentlewoman from North Carolina (Mrs. MYRICK) by reading another quote.

"The Danish researchers concluded that induced abortion has no effect on the risk of breast cancer." When reporting on a particular study, the New York Times stated: "This longstanding issue shall now be settled. No evidence exists to link induced abortion and breast cancer."

Mr. Chairman, I rise in strong opposition to the Coburn amendment. The amendment would stop the drug approval process in its tracks by placing unprecedented roadblocks in front of the FDA. It puts ideology ahead of science and compromises women's health.

The Coburn amendment would block the final approval of a drug, RU–486, that the FDA has already declared to be safe and effective. I repeat, this amendment would block final approval of a drug that the FDA has already declared safe and effective.

This amendment would make FDA drug approval contingent not on science but on politics. The FDA is charged with protecting the public's health, and should not be subject to congressional interference. Should we subject each FDA decision to a congressional vote? Mr. Chairman, let us allow the FDA to do its job free from right-wing intimidation. The American people do not want the Christian Coalition in charge of our Nation's drug approval process.

This amendment may also prohibit the development of new, more effective contraceptive methods, if Members believe, as some do, that any form of hormonal contraception, like in this bill, is tantamount to an abortion.

What about other drugs that as a side effect may induce abortion, like many chemotherapy drugs and anti-ulcer medication? Will research be halted on these lifesaving drugs as well? This amendment is too vague even to give us a clear answer to that question.

So, Mr. Chairman, this amendment is about much more than RU–486. It is about whether the FDA will be free to test, develop, and approve needed drugs without congressional interference. It is about whether politics or science will govern our Nation's drug approval process.

Since Roe v. Wade, the anti-choice minority has attempted to stymie contraceptive research and suppress advances in reproductive health. For example, there used to be 13 pharmaceutical companies engaged in contraceptive research. There are now four. Thankfully, despite pressure tactics, scientists have made some important progress. Among the most significant is the development of RU–486.

RU–486 would make a dramatic difference in the options available to women facing unintended pregnancies. It could make abortion, already one of the safest medical procedures, even safer. Women in France have been using RU–486 for a decade. It is also available in Sweden and Great Britain.

Over 400,000 women have had abortions using RU–486. The New England Journal of Medicine has published clinical trials confirming its acceptability and effectiveness. Also, RU–486 has another significant advantage over current abortion procedures, it can be given in the privacy of a physician's office.

What will the right do when it is approved? Will it picket every doctor's office in America? Will it harass every woman in the Nation? Thankfully, it cannot. That is why it is fighting to block the approval of this drug.

Mr. SMITH of New Jersey. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, first of all, I just want to respond briefly to the previous speaker. When I hear talk of the so-called anti-choice minority, I find that not only empirically unsound, because the data clearly shows America is moving increasingly toward the right-to-life position. But its insulting as well. Minority? I don't think so. As a matter of fact, two polls recently came out. One was done by Faye Wattleton's group, the former president of the Planned Parenthood Federation of America. According to The Center for Gender Equality Survey, January of

1999: "Seventy percent of women favor more restrictions on abortions;" women, 70 percent. That doesn't sound like a "minority" to me. The survey also found fifty-three percent of women today favor banning abortion except for rape, incest, and life of the mother. Rape, incest and life of the mother is about two or three percent of all the reasons as to why abortions are procured. So most women want most abortions made illegal.

Most of the 4,000 babies who die, each day in America from abortion would be saved if the opinions of a majority of women—if their sentiment—were enacted into law. The Coburn amendment does far less than what a majority of women want and we are not talking even remotely about banning abortion in this pending amendment. Yet, 53 percent of women today favor banning abortion, except for rape, incest, or life of the mother.

The survey interestingly points out that that is up from 45 percent of women just 2 years ago. So there is a sea change occurring. Americans are beginning to wake up to the fact that abortion is violence against children.

There is also a USA Today CNN Gallup poll that found that 55 percent of all men and women say abortion in America should be legal only under rape, incest, or threat to the life of the mother. So again, a majority of men and women and a majority of just women that have been found in the USA Today-CNN poll and the Center for Gender Equality survey that the majority is in favor of protecting the lives of innocent unborn children, except in the most extreme circumstances that, frankly, rarely, rarely happen.

If we had legislation that protected those children, again, we would be saving most of the lives. When polled on funding, an overwhelming majority of Americans in every poll, and I ask Members to look at their own polls in their own districts, most will show clearly an overwhelming majority of Americans are against using taxpayer-funded monies to pay for abortions, except in the rarest of cases.

This legislation, this amendment, the amendment offered by the gentleman from Oklahoma (Mr. COBURN) is the Hyde amendment of the FDA. Let us be very clear about it, it is the Hyde amendment being applied to testing of those drugs that are used to procure an abortion.

I believe history and human rights observance are on our side, the pro-life side. Some day the viewpoint from the pro-abortion side will be seen as so misguided and even cruel that people will say, how could they have imposed such violence on innocent, unborn children, especially at a time when we know more about unborn children than ever before in the history of mankind or womankind. Today microsurgery on unborn children, is almost common place. Children are literally lifted out of the mother's womb and surgery is performed, and then they are reinserted to grow and develop and mature until birth time.

Birth has to be seen, I say to my colleagues, as an event that happens to each and every one of us. It is not the beginning of human life. That happens much, much sooner than that at fertilization.

What the gentleman from Oklahoma (Mr. COBURN) is trying to do with his amendment is to say that babies are not junk. They are not throwaways. Some Members want to allow the FDA to invent the newest form of mousetrap, to come up with another more lethal way of destroying unborn children. We can't allow that to happen. And RU–486 is not really a morning after drug, it is used up to 7 weeks after fertilization. It causes the abortion to occur usually after 7 weeks into the gestational cycle. That is not morning after.

I find it offensive, that my tax dollars, American people, not some so-called anti-choice minority but a pro-life majority are used to test and approve deadly poisons for children.

The pro-abortion side does not enjoy a majority in this country. Through manipulation of poll data over the years the pro-abortion side has given the impression, the perception that that is the case, but now the pollsters are now asking more specific and enlightening questions, and all of a sudden it is revealing that, one, more people are pro-life, and also, when they ask the same question over the last several years, there has been a change in our direction.

My friend from New York Mrs. LOWEY says there is no linkage of abortion and breast cancer. Yet 10 out of 11 studies on American women report an increase in breast cancer when women under goes abortion. The "denial" people remind me, of the tobacco Institute denials who year after year said there is no connection between smoking and lung cancer.

There is a compelling linkage of breast cancer and abortion. Dr. Janet Daling, with a National Cancer Institute-funded study, found that after just one abortion there is an increase in the aggregate of all women of about 50 percent in the propensity to get breast cancer. She is not a pro-lifer. She does not agree with my position or that of the gentleman from Oklahoma (Mr. COBURN).

She also found that if a woman aborts her first baby that number shoots up to 150 percent. Shame on those who say there is no linkage. They are misleading women. They are misleading women. And putting women at risk.

Dr. Daling also found that where there is a history of breast cancer in that family, the vote skyrockets to 270 percent when abortion is involved. So if the mother, or the grandmother or sister or someone in that family has had breast cancer, one abortion means that there is a greater likelihood that she will get breast cancer. Why the coverup

We would hope that the FDA would spend more time looking at drugs to mitigate breast cancer and to try to get rid of that terrible, terrible disease, and that the whole abortion establishment would stop the cover-up, and begin informing women about their risks.

Let me just also point out, Mr. Chairman, that RU–486 and chemical abortions, just like dismemberment abortions, just like those abortions where the baby's brains are literally sucked out, partial birth abortions, chemical abortions are just another way of killing the baby.

I think it is time to stop pro-abortion sophistry and the ignoring of the basic fact that every act of abortion takes a life. It is violence against children. Some day we are going to realize that, Mr. Chairman. We do not want our tax dollars being used to perfect another way, another chemical poison, another baby pesticide to kill babies. That is what we are talking about. Come up with drugs that heal, do not promote drugs and make me and my colleagues on the pro-life side on both sides of the aisle fund and pay for killing agents.

Mrs. LOWEY. Mr. Chairman, will the gentleman yield?

Mr. SMITH of New Jersey. I yield to the gentlewoman from New York.

Mrs. LOWEY. Mr. Chairman, I would just like to refer my colleague again to statements from the National Cancer Institute, because we feel so strongly that we should not be mixing up politics and science, confusing our own personal views, and I respect the gentleman's, on whether or not women should have a choice. I would expect that the gentleman respects others'.

In 1996 the National Cancer Institute, concerned that some anti-abortion groups were misrepresenting the science on the subject, issued a statement, not my statement, their statement, and I quote, "The available data on the relationship between induced abortions or spontaneous abortions, miscarriages, and breast cancer are inconsistent, inconclusive. There is no evident of a direct relationship between breast cancer and either induced or spontaneous abortion."

Mr. SMITH of New Jersey. Reclaiming my time, Mr. Chairman, as I pointed out earlier in the debate 10 of the 11 studies on American women reported an increase on breast cancer when the women had an abortion. You may say there needs to be more studies. I say there needs to be more studies. Everybody says that.

But when we get a preponderance of studies pointing in the same direction, I think we should alert women that there is a negative devastating side effect sometimes manifesting itself 20 to 30 years down the line that cannot be ignored and trivialized.

When Janet Daling's study came out, which was National Cancer Institute-funded it received adequate coverage in

the Washington Post for one day. Then all trace of the story was killed with spin from the abortion rights side.

Mr. COBURN. Mr. Chairman, I ask unanimous consent to reclaim control of the time.

The CHAIRMAN. Is there objection to the request of the gentleman from Oklahoma?

There was no objection.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I want to respond to the National Cancer Institute study. The gentlewoman added one word there that totally throws out what they said, "spontaneous." If we add all the spontaneous abortions in with the induced abortions, we will not get an effect, because the number of spontaneous abortions is close to 600,000 to 700,000 per year, 800,000 in some studies. So by combining that data, a normal response to a wrong and incomplete reproductive event to the termination of a normal event, we do not have good data. They know that. That is why they put that material in there.

I want to continue my point, if I may. I will be happy to debate back and forth with the gentlewoman.

Mr. Chairman, I heard from this floor statements exactly opposite of what I said was the intention of my amendment. I am deeply concerned that people would use untruth about what this intended amendment is. Everyone knows me well enough that I am not going to oppose good research for things that help people get well.

There is nothing, and it does not matter what the gentlewoman says, there is nothing in this amendment that will eliminate any cure for cancer, eliminate any process under which any drug can be studied for cancer, because the actual application that the Food and Drug uses, which is right here, it says, what is the purpose for the IND. And if the purpose is chemical inducement for abortion, then they cannot do it. If it says anything else other than that, they cannot.

Finally, I would like to comment about the comments on whether or not we ought to be involved in this.

□ 1500

If the issue of life is not something this House should debate, I do not know what we should debate. There is nothing more important, whether it is the end of life or beginning of life.

We can have our differences. We have a Supreme Court ruling; I understand that. But to say we should not be debating and then finally to say that Congress should not try to work what it thinks the will is, I would propose that most of those who oppose this amendment voted for the amendments that limited drive-through deliveries, that limited drive-through mastectomies, so they have already said that they believe that Congress should practice medicine.

My colleagues cannot claim both sides of this issue. Either they think it is a proper position for this government or this Congress to get involved in things that are wrong or they do not.

Now my colleagues may not agree with the issue, but to use the false premise that we should not be discussing this is intellectually dishonest; it is inappropriate and misstates the situation.

There is nothing in this amendment that will limit NCI's research whatsoever into any cancer treatment, into any treatment whatsoever in any way. To claim otherwise is to distort the truth for purposes of debate and to not carry out an equitable and fair debate.

Mr. Chairman, I reserve the balance of my time.

Ms. KAPTUR. Mr. Chairman, may I inquire of the Chair the remaining time on both sides, please.

The CHAIRMAN. The gentlewoman from Ohio (Ms. KAPTUR) has 44½ minutes remaining. The gentleman from Oklahoma (Mr. COBURN) has 40½ minutes remaining.

Ms. KAPTUR. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I wish to state that, as I listened to the gentleman from Oklahoma (Mr. COBURN) and his desire to try to protect life, I think that his amendment and the words of his amendment, in fact, do not do that. So there is not a disagreement with the objective, but rather the means to get there.

Mr. Chairman, I yield 3 minutes to the distinguished gentleman from California (Mr. WAXMAN).

Mr. WAXMAN. Mr. Chairman, I thank the gentlewoman from Ohio (Ms. KAPTUR) very much for yielding to me this time.

This bill does not provide taxpayers subsidies for abortion. This bill before us is an appropriation to fund the Food and Drug Administration. The Food and Drug Administration receives applications from those private industries that manufacture drugs who come to them and say we want to market our drug. But the law says we must apply to FDA to assure the public that the drug is safe and effective. The FDA then uses its scientific method to determine whether the drug ought to be sold as safe and effective.

The Coburn amendment would prevent the FDA from using science. It would say to the FDA they may not approve a drug that is safe and effective because we are going to substitute a political judgment for what has been a scientific judgment under which the FDA has been mandated in carrying out its responsibilities. So what we are doing is preventing taxpayers' funding of the Food and Drug Administration to determine whether a drug is safe and effective.

Now, there is an interesting argument that the gentleman from Oklahoma (Mr. COBURN) makes, and I am sure he is sincere, that his amendment would only apply to a drug solely to be used for abortion purposes. But that is not what his amendment says. His amendment says that the FDA cannot use any of its funds for testing, development, or approval of any drug for the chemical inducement of abortion. Well, "for the chemical inducement of abortion" may be a side effect of a drug that may be intended to cure cancer. It may be intended for some other purpose.

Now abortion is legal. If abortion is legal, why should we not allow funds to be used by private enterprise to develop a drug that would lead to safer abortions, earlier, safer abortions?

We have heard the story about the link of abortions with breast cancer. I have seen no evidence of that. But let us say that there is a drug that would allow a termination of a pregnancy without any additional risk that may now be out there for those who do decide to terminate a pregnancy.

This amendment is a political amendment. It really is inappropriate in this legislation not to allow the FDA to do its job, which is to use science, to allow research based on science as the FDA considers whether a drug ought to be marketed to the American people.

I would hope that we would oppose this amendment and let FDA do its job and allow a procedure that is legal to be done in the safest possible way.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

I would like to respond to the gentleman from California (Mr. WAXMAN). Number one, the definition of "for" under the dictionary that we have in the House is with the object or purpose of.

The gentleman refuses to address our issue. Our issue is that Federal dollars should not be used to enhance the taking of life. Now, his claim that he has no knowledge of the connection between breast cancer and abortion, I can take that. He probably had not read the studies. I have read every study. Having been trained in science and having read all studies associated with breast cancer and abortion, I think there is some legitimacy to it. I do not know how much there is, but I have read it at least.

Number two is, for the gentleman to object that this is not a place for this debate, again it is not inappropriate, for we have an opportunity as Members of this House to put limitation amendments on appropriations bills. We may not like it, and I understand that, but it does not mean that it is inappropriate or wrong for us to do it.

I also have the legislative history where my dear friend, the gentleman from California (Mr. WAXMAN), has been very effective in doing some of these same things in the past himself. So the use of a limitation amendment on an appropriation bill is both appropriate and within the rules of the House.

So again I want to say this amendment will not, and I will take my colleagues to the application of the Food

and Drug Administration, one has to list a purpose or indication for a drug when one applies. If that is something other than the inducement of abortion, then they can approve anything. The gentleman from California (Mr. WAXMAN) knows that. He knows what the forms say. He knows more about the Food and Drug Administration than anybody in this Congress. I understand that. But he also knows full well that this amendment will have its intended purpose, and that no drug whatsoever which has a purpose other than that will be limited in any way.

Mr. WAXMAN. Mr. Chairman, will the gentleman yield to me?

Mr. COBURN. I am happy to yield to the gentleman from California.

Mr. WAXMAN. Mr. Chairman, I will insert for the RECORD a statement from the Food and Drug Administration where they say very clearly they do not read the gentleman's amendment as he does. Their lawyers have said this will prevent them from dealing with any drug that is brought to them for approval that may have the consequence of terminating a pregnancy.

But my view is, even if its original intended purpose is to terminate a pregnancy, if it is a safer way to do that, we may be saving lives as a result. We may be saving the life of the mother.

Mr. COBURN. Reclaiming my time, let me give the gentleman from California some reasons why we have breast cancer associated with abnormal pregnancies. When a woman is pregnant, there is a large increase of both estrogen and progesterone. The abrupt termination of those, one has turn-on factors in the breast tissue which are not modulated in a normal cycle that the body knows how to do it. That is why we also see an increased risk of breast cancer in women who have late onset pregnancies.

This is not something that is new to the medical community. This is something that we suspect, and now we are starting to see data for. I understand the gentleman's opposition. I would say I would be happy to take an amendment from the gentleman from California (Mr. WAXMAN) that puts the word "solely" in there. I would happily agree to that. But I think his real objection is that we should not be doing this. But the point is I am happy to accept an amendment that will say solely for that, because, as a practicing physician, I know we sometimes get consequences that are ill-effective, and I have no intention of stopping it.

The final point that I would make is the lawyers for the FDA ought to read the legislative history. This passed the House last year, and the history on it shows very much, we actually even had a ruling from the Chair which the gentleman from California (Mr. WAXMAN) had the point of order on, which said this would do that, and the Chair ruled it would not.

Mr. Chairman, I yield 5 minutes to the gentleman from Indiana (Mr. HOSTETTLER).

(Mr. HOSTETTLER asked and was given permission to revise and extend his remarks.)

Mr. HOSTETTLER. Mr. Chairman, I rise in strong support of this amendment from the gentleman from Oklahoma (Mr. COBURN). The Supreme Court has told us that we have to allow the killing of unborn children on demand. It has not, however, told us the government has an obligation to facilitate this service.

This amendment would help ensure that American taxpayers do not end up funding the approval of drugs that are designed to kill our unborn children. FDA's mission, as it was created by this very Congress, should be to approve drugs that save lives, not end lives.

I would just hasten to add that Congress does have oversight responsibility with regard to all agencies of the Federal Government. It has been stated that Congress is sticking its nose into places it should not be. Well, if Congress should not be here now, then it is assumed that the proponents of that philosophy say that the Federal Government should not have been involved in the Food and Drug Administration's creation.

Secondly, there has been the point made with regard to the Supreme Court and the Supreme Court decision that has been made. Earlier today we heard an oath from a new Member that said he swore to support and defend the Constitution of the United States. He did not say anything about according to what the Supreme Court says that the Constitution says.

Separation of powers says that the House of Representatives, the Congress, has the constitutional obligation to determine constitutional intent; and that is what the amendment of the gentleman from Oklahoma (Mr. COBURN) is doing right here, saying that it is Congress' obligation to determine how the taxpayers' money is spent.

The point has also been made that Congress are not scientists. Well, there are several of us that happen to be scientists. We are not in the area with regard to medical science, but we have been told about other doctrines of science, other theories of science; and that is one of those old theories that we are asked to subscribe to today.

□ 1515

And that is that we are led to believe that if a child, if an individual is conceived, that 9 months later it turns into something that it was not. During the Dark Ages and shortly thereafter, that was a scientific theory that was subscribed to, called spontaneous generation, which said basically if rancid meat sat in the corner for 24 days, there will be flies there. So that meant that rancid meat ultimately turned into flies.

Well, that is not the point here. The point is that a child at conception is a child at conception, it is a child 2 months after conception, it is a child 9 months after conception, and it is a child 2 years after it is born.

We should not, as Members of this House, be asked to subscribe to a theory in science that was done away with hundreds of years ago by scientific knowledge at that time. Therefore, we are being asked to facilitate the FDA doing something safe and effective. If that child is a child at conception, and it does not automatically spontaneously generate into a child sometime later, then we are to make sure that drugs are safe and effective for children that are inside the womb as well and not be facilitating the destruction of that human life.

Finally, I will say that there has been much said here about cancer survivorship, and I would be one that would say that I am pleased at the rate of survivorship of Members of this House, Members of this Chamber. My mother is a cancer survivor. However, my father had cancer and he is not a survivor of cancer. This weekend I am going to take part in a relay for life where those survivors of cancer are going to come and celebrate life. My father will not get to take part in that process this year because he is not a survivor of cancer, but I can tell my colleague this: that the way my father raised me is such that he would not take one innocent child's life in order for him to survive cancer.

And that is not what this amendment does. It says and I quote, "None of the funds made available in this act may be used by the Food and Drug Administration for the testing, development, or approval, including approval of production, manufacture or distribution, of any drug for the chemical inducement of abortion."

This amendment by the gentleman from Oklahoma simply deals with a phenomenon of the day, and that is RU486, an abortifacient, that is not being used to treat people and cure people of cancer as it could have my father. Let us remove all the veneer, let us remove all of the camouflage over this and tell the story as it is. The gentleman's amendment will not stop one drop of research into saving people's lives that have cancer. I wish that research would have happened a few years earlier, so that my father could have taken part in that relay for life this weekend.

Let us do say a word for life today. Let us say that innocent preborn life is worth securing, is worth protecting and is at least worth not spending taxpayer dollars on to find a more efficient way to exterminate it.

Ms. KAPTUR. Mr. Chairman, I yield 2 minutes to the gentlewoman from Colorado (Ms. DEGETTE).

Ms. DEGETTE. Mr. Chairman, I am frankly disturbed by the claims that are being made by the proponents of this amendment. The proponents of the amendment say that the drug cannot be used for the sole purpose of abortion or the primary purpose of abortion, but

that is not what the text of the amendment says. What the text of the amendment says is none of the funds appropriated shall be used for the testing, development or approval of any drug for the chemical inducement of abortion. Those words are not in there.

But there are more problems than that. The other problems are that there is no recognized definition by the FDA of the words "chemical," "inducement," or "abortion." So nobody is filing applications with the FDA saying we want to use this research solely for the purpose of the chemical inducement of abortion.

The truth is the way this amendment is written it would prevent research on many, many drugs which may have a side effect of causing abortion. And if my colleagues believe the last speaker, many people believe that that is appropriate. Many people believe that it is a worthwhile societal goal to have millions of cancer victims die in order to stop what may be abortions. That is unacceptable both from a human and a scientific standpoint.

The truth is under this amendment we would be banning research of drugs which would cause miscarriages by treating cancer, hypertension, cirrhosis, rheumatoid arthritis, and even some vaccines. We cannot sacrifice scientific research into abortion, which is legal, or equally importantly into cancer and all these other things simply because of a political agenda. And that is what we are talking about here. We are talking about a political agenda.

And the reason this amendment is written so broadly is because there are people who would ban drugs whose primary purpose is for other purposes, like cancer research, in order to stop abortion. And that is wrong. Defeat the amendment.

Ms. KAPTUR. Mr. Chairman, I yield 2 minutes to the gentlewoman from Maryland (Mrs. MORELLA).

(Mrs. MORELLA asked and was given permission to revise and extend her remarks.)

Mrs. MORELLA. Mr. Chairman, I thank the gentlewoman for yielding me this time and I rise in strong opposition to this amendment which would restrict the FDA from its current system of research and testing of drugs that could eventually save lives.

Reproductive health drugs should be subject to the FDA's strict science-based requirements which any drug must meet before approval can be granted, but this amendment would prevent the FDA from reviewing any drug that could possibly induce miscarriages as a side effect.

Health research is threatened when we legislate decisions that should be left to medical researchers and doctors. Under current law, a company that wants to begin clinical trials on a new drug submits its application to the FDA for approval and, if the application has not been responded to within 30 days, the company is free to move forward. With this amendment, no funds could be used to oversee or even disapprove of such tests.

Mr. COBURN. Mr. Chairman, will the gentlewoman yield?

Mrs. MORELLA. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, I would say to the gentlewoman that there is nothing in the legislative history or the ruling of the Chair from last year or the legal parameters that we have had that makes the gentlewoman's statement a true statement.

The fact is that all drugs whose sole purpose is something other than the chemical inducement of abortion have free reign at the FDA, and I thank the gentlewoman

Mrs. MORELLA. Reclaiming my time, Mr. Chairman, the gentleman's amendment, though, would say review of any drug that could possibly induce a miscarriage as a possible side effect.

Well, now this amendment is opposed by such groups as the National Coalition for Cancer Research and the American Medical Association, and they believe very strongly, as we do, that attempting to legislate any drug's approval or disapproval is inappropriate and that not only does it threaten the credibility of the drug approval process, but it would impede development of pharmaceuticals that may be used either as contraceptives or to treat diseases related to reproduction.

As a matter of fact, it was during last year's debate that drug companies stated that researchers and pharmaceutical companies would be less likely to invest in drugs that might cause miscarriages, and currently many drugs do have this side effect.

So if disease- or condition-specific approval is dictated by legislative action, we are in big trouble. So I urge my colleagues to vote against this amendment.

Mr. COBURN. Mr. Chairman, I yield 5 minutes to the gentleman from Florida (Mr. WELDON), and I would note for the House that he is a medical doctor.

Mr. WELDON of Florida. Mr. Chairman, I thank the gentleman for yielding me this time, and as Yogi Berra said, "It's like deja vu all over again." We are having this argument now and it is the same set of arguments as we had last year when the Coburn amendment passed the House, I believe by a margin of 223 to 202. I would encourage all my colleagues to vote in support of the Coburn amendment.

I believe very strongly that this is a very reasonable and prudent amendment. As has been very, very clearly stated by the gentleman from Oklahoma, when these pharmaceutical companies, medical schools, individuals put in these applications for new drug approval, they put down what its indication is. And the Coburn language is very specific. We had a ruling from the Chair on this issue last year. If the specific indication is to induce chemical abortion, under the provision of his amendment they will be barred from doing that.

Now, I practiced internal medicine for 15 years prior to coming to the House. I still see patients occasionally on weekends. I have had the unfortunate experience of diagnosing people with cancer; indeed, the even more unfortunate experience of seeing many of my patients die. And I would not support any amendment that in any way would interfere with the new development and approval of drugs for the treatment of cancer. And I think it is very disingenuous for anybody to imply that this amendment would have that kind of an implication. This amendment is very, very clear in its language. It is very, very well targeted.

I would also like to point out that what we are talking about today is very, very significant. The FDA has been around for years, and it has safeguarded the American people from the introduction of many potentially dangerous drugs. A great example of this is thalidomide, a drug that was introduced in Europe and produced terrible birth defects. But our American Food and Drug Administration never approved that drug and, thus, prevented millions of American babies from being born with such a type of malformation.

The Food and Drug Administration has never had a drug application before it where the specific intent of the drug was to lead to the death of an unborn baby. Now, abortion, obviously, is a very controversial issue. Every time these issues come up, the arguments are very, very impassioned. And they should be because it is an issue of life and death.

We all know that the baby in the womb has a beating heart. At 40 days it has detectable brain waves. Those are the criteria that I used to use when I practiced medicine to make a determination as to whether or not somebody was dead or alive. So this is a very, very significant issue. And to have the U.S. Food and Drug Administration reviewing a drug and approving a drug where its intended purpose is to kill the unborn baby in the womb, I think, is very, very inappropriate. I think it is very, very appropriate for us to speak on this issue. So, therefore, I would encourage all of my colleagues to vote "yes" on the Coburn amendment.

I just want to touch on one additional issue that has come up in the course of this debate, and that is the reported possible link between abortion and breast cancer. My colleagues, I have reviewed the studies on this issue and the studies are very, very compelling that there really is a link. The statement released by the NCI, I believe, is a very disingenuous statement. It really sincerely ignores the facts on this issue.

If my colleagues actually take the time to read the studies, it is very, very bothersome to me that there are a lot of people within the cancer research community that are turning a blind eye to this issue.

Now, finally, let me close by saying the President of the United States once

said in a speech that he wanted to make abortion safe, legal and rare. There are lots of us who hold that abortion is never safe for the unborn baby in the womb, and I do not think anybody would argue with that. Some people may want to turn a blind eye to the humanity of that child in the womb, but it is never safe for the child in the womb.

Might I also say that there has been absolutely no effort on the part of the administration to truly make abortion rare. Indeed, in trying to push through something like this, we are in many ways trying to facilitate abortion, trying to make it easier, make it more common. And I do not think we should be going in that direction.

I applaud the gentleman for introducing this amendment, and I encourage everyone to support it.

Mrs. LOWEY. Mr. Chairman, I ask unanimous consent that I be allowed to manage the time of the gentlewoman from Ohio (Ms. KAPTUR).

The CHAIRMAN. Is there objection to the request of the gentlewoman from New York?

There was no objection.

Mrs. LOWEY. Mr. Chairman, I yield 2 minutes to the gentleman from Texas (Mr. BENTSEN).

(Mr. BENTSEN asked and was given permission to revise and extend his remarks.)

Mr. BENTSEN. Mr. Chairman, I rise in strong opposition to this amendment offered by the gentleman from Oklahoma (Mr. COBURN).

The author of this amendment may, in fact, believe that it is narrowly drawn and will not affect other research that is being done, but I think his comments a few speakers ago, when the gentleman from California was talking, that he was willing to accept a clarifying amendment, indicates even a specter of doubt in his own mind that there may be a problem with this amendment.

The fact is, even with the ruling of the Chair, this issue would not be decided by the Chair; it is ultimately decided across the street at the Supreme Court.

□ 1530

That is what is to happen if we go through with this type of amendment because it may address RU–486 today, but it will open the door for lawsuits to address other types of research tomorrow and it will not be decided in this body or in the other body, it will be decided in the courts. This is a very dangerous precedent-setting amendment that takes the Congress, in my opinion, down the wrong path where we do not want to go.

The gentleman raised the issue of drive-through mastectomies and drive-through deliveries, and, yes, voted for those. I do not know if the gentleman did or not. I think that is a dangerous position for us to take. But here we are going even further. And I think this amendment is so broadly drawn that it creates a serious problem, and I think the House ought to reject it.

Our other colleague from Indiana talked about removing the veneer. Well, let us do remove the veneer. This is not just about RU–486. This is about chipping away once again at "Roe v. Wade" and getting this in front of the Supreme Court again and seeing if they can overturn a woman's right to choose. That is what this is about. But in the wake of doing that, it creates a lot of damage in the research world.

I hope my colleagues will oppose this poorly drafted amendment.

Mr. COBURN. Mr. Chairman, I yield 3 minutes to the gentlewoman from Connecticut (Mrs. JOHNSON) who is, I might say, in opposition to my amendment.

Mrs. JOHNSON of Connecticut. Mr. Chairman, I thank the gentleman for yielding to me, knowing that I oppose his amendment. And I do oppose his amendment very strongly.

The law of the land is that abortion is legal, whether we like it or not. The law of the land and Supreme Court decisions have given women total control over the decision of whether they will get pregnant and carry a pregnancy during the first trimester. That right is compromised as the fetus grows and women have essentially no right to abortion except under extreme circumstances that are life-threatening toward the end of their pregnancy.

Now, that is simply the law of the land. If my colleagues do not like it, bring a bill to ban abortion, and let us debate that on the floor as the representatives of the people. Let us see if America wants a policy that bans abortion.

Italy has reversed their policy banning abortion because if we ban abortion, we just raise the number of women who die, who die getting illegal abortions. And we know that that was true in our history.

When we first made abortions legal, the big change was not an increase in abortions, because there was not any increase in abortion. The big change was a radical, precipitous decline in maternal deaths. So, mark my words, this is about abortion. Women have a right to abortion and they have a right to a variety of safe, legal procedures. Women in Europe have had access to this method for 20 years.

This is not about thalidomide. This is about something that women in Europe have used for 20 years. Our FDA has reviewed it on the basis of science. That is their job. And under that standard, they have found it to be an effective agent. And women have every bit as great a right in America to a pharmaceutical agent as they do to the surgical procedures. Why would men, in America particularly, want to make the decision for women that they have to go, in a sense, under the knife rather than taking a pharmaceutical pill?

So this is, by gum, about a woman's right to choose and the right to abortion in the very earliest months when even there may not have been any fertilization of the egg. This is not necessarily an abortive phase. It depends on what happened and what did not happen, which they do not know at the time they take it. It is a very big advance. And to deny it and stop it on the floor this way is to indicate that we will approach contraceptive research the same way and that we will narrow rigorously the options available to women to manage their reproductive capability and, with it, their health.

I strongly oppose this amendment. This Congress should not be banning by procedure methods of abortion.

Mrs. LOWEY. Mr. Chairman, I yield myself such time as I may consume to respond to the gentleman from Florida (Mr. WELDON) who I believe has left the floor.

But he referred to this administration and said they have done nothing to make abortion rare. I would invite him and my other colleagues to join us in supporting our contraceptive coverage bill, because that is really the way we reduce the number of abortions. Having the Federal Employee Health Benefit Plan and other private insurance plans cover contraceptives will reduce the number of abortions, and the administration has been strongly supportive of that.

Mr. Chairman, I am delighted to yield 2 minutes to my colleague, the gentlewoman from California (Ms. WOOLSEY).

(Ms. WOOLSEY asked and was given permission to revise and extend her remarks.)

Ms. WOOLSEY. Mr. Chairman, I rise in strong opposition to the Coburn amendment.

In my first term in the House of Representatives in 1993, during the Year of the Woman, with my good sisters and a good number of men, we fought here on the House floor so that the United States could have expanded healthy alternatives to surgical abortions. We supported research development and availability of drugs for medical abortions, like RU–486, in the United States.

Since then, I have witnessed RU–486 being made available in Europe, while here in our country in the United States, here in this Congress, we have had to fight back the far right's constant blows against RU–486 and women's health in general.

I am saddened to say it, but this is the same attack by the conservatives as last year and the year before and the year before that. This amendment seeks to deny women the right to early and safe drugs, such as RU–486, when faced with a crisis pregnancy. Further, because it bans the Federal Drug Administration from approving drugs like RU–486, it represents an unprecedented threat to the FDA's approval process.

Let us make no mistake about it. These repeat attacks are an unwarranted intrusion on a woman's life and a woman's right to good health, and this attack is by the extreme right. Let

us get the far right out of women's health, get politics out of science, and allow the FDA to determine what drugs are safe for women.

Once again, I urge my colleagues, vote against the Coburn amendment, vote for women and women's health.

Mrs. LOWEY. Mr. Chairman, I am pleased to yield 3 minutes to the gentleman from Washington State (Mr. MCDERMOTT).

Mr. McDERMOTT. Mr. Chairman, I think, as a physician, I listen to this debate and it is very interesting to watch us practice medicine out here on the floor of the House of Representatives.

It is pretty clear that if the gentleman from Oklahoma (Mr. COBURN) wanted to ban RU–486, that is what he would have put in this amendment. But it is very clear that this is not what the intention is. The intention is to get a law out there that they can then get involved in lawsuits. It is a very well-known political strategy over the last 10 years to start something and get involved in the courts and tie it up forever.

Now, if they have pharmaceutical companies, and the gentleman from Oklahoma (Mr. COBURN) knows this, they screen all kinds of drugs. Right now, I heard thalidomide mentioned here on the floor. And it became a very bad drug because of its effects on newborn babies and causing defects. It is now being used for another illness. And when pharmaceutical companies screen, they do not know exactly what it is going to be used for. And what they are essentially doing here is opening the door for a lawsuit against the pharmaceutical company who comes to the FDA, having spent $20 or $40 or $100 million developing a drug, and if somebody says, this causes abortion, therefore, we have a cause of action against them and we stop it, they are interfering in a process that is presently legal.

A woman has a right to an abortion, and pharmaceutical companies have a right to develop drugs to do that in a very safe way. And for us to get into that position, the logical slope that they are headed down here, has already been mentioned. The next thing will be, when the sperm meets the egg, if that is a baby, then the next thing is going to be we must ban all birth control.

We already have difficulty getting birth control paid for by the Federal Employees Health Benefit Program. And so we know what is in their minds. But beyond that, the next thing will be an amendment out here on maybe the HHS appropriation to prevent any money from being used for medical school training of any school that trains anybody to do abortions. Because if we go back and back and back up the stream, why should we waste money training physicians, obstetricians, in the skill of doing a safe abortion? We should not because they are ending the life of a child, and we get into all this inflammatory rhetoric.

Now, everybody knows that is wrong. And this amendment is just the beginning of it. It is designed to do that and it is designed to hide what it is up to.

Mrs. LOWEY. Mr. Chairman, I am pleased to yield 2½ minutes to my colleague, the gentlewoman from New York (Mrs. MALONEY).

Mrs. MALONEY of New York. Mr. Chairman, I thank the gentlewoman for yielding me the time for her leadership on this issue.

Mr. Chairman, I rise in opposition. This is an antichoice, an antiscience science amendment. It is not just about RU–486. It is about FDA's ability to test, research, and approve any drug based on sound scientific evidence which may have as a side effect a miscarriage. It could slow or stop research on a wide range of life-saving drugs.

Science, not politics, should determine what drugs are approved. This is why the National Coalition for Cancer Research, the American Medical Assocation, the American Public Health Association, among others, oppose this amendment.

Many drugs, including chemotherapy and antiulcer medication, have the side effects of inducing abortion. This is why pregnant women are advised against taking certain medications.

One of the drugs targeted by this amendment, mefipristone, is not just a drug to make abortion safer. It has also shown to be useful in treating uterine fibrosis, endometriosis, glaucoma, and certain breast cancer tumors.

Another drug targeted by this amendment, methotrexate, has also been used to treat a wide array of conditions including arthritis, lupus, and some forms of cancerous tumors. Blocking research and development of safe and effective drugs in the name of abortion politics is just plain wrong. Never before has Congress told the FDA to approve or disapprove of a particular drug.

This vote is the 108th antichoice vote before this Congress since the new majority came to power. We should not be attempting to appeal or repeal a woman's right to choose procedure by procedure. This is antiscience, antichoice, antiwoman. I urge a "no" vote.

Mr. COBURN. Mr. Chairman, might I inquire of the time remaining?

The CHAIRMAN. The gentleman from Oklahoma (Mr. COBURN) has 23½ minutes remaining. The gentlewoman from New York (Mrs. LOWEY) has 27 minutes remaining.

Mr. COBURN. Mr. Chairman, I yield 2 minutes to the gentleman from South Carolina (Mr. DEMINT).

□ 1545

Mr. DEMINT. Mr. Chairman, I rise in support of this amendment, because I think it is important for this Congress to change the culture of this country by renewing our commitment to the value of life. This is not the time to send a signal to all Americans that abortions of convenience are a way to solve the problem of promiscuity and recreational sex. It is a hoax on the American people and women, in particular, to suggest that this is a healthy way to handle an unwanted pregnancy. We must not send the signal that it is easy as a pill to end an unwanted pregnancy.

This is one of the most important issues facing our country today, because as we look around at the violence and the apparent disregard for life in every walk of life, we have got to question if this type of ease in ending life is contributing to that. This amendment will do what it needs to do in stopping the approval of a way of life in America, in restoring value to life to all ages in America.

Ms. KAPTUR. Mr. Chairman, I ask unanimous consent to reclaim my time.

The CHAIRMAN. Is there objection to the request of the gentlewoman from Ohio?

There was no objection.

Ms. KAPTUR. Mr. Chairman, I yield 3 minutes to the very distinguished gentlewoman from the District of Columbia (Ms. NORTON).

Ms. NORTON. Mr. Chairman, I thank the gentlewoman from Ohio for yielding me this time, because I would like to devote my time to why I think there is confusion about this amendment. The gentleman may be a doctor, but in drawing his amendment it is clear that he is not a lawyer. He says he has drawn an amendment to stop the FDA from approving RU–486. The language he has used instructs us on an amendment to stop the FDA from testing drugs that can treat cancer, high blood pressure, ectopic pregnancy, fibroids, epilepsy. The list is very long. The reason is that although the gentleman mysteriously says that he would accept an amendment to limit the language, he does not propose language of that kind. Why has he brought broad language here?

The reason that his language is defective is that, in the law, it is overinclusive and overbroad. Therefore, in the words he used, it must have unintended effects. In the law it is called a chilling effect. What that means in this case is that a pharmaceutical company will not come forward with a drug that may cure cancer because that company believes it may be sued because of the overinclusive language he has used. It ought to stop every Member in this body when they know that every chemotherapy drug can cause a miscarriage. If, in fact, this amendment had been in the law at the time these drugs were being produced, people who are alive today by the hundreds of thousands would be dead.

I ask you, how many people would be dead today if we consider how many drugs are on the market that have unintended effects that none of us could possibly approve, deadly effects? That is why politics and medicine, or politics and science are like oil and water. You get into politicians overreaching

when you insert political judgments into what should be only scientific matters.

Nor is this one of those great ethical issues on the frontiers of science, where ethicists and politicians have some reason to intrude, because abortion is legal, and I regret to say that miscarriages are also legal. We are entitled to ask, where does it begin, where will it end? I believe we must today let it end with legitimate scientific research. If we care anything about the many drugs that will be stopped by this amendment, we must defeat the Coburn amendment.

Ms. KAPTUR. Mr. Chairman, I yield 1 minute to the distinguished gentleman from Washington (Mr. MCDERMOTT).

Mr. MCDERMOTT. Mr. Chairman, in the earlier debate I did not say something that I think needs to be said out here. We hear all these polls, that the American people do not like abortion and all this stuff. But I would tell you, in the election of 1998 in the State of Washington, the issue of partial-birth abortion was on the ballot, and the people turned it down.

Now, you can tell me all you want about polls but the only poll that really matters is when people actually come out and vote. I believe that the gentlewoman from the District of Columbia (Ms. NORTON) has really put her finger on the whole issue. Because if you open up a cause of action against every pharmaceutical company that brings anything to the market or to the FDA for approval that might cause an abortion, you are going to chill the pharmaceutical industry, which is exactly the reverse of what I see in the appropriations process. We put all this money into the National Institutes of Health because we treasure our health care system, including the pharmaceutical industry. It is a bad amendment.

Ms. KAPTUR. Mr. Chairman, I yield 2 minutes to the distinguished gentleman from New York (Mr. NADLER).

(Mr. NADLER asked and was given permission to revise and extend his remarks.)

Mr. NADLER. Mr. Chairman, I rise today in strong opposition to this amendment. This amendment would ban FDA approval of RU–486 which has been found safe and effective for early, nonsurgical abortion and is awaiting final approval by the FDA. RU–486 would expand access to safe abortion for American women. Its consideration for approval should be dependent on the science, not dictated by antichoice ideologues.

This debate is not about RU–486 or abortion. It is about the FDA's ability to test, research, and approve any drugs for a legal purpose based on sound scientific evidence. Reproductive health drugs should be subject to the FDA's strict science-based requirements that any drug must meet before approval can be granted, but they should not be singled out because they are reproductive health drugs.

The FDA found mifepristone which has been available in Europe widely for nearly 20 years, safe and effective for early medical abortion 3 years ago. The approval was based on extensive clinical trials in this country and in France. They await information on manufacturing and labeling of the drug before final approval can be issued.

This amendment could have dangerous implications for the development of drugs that are used for purposes other than terminating a pregnancy. Many drugs, including those for chemotherapy and antiulcer medication, have the side effect of inducing an abortion. That is why pregnant women are advised that taking such a medication could imperil their pregnancy. New developments in the treatment of these and other conditions, for cancer and for other conditions, would be prohibited under the broad scope of this amendment. New contraceptive development would also be targeted.

Mr. Chairman, the right to abortion services should be safe and legal. The Supreme Court grants this right. What this amendment would do, even at the price of letting people who otherwise would not have to die from cancer, die from cancer because it would prevent the development, the approval of certain chemotherapies, what this would do is to deny the FDA the right to approve a drug simply because it would do what is legal and is a guaranteed right and that, Mr. Chairman, is wrong. That is why the amendment should be rejected.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

We have heard again the tactic from the other side, it is to misdirect, to dodge. This is not about creating lawsuits. This is not about preventing drug research in other areas. This amendment is written very clearly. I would happily have taken an amendment from the gentleman from California (Mr. WAXMAN) because then I would have felt he would have been obligated to vote for the amendment, and that is why he would not offer it. We understand that.

This is about spending Federal money in a way to figure out how to kill unborn children. That is what this amendment is about. There is no ulterior motive to it. It is saying, is it a principle position of this country to tax working families and then take that money and spend it on science on how to figure out how to kill an unborn baby. That is what this amendment does. They know that is what it does. The only thing that we are hearing is that this will limit cancer research, this will make unintended consequences. That is not true at all. Having been in the drug manufacturing business, having applied for NDAs and INDs, I understand full well how the FDA works. There is an area on the application. You have to specify what you are applying that drug for. If it is for anything other than the inducement of abortion, this law will have no effect.

The other side understands that but they do not have an argument against that, so, therefore, they use an argument that is not based on any intellectual honesty. It is based on a dishonest pass out of bounds. This is about, and I am not ashamed to say, I do not think one dollar of Federal taxpayer money should be used to figure out how to kill an unborn child. I have no embarrassment for that whatsoever. I am proud to make that statement.

If we look at what is going on in our country, we understand where violence comes from. The first act of violence is to violate a baby in its mother's womb. When we decide that that life has no value, then no life has value, regardless of what the Supreme Court said. At 19 days postconception, a baby has a heartbeat. At 41 days postconception, the baby has brain waves. In this country, in every State, in every territory you are alive if you have brain waves and a heartbeat, and you are only dead if you do not. So explain to me why a baby at 5½ weeks postconception is not considered alive when if you are considered the opposite of that, you are considered dead. We are schizophrenic in our law because we cannot have equal justice under the law for the unborn when we want the convenience of doing what we in fact know is wrong.

Mr. Chairman, I yield 2 minutes to the honorable gentleman from Illinois (Mr. HYDE), the chairman of the Committee on the Judiciary.

Mr. HYDE. Mr. Chairman, I want to congratulate the gentleman from Oklahoma (Mr. COBURN) for making a necessary stand for life and against the culture of death. The question is about abortion. It is a shame that in discussing this life-and-death issue, the forces of prolife are demonized as antichoice ideologues.

One good thing that has come from this debate has been the use of the word "abortion." You are getting away, however slowly, from the euphemism of "choice," because, of course, there is no choice for the unborn whatsoever. The question is, should Federal funds be used to pay for learning how to make chemical warfare on a defenseless, unborn child? You relegate that child to nothingness because you do not consider the well-being of the child. You only consider the woman who for one reason or another wants an abortion, and that is a tragedy. But life is precious. And once it has begun, that life ought to be protected.

Now, yes, abortion is legal. More is the pity. What a shame on this country's conscience. But the policy of this government and this Congress has been not to coerce money from working people to pay for the extermination of a human life once it has begun. Those people arguing against the gentleman from Oklahoma are all for abortion. They think that is a good thing. God bless them for thinking so. I think it is a horrible thing. I think it is morally wrong. I do not think people ought to be coerced into supporting it because it

is morally wrong. I hope Members will support the Coburn amendment as I do.

Ms. KAPTUR. Mr. Chairman, I yield 3 minutes to the very distinguished gentlewoman from California (Ms. PELOSI).

Ms. PELOSI. Mr. Chairman, I thank the distinguished ranking member of the committee for yielding me this time and for her great service on the Subcommittee on Agriculture.

Mr. Chairman, I want to respond to some of the comments made by the distinguished gentleman from Illinois (Mr. HYDE), and distinguished and respected he is. He talked about the chemical warfare that we would be waging on the unborn. But I want to point out to my colleagues that the Hyde amendment allows for termination of a pregnancy in cases of rape, incest and life of the mother. If this is indeed the Hyde amendment and what the gentleman from Illinois believes and those who support the Hyde amendment, then why would they not want to have women have access to safe, early, nonsurgical abortion?

□ 1600

I certainly respect the gentleman's religious beliefs and understand them, as a Catholic, myself, and mother of five, grandmother of four, and that we do not think abortion is a good thing. Abortion is a failure, it is a failure across the board. But to deprive the FDA of the opportunity to engage in research which would provide safe, nonsurgical terminations of pregnancy in case of rape, incest and life of the mother seems entirely contradictory to what the amendment offered by the gentleman from Illinois (Mr. HYDE) is, if he sincerely believes in that, and I do believe he is sincere. It would trample on the FDA's ability to test, research and approve drugs based on sound scientific evidence, and in that respect the amendment offered by the gentleman from Oklahoma (Mr. COBURN) is starting to have this body, this room, this Chamber, look like the Flat Earth Society again, Mr. Chairman.

We have our Flat Earth Society days around here, and this appears to be one of them. RU-486 has been available to women in Europe for nearly 20 years. After extensive clinical trials in this country and France, the FDA has determined that this drug is safe and effective for an early medical abortion such as the kind allowed under the Hyde amendment for rape, incest and the life of the mother.

But this amendment is not about access to one safe and effective drug. The Coburn amendment would have a dangerous chilling effect on the development of drugs that are used for a wide variety of purposes, Mr. Chairman. Drugs used to treat other conditions including cancers and ulcers can induce abortion. The FDA's ability to consider approval of these therapies would be abolished.

And RU-486 also has promise for other potential medical uses including treatments for breast cancer, HIV and burns. The Coburn amendment forces researchers to turn away from these promising treatment opportunities.

Mr. Chairman, the Coburn amendment puts a social agenda ahead of a woman's needs, ahead of needs of individuals confronting a variety of diseases, ahead of rulemaking authority of the FDA. Once again, this Congress must decide whether to put political agendas ahead of health research.

Mr. Chairman, I urge my colleagues to oppose the Coburn amendment.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

I wonder if the gentlewoman from California (Ms. PELOSI) might stand and take a question? Might I inquire, and I would be happy to yield her to answer, what part of my amendment would eliminate RU-486 from being used in breast cancer research, burns or any other portion?

Ms. PELOSI. Mr. Chairman, will the gentleman yield?

Mr. COBURN. I yield to the gentlewoman from California.

Ms. PELOSI. Mr. Chairman, I say the gentleman's amendment would have a chilling effect on the research. Medical research thrives, we have free and open inquiry.

Mr. COBURN. Reclaiming my time, there is nothing in the amendment that will have such an effect.

Again, we are seeing an attempt at characterizing the amendment in something other than it is. I understand why, because there is not a good factual argument against the Federal Government taking taxpayer dollars to figure out how to kill children. It is another part of the problem that we find ourselves in our society today.

There is nothing in this amendment that will limit in any way what the FDA can do if a drug manufacturer comes and uses, says I want to take 486 and get an indication for it for burns and breast cancer treatment; there is nothing in this amendment that will limit them from it. All they have to do is say that is what we are going to do with it.

And if they want to then let a doctor use it in an unapproved way, that is up to them. But to approve a drug for the very purpose of taking life goes against everything our country is founded on: the pursuit of life. And we are pursuing ways to take life.

Mr. Chairman, I reserve the balance of my time.

Ms. KAPTUR. Mr. Chairman, I yield 3 minutes to the gentlewoman from Texas (Ms. JACKSON-LEE), a distinguished Member.

Ms. JACKSON-LEE of Texas. Mr. Chairman, I thank the gentlewoman from Ohio.

Mr. Chairman, I yield to the gentleman from Virginia (Mr. MORAN).

Mr. MORAN of Virginia. Mr. Chairman, I wonder if the gentleman from Oklahoma is aware that NIH is currently looking at RU-486 as potentially a very effective method of addressing both breast cancer and brain tumors. They feel that there is a substantial potential with RU-486. That ability to research the capability of RU-486 would be completely terminated under this legislation.

So my colleague's suggestion is inconsistent with the facts.

Mr. COBURN. Mr. Chairman, will the gentlewoman yield?

Ms. JACKSON-LEE of Texas. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, there is nothing in this amendment that will keep a drug manufacturer or the manufacturer of RU-486 from making an application to use that drug in any way they want except the chemical inducement of abortion. That is a fact.

Mr. MORAN of Virginia. The lawyers' opinion is quite different, but I think we will make that point subsequently on the record.

Ms. JACKSON-LEE of Texas. Mr. Chairman, I thank the gentleman from Virginia, and I would like to pick up where the gentleman left off, particularly acknowledge the gentleman from Oklahoma (Mr. COBURN), that none of us rise to the floor of the House to challenge any of the beliefs, and I know the very sincere beliefs held by you and many who oppose the women's right to choose along with my respected colleague on the Committee on the Judiciary.

But if I might share with those who are listening, the language of this amendment, which indicates that none of the funds appropriated or otherwise made available by this act may be used by the Food and Drug Administration for testing, development or approval including approval of production, manufacturing or distribution of any drug for the chemical inducement of abortion. It may sound narrowly focused, but if I may draw the gentleman's attention to the fact that chemotherapy drugs can cause a miscarriage, most of these drugs would not have been developed and future drugs may be jeopardized just by the broadness of the language.

I rise today in opposition to the Coburn Amendment that would limit FDA testing on the drug mifepristone or RU-486. This amendment, as drafted, would limit FDA testing on any drug that might induce miscarriage, including drugs that treat cancer, ulcers and rheumatoid arthritis.

The FDA is charged with determining whether a drug is safe and effective. Mifepristone satisfied that requirement in 1996 based on clinical trials and it is expected to receive final approval soon.

Mifepristione was developed as a drug that induces chemical miscarriage. It has other potential use in treating conditions such as infertility, ectopic pregnancy, endometriosis, uterine fibroids and breast cancer.

For example, chemotherapy drugs can cause miscarriage. Most of these drugs would have not been developed, and future drugs may be jeopardized. Research of potential treatments for each of these conditions is crucial to women's health. Controversy concerning this particular drug should not be a barrier to treatment.

Science should dictate what drugs are approved by the FDA, not politics. Congress has never instructed the FDA to approve or disapprove a drug. The FDA protocol for drug approval depends upon rigorous and objective scientific evaluation of a drug's safety. Ultimately, this is a decision that should be made by the researchers and doctors.

This amendment could jeopardize the integrity of the FDA approval process. Under this process, a company that wants to begin clinical trials on a new drug must submit an application for FDA approval. If that application has not been approved within 30 days, the company may move forward.

This amendment would prevent the FDA from reviewing any application for a drug that might induce miscarriage. No funds would be available for the FDA to even oversee any trials.

Therefore, I urge my Colleagues to oppose this amendment. We cannot afford to inhibit research on certain health conditions based upon the controversy of the particular drug. We also cannot allow the FDA to be limited in its ability to approve drugs based on politics.

Ms. KAPTUR. Mr. Chairman, I yield myself such time as I may consume.

It is very clear that we have a difference of philosophy and maybe religious beliefs. I happen to think that I am a person who believes in life and that I support the right to life. I also support the right-to-life decision-making being that of the woman, her God and her family, and what we are doing here is to now just intrude into the very infrastructure of government to be able to say that not even our Food and Drug Administration, which has the main responsibility of dealing with the drugs that Americans take to heal themselves, now we are suggesting that even the most benign of drugs that may ultimately cause or induce a miscarriage, we now are prohibiting women, we are prohibiting those who have ulcers, those who have breast cancer, from even getting that fair treatment by the FDA doing that right kind of testing.

This interferes with the 30-day process that the Food and Drug Administration has for any new drug that, if they do not comment on it, the manufacturer can move forward. I think it is tragic when we as a government globally decide to interfere with the private rights of a woman and deny the good testing of a drug that may save lives.

I believe in life. I want to save lives. This amendment should be defeated.

Mr. Chairman, I yield 2 minutes to the gentleman from New York (Mr. WEINER).

Mr. WEINER. I appreciate the opportunity, Mr. Chairman, to speak on this amendment.

As my colleagues know, I think the amendment offered by the gentleman from Oklahoma is fraught with two fundamental problems. One is a philosophical inconsistency. I have come, in my brief time here, to view Mr. COBURN as a consistent, conservative voice in this Congress, something that he should be proud of perhaps.

Yet by the same token we have an amendment here that is so counter to that philosophy that we here in this Chamber are now going to wade into the operations of doctors and physicians and clinical experts to decide how to interpret the word "for," because that is what this comes down to. How Mr. COBURN interprets the word "for" is very narrowly. It says it is only RU–486.

The American Medical Association, the American College, American College of Obstetricians and Gynecologists, the American Medical Women's Association and others interpret it is that a whole litany of research will now be off the table because that word "for" is ambiguous, and that is the second problem with this bill. It is intellectually ambiguous.

It is difficult to determine when research begins what the outcome might be. It is difficult for scientists sometimes to know when they are doing research on figuring out how to put a shuttle into space, that they might get technology that produces something far different.

The same is true here, that the problem with this amendment is, it is crafted in such a way that the gentleman says it is to simply stop RU–486 except if RU–486 turns out to cure cancer, then it is okay.

Mr. Speaker, that is not a way for us to be operating in this Chamber. This is a very dangerous amendment.

I understand the argument that the gentleman is making about abortion. I disagree with it with every ounce of my strength, but I understand that. The problem is with this amendment is it conceivably opens the door to prohibitions about all kinds of other types of research.

It is simply not the type of business we should be doing here, and it is not the type of business that anyone that considers themselves in this body a conservative and is intellectually honest in that position should be taking.

Ms. KAPTUR. Mr. Chairman, I yield 2 minutes to the gentlewoman from New York (Mrs. LOWEY).

Mrs. LOWEY. Mr. Chairman, as we close this debate, I would like to address some remarks again to my good friend, the gentleman from Oklahoma (Mr. COBURN) because I respect his point of view. We may differ on this issue, but I certainly respect his point of view.

As a mother and grandmother of four-and-a-half, I have to tell my colleague after 10 years of serving in this body I am so tired of debating abortion on the floor of the House, restriction after restriction, ban after ban, amendment after amendment. If we really want to reduce the number of abortions, please work with us to increase funds for family planning. Work with us to ensure that women have access to prescription contraceptives.

I have been working to prevent unintended pregnancies, reduce the numbers of abortions. We need to make abortions less necessary, not more dangerous, and I am sorry that this amendment is being offered to an otherwise outstanding bill.

The amendment was offered last year. Although it passed the House narrowly, it faced a veto threat from the administration, rejected by the Senate members of the agriculture appropriations conference committee, and strong opposition from medical groups, patient advocacy organizations and the biomedical community. It was wisely stripped out of the final version of the bill signed by the President.

The amendment faces the same widespread opposition today, but I hope that this year my colleagues will send this amendment to the defeat it frankly deserves right here in the House floor.

Mr. Chairman, Congress should not inject politics into the FDA's drug approval process. This amendment ignores sound science, it puts women's health in jeopardy, and it should be defeated.

Ms. KAPTUR. Mr. Chairman, I yield 2 minutes to the gentleman from Virginia (Mr. MORAN).

Mr. MORAN of Virginia. Mr. Chairman, I thank the distinguished ranking member of the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies.

The prior gentlewoman from New York was so right. We spend an enormous amount of our time in this body trying to restrict women's access to the best and safest reproductive health care. If we can channel this energy into more productive activities, maybe we can find more money for the women and infant care program or even help to prevent more of the unplanned pregnancies that are the cause of this problem. None of us want to support abortion, and hopefully all of us want to create an environment where there will be far fewer abortions.

But what we are talking about today is really the political practice of medicine, and this amendment should be opposed. The drug mifepristone known as RU–486 has been proven a safe and effective method through clinical trials.

We now know that there are researchers at the National Institutes for Health that believe that RU–486 could be a very effective drug in treating breast cancer, in treating brain tumors, and yet this amendment would preclude that kind of research from being conducted because as part of the FDA approval process, drug trials can proceed only if the FDA does not disapprove of a trial. If the FDA is prohibited from reviewing applications under the Coburn amendment, research may be conducted without the safety of review and oversight of the FDA. So women would be asked to participate in trials with no review of the safety of the protocol.

So that is not going to happen, and as a result, we may be precluding very important advances in medicine. But

we also are told by the lawyers that there is, and I accept the fact it is unintentional, but it is a very important side effect because there are many drugs whose principal purpose may not be abortion, but in fact, are effective in chemotherapy, cancer treatments, hypertension, cirrhosis, rheumatoid arthritis, ectopic pregnancies, ulcers, epilepsy, severe viral infections, all kinds of drugs that may have a corollary effect of inducing abortion.

Those drugs are important. We should be supporting them. We should not be engaged in the political practice of medicine. I urge rejection of this amendment.

□ 1615

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, I would say to my friend from Ohio and the gentleman from Virginia and the gentlewoman from New York this is not a fun debate for me either. I am not happy that we are here doing this. But, you know, if one child is not aborted because we have this debate, I am willing to do it all night long, 365 days a year. That is how much I value life.

Now, I want to discuss for a minute, you say we should not be politicizing the FDA with this action. Well, I want to tell you, the FDA is already politicized. How many drugs do you know of that have been approved of basically on research done overseas? There is zero, except one. Guess what drug that is? Guess what drug that is? That is RU-486.

The vast majority of the studies on RU-486 were not conducted in this country; they were conducted overseas. That totally is a whole new precedent for the FDA. They have never before done that on any new drug approval.

The second thing I would say is this amendment will have no effect whatsoever on any other utilization of any other drug. Cytotec, which is the second drug used with RU-486, is used to protect the lining of the stomach. It is a prostaglandin inhibitor. We use prostaglandins today. We are actually starting to use Cytotec, a very strong component of this, to induce labor. I did it about a week ago, first time.

So we did not learn that from it being studied on the basis of it being an abortifacient or a drug to induce abortion. We learned that because that drug was developed to protect the lining of the stomach for people who have ulcers, consequently learning that you do not dare take that drug if you are pregnant.

Well, if it works in terms of causing uterine contractions, what about using it to induce labor? Maybe it is safer than pitocin or other prostaglandins. So there is no limitation that is going to come about from this amendment.

Five percent of the women who take this drug get a uterine infection, which, when you have a uterine infection, number one, it will affect your ability to conceive in the future. One hundred percent of the women lose more blood with a chemically induced abortion than they would either through a spontaneous or a surgical abortion. It may not be important to you, but if it is you losing the blood, it becomes very important.

Number three, more than one-third of them end up delivering the conceptus outside of the clinic. In France, they have very selected rules on how you can use this drug. None of those are protected and planned in this country.

So is the issue all of the things that we have heard: Not being able to use research? Not being able to get cancer drugs? No, it is not. The issue is nobody from the opposing viewpoint, either from the Republican or Democrat side of the aisle, answered the question, should Federal money be used to help find ways to kill babies? Nobody wants to answer that question. That is because there is not a good answer. Nobody agrees with it. So, therefore, we see arguments that are something other than that. We distort what the argument is because there is not a good argument.

We will not limit in any way the ability of the FDA to do any research. What we will say is, is if your number one goal is to figure out how to kill an unborn baby, number one, first of all, this does not work in 2 days or 3 days or 5 days or 6 days postconception. I am sorry if that is what people think. This works 4 and 5 and 6 and 7 and 8 weeks after. It is not a morning-after drug. That is now how it is going to be used.

What this is going to do is say if you are intending to bring a drug to the market, then the FDA should not spend the first Federal taxpayer's money to figure out how to kill a baby. All right, if that is a consequence of it, of some other intended purpose, maybe that is okay. Because these drugs, Cytotec is going to be used for that. You do not have to have approval of the FDA to use drugs in ways other than how they are indicated. We all know that.

So Cytotec is already being used to induce abortions. The point is should we spend the money, your children's, your grandchildren's, our community's money, to figure out how to take a life? My answer is no. I ask you, should we really do that? I do not believe most people think we should.

That does not say that abortion still is not legal. It is. The question comes, when you have done, as I have, and sat there at the bottom of a table when a woman delivers a 10-week fetus or a 12-week fetus, and hold it in your hand, and she is distraught and crying because that baby was created by her and her partner, and is totally unique to anything else that has ever been created or ever will be created. It has a totally unique genetic structure, it is a God-ordained being, and we are going to say it is okay, we are going to figure out ways to kill those God-ordained beings, and we are going to say for convenience sake, because we made a mistake, because somebody erred, because somebody failed to protect themselves, that it is okay to destroy that life, I reject it. I do not dislike anybody who disagrees with me on that, but I reject that as an argument of the heart and of the soul.

If we are going to decide in this country that you are dead when you do not have heartbeat and brain waves, but you are alive in all 50 States and territories when you do, how can we reject the argument that at 41 days every fetus, every unborn child, has a heartbeat and a brain wave? Now, you cannot deny that scientific fact. That is absolutely proven. So the response to that question is "we will talk about something different."

It is a hard issue, I understand. I wish we did not have unintended pregnancy. The gentlewoman from New York (Mrs. LOWEY) and I have the same goal on that. We believe in getting there a different way. I am not supporting some of her contraceptive research, because I am seeing what is happening with contraceptives and sexually transmitted disease and cancer of the cervix, which is at an all-time high in this country, under the false assumption you are safe, when a condom offers no protection from human papilloma virus whatsoever, yet we tell all our kids they are safe.

Well, I am tired of all the deceit around the arguments. There is good science. I am a scientist by training. I have read the studies. I have looked at it. This amendment is designed for one thing only.

The gentleman from Washington State gave me more credit. I have never thought out about to figure out how to be devious enough to set up lawsuits. My purpose was to say no taxpayer money from Oklahoma or anywhere else ought to be used in figuring out how to kill children.

Mr. Chairman, I yield back the balance of my time.

Ms. KAPTUR. Mr. Chairman, I yield myself such time as I may consume to close at this point.

Mr. Chairman, I rise in opposition to the gentleman's amendment for many of the reasons that were stated earlier. The first one is that I do not think that this Congress should be prejudging medical science. We have talked this afternoon about how scientific discoveries and how science proceeds, often with unintended consequences. We have talked about how many of the drugs currently being used to treat mental illness in this country were discovered by accident.

They were not discovered in this country, they were discovered in France. They were discovered during operating room procedures when patients were trying to be put at ease and the process of pain remediated during operations, and, all of a sudden, for some reason, certain drugs worked. Eventually they came to this country, and even today we do not understand

why they work to help patients with serious mental illness. But for some in our population, they have been able to be given great relief and help through those drugs.

The same was talked about with x-rays. When the scientists invented x-rays, it was an accident. They really went in there with one objective, and, all of a sudden, they made a mistake and it turned out to be an x-ray, and sometimes science is not quite as scientific as it seems. I think that this particular Chamber should not be judging what is science and what is not science.

For the amendment of the gentleman from Oklahoma (Mr. COBURN), which I would really encourage the Members to read if they are going to be voting on this, because I do not think his amendment says what he purports to do in his oral remarks here, but this amendment would absolutely set a dangerous precedent.

This Congress has never legislated the approval or disapproval of any drugs. That is the job of the Food and Drug Administration. We pay for scientists. We, as taxpayers, pay to make sure that what reaches our shelves is safe; but we do not prejudge what is medically relevant.

We also know that many drugs are tested at the end of use for treatment of more than one illness, disease, or condition. We do not really control that. So I would say that on the basis of science alone this amendment should be rejected.

I think that the committee also on which we serve, and we are a very responsible committee, we are the first one on this floor, we are trying to clear this bill under regular order, and I do believe that the gentleman from Oklahoma (Mr. COBURN) has been given sufficient time, actually a lot of time over the last several weeks, to express his points of view, which have been very well articulated.

But the truth is, our subcommittee never had any hearings on this particular matter. The reason is we are the Committee on Appropriations. We do not try to tell FDA what to do. We expect the authorizing committees will deal with that.

If my experience proves me right, my guess would be that if there are concerns about something that is inappropriate, that is best taken to the authorizing committees.

This amendment is not going to be in the Senate bill, and it is not going to become a part of the final legislation.

So I would say based on science, based on safe procedures, that this is something the FDA should be implementing, and also based on regular order, the gentleman's amendment should be defeated. I would urge my colleagues to do so.

Mr. STARK. Mr. Chairman, I rise in strong opposition to the Coburn amendment to the Agriculture Appropriations bill that would ban the Federal Drug Administration from using funds to test, develop, or approve Mifepristone (RU–486)—a drug which has been found to be safe and effective for early, non-surgical abortion.

This is yet another political vote and political debate on a drug whose benefits have been scientifically proven. This amendment is an unwarranted intrusion into the work of the FDA, whose job is to decide whether to approve RU–486 or other drugs based on health and safety—not abortion politics.

Medical abortions and RU–486, if approved, would allow more choices to women seeking abortion. Medical abortions are a better health option for some women. Medical abortions allow women to avoid surgery as well as protect their privacy—women can receive RU–486 in pill form in a regular doctor's office, and be spared the trauma of protesters and violence that continue to stigmatize these women for exercising their constitutionally protected right to choose.

Approval of RU–486 is critical so that doctors may use this procedure when they believe it is the safest way to end a pregnancy and leave the woman with the best chance to have a healthy baby in the future.

New contraceptive development would also be targeted. Many anti-choice groups believe that some contraceptive methods cause. an abortion. This is untrue. If that contention were accepted as fact, research and development of man new contraceptives would come to a halt. This amendment would deprive women of the benefits of significant contraceptive advances.

Make no mistake, a vote for this amendment endangers the health of women, and adds to the long list of barriers set by the majority in Congress that make reproductive health services more dangerous and difficult to obtain. I strongly oppose the Coburn amendment.

Ms. KAPTUR. Mr. Chairman, I yield back the balance of my time.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Oklahoma (Mr. COBURN).

The question was taken; and the Chairman announced that the noes appeared to have it.

RECORDED VOTE

Mr. COBURN. Mr. Chairman, I demand a recorded vote.

A recorded vote was ordered.

The vote was taken by electronic device, and there were—ayes 217, noes 214, not voting 4, as follows:

[Roll No. 173]

AYES—217

| | | |
|---|---|---|
| Aderholt | Bryant | Cunningham |
| Archer | Burr | Deal |
| Armey | Burton | DeLay |
| Bachus | Buyer | DeMint |
| Baker | Callahan | Diaz-Balart |
| Ballenger | Calvert | Dickey |
| Barcia | Camp | Doolittle |
| Barr | Canady | Doyle |
| Barrett (NE) | Cannon | Dreier |
| Bartlett | Chabot | Duncan |
| Barton | Chambliss | Dunn |
| Bateman | Coble | Ehlers |
| Bereuter | Coburn | Emerson |
| Berry | Collins | English |
| Bilirakis | Combest | Everett |
| Bliley | Cook | Ewing |
| Blunt | Cooksey | Fletcher |
| Boehner | Costello | Forbes |
| Bonilla | Cox | Fossella |
| Bono | Crane | Gallegly |
| Borski | Crowley | Gekas |
| Brady (TX) | Cubin | Gillmor |
| Goode | Manzullo | Saxton |
| Goodlatte | Mascara | Scarborough |
| Goodling | McCrery | Schaffer |
| Goss | McHugh | Sensenbrenner |
| Graham | McInnis | Sessions |
| Green (WI) | McIntosh | Shadegg |
| Gutknecht | McIntyre | Shaw |
| Hall (OH) | McKeon | Sherwood |
| Hall (TX) | McNulty | Shimkus |
| Hansen | Metcalf | Shows |
| Hastert | Mica | Shuster |
| Hastings (WA) | Miller, Gary | Simpson |
| Hayes | Mollohan | Skeen |
| Hayworth | Moran (KS) | Skelton |
| Hefley | Murtha | Smith (MI) |
| Herger | Myrick | Smith (NJ) |
| Hill (MT) | Nethercutt | Smith (TX) |
| Hilleary | Ney | Souder |
| Hobson | Northup | Spence |
| Hoekstra | Norwood | Stearns |
| Holden | Nussle | Stenholm |
| Hostettler | Oberstar | Stump |
| Hulshof | Ortiz | Stupak |
| Hunter | Oxley | Sununu |
| Hutchinson | Packard | Talent |
| Hyde | Paul | Tancredo |
| Istook | Pease | Tauzin |
| Jenkins | Peterson (MN) | Taylor (MS) |
| John | Peterson (PA) | Taylor (NC) |
| Johnson, Sam | Petri | Terry |
| Jones (NC) | Phelps | Thornberry |
| Kanjorski | Pickering | Thune |
| Kasich | Pitts | Tiahrt |
| Kildee | Pombo | Traficant |
| King (NY) | Portman | Vitter |
| Kingston | Quinn | Walden |
| Klink | Radanovich | Walsh |
| Knollenberg | Rahall | Wamp |
| Kucinich | Regula | Watkins |
| LaFalce | Reynolds | Watts (OK) |
| LaHood | Riley | Weldon (FL) |
| Largent | Roemer | Weldon (PA) |
| Latham | Rogan | Weller |
| LaTourette | Rogers | Weygand |
| Lewis (CA) | Rohrabacher | Whitfield |
| Lewis (KY) | Ros-Lehtinen | Wicker |
| Linder | Royce | Wolf |
| Lipinski | Ryan (WI) | Young (AK) |
| LoBiondo | Ryun (KS) | Young (FL) |
| Lucas (KY) | Salmon | |
| Lucas (OK) | Sanford | |

NOES—214

| | | |
|---|---|---|
| Abercrombie | DeGette | Houghton |
| Ackerman | Delahunt | Hoyer |
| Allen | DeLauro | Inslee |
| Andrews | Deutsch | Isakson |
| Baird | Dicks | Jackson (IL) |
| Baldacci | Dingell | Jackson-Lee (TX) |
| Baldwin | Dixon | Jefferson |
| Barrett (WI) | Doggett | Johnson (CT) |
| Bass | Dooley | Johnson, E. B. |
| Becerra | Edwards | Jones (OH) |
| Bentsen | Ehrlich | Kaptur |
| Berkley | Engel | Kelly |
| Berman | Eshoo | Kennedy |
| Biggert | Etheridge | Kilpatrick |
| Bilbray | Evans | Kind (WI) |
| Bishop | Farr | Kleczka |
| Blagojevich | Fattah | Kolbe |
| Blumenauer | Filner | Kuykendall |
| Boehlert | Foley | Lampson |
| Bonior | Ford | Lantos |
| Boswell | Fowler | Larson |
| Boucher | Frank (MA) | Lazio |
| Boyd | Franks (NJ) | Leach |
| Brady (PA) | Frelinghuysen | Lee |
| Brown (FL) | Frost | Levin |
| Brown (OH) | Ganske | Lewis (GA) |
| Campbell | Gejdenson | Lofgren |
| Capps | Gephardt | Lowey |
| Capuano | Gibbons | Luther |
| Cardin | Gilchrest | Maloney (CT) |
| Carson | Gilman | Maloney (NY) |
| Castle | Gonzalez | Markey |
| Clay | Gordon | Martinez |
| Clayton | Granger | Matsui |
| Clement | Green (TX) | McCarthy (MO) |
| Clyburn | Greenwood | McCarthy (NY) |
| Condit | Gutierrez | McDermott |
| Conyers | Hastings (FL) | McGovern |
| Coyne | Hill (IN) | McKinney |
| Cramer | Hilliard | Meehan |
| Cummings | Hinchey | Meek (FL) |
| Danner | Hinojosa | Meeks (NY) |
| Davis (FL) | Hoeffel | Menendez |
| Davis (IL) | Holt | Millender-McDonald |
| Davis (VA) | Hooley | |
| DeFazio | Horn | |

| | | |
|---|---|---|
| Miller (FL) | Rangel | Sweeney |
| Miller, George | Reyes | Tanner |
| Minge | Rivers | Tauscher |
| Mink | Rodriguez | Thomas |
| Moakley | Rothman | Thompson (CA) |
| Moore | Roukema | Thompson (MS) |
| Moran (VA) | Roybal-Allard | Thurman |
| Morella | Rush | Tierney |
| Nadler | Sabo | Toomey |
| Napolitano | Sanchez | Towns |
| Neal | Sanders | Turner |
| Obey | Sandlin | Udall (CO) |
| Olver | Sawyer | Udall (NM) |
| Ose | Schakowsky | Upton |
| Owens | Scott | Velazquez |
| Pallone | Serrano | Vento |
| Pascrell | Shays | Visclosky |
| Pastor | Sherman | Watt (NC) |
| Payne | Sisisky | Waxman |
| Pelosi | Slaughter | Weiner |
| Pickett | Smith (WA) | Wexler |
| Pomeroy | Snyder | Wilson |
| Porter | Spratt | Wise |
| Price (NC) | Stabenow | Woolsey |
| Pryce (OH) | Stark | Wu |
| Ramstad | Strickland | Wynn |

NOT VOTING—4

| | |
|---|---|
| Brown (CA) | McCollum |
| Chenoweth | Waters |

□ 1646

Mr. REYES changed his vote from "aye" to "no."

Messrs. DREIER, TAYLOR of North Carolina, OXLEY and BATEMAN changed their vote from "no" to "aye."

So the amendment was agreed to.

The result of the vote was announced as above recorded.

AMENDMENT NO. 17 OFFERED BY MR. CHABOT

Mr. CHABOT. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 17 offered by Mr. CHABOT:

Insert before the short title the following new section:

SEC. . (A) LIMITATION.—None of the funds appropriated or otherwise made available by this Act may be used to award any new allocations under the market access program or to pay the salaries of personnel to award such allocations.

Mr. CHABOT. Mr. Chairman, the rationale behind this amendment is simple. Hard-working taxpayers should not have to subsidize the advertising costs of America's private corporations, yet this is exactly what the Market Access Program does.

Since 1986, the Federal Government has extracted well over $1 billion from the pockets of American taxpayers and handed it to multimillion dollar corporations to subsidize their marketing programs in foreign countries. In other words, the U.S. taxpayer is helping successful private companies and trade associations advertise their wares in foreign countries.

Mr. Chairman, I think the American people would agree that their money could be better spent on deficit reduction for education. Rather than subsidize private businesses and corporations, that money could much better be spent on deficit reduction or on education or on saving Social Security, on the environment, or on tax cuts.

In the past, we have witnessed MAP supporters present some good-sounding arguments for preserving what is in my view a corporate welfare scheme. The only problem is that when we cut through the pro-MAP propaganda, there is no credible evidence to back up their claims.

Let me give my colleagues an example. MAP supporters have argued that this so-called business government partnership creates jobs. But I think, Mr. Chairman, that the American people know that the only jobs usually created by big government spending programs are for big government bureaucracies.

This view of the MAP program is backed by the General Accounting Office. GAO studies indicated that this program has no discernible effect on U.S. agricultural exports. So if the program cannot increase U.S. exports, how can it possibly create more private-sector jobs?

For years, supporters of MAP have lauded the economic benefits created by the program. However, in April 1999, a GAO report, requested by myself and Senator SCHUMER and a bipartisan group of House Members, concluded that the economic benefits of this program are uncertain at best.

According to that report, it seems that the Foreign Agricultural Service, the bureaucracy which administers this corporate welfare program, has used certain assumptions that the OMB has determined to be inadequate for economic benefit analysis. For example, the Foreign Agricultural Service assumes that there are no opportunity costs for promoting one product over another.

But even if my colleagues do believe these supposed benefits, they have all the more reason to support this amendment. These numbers, if accurate, prove that, given these positive returns on an investment overseas, MAP-supported corporations and trade associations ought to be spending their own money and not the money of the taxpayers of this Nation.

My opposition to MAP is not based solely on the false premises of its supporters. I am offering this amendment today because we simply do not need this wasteful program. Let us be honest. Most American businesses do not benefit and do not try to take advantage of government handouts like this MAP program.

In the case of MAP, as in most corporate welfare programs, beneficiaries consist primarily of politically well-connected corporations and trade associations. Most, if not all of these organizations, would advertise their products overseas, even without MAP funds. They probably would work much harder to ensure that the money is well spent.

Let me give just one example of the kind of waste and mismanagement that this program breeds. We all remember a few years ago when the California Raisin Board sponsored the "I heard it through the grapevine" raisin commercial. Based on the success of that commercial in the U.S., MAP decided that it would be a good idea to use that commercial to attempt to boost raisin sales in Japan and put $3 million into the project.

Not surprisingly, however, the ads played in English, leaving many Japanese confused, unaware that the dancing characters were raisins. Most thought they were potatoes or chocolate. In addition, many Japanese children were afraid of the wrinkled, misshapen figures. This, of course, is the kind of wasteful spending that inevitably occurs when we give someone the ability to spend other people's money.

Mr. Chairman, Congress should end the practice of wasting tax dollars on special interest spending programs that unfairly take money from hard-working families to help profitable private companies pad their bottom line. MAP is a massive corporate welfare program that we should eliminate today.

Finally, in MAP, MAP's proponents have argued that due to recent reforms, big corporations no longer receive MAP funds. It is true that in June 1998, in order to correct some of the more egregious abuses of the MAP, Market Access Program, the Foreign Agricultural Service revised its regulations to limit a company to 5 years of assistance in a particular country. After this 5-year period had expired, companies were to be graduated from the country's market. Translation: These billion-dollar corporations were no longer to receive tax dollars to fund their product promotions.

So I would strongly urge my colleagues to vote to get rid of this very wasteful program.

Mr. SKEEN. Mr. Chairman, I rise in opposition to the amendment.

Mr. Chairman, this is an annual debate, and I am not sure why we have to have it. Virtually all of our competitor nations spend money to promote their products against ours. We have had testimony from both USDA and many private-sector companies about the success of the program, particularly for small enterprises.

Mr. Chairman, I oppose the amendment and ask my colleagues to do the same.

Ms. KAPTUR. Mr. Chairman, I move to strike the last word.

□ 1700

Mr. Chairman, I rise in opposition to the gentleman's amendment and am somewhat surprised that a Member from Ohio, where agriculture is our leading industry, would offer this particular amendment. If one reads the changes that have been made in this program, particularly targeting its benefits at small- and medium-sized operations, I think some of what the gentleman has said might have been true many years ago, but they are certainly not true today.

If one looks at what is happening in rural America, which is swimming in surpluses, and we know that for this

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**(excerpts)**

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# House of Representatives

The House met at 12:30 p.m. and was called to order by the Speaker pro tempore (Mrs. BIGGERT).

## DESIGNATION OF SPEAKER PRO TEMPORE

The SPEAKER pro tempore laid before the House the following communication from the Speaker:

WASHINGTON, DC,
*July 10, 2000.*

I hereby appoint the Honorable JUDY BIGGERT to act as Speaker pro tempore on this day.

J. DENNIS HASTERT,
*Speaker of the House of Representatives.*

## MESSAGE FROM THE SENATE

A message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate has passed a bill and a concurrent resolution of the following titles in which the concurrence of the House is requested.

S. 2071. An act to benefit electricity consumers by promoting the reliability of the bulk-power system.

S. Con. Res. 129. Concurrent Resolution expressing the sense of Congress regarding the importance and value of education in United States history.

## MORNING HOUR DEBATES

The SPEAKER pro tempore. Pursuant to the order of the House of January 19, 1999, the Chair will now recognize Members from lists submitted by the majority and minority leaders for morning hour debates. The Chair will alternate recognition between the parties, with each party limited to not to exceed 30 minutes, and each Member, except the majority leader, the minority leader, or the minority whip, limited to not to exceed 5 minutes.

The Chair recognizes the gentleman from Illinois (Mr. WELLER) for 5 minutes.

## THE MARRIAGE TAX PENALTY

The SPEAKER pro tempore. Under the Speaker's announced policy of January 19, 1999, the gentleman from Illinois (Mr. WELLER) is recognized during morning hour debates for 5 minutes.

Mr. WELLER. Madam Speaker, over the last several years many of us have asked a question that we hear back at home time and time again. I represent the South Side of Chicago, the south suburbs, Cook and Will Counties, communities like Joliet, bedroom communities like Morris, Frankfort, a lot of farm towns.

I find whether I am in the city, the suburbs, or the country people often ask a pretty basic, fundamental question. That is, they ask a question: Is it right, is it fair that under our tax code 25 million married working couples pay on average $1,400 more in taxes just because they are married? They ask that fundamental question of fairness: Is it right, is it fair, that under our Tax Code if one chooses to get married, their taxes are going to go up?

We call that the marriage tax penalty, and it occurs where we have a husband and wife who are both in the work force, a two-earner household who, when they choose to join together in holy matrimony, one of our society's most basic institutions, they end up paying higher taxes than if they stayed single or got divorced. The vast majority of folks back home tell me they believe that is wrong.

The marriage tax penalty essentially works this way. Let me introduce a couple here, Shad and Michelle Hallihan, two public school teachers from Joliet, Illinois. They just had a baby this year and are starting a family. But because they are both in the work force, they suffer on average the average marriage tax penalty of almost $1,400.

Back home in Joliet that $1,400, that is 3 months of day care for their child at the local day care center while they both teach. That is a year's tuition at Joliet Junior College. The marriage tax penalty on average is real money to real people.

For some here in this House and some over in the Senate, particularly the folks down at the White House, they want to spend that money here in Washington rather than letting good folks like Shad and Michelle Hallihan keep what they suffer in the marriage tax penalty, money they could spend on their newborn baby.

Madam Speaker, Shad and Michelle's marriage tax penalty occurs because when we are married, we file jointly, we combine our income. So Shad and Michelle with their current income, if they stayed single or just chose to live together, they would each pay in the 15 percent tax bracket. But because they combine their income when they file jointly, they are forced to pay in a higher tax bracket, which causes them to pay $1,400 more in higher taxes.

I am proud to say as a key part of the Republican agenda this year this House passed overwhelmingly the Marriage Tax Elimination Act, H.R. 6. Every Republican and thankfully 48 Democrats broke ranks with their leadership and said they, too, wanted to eliminate the marriage tax penalty. We passed it out of the House with overwhelming bipartisan support.

Unfortunately, I guess I should congratulate the Senate Democrats because they prevented the Marriage Tax Elimination Act from moving through the Senate. Of course, we are now moving it through the budget process to get around their parliamentary procedure that they are using to prevent us from eliminating the marriage tax penalty.

Later this week we are going to be voting on an agreement between the House and Senate which essentially wipes out the marriage tax for 25 million couples. In fact, the legislation we will be voting on later this week is

the Long Island Sound and their families faced tough times. By the fall of 1998, over 95 percent of the oysters on 1,750 acres of oyster beds had died, devastating the $62 million industry and the families that relied on it for survival.

The USDA provided $1.5 million in disaster assistance last year to help get these families through the crisis and to ensure the long-time survival of Connecticut's valuable oyster industry. It was the right thing to do. It helped these small businesses get through tough times. The oystermen thought that they had weathered the storm.

But after surviving the crisis, just a few weeks ago the oyster harvesters got a letter in the mail from the USDA saying it was sorry, it made a mistake, and it wanted its money back; it wanted the $1.5 million returned. That money that was invested in reseeding oyster beds so that there would be an oyster harvest in the future, and it went to pay mortgages, to repair boats, and to feed and educate children.

Mr. Chairman, these are not people that have $1.5 million to give back to the Department of Agriculture. They should not be forced to mortgage their homes and futures to pay for a bureaucratic mistake.

My amendment would simply prohibit any funds made available in this act or in any other act from being used to recover part or all of any payment erroneously made to any Connecticut oyster harvester for oyster losses in 1998.

CBO has ruled it as budget neutral, taking no essential funds out of this bill. I call on my colleagues to support the amendment and bring justice home to the oyster harvesters of Connecticut.

Mr. SKEEN. Mr. Chairman, I move to strike the last word.

Mr. Chairman, I accept the gentleman's amendment and recommend that the House do so as well.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Florida (Mr. BOYD).

The amendment was agreed to.

AMENDMENT NO. 6 OFFERED BY MR. COBURN

Mr. COBURN. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 6 offered by Mr. COBURN:

Insert before the short title the following title:

**TITLE IX—ADDITIONAL GENERAL PROVISIONS**

SEC. 901. None of the funds made available in this Act may be used by the Food and Drug Administration for the testing, development, or approval (including approval of production, manufacturing, or distribution) of any drug solely intended for the chemical inducement of abortion.

Mr. COBURN. Mr. Chairman, we have addressed this amendment 2 years prior to now, and we have passed it each year in the House.

What this amendment does is limit and prohibit the use of funds by the Food and Drug Administration in approving any drug that's sole intended purpose is the chemical inducement of an abortion.

Why is this important? First of all, if we go and look at the authorizing language to the Food and Drug Administration what we will find is that, in fact, its charge and its mission is to provide safety and efficacy for life and health. There is nothing about the chemical inducement of an abortion that is safe, either for the mother or for the unborn child. The other reason that this is important is that it violates the very premise under which the FDA was authorized.

What this amendment would do is it would limit the expenditure of Federal funds by the Food and Drug Administration in their efforts to approve drugs whose sole purpose is to terminate life, to take the life of an unborn child.

One of the things that has come to light over the last 3 years that now cannot be disputed scientifically is that we have an ever enlarging number of women who encounter breast cancer. And although it is not politically correct in our culture today, the fact is that having an abortion markedly increases one's risk for breast cancer. There are now 10 out of 11 studies that prove that without a shadow of a doubt. An analysis of all those studies combined, plus other studies, show that there is a 30 percent increase in the risk for breast cancer.

We have funded through this Congress and many others marked research in breast cancer. We just passed a breast cancer and cervical cancer bill through this House with the whole goal to extend the life of these women. It would seem fitting to me that we would not want to allow the FDA to go down a course in which their whole intended purpose is to take the life of the unborn child.

The other thing that is important in this is that drugs that are intended solely for this purpose are intended so to take the life of a child under 9 weeks of age. We also have irrefutable evidence that now an unborn child at 19 days post conception has a heartbeat, and at 41 days post conception has brain waves.

If we look at our definition of death in this country and we say that the absence of brain waves and the absence of a heartbeat is death, then certainly the opposite of that is life. So what we are talking about is taking unborn life. Whether we fight about when life begins or not, we know it is present at 41 days. So we are talking about authorizing an agency of the Federal Government to figure out how best to provide a drug to take that life.

□ 1700

That is not what this country is about, it is not what this bill should be about, and I would ask that the Members support this amendment.

Ms. JACKSON-LEE of Texas. Mr. Chairman, I rise today, once again, in opposition to the Coburn Amendment that would limit FDA testing on the drug Mifepristone or RU–486. As Congressman COBURN has tried year after year, this amendment, as drafted, would limit FDA testing on any drug that might induce miscarriage, including drugs that treat cancer, ulcers and rheumatoid arthritis.

Although this debate is truly about the FDA's ability to test, research and approve any drug based on sound scientific evidence, I find this continual assault on a women's choice and right to control her body frustrating, to put it lightly.

Just yesterday, the Supreme Court upheld a woman's right to choose whether or not an abortion is right for her, without the State enacting undue restrictions. By ruling the Nebraska "partial birth" ban unconstitutional, the Court reiterated that *Roe* v. *Wade* is still the law of the land and cannot be undermined with ambiguous anti-abortion language.

The Supreme Court's decision spotlights the judicial branch's role in protecting and preserving the reproductive rights of American women as the Constitution provided. In a similar vein, the Federal Drug Administration is charged with determining whether a drug is safe and effective without political interference. However, Mr. COBURN's Amendment would interject politics into this process with no regard to the health and well being of women in the country.

Mifepristone is a proven safe drug that has been used in France since 1988 after the French Minister of Health declared Ru–486 "the moral property of women," thus showing the enlightened state of affairs in France that continues to elude this country.

However, Mifespristone has continually satisfied the FDA's safety requirement in 1996 based on clinical trials and after two favorable letters it is expected to receive final approval soon.

Although Mifepristone was developed as a drug that induces chemical miscarriage, I am more concerned about its other potential uses in treating conditions such as infertility, ectopic pregnancy, endometriosis, uterine fibroids and breast cancer.

The problem with characterizing this amendment as an abortion drug is that Mifepristone has the potential for so many other uses. Thus if we only highlight one use of Mifepristone, then we might as well do the same for chemotherapy drugs which can also cause miscarriage.

Yet, because of the FDA's arduous approval process, many drugs have been found to be safe and effective, notwithstanding their potential usefulness in inducing miscarriage.

Thus, if we go by the Coburn standard, most of these drugs would have not been developed, and future drugs may be jeopardized. Research of potential treatments for each of these conditions is crucial to women's health. Controversy concerning this particular drug should not be a barrier to treatment.

Science should dictate what drugs are approved by the FDA, not politics. Congress has never instructed the FDA to approve or disapprove a drug. The FDA protocol for drug approval depends upon rigorous and objective scientific evaluation of a drug's safety. Ultimately, this is a decision that should be made by the researchers and doctors.

This amendment could jeopardize the integrity of the FDA approval process. Under this

process, a company that wants to begin clinical trials on a new drug must submit an application for FDA approval. If that application has not been approved within 30 days, the company may move forward.

This amendment would prevent the FDA from reviewing any application for a drug that might induce miscarriage. No funds would be available for the FDA to even oversee any trials.

Therefore, I urge my Colleagues to oppose this amendment. We cannot afford to inhibit research on certain health conditions based upon the controversy of the particular drug. We also cannot allow the FDA to be limited in its ability to approve drugs based on politics.

Ms. WOOLSEY. Mr. Chairman, I rise in strong opposition to the Coburn amendment.

Since being elected to Congress eight years ago, I have been working with many of my colleagues for the right of all women in the United States to have safe, healthy alternatives to surgical abortions.

While we've seen RU–486 become available in Europe, we're still fighting for expanded research, development, and availability of drugs for medical abortions, like RU–486, here in the United States.

Even worse, in Congress we continue to face these outrageous efforts by the far right to block the Food and Drug Administration's approval of RU–486.

I'm sad to say it, but the Coburn amendment is the same attack that conservatives have tried every year.

Mr. Chairman, pure and simple, the Coburn amendment is an attack on a woman's right to make decisions that affect her health.

It seeks to deny a woman's right to safe medicines like RU–486 even when faced with a crisis pregnancy.

Furthermore, I ask my colleagues to realize that by prohibiting the FDA from approving these medicines—This amendment will also have a life-threatening impact on other women and men.

It harms those who have medical conditions, such as tumors, that can be treated with drugs like RU–486.

We cannot let the far right stand in the way of women's health or patients' lives.

I urge my colleagues—vote against the Coburn amendment!

Mr. SMITH of Michigan. Mr. Chairman, I am concerned about the implications on research if this amendment passes. Scientific study and preliminary evidence show Mifepristone (RU–486) has significant promise for the treatment of: Breast Cancer, Ovarian Cancer, Prostate Cancer, Cushing's Disease (a Pituitary Gland Disorder), Meningioma (benign brain tumors), and Ectopic Pregnancy.

If we block the FDA from testing or approving mifepristone, we may be penalizing thousands of Americans who have nothing to do with the abortion issue.

I feel this vote has greater ramifications than just abortion.

I am also concerned about preserving the scientific integrity of the FDA's drug approval process.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Oklahoma (Mr. COBURN).

The question was taken; and the Chairman announced that the ayes appeared to have it.

Mr. COBURN. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The CHAIRMAN. Pursuant to House Resolution 538, further proceedings on the amendment offered by the gentleman from Oklahoma (Mr. COBURN) will be postponed.

The point of no quorum is considered withdrawn.

AMENDMENT NO. 47 OFFERED BY MR. ROYCE

Mr. ROYCE. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 47 offered by Mr. ROYCE:
Page 96, after line 7, insert the following:

**TITLE IX—ADDITIONAL GENERAL PROVISIONS**

**SEC. 901. ACROSS-THE-BOARD PERCENTAGE REDUCTION.**

Each amount appropriated or otherwise made available by this Act that is not required to be appropriated or otherwise made available by a provision of law is hereby reduced by one percent.

Mr. ROYCE. Mr. Chairman, I realize that this year's agricultural appropriations bill is below last year's level, and I applaud the chairman for his efforts on that. However, even more reductions can be made in this bill, and should be made, because, frankly, Congress should continue to cut government waste.

Just a few weeks ago, the President signed into law a $15.3 billion crop insurance and emergency farm package. That measure marks the third big bill out of the agricultural economy in the last 3 years.

Now, this emergency bill amounts to a mini-farm bill affecting most divisions of the agricultural department and sprinkling pet programs to special interest groups. In effect, Congress has been passing more than one agricultural appropriations bill each year; we have been passing two.

In fiscal year 1999, Congress passed $6.6 billion in supplemental assistance. So far in fiscal year 2000, Congress has passed four different measures amounting to $15 billion in emergency agricultural spending, and this includes the $210 million of emergency spending attached to the military construction supplemental passed by this House just before the July 4th recess. Not even into fiscal year 2001 yet, Congress has already passed $1.6 billion in emergency funding.

Mr. Chairman, Congress cannot afford to past two appropriations bills for agriculture each and every year.

Since late 1998, Congress has allotted $22 billion in disaster market loss payments to growers, roughly doubling the subsidies promised under the 1996 Freedom to Farm law. Lawmakers are beginning to use this annual ritual of emergency packages as their vehicle of choice for moving pet projects.

Under the guise of a national emergency, Congress rams through emergency spending bills full of unnecessary, unwanted, unauthorized, unmitigated pork. The emergency package for Colombia-Kosovo and disaster relief included millions for a Coast Guard jet, for instance, for Alaska. It included money for an ice breaker and other egregious pork. If we do not cut back now, our senior citizens will pay the bills when Medicare or Social Security runs dry, and that is not a legacy any one of us wants to live with.

The Department of Agriculture in its current configuration still reflects the needs of an America that existed prior to the industrial revolution. These Depression-era programs still work to prop up commodity prices.

Most agriculture spending aimed at farmers is based on a restrictive centralized planning system. Sixty percent of farm payments goes to 15 percent of the farmers with gross sales in excess of $100,000. Very little of these price supports goes to those who really need it, the small family farmers.

Attempts to manipulate markets and subsidize the economic life of a group of businessmen only harm consumers and farmers. Programs dedicated to agriculture comprise 34 percent of the Department's budget. The remainder goes to forestry, rural development, and welfare.

Back in 1862, when Abraham Lincoln created this agency, five out of 10 American workers were employed in agriculture. Well, that is no longer the case today; yet the Agriculture Department is the fourth largest agency in the President's cabinet, behind Defense, Veterans and Treasury. There is now about one bureaucrat for every six full-time farmers, and not a single one of these bureaucrats helps crops grow.

I support a gradual and consistent reduction in this appropriations bill. We have made progress in the 1996 reforms, but we need to do more; and we need to ensure that these reforms stay put. We must continue to wean agricultural special interests from their dependence on the Federal Government.

My amendment is supported by Citizens Against Government Waste. A 1 percent across-the-board reduction will save American taxpayers $750 million next year alone. It is my hope that this money will go to debt reduction.

Again, the chairman has done an admirable job, but more can be done; and saving one penny on every dollar is the very least we can do. I urge my colleagues to support this amendment.

Mr. SKEEN. Mr. Chairman, I rise in opposition to the gentleman's amendment.

Mr. Chairman, the process associated with the appropriation is long. It includes oversight hearings and evaluations of many proposals. The subcommittee reviewed detailed budget requests and asked several thousand questions for the record. In addition, the subcommittee received over 2,900 individual requests for spending considerations from Members of the House.

The funding presented in this year's bill represents the culmination of

many months of work by the subcommittee. The gentleman has not been specifically involved in the process.

The gentleman's amendment moves to arbitrarily cut funding without any consideration to the merit or value of the needs facing American agriculture. This approach ignores the methodical process that the committee used to fund the line items in this bill.

If the gentleman were truly interested in reducing the bill in a logical manner, he would identify the specific programs and accounts that should be reduced with his amendment. Then we could have a valuable debate on the individual merits of the funding proposal. But the gentleman's amendment simply employs the Draconian reduction approach to the discretionary portion of the bill, with little understanding as to its negative impact on vital programs funded by this bill.

I urge my colleagues to defeat the gentleman's amendment.

Mr. OBEY. Mr. Chairman, I move to strike the last word.

Mr. Chairman, this amendment is one of the best substitutes for thinking that I have seen on the floor in quite some time. The gentleman has given as one of his reasons for proposing this 1 percent cut the fact that he does not like the fact that there are some agriculture commodity supplementals that have been passed by the Congress. The fact is, those are not in this bill. They do not have diddly to do with this bill. They ought to be in this bill, because, I promise you, before the Congress is finished, it will respond to the problem on the farm with respect to prices.

The Senate has already passed $1.2 billion in additional assistance to farmers who are being crippled by low prices, thanks to the spectacular failure of the Freedom to Farm Act; and before this bill is finished, the House will have to accept some of what the Senate is talking about with respect to dairy funding, with respect to livestock funding and the rest.

But the fact is, right now the bill the gentleman is trying to cut does not contain those items, and because he does not like the fact that somewhere along the line those items might be funded, he apparently is willing to cut funding for child nutrition, to cut funding for agencies that protect the public against diseased food and items like that.

The gentleman would cut the regulation and safety of drugs and medical devices by FDA, he would cut rural water and sewer and housing and economic development, he would cut vital conservation programs on the farm, he would cut the APHIS program to help control plant and animal pests and diseases.

I just went through several national forests over the past 2 weeks and saw the incredible damage done to those forests by pests. In fact, I saw some spectacular damage in California. I would ask the gentleman whether he believes that pest control programs in California are really a waste of the taxpayers' money or not. It is destroying the timber harvests, it is destroying agricultural products of all kind, and, whether the gentleman recognizes it or not, forests are an agricultural product. At least they are seen that way by a lot of people who harvest forests for a living.

I would say that if the gentleman is comfortable in cutting USDA's Food Safety and Inspection Service, which is responsible for the inspection of meat and poultry, he may be comfortable doing that. I am not. If the gentleman is comfortable saying that 74,000 fewer low-income pregnant women and children will be served by the WIC program, he may be comfortable with that. I am not.

Mr. Chairman, with that, I think we ought to just let the chips fall where they may. I intend to oppose the amendment, and I would hope that other thoughtful Members of the House would as well.

Mr. LATHAM. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in opposition to this amendment, and to just maybe clarify some of the statements made earlier.

The funding that was put in the supplemental was for hurricane damage. These are real emergencies. It has gone on now about a year, and without a vehicle to help the people out there that were so devastated last year.

I just want to remind the House also, the $15 billion bill that went through, that is spread out. The crop insurance portion of it is spread out over 5 years, and the intention is to have a crop insurance program in place policy-wise and funding-wise that is going to actually help farmers manage risk.

I think we have an extremely good product, and farmers will now have a vehicle where they can insure both price and yield risk, and hopefully the dependency for additional supplementals will be curbed dramatically in the future with that type of program in place. Also for livestock producers, it has a plan in there so that they can also cover both fatality and price risk.

So while I do not disagree with the intention of the gentleman, I think that we need to maintain fiscal sanity around here, but I have also heard over the 3 days of debate on this bill how this bill is currently underfunded to begin with. I think, like the gentleman from Wisconsin said, there are very vital services that are in this bill that would be dramatically harmed and programs that would be dramatically harmed with this type of cut.

I will say in reference to concern about the current farm policy that I do not know how one can say that our current farm bill really is responsible for the Asian financial collapse, where most of our major customers of the world have not been able to buy our products in the past few years. Fortunately, the economy in those areas is rebounding. Hopefully, the future will be better. I do not know how one can say anything about farm policy being the cause for 3 years of record worldwide production and surpluses. That simply is not the cause of what the price situation is as far as our grains are concerned, certainly.

Also when one looks at what our export policy is with the embargoes that we have on 40 percent of the world's population today, they are totally wrong and also have a great effect as far as the prices we see in agriculture.

So while I will match my record with anyone as far as being fiscally responsible here, I think this is ill conceived, will do a great amount of damage, and I would certainly hope that the House would reject it.

Mr. ROYCE. Mr. Chairman, will the gentleman yield?

Mr. LATHAM. I yield to the gentleman from California.

Mr. ROYCE. Mr. Chairman, the point I want to make to the House and the point I would like to make to the gentleman is that the actual economic loss from the weather-related disasters that the gentleman has cited was $1.5 billion. Congress responded to this by adding $4.2 billion in emergency disaster relief. This is the impulse that I am trying to check with this amendment, to cut 1 percent, because I think this has been the response; and it has been overly generous in terms of what it has done with the taxpayers' funds.

□ 1715

Mr. LATHAM. Mr. Chairman, reclaiming my time, I agree with the gentleman that the problem was at that time that not all of the losses in the agriculture sector were known. If we talk to the Members from North Carolina, from the South who were dramatically affected, there are additional costs, and I think there was $210 million in the supplemental to address those issues that were not addressed previously.

Again, I agree with the gentleman that we have to make sure that we keep a handle on spending, but certainly there was a real emergency and there continues to be because a lot of needs were not addressed previously.

So I appreciate the gentleman's comments.

Mr. BOYD. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I also want to stand in opposition to the gentleman from California's amendment. I would agree with the gentleman that ad hoc disaster assistance payments on an annual or even sometimes more than an annual basis is not the way to run a good railroad here. I think the reason we have had to do that is because we have had a failed national agricultural policy called Freedom to Farm.

However, the gentleman's amendment does not deal with that problem; what his amendment does is go after

such programs as Federal food safety programs, the APHIS programs which control the pests and diseases which we have all talked about here in the last month or two, such things as plum pox and citrus canker and glassy wing sharpshooter, and all of those sorts of invasive pests that come from other countries which the APHIS has the responsibility of keeping out of this country.

The regulation of safety and drugs and medical devices by the FDA would be cut by this gentleman's amendment; nutrition programs for children and the elderly; housing, water and sewer, and economic development programs available in rural and small town America; conservation programs of vital importance; those are the programs that the amendment cuts.

So I would implore the gentleman from California, Mr. Chairman. If he would like to work with us on improving the national agricultural policy of this Nation, I would very much like to do that, but I do not believe that this amendment is the right way to go, and I urge its defeat.

Mr. SMITH of Michigan. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, the gentleman from California is rightly concerned about expenditures growing. I have mixed emotions on how to cut Federal spending.

In this case, if I could call on the gentleman from California, I would inquire, does he have an idea of the millions of dollars that this is going to cut from some important programs. The answer is roughly $145 million. $145 million that is going to come out of the Food and Drug Administration, that is going to come from food safety programs, that is going to come out of reductions to the farm service agencies that already are having difficulty serving farmers like they should. All the regulations that we have developed in this country are now overwhelming those county offices. So I am particularly concerned about the ability of farmers to receive help in keeping up with all of the rules and the regulations. This amendment would cut other farmer assistance programs.

Mr. Chairman, we are faced with a serious situation where other countries of the world are helping and subsidizing their farmers 5 times as much as we are; for example, in Europe. So how, when they subsidize their farmers to that level, can we cut spending, even by the one percent suggested.

We are going to have to make a decision. Do we want to keep agricultural production and the agriculture industry in this country alive and well, or are we going to let that industry fade. I say that we better think very carefully, not just this Congress, but the American people better think very carefully about whether we want to produce our own food and fiber in this country; whether we want to know that it is produced in a safe way; whether we want the freshness and reliable supply.

In this case, I speak very strongly against the amendment. We do need to increase the efficiency of U.S. Department of Agriculture operations, however it is a disservice to farmers to take $145 million out of the discretionary spending of the agriculture budget.

The CHAIRMAN. The question is on the amendment offered by the gentleman from California (Mr. ROYCE).

The question was taken; and the Chairman announced that the noes appeared to have it.

Mr. ROYCE. Mr. Chairman, I demand a recorded vote.

The CHAIRMAN. Pursuant to House Resolution 538, further proceedings on the amendment offered by the gentleman from California (Mr. ROYCE) will be postponed.

AMENDMENT NO. 36 OFFERED BY MR. CROWLEY

Mr. CROWLEY. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 36 offered by Mr. CROWLEY:

Insert before the short title the following title:

**TITLE IX—ADDITIONAL GENERAL PROVISIONS**

SEC. 901. None of the amounts made available in this Act for the Food and Drug Administration may be expended to enforce or otherwise carry out section 801(d)(1) of the Federal Food, Drug, and Cosmetic Act.

Mr. SKEEN. Mr. Chairman, I reserve a point of order.

The CHAIRMAN. The gentleman from New Mexico (Mr. SKEEN) reserves a point of order.

The Chair recognizes the gentleman from New York (Mr. CROWLEY).

Mr. CROWLEY. Mr. Chairman, earlier this year, working with the House Committee on Government Reform's minority office and the gentleman from California (Mr. WAXMAN), the gentlewoman from New York (Mrs. LOWEY) and myself conducted a study of the cost that seniors in our congressional districts pay for their prescription drugs versus the cost paid by their counterparts in Canada and Mexico for the exact same drugs. Both the gentlewoman from New York (Mrs. LOWEY) and I were startled by the results, to say the least.

We found that seniors in our districts in New York pay, on average, 91 percent more than seniors in Canada and 89 percent more than seniors in Mexico for the exact same drugs; twice as much for the exact same drugs, same dosage, same in every way, expect price. We did not study arcane drugs not used in the real world to skew our data, but rather the 5 most popular prescription drugs sold to seniors in the U.S. today: Zocor, Prilosec, Procardia, Zoloft, and Norvasc.

Let me put it in perspective. I have a constituent in Long Island City, New York who has to purchase 100 capsules of Prilosec every 3 months for his wife. He pays almost $400 for these drugs. I have a letter from the gentleman who writes, "Isn't it an outrage for us to pay this price for medication my wife will have to take on a regular basis."

Well, my answer to that gentleman is yes, it is an outrage, especially in light of the fact that this same drug that costs $400 in Queens, New York would have cost him $107 in Mexico and $184 in Canada.

Similar results were borne out by a number of other studies conducted throughout the United States, studies which mirrored the results that the gentlewoman from New York (Mrs. LOWEY) and I saw in our respective districts. But if my constituent or any American went to Mexico or Canada to buy this drug and tried to bring them back over the border into the United States, he or she would be committing a Federal crime and could theoretically be punished for that crime.

The only thing criminal I see are these extremely high prices that they are forced to pay for drugs in the United States. Mr. Chairman, $400 for Prilosec, a drug that was researched, patented and manufactured here in the United States. It begs the question, Mr. Chairman: why is Prilosec cheaper in Canada and Mexico than here in the United States where it was made and developed in the first place? It is because in the United States the major drug manufacturers practice price discrimination whereby they charge those least able to pay, such as seniors on a fixed income, more for their medications than they charge others such as HMOs and large hospitals, that enjoy sweetheart deals with the drug manufacturers.

Price discrimination is illegal in Canada and in Mexico. That is why I am offering this amendment today, to highlight the practice of price discrimination by the pharmaceutical industry that is being used against millions of American seniors who need prescription drug medication. More simply put, Mr. Chairman, Americans are being gouged by the American pharmaceutical industry.

I go about trying to stop this practice of price discrimination by prohibiting funding to enforce Section 801(d)(1) of the Federal Food, Drug and Cosmetic Act. Currently, this section of Federal law restricts the rights of an individual to cross across international borders to purchase one's prescription drugs. This amendment will not only allow border residents to travel, but also force this Congress to confront and stop the practice of price discrimination in the pharmaceutical industry.

Mr. Chairman, I hear from my constituents all the time about the high cost paid by them for medications. That further reinforces my determination for this Congress to pass legislation mandating the inclusion of a prescription drug benefit under the Medicare program. Unfortunately, the seniors of America did not get that before

the recess, despite all of the rhetoric from the other side of the aisle.

So I offer this amendment as a first step towards the assistance of America's seniors. Prescription drug medications are not a luxury, they are a necessity. Sometimes we forget that here as we enjoy our generous taxpayer-subsidized, top-of-the-line health insurance.

Let me make clear what my amendment will and will not do so as not to confuse the debate. It will decriminalize seniors who must travel south of the border to purchase their prescription drugs. It will highlight the fact that seniors in America are the continued victims of price discrimination which this GOP-controlled Congress continues to ignore. It will continue to prohibit the importation in the United States of non FDA-approved drugs that could be dangerous.

This amendment does not weaken inspection standards for the importation of foreign-made drugs into the U.S. At no time does this amendment change the existing Federal regulations regarding the importation of foreign manufactured drugs into the U.S. This amendment will not weaken the ability of our government to inspect and seize illegal narcotics being brought into the United States.

The CHAIRMAN. Does the gentleman from New Mexico (Mr. SKEEN) insist on his point of order?

Mr. SKEEN. Mr. Chairman, I withdraw my reservation of a point of order.

The CHAIRMAN. The gentleman's reservation of a point of order is withdrawn.

Mr. SKEEN. Mr. Chairman, I rise in opposition to the gentleman's amendment.

Although it is well-intentioned, this amendment will go far beyond its stated purpose. The amendment would eliminate the ability of the Food and Drug Administration to trace a drug back to the original manufacturer. It is in opposition to the intention of Congress as expressed in the Prescription Drug Marketing Act of 1987 and, most significantly, this amendment may harm the very people the gentleman intends to help.

The amendment assumes that all drugs with the same name are, in fact, the same. Let me assure my colleagues that this is not the case when dealing with imported drugs. There are many ways in which a drug may differ from one that one would pick up at one's pharmacy. Drugs that look legitimate may be counterfeit, sub-potent or contaminated. There is a great profit, and great potential harm, in counterfeit drugs. This amendment would severely hamper the efforts of the Food and Drug Administration inspectors to stop counterfeit drugs.

The amendment further assumes that drug regulation in other countries brings the same measure of safety that drug regulation in the United States brings. This is a false assumption. There is a reason that U.S. drug approval is considered the "gold standard." The FDA scientists inspect all manufacturing facilities and set standards for storage and handling of the drug. There is great variability in the quality controls on manufacturing throughout the world. It seems absurd that without any FDA inspection, consumers would take complex drugs made in countries in which they would not drink the water.

The amendment takes a shotgun approach to a very specific economic problem. It is not a solution that gives priority to people's health. In fact, it puts their health at risk. Is it fair for certain members of society, because of economic concerns, to have a lesser assurance of drug safety? Taking risks with drugs is not the way to solve an economic problem.

I would encourage my colleagues to address those concerns in other prescription drug discussions, and not in this bill.

□ 1730

When we take medication and are confident in its safe and effective use, we have the regulatory system that we have created to thank. I urge Members to keep the system strong and fair for all Americans by voting no on this amendment.

Mr. COBURN. I move to strike the last word, Mr. Chairman.

Mr. Chairman, I rise in strong support for this amendment. I believe the gentleman from New York has hit on an issue that we talked about during the prescription drug debate.

I want to carry it a little further. The drug that he utilized, one of those, is Prilosec. There are three drugs on the market to compete with that in the United States. They all do essentially the same thing. Prilosec is about to go off patent. It is a $5.9 billion per year drug, per year.

Of the two drugs that have come to market to compete with it, they are priced exactly the same. To me, that smells like no competition, it smells like a wink and a nod. Why, in a market that is a $6 billion market, would there not be any price competition for a drug that does essentially the same thing?

I believe there may be some legitimate concerns about minimal packaging or safety, but the thing we need to remember is that this amendment is directed towards drugs made in this country, shipped to Canada and then come back, or into Mexico and then come back. So these are drugs that have already been licensed, they have been manufactured in an FDA facility, and in fact they should be, under NAFTA, readily coming across our border without any inhibition whatever if there is a bona fide prescription for that drug in this country.

We have a crisis in prescription drugs, but it is not a crisis in Medicare, it is a crisis in price. The reason we have the crisis in price is there is not adequate competition in the pharmaceutical industry.

I would direct the Members of this body to go to the FTC's website where they have identified four manufacturers over the last year raising the cost for prescription drugs close to $1 billion on four separate drugs because they colluded with people to not bring other drugs to market. They were actually paying their competitors not to bring drugs to market.

So I believe the gentleman from New York has a wonderful idea. I believe it is an appropriate idea. I think the safety concerns are a red herring. There are not the safety concerns because they are actually manufactured in this country. The FDA will not have any limitations on it.

As far as traceability, we are going to be able to trace these drugs like any other drug. They are not going to be allowed to be sold in Canada with a prescription unless we can trace it and keep a record, just as in this country. There will be completely the same types of regulations in terms of pharmaceuticals.

As a practicing physician that sees that people cannot afford their medicines today, we have to do something. The first thing we need to do is to start competition. If the Justice Department is not going to investigate the pharmaceutical industry, we should be doing this and passing this amendment.

Mr. OBEY. Mr. Chairman, I move to strike the last word.

Mr. Chairman, I will certainly support this amendment, but I must say that I will be amused to see those persons in this Chamber who will today vote for this amendment who just a short time ago voted to prevent us from being able to directly attack the problem of pricing for prescription drugs.

The fact is if this amendment passes what we will be saying is that, for instance, American senior citizens will not have to worry about whether they are being penalized when they go to Canada to buy drugs that are cheaper than they would be if they bought the very same brand name product in the United States.

To me, if this House wants to do something really significant, it would pass the Allen bill, which would simply require that in addition to providing a prescription drug benefit for all seniors under Medicare, that it would also guarantee that Medicare would be able to assure that drug prices charged to Medicare and to senior citizens under Medicare would have to be at the same lower price that drug companies make available their products to their most favored volume customers. That is what we really ought to do.

This amendment goes as far as it can go, but I would say that I do not think seniors should be fooled that they have gotten much help from folks who vote for this amendment who last week voted against our being able to expand Medicare coverage for every single

American, and, for that matter, to attack the price issue at the same time.

Senior citizens should not have to leave America in order to be treated like Americans. They ought to be able to get the right treatment here at home, and they would if this Congress had guts enough to take on the pharmaceutical industry. It does not, so I guess this is the best we are able to do under the circumstances.

That is not the fault of the gentleman who offers the amendment, but it is the fault of every other Member of this House who chose last week to make a decision that prevented us from providing real direct help to seniors on the issue of prescription drug price. I do not think that many seniors are going to be fooled by people who will cast that vote last week and then run to embrace this amendment this week. I think they will recognize tokenism when they see it.

Mrs. EMERSON. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in strong support of this amendment, as well. It is really critical that we do something about the discrepancy in prices of prescription drugs in Mexico, Canada, and even in Europe as far as the prices that our senior citizens in rural Missouri are getting. We do not live close to any of the borders, just like the gentleman from New York (Mr. CROWLEY) said.

However, I have got more constituents than I can mention, and one comes to mind whose son has a very severe case of epilepsy. The only way she can afford the epilepsy medicine is to go to Canada to get it. It is a big problem because she is always scared of being punished by this government for having to do that, but she wants her son to be well, and she otherwise could not afford the drugs. So this is very important.

This is very similar to the legislation that the gentleman from Arkansas (Mr. BERRY), the gentleman from Vermont (Mr. SANDERS) and I introduced, the International Prescription Drug Parity Act, which would allow wholesalers, distributors, and pharmacists to reimport drugs back into the United States, subject to FDA safety regulations. It is very important because we must deal with the issue of price before we deal with the issue of prescription drug coverage. I think most people would agree with that.

I do, however, want to ask the gentleman from New York (Mr. CROWLEY) a couple of things, particularly with regard to the safety factor, because I cannot tell from the way his amendment is written if it is as tough with regard to safety as our legislation is.

Would the gentleman tell me about how the FDA would oversee or regulate the drugs that are reimported back into the United States, if he would?

Mr. CROWLEY. Mr. Chairman, will the gentlewoman yield?

Mrs. EMERSON. I yield to the gentleman from New York.

Mr. CROWLEY. Mr. Chairman, I thank the gentlewoman for yielding. This will not weaken the inspection standards for the importation of foreign-made drugs into the United States.

I understand the Committee on Commerce held hearings last month in June to address the concerns that the FDA had only inspected 25 percent of foreign drug manufacturers who brought medications by import into the United States.

My amendment will not weaken the FDA here at all, or even hamper their inspection services with regard to the foreign-made drugs being imported into the U.S. My amendment deals only with the reimportation, reimportation of American-made FDA-approved drugs back into the United States.

In fact, by taking the FDA out of the business of harassing seniors, the FDA might be able to free up additional resources to make sure what is being firsthand imported into America from abroad is safe for human consumption.

Additionally, by striking funding from the statute, we will not be opening up the borders for a free flow of non-FDA imported drugs to be brought into the United States. Section 21 of the U.S. Code states that it is illegal to bring non-FDA-approved drugs into the U.S.

My amendment does not change that law in any way. In fact, I understand why Section 801(d)1 was added to the law. Unfortunately, as of late, its interpretation has not been used to protect American consumers, but rather, large drug manufacturers, instead.

Mrs. EMERSON. I commend the gentleman and appreciate very much his explanation of the whole issue of safety, because we have got to get a handle on this issue once and for all, and I cannot bear to tell my constituents one more time that if they go to Canada or if they go to Mexico, they can get this drug for one-third to two-thirds less than they would pay here.

It is not fair for those people, and it is not fair that our American consumers are subsidizing the rest of the world. I thank the gentleman and I urge, again, strong support for this amendment.

Mr. GUTKNECHT. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in support of this amendment. Last week the House did take some action late one night, I think Thursday night or 1½ weeks ago, that will begin to open this door. But this issue needs to be talked about a lot by this Congress.

I have a chart here which sort of demonstrates the problem. Many of us in the last week have had town hall meetings back in our districts or have met with senior citizens. We had one in my district, and I learned or relearned what we have been hearing before.

That is one example of one of my constituents who was traveling in Europe. Her traveling partner needed to get a prescription refilled. The prescription here in the United States is $120. The price of having that prescription filled in Europe for the same drug made in the same plant by the same company under the same FDA approval was $32.

This person has to take that drug; has to have it refilled every month, so the savings of about $90 a month times 12 works out to about $1,000 a year. The differences between what Americans pay and what the rest of the world pays for the same drugs is just outrageous.

Let us take a drug like Coumadin. My 82-year-old father takes Coumadin. It is a blood thinner, a very commonly prescribed drug. Here in the United States, the average price is about $30.25 for a 30-day supply. That same drug made in the same plant by the same company under the same FDA approval in Europe sells for only $2.85.

Mr. Speaker, we have a serious problem right now. Part of the problem is that Americans are paying a disproportionate share of the cost for research and ultimately I think a disproportionate share of the profits for the large pharmaceutical companies.

It would be easy for us as a Congress to sit here and blame the pharmaceutical companies and say, shame on them. But the truth of the matter is that it is shame on us. It is shame on us for allowing this to continue. It is shame on our own FDA because, in view of these huge differentials, we would think that the FDA would be doing something to help senior citizens and other American consumers.

The fact of the matter is that our own FDA is making matters worse. These are excerpts from an actual letter sent to a senior citizen, a very threatening letter that in effect says if they continue to do this, we believe they may be in violation of Federal law and we may have to come after them.

If someone is an 82-year-old senior citizen taking Coumadin or Synthroid or some of these other commonly-prescribed drugs and trying to save some money by getting them either through Mexico, Canada, or Europe, the last thing our Federal Government ought to do is threaten us, especially when those drugs are absolutely legal, they are FDA-approved, and the problem is the FDA has put the burden of proof on the consumer.

Finally, I support this legislation or this amendment here today, as well, because in many respects our Justice Department has failed, as well. It has failed in its oversight responsibilities to make certain that there is adequate competition and that there is not collusion between the large pharmaceutical companies.

It is not just shame on the pharmaceutical companies, it is shame on us, it is shame on the FDA, it is shame on the Justice Department. It is time that this Congress sends a very clear message that the game is over. We are not going to continue to subsidize the

starving Swiss, we are not going to continue to subsidize the rest of the world in terms of prescription drugs, especially when our own seniors have to make very difficult decisions every day in terms of whether or not they are going to get the prescriptions that they need or the food they should have.

That is simply wrong, and we should not allow it to continue. I hope we can pass this amendment tonight to send one more clear message to the folks at FDA, the folks at Justice, and the people around the world that the game is over.

Mrs. MALONEY of New York. Mr. Chairman, I move to strike the requisite number of words.

(Mrs. MALONEY of New York asked and was given permission to revise and extend her remarks.)

Mrs. MALONEY of New York. Mr. Chairman, I rise in strong support of the Crowley amendment.

□ 1745

Mr. Chairman, I deeply support the Crowley amendment, and I am glad to see that many of our colleagues on the other side of the aisle also believe that we need to overturn the current FDA prohibition on U.S. citizens traveling to other countries to purchase prescription drugs manufactured in our country solely for individual use.

This important amendment is to decriminalize seniors who travel to Canada and Mexico for cheaper prescription drugs. I might also add that I strongly support the bill put forward by the gentleman from Maine (Mr. ALLEN) which would make seniors the same preferred customers as HMOs and also the President's plan to expand Medicare to cover prescription drugs.

These are all important measures, but this is an important amendment that addresses the issue of price discrimination being practiced by the drug manufacturers today.

In my home State of New York, breast cancer medications can cost over $100 per prescription while they are available in Canada and Mexico to their residents for a tenth of that price. Many women in our home State and, indeed, across the country are forced to dilute their prescriptions that fight breast cancer, to cut their pills in half because they cannot afford their prescription drugs in order to get by financially. And many in my home State get on the bus every weekend to go to Canada to purchase American manufactured drugs because it is cheaper than in their own country.

Mr. Chairman, this is just plain wrong. No doctor recommends it. No person deserves this type of treatment. They should be charged, at the very least, the same that the foreign governments are charging their citizens.

Recently, I conducted a study on price discrimination on consumers in the district that I represent which is Manhattan, East and West side, and Astoria, Queens, and compared the prices that were paid by consumers in other Nations, Mexico and Canada. I must add I was assisted in this by the gentleman from California (Mr. WAXMAN) and the staff of the Committee on Government Reform, and what we found was absolutely shocking.

We asked them to look at a total of eight drugs and compared the average costs in my district with the average costs paid by consumers in Mexico and Canada, and the drugs included in the study were some of the most widely prescribed drugs today. To take one example, the breast cancer drug Tamoxifen. Tamoxifen is sold under the brand name of Nolvadex, and it is the most frequently prescribed breast cancer drug in this Nation.

It is used by thousands of women across my State, across this Nation, across the country to treat early and advanced breast cancer. In fact, in 1998, the total sales of Tamoxifen were over $520 million. Yet women in this country who need Tamoxifen must pay 10 times what seniors in Canada pay.

Our studies showed that a 1-month supply of Tamoxifen costs only $9 in Canada, yet it costs over $109 in my district. This means that over the course of a year, women in my district will pay roughly 1,200 more than a woman in Canada. That is a price differential of over 10,000 percent.

This is a very important lifesaving drug that thousands of women need to survive. It is simply outrageous that drug companies are taking advantage of men and women suffering from this horrible disease.

But Tamoxifen is not the only drug that costs more in New York than in Canada and probably every other State in our country. In fact, all eight of the drugs which we studied costs at least 40 percent more in my district than they do abroad. The average price differential with Canada was 112 percent; with Mexico, it was 108 percent.

Prilosec, which is the top selling drug in the Nation, it is used for heartburn and ulcers, in the last 10 years, according to the manufacturer, more than 120 million prescriptions have been written for this drug, yet seniors and other consumers in my district they have to pay over $800 more each year for Prilosec than the consumers in Canada. Over $1,000 dollars more than seniors in Mexico.

Zocor, which is one of the most common cholesterol-reducing drugs in this country with over 15 million prescriptions in 1998, costs almost three times as much in my district as it does in Canada, and that is a difference of over $70 per month.

I would urge all of my colleagues on both sides of the aisle to support the Crowley amendment, it is long overdue, and also the Allen amendment, the President's plan and others to bring drug fairness into this country.

Mr. SKEEN. Mr. Chairman, I ask unanimous consent that all debate on this amendment and all amendments thereto close in 20 minutes.

The CHAIRMAN. Is there objection to the request of the gentleman from New Mexico?

There was no objection.

The CHAIRMAN. The Chair will divide the time evenly between the proponent of the amendment and the opponent of the amendment. The gentleman from New York (Mr. CROWLEY) and the gentleman from New Mexico (Mr. SKEEN) each will control 10 minutes.

Mr. CROWLEY. Mr. Chairman, I yield 3½ minutes to the gentleman from Texas (Mr. DOGGETT).

Mr. DOGGETT. Mr. Chairman, I want to thank the gentleman from New York (Mr. CROWLEY) for his leadership on this important issue. We have an incredible situation, where those who are least able to pay for the important prescription medications that they require, our uninsured seniors and uninsured families, in fact, of all ages across the country, are asked to pay the highest prices for their prescription medications of any place in the entire world.

This burden has been imposed on those least able to pay and the gentleman from New York (Mr. CROWLEY) has come forward with a constructive proposal that will at least benefit those, who are near the Canadian and Mexican borders, since Canada does not impose price discrimination.

I think it is, however, very important to recognize that while Canada does not encourage price discrimination, this House has encouraged price discrimination. I have on two separate occasions with my colleague, the gentlewoman from Florida (Mrs. THURMAN) advanced before the Committee on Ways and Means proposals that would permit seniors, not just to get on a bus to Canada or Mexico, but would allow them in their own neighborhood pharmacy to get prescription medications, as the gentleman from Maine (Mr. ALLEN) has proposed, at the price that the pharmaceutical companies make those available to their most favored customers.

Unfortunately, every single Republican on the Committee on Ways and Means has joined with the pharmaceutical industry in saying no, in saying that it is right to continue charging our seniors, who are uninsured, more than anyone else in the world. So I applaud the effort of the gentleman from New York (Mr. CROWLEY), but by blocking our proposal in committee, by blocking the gentleman from Maine (Mr. ALLEN) when he offered the proposal last week, as Republicans presented not a Medicare prescription drug plan, but a political ploy here on the eve of the election, seniors have been denied the relief that they so desperately need. And this House has been denied the opportunity to extend to all Americans what the gentleman from New York (Mr. CROWLEY) would tonight extend at least to those near the Canadian and Mexican borders to gain access to bring more reasonably priced medications.

Last week, I joined with some seniors in central Texas to explore this issue of at all places, the Austin Humane Society. I learned through a study that we conducted that in this country if you have four legs and a tail and need a particular prescription drug, if you can say meow or woof or arf, you get a much better deal on prescriptions than if you are simply a senior, who is in serious need of medication.

I know that the gentleman from Maine (Mr. ALLEN) and others have made similar findings in other parts of the country. We demonstrated that on one very important arthritis drug, Lodine, for example, that the manufacturer is charging 188 percent more to those who would use the exact same quality and quantity for animals, for a dog, a cat or a horse or a cow, than it does for a senior, who lacks insurance.

I think that such price discrimination is wrong, the kind of discrimination that says it is okay for the same quality and quantity and type of drugs for manufacturers price to charge the wholesaler 188 percent more than for an individual, a senior, who is in need of that drug. That is the kind of price discrimination that groups masquerading under names like Citizens for Better Medicare, which really is a front for the pharmaceutical industry, are imposing on us.

Tonight the gentleman from New York (Mr. CROWLEY) proposes that we do just a little bit about it, and I encourage the House to adopt his approach, but hope that eventually we can move on to a broader proposal like that advanced by the gentleman from Maine (Mr. ALLEN).

Mr. SKEEN. Mr. Chairman, I yield myself the balance of the time.

Mr. Chairman, I certainly understand the concerns of my colleague from New York (Mr. CROWLEY), and I do not feel that a restriction on a regulatory agency is the way to achieve prescription drug price reform.

Mr. Chairman, I yield back the balance of my time.

Mr. CROWLEY. Mr. Chairman, I yield 2½ minutes to the gentleman from Georgia (Mr. KINGSTON).

Mr. KINGSTON. Mr. Chairman, I thank the gentleman from New York (Mr. CROWLEY) for yielding me the time.

Mr. Chairman, I wanted to speak in favor of the amendment, and I do so with the greatest respect, of course, to the committee upon which I serve. But if we look at the seniors who are having to go across the border to get prescription drugs and other people who need it, they are not doing this because it is convenient, they are not doing it because they want to, they are not doing it because they want to support a Canadian pharmacy. They are doing it because they have to economically.

My dad is from Buffalo, New York, and I went to school in Michigan, and I know on those border States there is a lot of economic overlap and social overlap and everything else, and so for them to go to Canada to get cheaper drugs is not that unusual. But then imagine being 82 years old and getting a letter like this that says, however, future shipments of these or similar drugs may be refused admissions; that is very disturbing if we have to take something for high cholesterol or something for a heart condition. What am I doing?

These people are World War II veterans. They do not want to go around breaking the law, and that is what the implication is from FDA once they get it.

Mr. Chairman, look at these price differences. I think we cannot expect people who can save as much as 50 percent on a drug not to take advantage of it and to go overseas. But the second question about this is why are the drugs so less expensive in Canada than they are here, and I think that is where it becomes a universal quest for States that are not on the border. I mean, we need to know how come we can get Prozac for $18.50 and over here, it is $36. For Claritin, $44 versus $8.75. Prilosec, $109 versus $39.25.

We owe it to our constituents. Even if they are in Iowa, in the middle of the country geographically, if we are in a central State, domestically, in the United States of America, we would still need to know and we need to be able to tell our constituents why these drug prices are so different.

That is why I am supporting this amendment. I think, number one, we have to give people on the border States an opportunity; number two, we have to explore what are these differences, and this will help promote that debate.

Mr. CROWLEY. Mr. Chairman, I yield 1 minute to the gentleman from Minnesota (Mr. MINGE).

Mr. MINGE. Mr. Chairman, the amendment that is before us this afternoon brings in the sharp relief the anomaly that exists with respect to the cost of prescription drugs in North America. It simply is unconscionable that if we travel to Mexico or to Canada we can buy prescription drugs for dramatically less than we can here within the United States.

It is unacceptable that seniors, who are the most vulnerable, who have the least in terms of resources to pay for these prescription drugs are the ones that are victimized to the greatest extent by this situation.

It is also an irony that is not lost on the seniors in this country that their pets can access these same prescription drugs for dramatically less than they can.

□ 1800

Mr. Chairman, I would like to associate myself with the comments of my colleagues from both sides of the aisle that have spoken in favor of the Crowley amendment, and I urge that all of our colleagues join in supporting this amendment to the appropriations bill.

Mr. CROWLEY. Mr. Chairman, how much time is remaining?

The CHAIRMAN. The gentleman from New York (Mr. CROWLEY) has 3 minutes remaining.

Mr. CROWLEY. Mr. Chairman, I yield myself such time as I may consume.

Mr. Chairman, as the sponsor of this amendment, let me say that I am somewhat surprised at the support that this amendment has received from the other side of the aisle. I am astounded, quite frankly. I appreciate the support of many of the individuals who have spoken to me, some of whom are friends of mine from the other side of the aisle. I appreciate their comments on the floor. In no way do I believe that they are not being sincere at this point in time.

But just under 2 weeks ago, we stood here on this floor; and we passed a bill that I call to the floor a sham; and I continue to call that bill a sham.

The amendment that my colleagues have before them today is really of very little consequence, and I am the sponsor of this amendment. It basically takes away the authority of the FDA to prosecute any individual who reimports drugs that were made in this country. But it really is an attempt to shine a light on price discrimination in the United States.

But what this amendment does show, Mr. Chairman, in my opinion, is the hypocrisy of this House at times. In 1 week we can pass a sham of a bill, and a week and a half later, come back and pass an amendment that in and of itself will not go far enough to help most of the seniors in this country who are not insured, seniors who struggle on a weekly basis to pay rent, to pay their bills.

My constituent from Jackson Heights, Ann Greenbaum, pays $300 for a particular drug that her son needs, the exact same drug, and pays $15 under his plan. I will not say how old Mrs. Greenbaum is. She is considerably older than her son. These are the individuals we are trying to help.

My amendment, Mr. Chairman, will not help directly Ms. Greenbaum. What it does do, though, is highlight the hypocrisy of this House, how we can pass a bill that will not help the Mrs. Greenbaums of the world, will help some individuals, but certainly will not help enough.

Mr. Chairman, I yield back the balance of my time.

The CHAIRMAN. The question is on the amendment offered by the gentleman from New York (Mr. CROWLEY).

The question was taken; and the Chairman announced that the ayes appeared to have it.

Mrs. EMERSON. Mr. Chairman, I demand a recorded vote.

The CHAIRMAN. Pursuant to House Resolution 538, further proceedings on the amendment offered by the gentleman from New York (Mr. CROWLEY) will be postponed.

AMENDMENT NO. 52 OFFERED BY MR. ROYCE

Mr. ROYCE. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 52 offered by Mr. ROYCE:
Strike section 741.

Mr. SKEEN. Mr. Chairman, I reserve a point of order against the amendment.

The CHAIRMAN. The gentleman from New Mexico (Mr. SKEEN) reserves a point of order.

Mr. ROYCE. Mr. Chairman, the rationale behind this amendment is simple. Hard-working taxpayers should not have to subsidize the advertising costs of America's private corporations. In my view, that is what the Market Access Program does.

Since 1986, the Federal Government has extracted $2 billion from the taxpaying public and has spent it for advertising on the part of larger corporations and cooperatives in subsidies to basically underwrite their marketing programs in foreign countries.

I think the American people would agree that their money could be better spent on deficit reduction or education or the environment or tax cuts rather than these advertising budgets.

Originally, this bill contained a provision quietly inserted that would have allowed American tax dollars to be spent promoting the sale of luxury mink products in foreign countries. However, once we discovered their plan to expand eligibility in the MAP program, proponents reversed the course and agreed to strike the provision in the bill.

But an important question remains, if it is wrong to spend hard-earned American tax dollars on the promotion of mink products, why is it acceptable to spend those same tax dollars overseas to promote other products?

Last April, the GAO released an independent report, a report that was requested by the gentleman from Ohio (Mr. CHABOT) and myself and Senator SCHUMER. That report questioned the economic benefits of the foreign agricultural service study, which had advanced the arguments to begin with in the favor of this bill.

Mr. LATHAM. Mr. Chairman, will the gentleman from California yield for a parliamentary inquiry?

Mr. ROYCE. I yield to the gentleman from Iowa.

Mr. LATHAM. Mr. Chairman, what amendment are we debating?

Mr. ROYCE. Amendment number 52 to eliminate the Market Access Program.

The CHAIRMAN. The gentleman from California is correct.

Mr. ROYCE. Mr. Chairman, reclaiming my time, I would just like to share that in the report the GAO determined that the Foreign Agricultural Service overstated the program's economic input, used a faulty methodology, which is inconsistent with Office of Management and Budget cost benefit guidelines.

The GAO also determined that the evidence contained within the relevant studies which estimate MAP's impact on specific markets is inconclusive. In fact, for every targeted market in which MAP funds demonstrated a positive effect, the studies found other target markets in which there was no discernible effect at all.

So various studies commissioned by Congress, commissioned by the Trade Promotion Coordinating Committee have determined the economic benefits of the MAP program to be overstated, to be inconclusive, and to be speculative.

But even if one does believe the flawed studies used by the proponents, one has all the more reasons to support the amendment. Because if MAP works, then corporations and trade associations ought to be spending their own money on their advertising budgets. The taxpayers should not be spending it.

Finally, MAP proponents have argued that due to recent reforms, big corporations no longer receive MAP funds. It is true that, in order to correct some of the more egregious abuses of the Market Access Program of which we pointed out in the past, reforms were enacted that limit companies to 5 years of assistance in a particular country. After this time, companies were to be graduated from that country's market.

While in fact some of the corporations were graduated in 1998, the graduation requirements were waived for cooperatives. What was the result of that waiver? The result was that large corporations received the subsidies.

We simply do not need this wasteful program. Let us be honest. Most American businesses do not benefit and do not try to take advantage of government handouts like MAP. In the case of MAP, as in most corporate welfare programs, beneficiaries consist primarily of politically well-connected corporations and trade associations.

Most, if not all of these organizations, would advertise their products overseas even without MAP funds, and they probably would work much harder to ensure that the money is well spent.

Mr. Chairman, Congress should end the practice of wasting tax dollars on special interest spending programs that unfairly take money from hard-working families to help profitable private companies increase their bottom line.

MAP is a massive corporate welfare program in my opinion, and we should eliminate it. I urge the support of the amendment.

POINT OF ORDER

The CHAIRMAN. Does the gentleman from New Mexico (Mr. SKEEN) insist on his point of order?

Mr. SKEEN. Yes, Mr. Chairman.

The CHAIRMAN. The Chair finds that the amendment offered by the gentleman from California (Mr. ROYCE) proposes to strike from the bill a section already stricken on a point of order and, therefore, the amendment is not in order.

PARLIAMENTARY INQUIRY

Mr. ROYCE. Mr. Chairman, my question to the parliamentarian was whether offering amendment No. 51 or No. 52 would be in order. I believe he said 52. If I understand correctly, then the answer would have been No. 51.

It is amendment No. 51 that could be offered.

The CHAIRMAN. The gentleman from California (Mr. ROYCE) has the apologies of the Chair. In fact, the gentleman would be correct in offering amendment No. 51.

Mr. ROYCE. Mr. Chairman, that being the case, that concludes my opening arguments on amendment No. 51.

AMENDMENT NO. 51 OFFERED BY MR. ROYCE

The CHAIRMAN. The Chair will entertain the offer of the gentleman from California (Mr. ROYCE).

Mr. ROYCE. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate amendment No. 51.

The text of the amendment is as follows:

Amendment No. 51 offered by Mr. ROYCE:
Page 96, after line 4, insert the following:

**TITLE IX—ADDITIONAL GENERAL PROVISIONS**

SEC. 901. None of the funds appropri ıted or otherwise made available by this Act may be used to award any new allocations under the market access program or to pay the salaries of personnel to award such allocations.

Mr. SKEEN. Mr. Chairman, I move to strike the last word.

Mr. Chairman, this is a near-annual amendment, so I will not speak at length.

For many small companies in the United States, this program is the only way they have of promoting their products in markets overseas. Small companies cannot afford sophisticated marketing campaigns or presence overseas. The Market Access Program helps them reach those markets, increase their sales, increase employment, and, ultimately, benefit the farmers and ranchers that produce the raw materials.

I would also add, Mr. Chairman, that our competitors in Europe are spending far more than the authorized $90 million a year that the Market Access Program provides.

Mr. Chairman, I oppose this amendment and urge my colleagues to vote "no."

Mr. BOYD. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in opposition to the gentleman's amendment also. I think, as the distinguished gentleman from New Mexico (Chairman SKEEN) has said, the Market Access Program is a program that comes under attack every year in this appropriations process. But yet the Market Access Program is designed to help small and independents producers, small businesses get into foreign markets.

This Congress basically has said to our agricultural producers that the savior for your future is foreign markets. But, yet, we are unwilling, we

make an attempt on an annual basis to eliminate a program which helps small businesses and agricultural producers get into those markets.

Mr. Chairman, I know the gentleman from California (Mr. ROYCE) quoted some report. I would like to read from a report that was done by Deloitte and Touche, who was hired by the National Association of State Departments of Agriculture to evaluate MAP. I quote, "MAP is a significant source of support for new companies and new products entering foreign markets. MAP support is also beneficial to small firms as they begin to export. Our cases suggest that, without MAP support, many small firms would not be capable of carrying out standard marketing programs in key foreign markets."

Mr. Chairman, I encourage the Members to defeat the amendment.

Mr. LATHAM. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in strong opposition to this amendment. The MAP program is something that works. It not only enables our products to be sold overseas and to be promoted over there, but we have to keep in mind that any dollar spent in the MAP program are matched by the commodity groups themselves. So if one is a pork producer, one puts one's dollars in the program. If one is a corn or soybean producer or beef producer or rice, whatever product it is, one has to match those funds.

It is extraordinarily important that we maintain the market access and to promote our products overseas and to show the world the quality products that we have in America and to find markets for our products overseas.

The MAP program in years past had some problems with it. It has been reformed. It is not putting any particular hamburger brand or something promoting those type of products overseas. These are commodities that are being promoted overseas. It is extraordinarily important that we maintain this program.

I would just like to say also, the gentleman on an earlier amendment talked about the assistance that is needed for agriculture and the payments and the emergencies and all of that. Well, this will go farther to help us avoid those types of problems in the future than probably any other program. At a time when especially in the Southeast Asian market where they are recovering, we need to be there promoting American agricultural products so that we can regain the share of market that was lost before when they went through their financial crisis.

So just in closing, Mr. Chairman, I would strongly urge Members to defeat this amendment. It is very important for American agriculture to maintain this very small assistance for our farmers.

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Ms. WOOLSEY. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I rise in strong opposition to the Royce amendment. The Market Access Program, or MAP, is a valuable program and it serves our Nation's agricultural growers and our producers well. MAP has been a tremendous asset in opening overseas markets and keeping U.S. agricultural exports competitive in the world market. They do not play on an even playing field without the help of MAP.

As many of my colleagues know, I am privileged to represent Sonoma and Marin Counties, one of our Nation's premier wine-making regions of the country; and the wine industry is vital to my area. But it is not just vital to the people I work for in my congressional district, it is also vital to the entire State of California. In fact, California produces more than 90 percent of the United States' wine exports.

While our wine speaks for itself, we still need help crossing the borders. The same is true with fruits and almonds and the many other products where the U.S. excels. We also face uneven trade barriers around the globe with these products, and we need assistance from USDA. This assistance is very important.

This is why I am a steadfast enthusiastic supporter of this program. I regret that the program has been a perennial target for budgetary cuts, but I am very pleased that Congress each time, time and again, has understood the worthiness of this program and has, in their wisdom, continued to fund the MAP program.

I urge my colleagues to continue its support for the Market Access Program and to vote against the Royce amendment.

Mr. SMITH of Michigan. Mr. Chairman, I move to strike the requisite number of words in opposition to the amendment.

Mr. Chairman, we face challenges in this country if we are to maintain a strong agricultural industry. The challenge right now is that other countries are doing better than we are helping their farmers. As much as this country works to operate this particular program of marketing help to get the word out of the quality of our products and the price of our products, our appropriations are flat and we are losing ground with other countries.

For example, I would call to the attention for the gentleman from California that the European Union spends $92 million more than we do. Twice as much! The Cairns Group, countries of Australia, Canada, New Zealand, Brazil and others spend $306 million more than we do. So imagine, not only are countries such as the E.U. spending more than the United States in their so-called MAP program, in their effort to enhance marketing and promote their farmers' products, they are subsidizing their farmers up to five times as much as we do.

So on the one hand they are subsidizing their farmers to reduce the price they must charge for their exports and additionally they spend more on promotion—Huge competition for our American farmers, and in effect right now with the disastrous situation for farmers and ranchers in this country, it will put many of our farmers out of business. Again, not only are those countries subsidizing heavily to reduce their costs, but also they are spending much more than we are, double what we are, for example in Europe, to market their particular products at this lower subsidized price.

We have to make a decision in this country whether we are going to keep a strong ag industry in the United States. I think we should! This amendment should be defeated.

The export decline of the past several years has been harsh for America's farmers and ranchers, as well as for policy makers trying to address their concerns. While our export programs will never be a substitute for strong global markets and good agricultural policy we must ensure that the programs we administer are effective and efficient.

Mr. WEINER. Mr. Chairman, I move to strike the requisite number of words.

Mr. Chairman, I do not claim to be from an agriculture rich district. In Brooklyn and Queens we do not grow all that much, or at least all that much that is addressed here in this bill, but I can tell my colleagues that I have been someone who has supported agriculture bills in this House because I recognize that there is a confluence of interest that exists. But just the same way frequently those of us who advocate for urban programs are called to task to defend some things in the bills that we support that often are troublesome, such is the case here for my friends who support agriculture spending.

Just so it is clear to those who are watching this debate, who are not as familiar with agriculture programs, like I am, this is essentially a program that pays for advertising for some of the biggest corporations in the United States. In the life of this program, to give some sense of context to this, McDonald's has received over $7 million. The Sunkist Corporation received nearly $7 million. Ernest and Julio Gallo received $5 million of taxpayer money to help, in essence, advertize their products overseas.

The argument that has been made a couple of times on this floor is, listen, we have to do it because there are those in other countries who are paying to subsidize their products and advertize them as well. Well, we are not in other countries. We do not represent the taxpayers in those countries, and we can argue the efficacy of doing that at another time. But the question we have to ask is, is this the wisest way for us to form coalitions behind agriculture programs and help family farmers that we have heard so much about on the floor this past couple of weeks.

Is the Pillsbury Corporation, the Wrangler Corporation, Burger King,

Campbell Soup, General Mills, Hershey Foods, are these companies that really need our help with their advertising budget?

This is an amendment, and I commend the gentleman from Ohio (Mr. CHABOT) and the gentleman from California (Mr. ROYCE) for offering it, this is an amendment that simply says let us have a strong agriculture policy. Let us have an agriculture policy that helps our farmers stay in business, that helps those of us in urban areas to continue to thrive because the agriculture sector is doing as well as possible. Let us try to help people from the bottom up.

This is a classic case of going into the corporate boardrooms and saying here is a bag of money because that is essentially what the MAP program is. If my colleagues think that Tyson Food needs some help, then the MAP program is good; if my colleagues think the Ocean Spray Cranberries Company needs some help, then the MAP program is probably one my colleagues would support.

In order to ensure that we are able to keep these coalitions together that help agriculture bills and help other bills pass, we have to weed out, no pun intended, some of the things that are truly weak in these programs, and this is such a case. I would urge my colleagues to support this reduction in the MAP program.

Mr. SKEEN. Mr. Chairman, I ask unanimous consent that all debate on this amendment and all amendments thereto close in 10 minutes.

The CHAIRMAN. Is there objection to the request of the gentleman from New Mexico?

There was no objection.

The CHAIRMAN. The Chair will divide the time equally between the gentleman from California (Mr. ROYCE) proponent of the amendment, and an opponent of the amendment, the gentleman from New Mexico (Mr. SKEEN). The gentleman from California will control 5 minutes and the gentleman from New Mexico will control 5 minutes.

Mr. SKEEN. Mr. Chairman, I yield 2 minutes to the gentleman from Iowa (Mr. LATHAM).

Mr. LATHAM. Mr. Chairman, I just wanted to clarify something that was just previously said.

McDonald's does not get a dime of money, Tyson Food does not get a dime of money, the Sunkist Corporation does not get a dime of money. That is old news. As I mentioned earlier, this has been reformed.

The only thing we are promoting here are the products themselves. No brand names. No corporate brand names. So that argument is totally bogus. I want every Member to understand that. This promotion goes to promote pork, to promote eggs, to promote beef, soybeans, corn, whatever.

There is no McDonald's, there is no Sunkist, there is no Tyson. And for someone to say that is totally erroneous, and I want to just clarify that for the House.

Mr. SKEEN. Mr. Chairman, I yield 2 minutes to the gentleman from California (Mr. FARR).

Mr. FARR of California. Mr. Chairman, I thank the gentleman very much for yielding me this time.

Before anyone votes for this amendment, think what is going on in America. This is the harvest season. This is time we celebrate. People are eating corn on the cob, having back-yard barbecues, watermelons are being eaten. This is the is time we are celebrating county fairs all over the United States. We celebrate agriculture, our number one industry.

Our number one industry needs to find markets. We grow more food in the United States than we can consume. If we are going to keep the prices of agriculture low (and frankly I think in many cases they are too low), we need to keep the markets open for growers to be able to sell their crops.

So my colleagues, before voting for this amendment, which is a bad amendment, wake up and smell the coffee. Every time we watch television and we see Juan Valdez telling us to buy Colombian coffee, not to buy a particular brand but to buy Colombian coffee, that is market promotion. We see wine industries in Italy trying to sell us Italian wine. That is market promotion.

American consumers are being sold by market promotion by foreign competitors all the time and we do not realize that we need to do the same for our crops in this global market. So wake up and smell that coffee. Strike down this amendment. It is a bad amendment precisely because it will not allow the small businesses, that this bill emphasizes, to be able to take advantage of this expanded program. Not those large corporations, which was falsely stated, that use to get a lot of the market promotion. That stuff was struck out in 1998.

This market promotion helps keep agriculture viable in the United States. It is absolutely essential that we keep our markets open. And we have a trade surplus. That we keep this all in the black. So let us keep America strong, keep agriculture strong, and strike down this amendment. Thank you.

Mr. SKEEN. Mr. Chairman, I yield such time as he may consume to the gentleman from Washington (Mr. HASTINGS).

(Mr. HASTINGS of Washington asked and was given permission to revise and extend his remarks.)

Mr. HASTINGS of Washington. Mr. Chairman, I rise in opposition to this amendment.

I am very aware of the problems facing the agricultural economy. It is abundantly clear that the prosperity of our economy as a whole does not extend to our farmers and ranchers. Although agricultural producers' problems are as diverse as the crops they grow, there is one point on which they all agree—the need for more export markets. There is no question that exports are already vital to the health of the agriculture sector. Approximately one-third of all the harvested acreage in the United States is exported, and 62 percent of these exports are of high value products. Is it any wonder then that farmers and ranchers suffer when exports decrease, as they have in recent years, falling from $60 billion in 1996 to $49 billion last year?

Fortunately, we have effective tools at our disposal to enhance our nation's agricultural exports. The Market Access Program (MAP) is a program that works—and works well—without distorting world markets through export subsidies. How? By providing matching funds for commodity groups and small businesses to conduct market research, technical assistance, trade servicing, advertising and consumer promotions abroad. The American farmer produces some of the highest quality food products in the world, but we can't assume that every international consumer knows about them. MAP helps fill this education gap and allow our producers to create the new export opportunities so sorely needed by growers and processors.

A prime example of how these programs work to benefit agricultural producers took place in my district earlier this month. The National Potato Promotion Board and the Washington State Potato Commission sponsored a tour and a series of briefings on processed potato products, and dehydrated potatoes in particular, for food industry research and development executives from the Philippines, China, Korea, Japan, and Mexico. These representatives learned about American potato products and how they can be used in consumer products abroad. This tour, partially funded by MAP dollars, will likely result in new opportunities to export value-added agricultural products.

I believe that it is simple common sense to support this kind of successful promotion effort. That is why I introduced legislation to increase funding for MAP and the Foreign Market Development Program (FMDP) earlier this year. This legislation, H.R. 3593, the "Agricultural Market Access and Development Act," authorizes the Secretary of Agriculture to spend up to $200 million—but not less than the current $90 million—on MAP. Likewise, the bill requires that a minimum of $35 million be spent on the promotion of U.S. bulk commodities overseas through FMDP.

These increases are funded using unspent funds for the Export Enhancement Program (EEP), usually around $500 million per year. EEP promotes U.S. exports through direct subsidies and is therefore subject to Uruguay Round restrictions and slated for reduction.

Right now, foreign countries directly subsidize their agricultural exports and spend far more than the U.S. does each year promoting their products abroad. MAP and FMDP are the only programs that give our farmers and ranchers the chance to compete on a level playing field worldwide.

These are proven and effective programs—and they are good for our producers. It's time to expand MAP and FMDP so that more growers can benefit from export opportunities.

Mr. Chairman, for these reasons I rise in strong opposition to my friend's amendment to cut funding for the Market Access Program. We must work to open up opportunities to our farmers, not hamstring efforts to ensure agriculture success and independence. I urge my

colleagues to vote no on this amendment and support a level playing field for American agriculture in the world market.

Mr. SKEEN. Mr. Chairman, I yield the balance of the time to the gentleman from Minnesota (Mr. MINGE).

The CHAIRMAN. The gentleman from Minnesota (Mr. Minge) is recognized for 2 minutes.

Mr. MINGE. Mr. Chairman, I would like to thank the gentleman for yielding me this time.

I certainly share with my colleague from California who introduced this amendment a level of discomfort with the market promotion program, the way it was structured several years ago. I think all of us in this body did. But the fact of the matter is the program has been adjusted. The most difficult to justify portions of the program have been eliminated, and what we are left with is generally a program that is promoting American agricultural products in foreign markets in a way that benefits farmers as opposed to benefiting corporate America.

I visited some of these offices, particularly in Japan. I have seen the men and the women that work for the Federal Government and work for some of the commodity groups present their material to the public in those countries, and I know that what they are doing is introducing American agricultural products to foreign consumers to build markets for American agricultural products, to open new opportunities for farmers in the United States, and I urge my colleagues to join in supporting this program.

There is no sector of the American economy that is more troubled than farming. We need to make sure that we explore every opportunity for America's farmers, not slam the door shut at this point in our economic history.

Mr. ROYCE. Mr. Chairman, I yield myself the balance of my time.

Mr. Chairman, the Market Access Program is the leftover product of two previously failed USDA programs, the Market Promotion Program and the Targeted Export Assistance Program, and MAP funnels tax dollars to corporate trade associations and cooperatives to advertise private products overseas.

Now, let me reiterate my position here. I think advertising is a function of the private sector, not of the taxpayers. While proponents of the program claim that it boosts exports, claims that it creates jobs, there is no evidence to support it. General Accounting Office studies indicate that this program has no discernible effect on U.S. agricultural exports. The private sector knows how to advertise. It does not need government interference. Taxpayer dollars merely replace money that would be spent by private companies on their own advertising.

Provisions in the 1996 farm bill have attempted to reform MAP, but thus far have failed. The GAO audit and other audits find it overstated, inconclusive, and speculative in terms of its effect.

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Although the percentage of large companies that get MAP money have decreased, a number of corporations still receive millions of dollars indirectly through trade associations. The studies show that about three-quarters of the money indirectly benefits these corporations.

Under this year's bill, an attempt also was made to expand MAP. Fortunately, this provision was stricken; and now we go to the question of the program itself. I believe it is now time to end the program.

In the last 10 years, American taxpayers have shelled out $1 billion for this subsidy. I think the American people would agree that their money could be better spent, and I urge adoption of the amendment.

Mr. BARRETT of Nebraska. Mr. Chairman, I rise to oppose the Royce amendment to eliminate the Market Access Program (MAP).

Several weeks ago, the House passed legislation to grant PNTR to China. One of the best arguments for PNTR is that it will grant U.S. producers access to the Chinese market, much of which has been closed for too many years.

MAP is the program that will help U.S. producers—not large agribusinesses—gain that access. Exporting is a challenge, even for the most experienced. Many individual producers and small companies find it difficult to break into it and to be competitive internationally. MAP helps our producers, primarily through grants to state departments of agriculture, to overcome these hurdles by partially funding international market research and trade missions to foreign countries.

Access to the Chinese market does us no good if we can't take advantage of it. MAP will help our producers develop it and become better at international trade and marketing. Reject this short-sighted amendment. Support MAP.

Mr. ROYCE. Mr. Chairman, I yield back the balance of my time.

The CHAIRMAN. The question is on the amendment offered by the gentleman from California (Mr. ROYCE).

The question was taken; and the Chairman announced that the noes appeared to have it.

Mr. ROYCE. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The CHAIRMAN. Pursuant to House Resolution 538, further proceedings on the amendment offered by the gentleman from California (Mr. ROYCE) will be postponed.

The point of no quorum is considered withdrawn.

Mr. OBEY. Mr. Chairman, I move to strike the last word.

Mr. Chairman, in full committee I offered an amendment to deal with the concentration of economic power in the processing industry in this country. We cannot offer that amendment on the floor because of budget limitations, but I want to make clear that before this bill returns from conference, it ought to do a number of things.

I wanted to add funding for the Grain Inspection Packers and Stockyards Administration, for instance, and to the Agriculture Department's Office of General Counsel to bring both accounts up to the amount requested by the President. The reason that I wanted to do that is very simple: we can throw all the money in the world that we want to at farm programs, but unless we deal with the fact that the agriculture industry is largely dominated by oligopolies, we are not going to do very much to help either the consumer or the farmer in the process.

There are four companies that now control 81 percent of cattle purchases, beef processing and wholesale marketing, and in only 5 years we have seen the margin between the price paid to farmers and wholesale price of beef jump by 24 percent. It just doesn't apply to the beef industry.

If you look at the pork market, four companies now control 56 percent of the pork market, and the margin between the wholesale price of pork and the price paid to the farmer has jumped by more than 50 percent.

We have had a continuous consolidation in the grain industry and in the dairy industry and an amazing concentration of economic power in the poultry industry, where giant corporations such as Perdue and Tyson's are not only squeezing farmers, but also abusing workers and wreaking havoc on the environment in the process.

To really address these problems, it seems to me we need substantive legislation, for example to grant the Agriculture Department authority to review mergers and acquisitions affecting farming and food, and we need to do a variety of other things. That, obviously, is beyond the scope of this bill. But this bill, for instance, in addition to the other funding shortfalls that I have discussed, also has a serious shortfall in the Office of General Counsel. We need to correct those problems when this bill comes back from conference.

As I say, we are precluded from offering an amendment to do anything major on this right now because of the Budget Act, but it is my full intention to see to it that when we go to conference, this matter is corrected; because until we do correct it, the consumers are going to continue to get euchred by the situation, and so will virtually every small farmer in America.

Mr. SHERMAN. Mr. Chairman, I move to strike the last word.

Mr. Chairman, as you may know, I have an amendment at the desk. I rise to explain why I will not be offering that amendment.

Mr. Chairman, that amendment deals with the provisions of this bill which provide funds for the inspection and facilitation of agricultural imports, particularly those from the Islamic Republic of Iran. In March of this year the administration lifted our ban on imports from Iran as to four products, three of them agricultural products; and I believe that lifting this ban may have been the result of undue optimism, or at least premature optimism.

The rhetoric in Tehran has improved, but the actions of the Iranian government have not. A year and a half ago, 13 Jews were arrested in the southern Iranian city of Shiraz. They have been subjected to show trials. Ten have been convicted. The average sentence is 9 years. Some of the sentences go up to 13 years.

That is why, Mr. Chairman, I drafted an amendment that would say that those three agricultural imports cannot come into this country, or at least none of our taxpayer dollars could be used for the necessary inspection.

But just as I believe the lifting of the ban on those imports may have reflected premature optimism, I do not want to be guilty of premature pessimism. It is quite possible, I think, that the Iranian president or their appellate court system will in the next few weeks vacate those verdicts, or at least release the prisoners. So I think it is best that I not offer this amendment, especially because this amendment, if adopted, would lock us into a particular position for an entire fiscal year; and it would deny the use of those funds to facilitate imports from Iran for the entire fiscal year.

Instead, I think it better that I will join with others in introducing legislation that will provide for a ban on all Iranian exports to the United States, agricultural and non-agricultural, until such time as the President of the U.S. is able to certify that the Iranian government has made substantial improvements in the treatment of its religious minorities.

Mr. Chairman, the charges against the 13 jailed in Shiraz were absurd, since no Jew in Iran is allowed to come anywhere near anything of military or security significance.

Mr. Chairman, the trials were reminiscent of those of Joseph Stalin, show trials with forced confessions, no evidence and very little specificity to the charges; and the verdicts were harsh, 10 convictions subjecting the defendants to a total of 89 years in prison.

Many governments around the world have said that these trials are the yardstick by which Iran must be judged as to whether it has made improvements in human rights and whether it has made improvements in treating its religious minorities. Clearly, Iran has not yet improved its behavior, even as there has been hopeful rhetoric.

Mr. Chairman, I believe that we should adopt the slogan "no justice, no caviar." We should certainly not allow the import of caviar, pistachios, dried fruit, or carpets into this country until justice is achieved.

Not only is a ban on the imports to the United States from Iran helpful in that it applies some pressure economically to Iran, it is also the strongest way that we can signal our position and puts us in a stronger position to deal with other countries: Germany, where the Iranian foreign minister is visiting today; Japan, which, unfortunately, is funding hydroelectric facilities in Iran; and the World Bank, which, unfortunately, approved, but did not yet disburse, a loan of $231 million.

So, Mr. Chairman, my hope is that this amendment will turn out to be unnecessary; that the authorities in Iran will reverse the decision of the trial court, or at least pardon the defendants. If that does not occur, then we will be in the position to move with a separate bill that will allow more flexibility and a greater scope than is allowed in an amendment to an appropriations bill. A separate bill will apply to non-agricultural goods, as well as agricultural goods, and provide the flexibility of a presidential certification.

In addition, I would hope that if a month from now these obscenely harsh verdicts are not reversed, that the conference committee will see fit to add my amendment to this Agricultural Appropriations bill before it comes back to this House.

So that explains, why, Mr. Chairman, I will not be offering my amendment.

Mr. UPTON. Mr. Chairman, I move to strike the last word for the purpose of entering into a colloquy with the chairman of the Subcommittee on Agriculture of the Committee on Appropriations.

Mr. Chairman, I want to bring to your attention the fire blight problem which destroyed many apple and pear crops in Michigan. While back home this past week, I personally saw the devastation in literally orchard after orchard along the road.

In May, a severe disaster struck Michigan, all but destroying the apple and pear crops in this highly intensive agriculture region. In addition to extremely wet, warm, and humid weather conditions throughout the month, a severe thunderstorm passed over southwest Michigan in May, causing severe damage to fruit trees and fruit crops. The thunderstorm's hail, high wind, and heavy rain scarred and wounded the leaves, limbs and fruit on the trees. In the case of apple and pear trees, these wounds provided an avenue for the fire blight to enter the trees, causing severe and widespread disease.

The result is that nearly 7,650 acres of the 17,000 acres of apple trees in this region have been severely affected by fire blight. Some of the remaining 9,000-some acres are affected as well, depending upon apple variety; but the trees are expected to recover in future years. Of the acreage severely affected, we suspect that nearly some 2,000 acres of apple trees will, in fact, die. The remainder may be saved, but their production in the future will certainly be significantly reduced.

My governor, Governor Engler, in conjunction with myself, the gentleman from Michigan (Mr. HOEKSTRA), the gentleman from Michigan (Mr. EHLERS), the gentleman from Michigan (Mr. SMITH), and Senator ABRAHAM have requested Secretary Glickman to designate the affected counties in Michigan as a disaster area, which should help to some degree.

However, more must be done. I am pleased to report that Senator ABRAHAM in the other body is working with his colleagues to provide some additional funds for relief as this body considers the fiscal year 2001 agriculture appropriation bill.

I would ask the gentleman from New Mexico (Chairman SKEEN) that as this bill moves through the legislative process that the gentleman work with our colleagues in the other body to provide much-needed relief to growers in southwest Michigan whose crops have been devastated by this fire blight.

Mr. SKEEN. Mr. Chairman, will the gentleman yield?

Mr. UPTON. I yield to the gentleman from New Mexico.

Mr. SKEEN. Mr. Chairman, I thank the gentleman from Michigan for his attention to this important issue. I give him my assurance that as this bill moves through the legislative process, I will do all that I can to work with the other body to provide much needed funding for the growers in southwest Michigan whose crops have been devastated by fire blight.

Mr. UPTON. Mr. Chairman, reclaiming my time, I thank the gentleman for his assurance, and I look forward to working with him in the future to make sure that we get needed assistance back to our growers in the Midwest.

AMENDMENT OFFERED BY MR. COBURN

Mr. COBURN. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. COBURN:

Insert before the short title the following title:

**TITLE IX—ADDITIONAL GENERAL PROVISIONS**

SEC. 901. None of the amounts made available in this Act for the Food and Drug Administration may be expended to take any action (administrative or otherwise) to interfere with the importation into the United States of drugs that have been approved for use within the United States and were manufactured in an FDA-approved facility in the United States, Canada, or Mexico.

Mr. COBURN. Mr. Chairman, I ask unanimous consent that time for debate on this amendment be limited to 10 minutes in opposition and 10 minutes in favor.

The CHAIRMAN. Is there objection to the request of the gentleman from Oklahoma?

There was no objection.

The CHAIRMAN. The gentleman from Oklahoma (Mr. COBURN) will control 10 minutes, and a Member opposed to the amendment will control 10 minutes.

The Chair recognizes the gentleman from Oklahoma (Mr. COBURN).

Mr. COBURN. Mr. Chairman, I yield myself 3 minutes.

Mr. Chairman, first of all I want to thank the gentleman from Maine (Mr. BALDACCI), the gentleman from Minnesota (Mr. GUTKNECHT), and several others for their work in this area.

All this bill says is we are not going to intimidate seniors who are following the law, following NAFTA, and bringing drugs into this country from Canada or Mexico, as long as those are approved drugs and they have been manufactured in FDA-approved facilities.

Mr. Chairman, we have debated this issue to a great extent. All this amendment will do is say "hands off, FDA" on legal and qualified manufactured products. It does not have anything to do with limiting their ability on safety; it does not apply to anything but a legal drug. So that means my patients who now are trying to get their drugs from Canada, from Oklahoma, can in fact have a prescription mailed to Canada or Mexico and have it filled and shipped across the border, and the FDA cannot intimidate them and say they cannot do that. That is all we are talking about, drugs that are manufactured in this country and manufactured in FDA-approved facilities that are legal drugs.

Mr. Chairman, I reserve the balance of my time.

The CHAIRMAN. Is there a Member that rises in opposition to the amendment?

If not, does the gentleman from Oklahoma (Mr. COBURN) yield time?

□ 1915

Mr. COBURN. Mr. Chairman, I yield 5 minutes to the gentleman from Maine (Mr. BALDACCI).

Mr. BALDACCI. Mr. Chairman, I thank the gentleman from Oklahoma for his leadership in this area and his knowledge and the way he has been able to work together in a bipartisan fashion to get this issue addressed.

This is a very important issue to the State of Maine which borders Canada and which sees its citizens go regularly across the border in frustration as to why those same particular medicines cost so much less than they do in their own country. Recognizing that, the pharmaceutical industry, which I do not intend to vilify, has only said that they charge whatever the market will bear. I recognize, and this amendment recognizes, that many American citizens cannot bear what the pharmaceuticals are charging.

Mr. Chairman, I encourage my colleagues to support this amendment to be able to send a message that this is not an acceptable practice. We are watching many of our seniors have to split their drugs in half or not take them at all because they cannot afford them and they can go right across the border for the same drug that is manufactured in this country at a third or a fourth of the price, and only recognizing that it is the companies, in charging what they are charging, that is the differential between what they are paying and what the counterparts across the border will pay. We must ensure that the taxpayers who are providing the basic research at NIH and other research facilities, building the elemental research which the pharmaceutical industry builds upon those tax dollars, that the taxpayers of the United States have an opportunity to access in an affordable fashion.

Mr. Chairman, I commend the gentleman for his leadership in working together in a bipartisan fashion to address this issue and many other Members that are working on this issue, in the final analysis, to make sure that at the end of the day, the seniors have affordable, accessible prescription medicines so that they do not have to worry about the quality of their life and be able to be independent and live out their lives in a quality environment.

I support the amendment.

Mr. COBURN. Mr. Chairman, I yield such time as he may consume to the gentleman from New Hampshire (Mr. BASS).

(Mr. BASS asked and was given permission to revise and extend his remarks.)

Mr. BASS. Mr. Chairman, I rise in strong support of this pending amendment which would do more than any single action to lower the prices in this country for prescription medications.

Mr. COBURN. Mr. Chairman, I yield myself such time as I may consume.

Ms. KAPTUR. Mr. Chairman, will the gentleman from Oklahoma (Mr. COBURN) yield?

Mr. COBURN. I yield to the gentlewoman from Ohio.

Ms. KAPTUR. Mr. Chairman, I would ask very simple questions of those who have drafted this amendment and are offering it. Do the gentlemen wish to do anything in this amendment that would lessen the inspection that the FDA does of drugs that may be manufactured or sold in another country and used by U.S. citizens? I want to understand the full intent of the amendment, because when the FDA Commissioner came before our subcommittee and I asked the question about drugs from other countries, she said that they could not give certainty that they were of equal quality.

Mr. COBURN. Mr. Chairman, reclaiming my time, the drugs that are produced in FDA-approved facilities, they do assure at this time that they are made to the same standard as the drugs that are made in this country. Otherwise, they would not have their approved labeling from the FDA, and that is true in all FDA-approved facilities.

Ms. KAPTUR. Mr. Chairman, I thank the gentleman for the clarification.

Mr. COBURN. Mr. Chairman, reclaiming my time, I want to discuss a little bit about this problem.

We spent 2 weeks ago talking about the crisis in the pharmaceutical industry as far as our seniors in getting drugs. It is not just our seniors; it is everybody in this country is paying too much for drugs. There are five things that could happen tomorrow to lower the price for prescription drugs in this country. This is a small step that would help. It is not even one of the major ones.

The number one thing is to have a competitive market for prices in this country. We believe in free enterprise; there is not free enterprise in the pharmaceutical industry right now. All one has to do is look at the FTC Web site. There is documented collusion. We need to address that.

Number two, our President needs to stand up and bully pulpit the pharmaceutical industry's prices. We do not need price controls. We need competition. Competition allocates scarce resources better than any type of price control ever will. What we need is real competition. Ms. Reno has received a letter signed by me asking for an investigation of which as of today, now, 4 weeks later, there has been no response on the documented areas of collusion within the drug industry.

Number three, doctors need to do a better job giving generics to seniors, and they are not.

Finally, number four, the pharmaceutical companies are not all bad. They do a lot of good things. There are private, indigent programs in the pharmaceutical industry that the health professions need to utilize. They will supply their drugs.

Mr. Chairman, I yield the balance of my time to the gentleman from Maine (Mr. BALDACCI).

The CHAIRMAN. The gentleman from Maine (Mr. BALDACCI) is recognized for 4 minutes.

Mr. BALDACCI. Mr. Chairman, I yield 2 minutes to the gentleman from Minnesota (Mr. MINGE).

Mr. MINGE. Mr. Chairman, I would like to associate myself with the remarks of my colleagues from Oklahoma, from Maine, from New Hampshire and other Members that have spoken in support of this.

In Minnesota I know that we have had many seniors that have gone on bus trips and otherwise to Canada to purchase prescription drugs and often they come back with a feeling of intimidation. What we need to do is to assure them that if they are purchasing drugs that are safe, if they are purchasing drugs that are important for their health, that they are not subject to the harassment or the problems that they might face at the border when they come back.

Mr. BALDACCI. Mr. Chairman, I yield 2 minutes to the gentleman from Indiana (Mr. BURTON).

Mr. BURTON of Indiana. Mr. Chairman, I rise in strong support of this amendment, because the gentleman from Oklahoma raised the issue of collusion. We have held hearings with the advisory panels of the Food and Drug Administration and the CDC that makes recommendations on vaccines, and we have found through our committee investigations that many of the people who are on these advisory committees that are making the decisions on what kind of vaccines our children are getting are being paid by the pharmaceutical companies that own large amounts of stock in the pharmaceutical companies.

So I would just like to say that the collusion that the gentleman refers to is not limited to the price controls or price problems that he has been talking about here today. We believe that there are other problems that need to be addressed. So I think the gentleman is on the right track, and I support this amendment strongly.

Mr. BALDACCI. Mr. Chairman, I yield such time as he may consume to the gentleman from Oklahoma (Mr. COBURN), if he would like to follow up and reinforce the safety and labeling issues that have been raised here.

Mr. COBURN. Mr. Chairman, I am happy to address those issues. Number one, we cannot manufacture a drug that comes into this country unless we are manufacturing it in an FDA-approved facility. That is number one. So safety is not a concern, and they can do whatever they want if it is not manufactured in an FDA-approved facility. Number two, it does not apply to a drug that is not approved in this country. So as far as the drugs that are approved in this country, those are the ones that are manufactured in an FDA-approved facility that will come in safe.

All we are saying is, since NAFTA is here, and I would have voted against had I been a Member of Congress at that time, but since it is here, let us use it. Let us get some benefit out of it besides stealing some of our jobs. So let us utilize NAFTA. This will not hamper the FDA.

Mr. BALDACCI. Mr. Chairman, in closing, I just want to first of all say that we are not under any illusions that all of a sudden one amendment is going to turn things around, but I believe that it is like many things, that it sends a message out, and from a million different amendments and messages and resolutions, at the end of the day, they have to receive the message and have got to be able to sit down and fashion a proposal that works universally across the board, accessible and affordable to all of our seniors, regardless of where they live and what their income is.

I think what we are seeing here today on the floor of the House and have seen throughout the country is a frustration with recognizing that something is up. People have figured out long before all of us that something is up and we need to address it. This is just one vehicle, one way to be able to do it. There are many others, and I support many of the different approaches, but at the end of the day, we have to make sure the seniors are taken care of.

Ms. KAPTUR. Mr. Chairman, I reluctantly rise in opposition to the amendment.

The CHAIRMAN. The gentlewoman from Ohio (Ms. KAPTUR) is recognized for 10 minutes.

Ms. KAPTUR. Mr. Chairman, I am concerned about this amendment and perhaps others that will be offered only from the sense of safety.

I rise in opposition, reluctantly, to enter into a colloquy with the gentleman who is offering the amendment here on our side. That is to ask, if a senior citizen, for example, goes on a bus trip from Maine or Ohio up to Canada or down to Mexico, when they go to a pharmaceutical operation and they go to buy a drug, let us say it is Claritin, how do they know that that is manufactured in any of the countries the gentleman is talking about with his amendment? Is it labeled? How do they know that it was manufactured in an FDA-approved facility?

The gentleman says in his amendment that these drugs were approved for use within the United States and manufactured in an FDA-approved facility. Does it say that on the box? Can the gentleman assure me, unlike the FDA commissioner who appeared before our committee and did not have the confidence that the gentleman has that seniors could be assured of equal content and equal inspection of these drugs? How can the gentleman be so certain that they are getting a product of equal import? If the gentleman could answer that question.

Mr. BALDACCI. Mr. Chairman, will the gentlewoman yield?

Ms. KAPTUR. I yield to the gentleman from Maine.

Mr. BALDACCI. Mr. Chairman, I certainly will yield, if I can, to the gentleman from Oklahoma who is a physician and practices.

But my experience, and from people that I have talked to that have gone across the border from Maine to Canada have purchased the same drug where it is made in the USA, and it does not say right on the label that it has been inspected by the FDA, but it was made in the USA, and that it is the same drug that they are purchasing.

Their experience is that they paid $400 or $500 for what would be $1,000 in this country. It is no different than what has been happening in agriculture with the pesticides and other types of products that are manufactured in this country, are sold overseas, and trying to be able to reimport those because of a permit process, not because of safety, not because of any issue as it may pertain to the impacts of the health of the individual, but just because of those issues, our farmers have been disadvantaged, our seniors have been disadvantaged, and as the gentleman from Oklahoma has said, it seems that NAFTA is a one-way street. They build the wall, and nothing gets in, but everything tends to come out. The gentlewoman recognizes that in her fights that she has led in this Congress over the years with regard to those issues.

Mr. Chairman, the gentleman from Oklahoma (Mr. COBURN) may like to respond on the safety issues.

Mr. COBURN. Mr. Chairman, will the gentlewoman yield?

Ms. KAPTUR. I yield to the gentleman from Oklahoma.

Mr. COBURN. Mr. Chairman, I think a couple of points are important. Number one is when we get a drug in this country, we do not know where it is made, because a large portion of our drugs in this country are made in Europe, made in South America, made in Puerto Rico, in FDA-approved facilities. They have to meet that standard. That is number one. Will there be an accident? Sure, there will be. I will not deny that there will be a mistake made in filling a prescription just like there is every day in this country as well.

However, I would challenge the ranking member on this committee, how many people are not getting the medicines they needed to because they cannot afford to get them, and if we allow competition to resume, which this is just one way of doing it, whom of them will markedly benefit their health, their quality of life? People's lives are being shortened today because of the abnormally high and ridiculously increased prices of many pharmaceuticals out there.

Can we assure 100 percent safety? No. The FDA cannot now. As a matter of fact, what they do is they look at drugs and say, are they safe enough? There is not any drug that is absolutely safe.

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Aspirin is not absolutely safe. But are we going to markedly increase the risk for Americans with this? Absolutely not. The FDA knows those facilities.

Will they have absolute assurance on a drug like Viagra, will somebody try to prostitute that drug and make a substitute? They are doing that now and they are bringing them in. It is not going to be a new problem for the FDA, and it is not going to be more of a problem.

What it is going to be is more access at better prices for our seniors and everybody else in this country for the pharmaceuticals, because the competitive model is not working in this industry today. This will be a shot that says that we need the competition to work. That is why we want to do this.

Ms. KAPTUR. Reclaiming my time, Mr. Chairman, perhaps the officials from the Food and Drug Administration are listening to this debate. If there is any doubt in their minds as to the net effect of this amendment as we move towards conference, we can tighten up the language to make sure that we do nothing to lessen the food, drug, and safety laws of the country, which are the strongest in the world, to protect the health of our people.

I know that neither gentlemen would want to undermine that. Obviously, they would want to improve it. Maybe there is some way that FDA could indicate on the boxes that it is from an FDA-approved facility. I think we want to give consumers ultimate confidence that the purchase they are making will not harm them.

Mr. COBURN. If the gentlewoman will continue to yield, the European Union today has just as strong rules as we do. They import drugs from all

over. In terms of quality, efficacy, and safety, their laws are almost exactly the same. They are coming from a range of 13 to 15 countries. If they can do it, certainly we can do it with our neighbors.

Ms. KAPTUR. I would just say to the gentleman, in the food area they obviously do not have the same standards. In the drug area, their system is quite different.

Mr. BALDACCI. Mr. Chairman, if the gentlewoman will yield further, I appreciate the gentlewoman's suggestion. I would encourage the FDA and others that have any issue here, that can be tightened up in conference. I think that is an excellent suggestion, and I would look forward to working with the gentlewoman to tighten that up if it needed to be.

Ms. KAPTUR. I thank the gentleman for that. I withdraw my reluctant opposition, and look forward to the conference on the amendment.

Ms. DELAURO. Mr. Chairman, I am astonished that we are again debating an amendment that would stifle biomedical research and impose political will on an agency whose work is based on the non-partisan rule of science. This is an invasion into the FDA's drug approval process—a place where Congress has no right to be. We are not scientists. We created the FDA and charged it with determining which drugs are safe and effective for use in this country. We were wise to do so—the FDA has a long history of protecting the public from drugs that are uncertain or unsafe.

This amendment would change all that. In an attempt to impose their beliefs on all of America, anti-choice proponents of this amendment would have you believe that it would apply to drugs solely for the purpose of the chemical induction of abortion. But, in fact, we know that it would reach far beyond that.

Often times drugs are approved for one purpose, and later are found safe and effective for treating an entirely different condition. For example, the drug Doxil was originally approved by the FDA as an AIDS treatment. But later, in June of 1999, the FDA approved the same drug for the treatment of ovarian cancer. Even mifepristone, the target of this amendment, currently shows promise for use in the treatment of breast cancer, benign brain tumors, ovarian cancer, and even prostate cancer.

Let's call this amendment for what it is—an attempt to score a political point on abortion. Unfortunately, the casualties in this political move are biomedical research, independent scientific evaluation of medicines, and patient access to reproductive health drugs.

What this amendment would in fact do is begin a path whereby Congress decides, based on political and ideological considerations, what drugs it thinks America should or should not have access to, and then blocks the FDA from taking action to approve drugs deemed inappropriate. Let me ask you, what would this lead to next? Which political issue would be the target of the next attempt to thwart research or invade the FDA's drug approval process? We must be mindful of the dangerous precedent this amendment would set.

Now is not the time to limit the FDA in their work to determine the safety and efficacy of promising new drugs in America. This amendment would not only limit the FDA but it would have a chilling effect on biomedical research, particularly women's health research, which has been severely understudied for years. This amendment may be aimed at one issue, but it will have consequences for millions of Americans.

When we halt action on an entire category of drugs, we erase the possibility that those drugs could hold for treating other conditions. We stamp out the scientific pursuit of medicines that heal with one attempt to limit the safe practice of abortion—which I might remind my colleagues is still a legal right in this country.

This Congress has made biomedical research a priority. We have agreed that we have an obligation to fund the search for cures and better treatments for disease in this country. We have the unique opportunity as lawmakers to use public policy to actually improve people's health and improve their lives. But what this amendment would do is exactly the opposite—it would place political gain ahead of real progress. It would replace the gold standard of drug approval that this nation has come to trust with congressional restrictions based only on personal ideology—not sound science.

Speaking as both a legislator and a cancer survivor, I know the value of modern medicines. To be quite frank, I am offended by the idea that some lawmakers think they can dictate to the FDA what work they can do on proposals that could improve the lives of Americans.

I urge my colleagues—don't force your opinion regarding choice on the FDA and the people who rely on it for sound, scientific judgement. Allow the FDA to continue the important work it does in evaluating all potential pharmaceuticals. Do not subject the FDA scientists to the personal philosophies of some Members of this House. Preserve the promise of biomedical research and new drugs for all Americans. Defeat the Coburn Amendment.

Ms. SLAUGHTER. Mr. Chairman, I rise in strong opposition to the amendment offered by Representative COBURN.

For the past three years, Congress has revisited Rep. COBURN's amendment to prohibit the FDA from testing, developing, and approving drugs that could cause the chemical inducement of abortion. Like the so-called "partial birth abortion" ban, it has become a hallmark of the anti-choice agenda.

But this measure is not about abortion or even mifepristone. It is about Congress trying to dictate what the FDA is permitted to do and not to do. As a public health specialist by training, I am appalled that my colleagues would attempt to interfere with the FDA's ability to test, research, and approve any drug with political mandates.

Reproductive health drugs should be held to FDA's rigorous science-based requirements that any drug must meet before approval can be granted—just like any other drug. They should not be singled out simply because they deal with reproductive health.

In 1996, the Food and Drug Administration found mifepristone a safe and effective method for early medical abortion. This drug has been used successfully by more than 500,000 women around the world for over twenty years in countries like France, Sweden, and the United Kingdom, and was just recently made available in Spain, the Netherlands, Australia, and Israel. Every country in Europe, and beyond, seems to recognize the benefits of making this drug available to women—except the United States.

This measure seeks not only to deny American women access to mifepristone, it also threatens the health of Americans in general. In addition to providing safe, medical abortions, there is evidence that mifepristone has great potential to treat serious medical conditions such as inoperable brain tumors, prostate cancer, and infertility—as well as female specific conditions like endometriosis, uterine fibroids, and breast cancer.

I ask my colleagues, how many other uses are there for a drug like Viagra? Yet, Viagra hit the market in record time. What kind of message does that send to the world? The consideration of this measure and the failure of the United States to make this drug available tells the world that the health of Americans is negotiable and subject to the will of anti-choice politicians.

If passed, this amendment would not only compromise the integrity of FDA's scientific process, it would open the door for further invasions on the drug approval process. More importantly, it would set a very dangerous and irrevocable precedent in the medical community.

Over the past three decades, the face of reproductive health care has drastically changed to serve the needs of American women. And for the first time in history, a reproductive health drug has the potential to benefit not only American women, but to provide more appropriate care to millions of Americans. Who are we, Members of Congress, to interfere in the face of such immense scientific progress?

Americans trust that drugs approved by the FDA are safe. Vote "no" on the Coburn amendment and let the FDA do its job.

Ms. PELOSI. Mr. Chairman, I rise to oppose the Coburn amendment to the Agriculture Appropriations bill. I strongly disagree with this amendment because it would block the Food and Drug Administration from testing, developing, or approving any drug that would induce abortion, including RU–486. The Coburn amendment would limit the development of the next generation of safer, more effective contraceptives and this is wrong.

Women in America have a right to choose. We must protect this right. The goal of this Congress should be to reduce the number of abortions, protect the right of women to choose, and to make necessary medical choices safe and legal. It is wrong for Congress to tell the FDA to approve a particular drug or to disapprove one. Instead, it is the FDA's mission to decide whether a drug is "safe and effective." The Coburn amendment would make this decision for the FDA and substitute Congress' judgement over the judgement of medical professionals.

We must remember that RU–486 is a product proven to be medically safe. After extensive French and United States clinical trials, the FDA has determined that it is safe and effective for an early medical abortion. For about 20 years RU–486 has been available to Europe's women. The effect of this amendment is to ban RU–486 which can be used for a nonsurgical abortion. For women for whom surgical abortion poses risks or is otherwise inappropriate, the Coburn amendment unconstitutionally restricts the right to choose. For

women living far from clinics, it precludes the possibility of receiving RU–486 in their physician's office, again burdening the right to choose. Women have the right to choose and I support the current FDA medical approval process.

We should not trample on the FDA's ability to test, research and approve drugs based on sound scientific evidence. We should also remember this amendment is not limited to just this one safe and effective drug. It is not simply about access to RU–486 alone. It would have a dangerous chilling effect on developing other drugs for various other medical purposes. Drugs used to treat other conditions including cancers and ulcers can induce abortion. This proposed ban could limit the FDA's capacity to consider approving these other therapies and could force researchers to reject promising treatment opportunities.

I stand with the American Medical Association; the American College of Obstetricians and Gynecologists; and the American Medical Women's Association to oppose this amendment.

I urge my colleagues to oppose the Coburn amendment and protect a woman's right to choose. Vote "no" on the Coburn amendment.

The CHAIRMAN. The question is on the amendment offered by the gentleman from Oklahoma (Mr. COBURN).

The question was taken; and the Chairman announced that the ayes appeared to have it.

Mr. COBURN. Mr. Chairman, I demand a recorded vote, and pending that, I make the point of order that a quorum is not present.

The CHAIRMAN. Pursuant to House Resolution 538, further proceedings on the amendment offered by the gentleman from Oklahoma (Mr. COBURN) will be postponed.

The point of no quorum is considered withdrawn.

AMENDMENT OFFERED BY MS. KAPTUR

Ms. KAPTUR. Mr. Chairman, I offer an amendment.

The Clerk read as follows:

Amendment offered by Ms. KAPTUR:

Page 96, after line 4, insert the following new section:

**TITLE IX—ADDITIONAL GENERAL PROVISIONS**

SEC. ___. Within available funds, the Secretary of Agriculture is urged to use ethanol, biodiesel, and other alternative fuels to the maximum extent practicable in meeting the fuel needs of the Department of Agriculture.

Ms. KAPTUR. Mr. Chairman, I offer a sense of Congress resolution in the form of an amendment concerning ethanol and diesel fuels.

Mr. Chairman, we all have seen the price of fuel rise across the country, spike, and cause businesses and households a great deal of economic anxiety this summer. It was but yet another example of our overdependence on imported fuels to move this economy.

There is no one answer to that problem, but obviously we should all have a strong, very strong-willed position to move America toward any energy independence in our lifetime.

One of the most important departments to help us do that is the Department of Agriculture. In fact, the potential for the expanded use of ethanol and biodiesel and biofuels of all kinds using cellulose from our fields and forests is absolutely unlimited and it is renewable.

In addition to that, it is much less polluting. The State of Ohio, for example, I think leads the Nation in mixtures that involve ethanol. We have shown that research can be done in producing alternative fuels that benefit our environment, can actually help our engines burn more cleanly, and end our growing dependence.

Over 60 percent of the fuel used to power this economy comes from foreign sources. It is our major strategic vulnerability.

USDA has been helping in research, albeit slowly, over the years. We are making some progress. The intent of this resolution is to further encourage the Secretary of Agriculture to use ethanol, biodiesel, and other alternative fuels to the maximum extent practicable in all of USDA facilities across the country. There are hundreds.

One of the areas in which we are successfully working is in the district of the gentleman from Maryland (Mr. HOYER) in Beltsville, Maryland, at the chief research station in this country to power many of the land vehicles, tractors, and cars, used in that major research station.

What we are asking USDA to do in this sense of Congress resolution is to exert the maximum effort possible and look at the other sites around the country, including cooperative efforts with our land grant universities, with other research sites across the country, with the headquarters facilities here in Washington, D.C., and really help lead America forward and develop the set of connections that can move product from the farm into industrial and agricultural use by the end user.

So it is very straightforward, and if we are to be serious about alternative fuels, we must use every arrow in our quiver. We are asking the USDA to put added muscle behind this in every single facility that it operates across the country.

Mr. SKEEN. Mr. Chairman, will the gentlewoman yield?

Ms. KAPTUR. I yield to the gentleman from New Mexico.

Mr. SKEEN. Mr. Chairman, I accept the gentlewoman's amendment, and recommend that the House do so, as well.

Ms. KAPTUR. I thank the gentleman. I just wish we could power some of those sheep with some ethanol, but we will probably figure out a way to do that in the future.

Mr. SKEEN. We keep them well inoculated, and they do not buy their pharmaceuticals from anyplace other than home.

Ms. KAPTUR. I thank the gentleman for his support.

The CHAIRMAN. The question is on the amendment offered by the gentlewoman from Ohio (Ms. KAPTUR).

The amendment was agreed to.

AMENDMENT NO. 70 OFFERED BY MR. GILMAN

Mr. GILMAN. Mr. Chairman, I offer an amendment.

The CHAIRMAN. The Clerk will designate the amendment.

The text of the amendment is as follows:

Amendment No. 70 offered by Mr. GILMAN:

Page 85, after line 15, insert the following new section:

SEC. ___. The Secretary of Agriculture shall use $15,000,000 of the funds of the Commodity Credit Corporation to provide compensation to producers of onions whose farming operations are located in a county designated by the Secretary as a disaster area for drought in 1999 and who suffered quality losses to their 1999 onion production due to, or related to, drought. Payments shall be made on a per hundredweight basis on each qualifying producer's pre-1996 production of onions, based on the 5-year average market price for yellow onions.

Mr. SKEEN. Mr. Chairman, I reserve a point of order on the amendment.

Mr. GILMAN. Mr. Chairman, my amendment would require the Secretary of Agriculture to use $15 million of the funds of the Commodity Credit Corporation to provide compensation to producers of onions who were hard hit by drought in the 1999 growing season.

The reason for this amendment is quite obvious. Onion producers from my congressional district in Orange County, New York, have been devastated by either drought, wind, or rain 3 out of the past 4 years. Making matters worse, the USDA crop insurance program provided little or no assistance to these growers.

I had the opportunity to visit with our onion producers just this past week to learn of their outstanding plight. While it is imperative that these growers receive adequate assistance in order to survive, I will withdraw my amendment, since it is subject to a point of order in the House.

However, I would ask the distinguished chairman of our subcommittee, the gentleman from New Mexico (Mr. SKEEN), if I could speak with him on this important matter.

Mr. SKEEN. Mr. Chairman, will the gentleman yield?

Mr. GILMAN. I yield to the gentleman from New Mexico.

Mr. SKEEN. Mr. Chairman, I understand the gentleman's concern, and we will continue to do our best as the bill proceeds to conference.

Mr. GILMAN. Mr. Chairman, I would tell the gentleman, onion growers in Orange County, New York in my congressional district have suffered devastating losses 3 out of the past 4 years, 1996, 1998, and 1999. They are in desperate need of meaningful assistance. The small sums which crop insurance paid to these farmers due to the 1996, 1998 and 1999 losses failed to provide anything close to minimal relief.

Accordingly, our farming families continue to lose their farms, individuals are uprooted, a traditional way of life is jeopardized, and a segment of our

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**(excerpts)**

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# Senate

The Senate met at 9:30 a.m. and was called to order by the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland.

## PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Our Father in heaven, light of the world, give the Members of this body Your light. Shine Your light to help them see the truth. Shine Your light so they can see the path You desire them to travel. Shine Your light so they can see themselves as they truly are and not take for granted the freedoms they enjoy. Shine Your light so they may live expectantly, open for what You will do or give. Shine Your light so they may see You in all Your majesty and love. Lord, fill this Chamber with the light of Your presence, enabling each Senator to discern and do Your will.

We pray in Your radiant Name. Amen.

## PLEDGE OF ALLEGIANCE

The Honorable BENJAMIN L. CARDIN led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

## APPOINTMENT OF ACTING PRESIDENT PRO TEMPORE

The PRESIDING OFFICER. The clerk will please read a communication to the Senate from the President pro tempore (Mr. BYRD).

The legislative clerk read the following letter:

U.S. SENATE,
PRESIDENT PRO TEMPORE,
*Washington, DC, May 2, 2007.*

*To the Senate:*

Under the provisions of rule I, paragraph 3, of the Standing Rules of the Senate, I hereby appoint the Honorable BENJAMIN L. CARDIN, a Senator from the State of Maryland, to perform the duties of the Chair.

ROBERT C. BYRD,
*President pro tempore.*

Mr. CARDIN thereupon assumed the chair as Acting President pro tempore.

## RECOGNITION OF THE MAJORITY LEADER

The ACTING PRESIDENT pro tempore. The majority leader is recognized.

## SCHEDULE

Mr. REID. Mr. President, the Senate will now begin a 60-minute period of morning business, the majority controlling the first half, Republicans controlling the final portion. Following the usage of all morning business, we will resume consideration of S. 1082, the FDA authorization legislation.

Yesterday, Senator DORGAN offered an amendment relating to drug reimportation. A cloture motion was filed on that last night. The cloture vote will occur tomorrow morning. Amendments in the second degree to the Dorgan amendment would have to be filed 1 hour prior to the cloture vote. I hope other Members who have amendments will file them as quickly as possible, to work with the managers. We have Senators KENNEDY and ENZI who are handling the legislation. They have a good relationship. They have done a lot already on this complicated legislation.

Yesterday, I indicated to the staff on both sides of the aisle that it may be necessary to have votes as early as noon on Monday. I hope we can finish the FDA bill tomorrow. If we can, then likely there would be no votes and we would move to other legislation, which would be WRDA, which has passed the House overwhelmingly. It came out of committee under the guidance of Senators BOXER and INHOFE; and we should be able to finish that bill next week.

Immigration is still on line to come up in the last 2 weeks of this work period. Next Wednesday, a week from today, I will rule XIV legislation that will put us in line to move to this during the last 2 weeks of this work period. It is legislation that is badly needed. We have had numerous meetings of Democratic and Republican Senators that have been going on for about 3 months. Progress has not been as we anticipated on either side, but we are going to move to this. Something has to be done. If we don't complete this legislation over here, then it certainly won't be done this year. Next year, a Presidential election year will make it very difficult. The three areas, of course, that are of concern are border security, and it is necessary that we visit that to see what can be done; with temporary workers, a pathway to legalization for the 12 million people who are here with bad paper; then we have to finally make sure we do something to make sure the employer sanctions aspect of the law is meaningful. At the present time, it is not. We have a lot to do there. I have had conversations with Senator KENNEDY, Senator LEAHY, and a number of other interested Senators over the last several weeks, including Senator KYL and others on the Republican side.

Mr. President, the President did veto the spending bill we sent him last night. It is unfortunate, but he did veto it. There will be a veto-override vote in the House tonight, it is my understanding.

The first piece of legislation dealing with another bill to send to the President will come to us from the House. I have had a number of consultations with Speaker PELOSI. At this stage, we are going to wait and see what happens at the White House today. The ball is in the President's court. He has to come forward with something that is satisfactory to Democrats and a significant number of Republicans.

There has to be some change of direction in the war. We find ourselves in

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

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