RSC Republican Study Committee

Rep. Sue Myrick (R-NC), Chairman
Neil Bradley, Executive Director

432 Cannon House Office Building
Washington, D.C. 20515

www.house.gov/burton/RSC

ph (202) 226-9717 • fax (202) 226-1633

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Staff Contact: Neil Bradley

REP. GUTKNECHT'S DRUG IMPORTATION BILL (H.R. 2427) & ABORTION

Recently, a few groups and individuals, including the Traditional Values Coalition, and the Reverend Jerry Falwell, have advanced the argument that H.R. 2427, the Pharmaceutical Market Access Act of 2003, sponsored by Rep. Gil Gutknecht and 44 others, will promote abortion, make RU-486 more widely available, and / or make RU-486 "as easy to get as aspirin".[1] This document is prepared in response to these allegations.

NOTE: *The Republican Study Committee (RSC) has no position on H.R. 2427. Members of the RSC have taken positions for and against the bill for multiple reasons, although Members on both sides of the bill have agreed that the bill has nothing to do with abortion.*

Short Summary:

CLAIM	REALITY
Under H.R. 2427, a 16-year-old girl could legally import RU-486 over the Internet.	Only if the 16-year-old girl is a physician who has agreed to comply with distribution and usage guidelines prescribed by the FDA for RU-486, could she legally import RU-486 over the Internet and then only for her patients.
Under H.R. 2427, an inmate in a jail cell could legally import RU-486 and then distribute it to others.	Only if the inmate is a physician who has agreed to comply with distribution and usage guidelines prescribed by the FDA for RU-486 and is seeing patients in his jail cell who have signed the FDA required patient agreement, could he import RU-486 legally.
H.R. 2427, would make RU-486 as easy to get as aspirin.	This is true if you acquire your aspirin by visiting a physician, signing a patient agreement form, and otherwise complying with the other restrictions set out by the FDA for use of RU-486.

[1] Mailer paid for by the Traditional Values Coalition and mailed to constituents of numerous Members of Congress

DETAILED DISCUSSION OF ARGUMENTS:

1. CLAIM: H.R. 2427 Permits Importation of "Covered Products" Including RU-486.

FACT: The claim leaves out the important caveat that imported "covered products" must comply with FDA regulations.

H.R. 2427 does indeed allow the importation of covered products and this *could* include RU-486. However, to fully understand the impact of H.R. 2427 on the availability of RU-486 it is important to understand what a "covered product" is. Section 804 (k)(1) of the Federal Food, Drug, and Cosmetic Act (H.R. 2427 amends Section 804) provides that a "covered product" means, "a prescription drug, except that such term does not include a controlled substance in schedule I, II, or III under section 202(c) of the Controlled Substances Act or a biological product as defined in section 351 of the Public Health Service Act." For the purpose of importation, this definition is further limited by Section 804, which as amended by H.R. 2427 would read:

> "SEC 804 (a) REGULATIONS. -- Not later than 180 days after the date of the enactment of the Pharmaceutical Market Access Act of 2003, the Secretary, after consultation with the United States Trade Representative and the Commissioner of Customs, shall promulgate regulations permitting pharmacists, wholesalers, and qualifying individuals to import into the United States covered products.
> (b) LIMITATION. -- Regulations under subsections (a) shall –
> (1) require that each covered product imported pursuant to such subsection complies with sections 501, 502, and 505, **and other applicable requirements of this Act**; and…"
> (emphasis added; "this Act" refers to the Food, Drug, and Cosmetic Act)

In other words, a "covered product" in order to be imported under H.R. 2427, must comply with all other applicable requirements of the Food, Drug, and Cosmetic Act. For example, current law requires that prescription drugs be labeled.[2] Under H.R. 2427, an individual would not be permitted to bring in unlabelled prescription drugs because such drugs would not constitute a "covered product" in compliance with the other provisions of the Food, Drug, and Cosmetic Act.

Likewise, **under H.R. 2427 an individual would not be permitted to import RU-486 without complying with the requirements of the Food, Drug, and Cosmetic Act and the regulations issued pursuant thereto.** The FDA, under the authorities of the Food, Drug, and Cosmetic Act has issued significant restrictions on RU-486. Specifically, the FDA approved RU-486 with restrictions issued pursuant to 21 CFR 314.520 (Subpart H), which provides that:

> "(a) If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product, such as:
> (1) Distribution restricted to certain facilities or physicians with special training or experience; or
> (2) Distribution conditioned on the performance of specified medical procedures.
> "(b) The limitations imposed will be commensurate with the specific safety concerns presented by the drug product."

[2] See Section 502 of the Food, Drug, and Cosmetic Act

FDA's Official Restrictions on RU-486:

The restrictions on RU-486 issued under this authority, include the following as outlined in a memorandum issued by the FDA (Note: Mifepristone is the drug name and Mifeprex is the U.S. trade name for RU-486)

"Under 21 CFR 314.520, distribution of mifepristone is restricted as described below.

Mifepristone must be provided by or under the supervision of a physician 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 other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
- Has read and understood the prescribing information of Mifeprex
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, given her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and Must sign it as well
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSEAGE AND ADMINISTRATION in the event of an on-going pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure
- Must report any hospitalization, transfusion of other serious events to the sponsor or its designate
- Must record the Mifeprex package serial number in each patient's record"

"With respect to the aspects of distribution other than physician qualifications described above, distribution of Mifeprex will be in accordance with the system described in the Population Council's submission of March 30, 2000, which includes the following:

- Secure manufacturing, receiving, and holding areas for the drug
- Secure shipping procedures, including tamper proof seals
- Controlled returns procedures
- Tracking system ability to trace individual packages to the patient level, while maintaining patient confidentiality
- Use of authorized distributors and agents with necessary expertise to handle distribution requirements for the drug
- **Provision of drug through a direct, confidential physician distribution system that ensures only qualified physicians will receive the drug for patient dispensing** (emphasis added)

The Population Council agreed to approval under Subpart H in their letter of September15, 2000."

Source: FDA website: http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf

H.R. 2427 in no way changes these requirements. In order for RU-486 to be imported legally as a "covered product" under the provisions of H.R. 2427, the requirements outlined above would have to be complied with. In short, it would be as illegal for the average citizen to acquire RU-486 after enactment of H.R. 2427 as it is now. RU-486 would not become "as easy to get as aspirin".

2. **CLAIM: Under H.R. 2427 Anyone Can Import RU-486.**

FACT: H.R. 2427 does permit individuals to import "covered products" but as discussed above, H.R. 2427 does not permit individuals to import products that are not in compliance with the provisions of the Food, Drug, and Cosmetic Act. Pursuant to the restrictions implemented under the authority of the Food, Drug, and Cosmetic Act, RU-486 is not available to individuals. In fact it is only available to physicians who agree to certain conditions (see discussion above for more information). **If any other individual attempted to import RU-486, the drug would cease to be a "covered product" and it would be illegal, even under H.R. 2427, for the individual to import the drug.**

3. **CLAIM: H.R. 2427 Would Overturn Current Law Restrictions Over Transporting Abortion Products in the Mail.**

FACT: The Comstock Law (18 U.S.C. 1461) provides that it is illegal to mail "any article or thing designated, adapted, or intended for producing abortion." Setting aside the fact that the Comstock Law is rarely enforced and that questions have been raised about its constitutionality[3], to the extent that you would have apparently conflicting statutes (The Comstock Law and H.R. 2427), the Courts generally seek to harmonize the statutes and give both their fullest effect. In this instance, the statutes could largely be harmonized because the only importations of RU-486 that would be legal under H.R. 2427 are those that comply with the other requirements associated with RU-486 (see discussion regarding item #1). For example, a non-physician who attempts to import RU-486 via the mail would be in violation of H.R. 2427 and so there would be no conflict with the Comstock Law. In those rare instances where a physician seeks to import RU-486 via the mail in complete compliance with restrictions on that drug it would seem that H.R. 2427 would supersede the Comstock Law. However, those instances would be rare and it would not make RU-486 any more accessible than it is under current law.

4. **CLAIM: H.R. 2427 Would Overturn the FDA's "Import Alert" Regarding RU-486.**

FACT: The FDA did in fact issue an import alert instructing Customs Agents to look out for and prevent the importations of RU-486. Under H.R. 2427 it would not be permissible for the FDA to block all importation of RU-486 (just as it would not be permissible to block all importations of any other covered product – see #1 for discussion of "covered product"). However, the FDA would be able to stop the importation of a drug, including RU-486, which fails to comply with the requirements of the Food, Drug, and Cosmetic Act. **Nothing in H.R. 2427 would prevent the FDA from focusing its enforcement resources on making sure that RU-486 is not illegally imported, just as they currently focus their enforcement resources with the current Import Alert.**

5. **CLAIM: H.R. 2427 Does Not Permit the FDA to Issue Safety Restrictions on Imported Drugs.**

FACT: H.R. 2427 does not permit the FDA to issue special restrictions on a drug simply because *it is imported* (other than the restrictions contained in H.R. 2427). However, H.R. 2427 does not allow the importation of a drug if it isn't in compliance with the same restrictions (including safety requirements, issued under the Food, Drug, and Cosmetic Act) that would apply to the drug if it were purchased domestically. **In other words, the safety restrictions are not lifted simply because the drug is imported.**

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[3] See John Schwarts, "Abortion Provision Stirs On-Line Furor," *Washington Post*, February 9, 1996.

6. CLAIM: H.R. 2427 Will Reduce the Cost of RU-486.

FACT: The stated purpose of H.R. 2427 is to reduce the cost of drugs to U.S. consumers. Given the restrictions on RU-486, whether purchased domestically or imported, it is questionable whether or not importation would lower the cost of the drug. It is further questionable whether a marginal reduction in the cost of RU-486 to a physician would lead to more abortions. **If legislation lowering the overall cost of drugs is pro-abortion, then other legislation, such as tort reform — that would lower expenses for doctors and drug companies — could also be a pro-life issue because it would lower the cost of providing someone with RU-486.**

What Other Organizations and Individuals Are Saying:

FDA Official as quoted in *National Review Online:*

"Even opponents of the bill disagree with the TVC. I spoke with an FDA official, himself pro-life, who said, 'There are 900 million reasons to be against re-importation. That one seems quite remote.'"

Family Research Council:

Washington Update - July 15, 2003
To: Friends of Family Research Council
From: Colin Stewart, Executive Vice President
Date: July 15, 2003 - Tuesday

In This Edition:
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1) Drug Re-Importation Bad Idea, But Not a Pro-Life Issue
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Drug Re-Importation Bad Idea, But Not a Pro-Life Issue

Some organizations are straining to turn a bill allowing the re-importation of American-made pharmaceuticals from Canada into a pro-life issue. It isn't. H.R. 2427, the Drug Re-Importation Act, is a bad bill, but not because it would allow the importation of the RU-486 "morning after" abortion pill, as some allege. RU-486 is made in China, not the U.S. Importing this deadly drug, sadly, is already legal. The drug re-importation bill is a bad idea because it has the potential to fatally wound America's pharmaceutical industry. The U.S. dominates the world in the production of new wonder drugs because our free market system allows manufacturers to recover the staggering costs of research and development. Other countries with socialized medicine schemes support little or no pharmaceutical industry because price-controls make it impossible for companies to recover R&D costs. It's true that Canadians benefit from cheaper drugs because of government price controls, but they would not have new drugs at any price were it not for the research and development carried out by U.S. firms. H.R. 2427 would allow American-made drugs to be re-imported from Canada under that country's government-run price control system. In effect we would import price controls along with cheaper drugs (another step toward socialized medicine in America). While this might appear

attractive in the short term - after all, who opposes cheaper drugs? - in the long run U.S. drug companies would be pressured to lower domestic prices to conform to the cheaper re-imports from Canada. This would, in turn, reduce the profits needed to fund research into new treatments. Let's not kill the goose that is laying golden eggs.

Rep. Chris Smith, Chairman of the Pro-Life Caucus and Rep. Joe Pitts, Chairman of the Values Action Team:

July 16, 2003

Reimportation is NOT an abortion issue.

Dear Colleague:

While we do not agree on the reimportation of prescription drugs, we both have devoted our careers to defending the sanctity of human life. **We are disheartened by recent ads and targeted mailings that attack Members' pro-life credentials even in cases where Members have 100 percent pro-life voting records.**

While we both wish that RU-486 were not legal, this debate is not about abortion. Many pro-life Members are original cosponsors of legislation that would allow the reimportation of prescription drugs, and many pro-life Members staunchly oppose this proposal.

Any effort to tangle this issue with abortion is misleading. We must not confuse the fight to defend innocent life with a dispute over whether or not to import drugs from foreign countries.

Sincerely,

Joseph R. Pitts
Chairman, House Values Action Team

Chris Smith
Co-Chairman, House Pro-Life Caucus

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Former Rep. Tom Coburn:

Tom A. Coburn, M.D.

July 10, 2003

The Honorable Gil Gutknecht
425 Cannon House Office Building
Washington, D.C. 20515

Dear Gil:

I was shocked to learn that some opponents of free-market access for prescription drugs have begun arguing that your legislation, H.R. 2427, the "Pharmaceutical Market Access Act of 2003" somehow promotes abortion and, more specifically, the availability of abortion drugs such as RU-486.

As you may recall, while in the House I was the author of not only provisions to permit the reimportation of FDA-approved drugs, but also the author of the House-approved proposal to block FDA approval of RU-486. As a pro-life practicing physician who earned a 100 percent pro-life voting record while serving in Congress, I find it ludicrous that those who oppose your legislation would resort to ad hominem attacks with no basis in reality.

I can state unequivocally that your legislation in no way, shape, or form promotes abortion. Many pro-life members are original cosponsors of your legislation and, quite obviously, do not believe your bill violates their deeply held convictions about the sanctity of life. Those who argue that your legislation makes abortion drugs more accessible by lowering overall drug prices necessitate the conclusion that in order to be pro-life one must be in favor of increasing all drug costs. I suppose the argument would be the higher the drug costs the more fervent your pro-life beliefs.

In Washington, it was always sad to see organizations drift from their core principles and take positions that defied common sense and logic. Any organization that links your legislation with the abortion debate will, in the long-term, undermine their credibility and relevancy in Washington. While the pharmaceutical industry has produced many wonderful life-saving drugs, it would be unwise for anyone to believe that the industry that developed and fought for FDA approval of RU-486 is now motivated by a passion for the pro-life cause.

The fact that opponents of your legislation have resorted to these attacks is shameful, yet the obtuseness of their logic ultimately serves to highlight the soundness of your argument.

Sincerely yours,

Tom A. Coburn, M.D.
Former Member of Congress