



NARAL
Pro-Choice America

Mifepristone: A Proven Safe and Effective Choice

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By Nancy Keenan, president, NARAL Pro-Choice America

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“Chairman Souder and members of the subcommittee: I thank you for the opportunity to submit this testimony for the record.

Mifepristone, also known by its original name RU 486, is a safe and effective method of nonsurgical abortion. For nearly two decades, millions of women worldwide have safely used mifepristone – an early-abortion option that does not require surgery or anesthesia.¹ Since the Food and Drug Administration (FDA) approved mifepristone in 2000, nearly 600,000 women in the United States have used the medication.²

Many of the women who choose mifepristone over surgical abortion say it gives them a better sense of privacy and dignity. For exactly these reasons, unfortunately, anti-choice activists fought this medical advancement every step of the way. They opposed allowing the drug into the country, tried to interfere with the FDA’s review process and attempted to block the agency from approving it, and are even now trying to pull the medication off the market. Having failed to stop mifepristone’s approval for use in the United States, the anti-choice movement is now engaged in a campaign to undermine public confidence in the drug. But they will fail because the facts are clear, and today I would like to review several key points about the drug, its approval, and its history of safety.

First, contrary to what anti-choice advocates claim, mifepristone was *not* “fast-tracked” through the FDA approval process, and the drug is *not* subject to less oversight than other medications. During its approval process, mifepristone received no special treatment by the FDA and underwent the agency’s standard, rigorous process of review, including clinical trials required for all new medications.³ It is correct that the FDA approved mifepristone under a set of regulations called “subpart H” – but that authority can be used to fast-track drugs *or* to impose more conditions on a medication’s distribution and use.⁴ Mifepristone’s approval was granted under “subpart H” for the latter reason – not the former. Clear evidence of this is found in the fact that the FDA imposed additional, unusual restrictions on the medication’s prescription and use – which are still in effect today.⁵ For example, the medication is only available directly from a doctor – not a pharmacist; and the manufacturer requires doctors to enter into a detailed prescriber’s agreement that lists a series of specific conditions that the physician

must meet. These conditions are unusually strict. In other words, doctors who prescribe mifepristone, women, and the medication's manufacturer are already taking unusual steps to respond to political considerations around the drug.

The claim that mifepristone is receiving *less* oversight and is *less* regulated than other medications is flatly contradicted by simple facts.

Anti-choice advocates also suggest incorrectly that mifepristone is not safe. This claim is untrue. In fact, the adverse drug event rate for mifepristone is just 0.158 percent, meaning 99.841 percent of women using mifepristone have not reported an adverse drug reaction.⁶

Of course, no medication – even common, over-the-counter drugs – is entirely exempt from adverse events. As Dr. Janet Woodcock, currently deputy commissioner for operations of the FDA, and formerly director of the FDA's Center for Drug Evaluation and Research, has stated: “No drug...is 100 percent safe; no pharmacologically active medicine exists that does not have side effects.”⁷ Let me be clear: Every serious adverse drug reaction associated with mifepristone should be fully investigated, as reactions from other drugs are. Mifepristone should not receive “special treatment” from federal health agencies – but by the same principle, mifepristone should not be held to an unfair standard that is not imposed on other prescription medications.

There are more than 106,000 U.S. deaths from all adverse drug reactions each year,⁸ yet adverse drug reactions associated with mifepristone account for less than one one-thousandth of a percent of that number. In contrast, every year 150 accidental overdoses of Tylenol lead to deadly liver failure.⁹ Five men die from Viagra-related drug reactions out of every 100,000 prescriptions written.¹⁰ If politicians intend to pull drugs off the market that have such proven records of safety and efficacy as mifepristone's, then the same standard should be applied across the board.

While anti-choice activists who oppose mifepristone will continue to attack its proven safety, they will also insist upon mischaracterizing its evidence-based, or “off-label” use, as dangerous or unusual. Contrary to these unfounded claims, evidence-based use of *all* medications – including mifepristone – can be common, safe, and appropriate. Standard medical practice assumes that, in many instances, evidence-based drug use is essential to providing optimal patient care. Indeed, it is standard practice for doctors to use FDA-approved drugs for alternative uses, such as prescribing aspirin for the prevention of heart attacks.¹¹ While estimates vary about the total number of prescriptions written for evidence-based use, an American Medical Association (AMA) official has estimated that 40 to 60 percent of all prescriptions in the U.S. are written for evidence-based uses.¹² Many evidence-based uses are widely known and widely studied, and are, as a result, recommended by medical textbooks, research institutions, and professional organizations.¹³ In fact, AMA Vice President M. Roy Schwarz has stated that “[i]n some cases, if you didn't use the drug in the off-label way you'd be guilty of malpractice.”¹⁴ Attacking mifepristone's off-label use is simply an unscientific attempt to condemn a safe, common practice.

Mischaracterizing mifepristone's safety and prescription regimen also diverts attention from its potential to help treat medical conditions unrelated to its original purpose.

Beyond its clear benefit to women who have made the choice to end a pregnancy, mifepristone holds significant promise in scientific research. Clinical trials show that it may be useful in treating a wide variety of debilitating ailments including HIV, Cushing's disease, glaucoma, certain tumors (including breast cancer tumors), infertility, and endometriosis.¹⁵ Restricting the availability of mifepristone, vilifying its use, and casting doubt on the legitimacy of its FDA approval will have the added harmful effect of hindering study of its potentially significant contributions to science and medical care.

Having now addressed and dispensed with the claims most frequently heard about mifepristone, an outside observer might wonder why so much more attention is paid to this medication than to others, especially those without such strong records of proven safety. Simply put, the anti-choice movement opposes the right to choose, and will fight any medical advancement that allows women access to safe, legal abortion. But realizing that the public does not share this view, anti-abortion activists disguise their political agenda in the language of science and safety. This is a dangerous move, and it cannot be allowed to succeed.

The mission to insert politics into mifepristone's approval and use has the potential to cause significant collateral damage. The U.S. system of drug approval is commonly recognized worldwide as the gold standard of safety and efficacy. The system only works if it remains impartial and apolitical – immune from political pressure from all directions. Politicians have no direct role in the drug-approval process – nor should they. If Congress steps in to override the FDA's determination of a drug's safety and efficacy – or to add new, political criteria to drug approvals – then that unprecedented intrusion into the realm of science and public health would call the entire review process into question. Where would such a precedent lead? People infected with HIV have long suffered stigma and encountered challenges in receiving medical care. Should anti-gay politicians be allowed to pull potentially life-saving drugs off the market because of assumptions about how HIV-positive individuals contracted the virus? Some fringe anti-abortion activists oppose common childhood vaccines because they were discovered from research that used fetal tissue.¹⁶ Looking into the future, if discoveries are made from stem-cell research, will those who object to the research withhold the resulting treatments from the rest of us? In short, allowing the political objections of a few to hold sway over a system that is – and must remain – impartial would jeopardize our whole system of drug approval and oversight, with profound implications beyond any predictions we could make today.

Mr. Chairman and members of the subcommittee, today's hearing is billed as a discussion about the importance of women's health. I certainly share that goal; in fact, since its inception, the protection and promotion of women's health has been NARAL Pro-Choice America's paramount goal. But if that is the true subject of today's hearing, then it must be said that the real danger facing women's health today is the continuing imposition of more and more restrictions on legal abortion – including the demand from

anti-choice forces that mifepristone – a safe early-abortion option – be removed from the market.

Step by step, this Congress is making legal abortion more and more difficult to obtain. I urge you not to follow that course, and instead to work with us to make abortion less necessary, not more dangerous.

Thank you for allowing me to present this testimony.”

¹ E-mail from Danco Laboratories representative, to NARAL Pro-Choice America representative (Jan. 10, 2006) (on file with NARAL Pro-Choice America).

² Andrew Bridges, *Women's Deaths Mystery Widens*, AP, May 10, 2006.

³ National Abortion Federation (NAF), *Frequently Asked Questions About Mifepristone* (2003) at www.arhp.org/files/mifepristoneQA.pdf (last visited Oct. 11, 2005).

⁴ 21 C.F.R. § 314.520; U.S. Food and Drug Administration, Department of Health and Human Services, *NDA's Approved Under Subpart H* (Sept. 30, 2004), at <http://www.fda.gov/cder/rdmt/accapp.htm> (last visited May 9, 2006).

⁵ Letter from Center for Drug Evaluation and Research, to Sandra P. Arnold, Vice President, Corporate Affairs, Population Council (Sept. 28, 2000) (at <http://www.fda.gov/cder/foi/appletter/2000/20687appltr.htm>).

⁶ Andrew Bridges, *Women's Deaths Mystery Widens*, AP, May 10, 2006.

⁷ Statement By Janet Woodcock, M.D., Director, Center For Drug Evaluation And Research, Food And Drug Administration, Before The Subcommittee On Oversight And Investigations, Committee On Energy And Commerce, U.S. House of Representatives, Dec. 11, 2002, at <http://www.fda.gov/ola/2002/accutane1211.html> (last visited May 5, 2006).

⁸ *Adverse Drug Reactions May Cause Over 100,000 Deaths Among Hospitalized Patients Each Year*, AM. MED. ASS'N SCI. NEWS UPDATES, Apr. 15, 1998, at <http://www.vaccinationnews.com/DailyNews/August2001/AdvDrugReactKillMany.htm> (last visited May 10, 2006).

⁹ Association of Reproductive Health Professionals, *Mifepristone Safety Overview*, at <http://www.arhp.org/files/mifepristonefactsheet.pdf> (last visited Oct. 17, 2005).

¹⁰ Association of Reproductive Health Professionals, *Mifepristone Safety Overview*, at <http://www.arhp.org/files/mifepristonefactsheet.pdf> (last visited Oct. 17, 2005).

¹¹ Marvin M. Lipman, *Using Approved Drugs for Unapproved Purposes*, CONSUMER REP. HEALTH, Feb. 1998, at 10.

¹² Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. LEGAL MED. 365 (1999); Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, WASH. POST, at Z11 (Mar. 29, 1994); see also James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 80 (1998) (reporting that off-label/evidence-based prescriptions may account for more than 25 percent of the 1.6 billion prescriptions each year, with some estimates running as high as 60 percent).

¹³ Veronica Henry, *Off-Label Prescribing: Legal Implications*, 20 J. LEGAL MED. 365 (1999).

¹⁴ Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, WASH. POST at Z11 (Mar. 29, 1994).

¹⁵ Feminist Majority Foundation, *The Medical Uses of Mifepristone* (2005), at <http://www.feminist.org/action/action120f.htm> (last visited Oct. 12, 2005); *Mifepristone: Emergency Contraception and Other Uses*, 11 THE CONTRACEPTION REP. 13 (Dec. 2000), at <http://www.contraceptiononline.org/contrareport/article01.cfm?art=109> (last visited Oct. 12, 2005); Institute of Medicine, COMMITTEE ON ANTIPROGESTINS, CLINICAL APPLICATIONS OF MIFEPRISTONE (RU 486) AND OTHER ANTIPROGESTINS 1, 8-13 (Molla S. Donaldson et al. eds., 1993).

¹⁶ See, e.g., Mike Wending, *Smallpox Vaccine's Stem Cell Link Prompts Pro-Life Group's Concern*, BPNEWS.NET, Nov. 28, 2001; American Life League, *Medical Cannibals: The Moral Implications of Fetal Tissue Vaccines*, at <http://www.all.org/article.php?id=10169> (last visited May 9, 2006); Children of God for Life, *Our Mission: The Purpose of the Campaign for Ethical Vaccines Is...*, at www.cogforlife.org (last visited May 11, 2006).