



NARAL
Pro-Choice America

MIFEPRISTONE IS A SAFE CHOICE

MIFEPRISTONE IS EXTREMELY SAFE

- More than 800,000 women in the United States have used mifepristone since its FDA approval in 2000.¹ The rate of reported adverse events for mifepristone is very low: approximately 0.28 percent. In other words, fewer than 3 out of every 1,000 women who use mifepristone have any adverse event. The vast majority of adverse events reported to Danco, the manufacturer of mifepristone, are not serious, not emergencies, and are expected. The incidence of serious adverse events is extremely low.²
- Every single drug or medication, no matter how common it seems or how frequently it is used, carries some risk of side effects. Danco and the Food and Drug Administration have confirmed just six deaths in the United States following the use of mifepristone.³ Four women tested positive for a rare bacterium usually associated with pregnancy-related toxic shock syndrome; the FDA found no presence of this bacterium in mifepristone when it tested the drug.⁴ Of the two most recent deaths, reported to the FDA in March 2006, one was determined to be unrelated to the use of mifepristone, and the other, with symptoms of infection, continues to be under investigation.⁵

MIFEPRISTONE IS SAFER THAN OTHER COMMON AND WIDELY USED DRUGS

- Five men die from Viagra-related drug reactions out of every 100,000 prescriptions written.⁶
- Every year, 150 accidental overdoses of Tylenol lead to deadly liver failure.⁷
- Many other commonly prescribed medications have adverse reaction rates that far exceed that of mifepristone:

DRUG	ADVERSE REACTION RATE ⁸
Advair Diskus 100/50 (asthma)	At least 27%
Wellbutrin (anti-depressant)	At least 22.3%
Adderrall XR (Attention Deficit Disorder with Hyperactivity (ADHD))	At least 14%
Xanax (anti-anxiety)	At least 13.9%
Claritin Tablets (allergy)	At least 12%
Lipitor 10 mg. (cholesterol)	At least 10.3%

Celebrex (arthritis)	At least 8.8%
Imitrex 100 mg. (migraines)	At least 8%
Flonase Nasal Spray 100 mcg (allergy)	At least 7.2%
Nexium (heartburn)	At least 5.5%
Cipro (ciprofloxacin) (antibiotic, commonly used for Urinary Tract Infections (UTI))	At least 5.2%
Zithromax (antibiotic)	At least 5%
Singulair (asthma)	At least 4.2%
Ritalin (ADD, ADHD)	At least 3.1%
Naproxen (anti-inflammatory)	At least 3%
Mifepristone	0.22% ⁹

OTHER HEALTH COMPLICATIONS ARE MUCH MORE COMMON THAN MIFEPRISTONE ADVERSE DRUG REACTIONS

- 106,000 people die from adverse reactions to drugs per year.¹⁰ Mifepristone accounts for just 0.0009 percent (less than one one-thousandth of a percent) of these ADR deaths.
- 7,000 people die from medication errors in hospitals per year.¹¹
- 12,000 people die from unnecessary surgery per year.¹²
- 20,000 people die from medical errors in hospitals (excluding medication errors) per year.¹³

ATTACKS ON MIFEPRISTONE ARE PART OF A LARGER EFFORT TO MAKE ALL ABORTION CARE ILLEGAL, WHICH WOULD SERIOUSLY THREATEN WOMEN'S HEALTH

- Anti-choice activists and lawmakers who are trying to remove mifepristone from the market believe that abortion should be outlawed entirely, and they often claim that abortion in general is harmful to women's health. This is simply not true — legal abortion is extremely safe.
 - The legalization of abortion in the United States has led to the near elimination of deaths from the procedure.¹⁴
 - Between 1973 (when abortion became legal nationwide) and 1997, the number of deaths per 100,000 legal abortion procedures declined from 4.1 to 0.6.¹⁵
 - Legal abortion entails half the risk of death involved in a tonsillectomy and one-hundredth the risk of death involved in an appendectomy.¹⁶ The risk of death from abortion care is lower than that from a shot of penicillin.¹⁷
- **In fact, the most serious threat to women's health is making abortion illegal:** In 1962, about one million illegal abortions took place, and more than 5,000 women died as a result (the

numbers may have even been higher due to inaccurate autopsies).¹⁸ That equals a fatality rate of at least one in 1,000, or 114 times that of mifepristone.

- One of the major architects of the movement to pull mifepristone from the market is Concerned Women for America, an avowedly anti-choice organization whose goal is to “bring Biblical principles into all levels of public policy.”¹⁹ The organization opposes not only mifepristone²⁰ but a woman’s right to choose generally. The group openly calls for *Roe v. Wade* to be overturned,²¹ and even opposes common forms of birth control.²² It is hypocritical — to say the least — for an organization to claim that it is out to protect women’s health and lives when it simultaneously advocates for returning to a time when thousands of women needlessly died or were permanently injured every year.

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Notes:

¹ Email from Abigail Long, Director of Marketing and Public Affairs, Danco Laboratories, to Adam Zimmerman, Legal and Policy Research Associate, Legal and Policy Research Department, NARAL Pro-Choice America (Nov. 2, 2007) (on file with NARAL Pro-Choice America).

² Email from Abigail Long, Director of Marketing and Public Affairs, Danco Laboratories, to Adam Zimmerman, Legal and Policy Research Associate, Legal and Policy Research Department, NARAL Pro-Choice America (Nov. 2, 2007) (on file with NARAL Pro-Choice America).

³ Press Release, U.S. Food and Drug Administration, *Mifeprex (mifepristone) Information* (Apr. 10, 2006), at <http://www.fda.gov/cder/drug/infopage/mifepristone/default.htm> (last visited Jan. 3, 2008).

⁴ *Clostridium sordellii Toxic Shock Syndrome After Medical Abortion with Mifepristone and Intravaginal Misoprostol — United States and Canada, 2001-2005*, 54 *Morbidity and Mortality Weekly Report* 724 (July 29, 2005); U.S. Food and Drug Administration, *FDA Public Health Advisory: Sepsis and Medical Abortion* (Nov. 4, 2005), at <http://www.fda.gov/cder/drug/advisory/mifeprex.htm> (last visited Jan. 9, 2008).

⁵ National Abortion Federation (NAF), *Frequently Asked Questions about Mifepristone*, (Oct. 25, 2006); Press Release, U.S. Food and Drug Administration, *Mifeprex (mifepristone) Information* (Apr. 10, 2006), at <http://www.fda.gov/cder/drug/infopage/mifepristone/default.htm> (last visited Jan. 3, 2008).

⁶ Association of Reproductive Health Professionals, *Mifepristone Safety Overview*, at <http://www.arhp.org/files/mifepristonefactsheet.pdf> (last visited Jan. 3, 2008).

⁷ Association of Reproductive Health Professionals, *Mifepristone Safety Overview*, at <http://www.arhp.org/files/mifepristonefactsheet.pdf> (last visited Jan. 3, 2008).

⁸ PHYSICIANS’ DESK REFERENCE (57th ed. 2003). Percentages were excerpted from adverse reaction percentages listed in the Physician’s Desk Reference for the listed drugs. “At least” reflects minimum percentage of adverse reactions, based on elimination of some particularly high outliers. In addition, high adverse reaction rates involving some especially common side effects are not cited; for example,

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“sweating” was not cited, with cited percentage reflecting more serious side effects that would have been comparable to those possible with ingestion of mifepristone.

- ⁹ Jillian T. Henderson et. al, *Safety of Mifepristone Abortions in Clinical Use*, 72 *CONTRACEPTION* 175 (2005).
- ¹⁰ Barbara Starfield, *Is U.S. Health Really the Best in the World?*, 284 *JAMA* 483, 483-484 (2000).
- ¹¹ Barbara Starfield, *Is U.S. Health Really the Best in the World?*, 284 *JAMA* 483, 483-484 (2000).
- ¹² Barbara Starfield, *Is U.S. Health Really the Best in the World?*, 284 *JAMA* 483, 483-484 (2000).
- ¹³ Barbara Starfield, *Is U.S. Health Really the Best in the World?*, 284 *JAMA* 483, 483-484 (2000).
- ¹⁴ Phillip G. Stubblefield & David A. Grimes, *Septic Abortion*, 331 *NEW ENG. J. MED.* 310 (1994).
- ¹⁵ Laurie D. Elam-Evans et al., Centers for Disease Control & Prevention, *Abortion Surveillance – United States, 1999*, 51 *MORBIDITY & MORTALITY WEEKLY REP.* 28, tbl. 19 (2002).
- ¹⁶ Warren M. Hern, *ABORTION PRACTICE* 23-24 (1984).
- ¹⁷ Nancy Felipe Russo, *Unwanted Childbearing, Abortion, and Women’s Mental Health: Research Findings, Policy Implications*, *ROCKY MOUNTAIN PSYCH.* 9 (1992).
- ¹⁸ Zad Leavy & Jerome M. Krummer, *Criminal Abortion: Human Hardship and Unyielding Law*, 35 *S. CAL. L. REV.* 123, 124 (1962).
- ¹⁹ Concerned Women for America, *About CWA*, at <http://www.cwfa.org/about.asp> (last visited Jan. 3, 2008).
- ²⁰ See Concerned Women for America, *Hot Topics: RU486 Citizen Petition*, at <http://www.cwfa.org/hot-topics.asp> (last visited Jan. 3, 2008).
- ²¹ Concerned Women for America, *Roe v. Wade*, at <http://www.cwfa.org/articledisplay.asp?id=1342&department=CWA&categoryid=life> (last visited Jan. 3, 2008); Tony Nassif, *Roe v. Wade: Medical Discoveries Cry for Reversal* (Jan. 22, 2003), at <http://www.cultureandfamily.org/articledisplay.asp?id=3137&department=CFI&categoryid=cfreport> (last visited Jan. 3, 2008).
- ²² Concerned Women for America, *Contraception or Deception* (Aug. 22, 2002), at <http://www.cwfa.org/articledisplay.asp?id=1559&department=CWA&categoryid=life> (last visited Jan. 3, 2008).