



### **Mifepristone is a Safe Choice**

Mifepristone (also known by its original name RU 486 and its trade name, Mifeprex®) is the first and only Food and Drug Administration (FDA)-approved medication providing women with a safe and effective, nonsurgical option for early pregnancy termination. Mifepristone has been tested extensively and used safely and effectively worldwide since 1981, and in the United States since 2000.

### **Mifepristone is Extremely Safe**

- More than one and a half million women in the United States have used mifepristone since its FDA approval in 2000.<sup>1</sup> The rate of reported adverse events for mifepristone is very low: approximately 0.2 percent.<sup>2</sup> In other words, approximately two out of every 1,000 women who use mifepristone have an adverse event. The vast majority of adverse events reported to the FDA are not serious, not emergencies, and are expected. The incidence of serious adverse events is extremely low.<sup>3</sup>
- Every single medication, no matter how common it seems or how frequently it is used, carries some risk of side effects. Danco and the FDA have confirmed that between 1996 and 2011, there have been just eight deaths in the United States following the use of mifepristone.<sup>4</sup> 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.<sup>5</sup>

### **Mifepristone is Safer Than Other Common and Widely Used Medications**

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

<b>DRUG</b>	<b>ADVERSE REACTION RATE<sup>8</sup></b>
Advair Diskus 100/50 (asthma)	At least 27% <sup>9</sup>
Wellbutrin (anti-depressant)	At least 22.3% <sup>10</sup>
Xanax (anti-anxiety)	At least 13.9% <sup>11</sup>
Lipitor 10 mg. (cholesterol)	At least 12.9% <sup>12</sup>

Clarinet (allergy)	At least 10% <sup>13</sup>
Celebrex (arthritis)	At least 8.8% <sup>14</sup>
Imitrex 100 mg. (migraines)	At least 8% <sup>15</sup>
Flonase Nasal Spray 100 mcg (allergy)	At least 7.2% <sup>16</sup>
Nexium (heartburn)	At least 5.5% <sup>17</sup>
Monurol (fosfomycin) (antibiotic, commonly used for urinary tract infections)	At least 5.2% <sup>18</sup>
Botox	At least 5% <sup>19</sup>
Zithromax (antibiotic)	At least 5% <sup>20</sup>
Singulair (asthma)	At least 4.2% <sup>21</sup>
Ritalin (ADD, ADHD)	At least 3.1% <sup>22</sup>
Naprelan (anti-inflammatory)	At least 3% <sup>23</sup>
Mifepristone	0.28% <sup>24</sup>

**Other Health Complications Are Much More Common Than Mifepristone Adverse Reactions**

- 700,000 people visit the emergency room and 120,000 people are hospitalized from adverse reactions to drugs (ADR) per year.<sup>25</sup>
- 1.5 million people are injured each year due to medication errors – approximately 400,000 of those injuries occur in hospitals, 800,000 occur in long-term care settings, and 530,000 occur among Medicare recipients in outpatient clinics.<sup>26</sup>
- In 2010, more than 38,000 Americans died of unintentional overdoses of pain medications such as methadone, oxycodone, and hydrocodone.<sup>27</sup>
- Nearly 100,000 adults are treated in emergency departments each year because of adverse events from antibiotics.<sup>28</sup>

**Evidence-Based Use of Mifepristone**

When the FDA first approved mifepristone for use in the United States, it was based on the medication’s initial treatment protocol as developed in France. Almost immediately, researchers found better, evidence-based ways in which the medication could be used safely and effectively. In the United States, providers followed suit and developed new treatment guidelines.<sup>29</sup>

Since that time, anti-choice organizations and legislators have attacked this evidence-based, or “off-label” use of mifepristone in an attempt to scare women and further restrict their access to the medication. Contrary to these unfounded claims, evidence-based use of all drugs – including mifepristone – is common, safe, effective, and appropriate.

- Estimates vary about the rates of off-label use. By one measure, more than one in seven prescriptions for common medications is for off-label use.<sup>30</sup> By another, an American Medical Association (AMA) official has estimated that 40 to 60 percent of all prescriptions in the United States are written for evidence-based uses.<sup>31</sup>
- 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.<sup>32</sup> Today, heart and seizure medications are the medications most commonly prescribed for other purposes.<sup>33</sup>
- Research with mifepristone has shown that alternatives to the FDA-approved regimen are safe, effective, and in most cases, preferable to the FDA regimen.<sup>34</sup>

### **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 believe that abortion should be outlawed entirely are trying to remove mifepristone from the market, 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.<sup>35</sup>
- 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.<sup>36</sup> 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).<sup>37</sup> 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.”<sup>38</sup> The organization opposes not only mifepristone but a woman’s right to choose generally. The group openly calls for *Roe v. Wade* to be overturned, and even opposes common forms of birth control.<sup>39</sup> 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:

- <sup>1</sup> H. Boonstra, *Medication Abortion Restrictions Burden Women and Providers—and Threaten U.S. Trend Toward Very Early Abortion*, GUTTMACHER POL. REV., Winter 2013, Vol. 16, No. 1, at <http://www.guttmacher.org/pubs/gpr/16/1/gpr160118.pdf> (last visited Nov. 7, 2016).
- <sup>2</sup> U.S. Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011* (Apr. 30, 2011), at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf> (last visited Nov. 11, 2016); UD Upadhyay, et al. *Incidence of Emergency Department Visits and Complications After Abortion*, OBSTET GYNECOL., Jan. 2015, 125(1).
- <sup>3</sup> U.S. Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011* (Apr. 30, 2011), at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf> (last visited Nov. 7, 2016)
- <sup>4</sup> U.S. Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011* (Apr. 30, 2011), at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf> (last visited Nov. 7, 2016); Press Release, U.S. Food and Drug Administration, *Mifeprex (mifepristone) Information* (July 19, 2005), at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111341.htm> (last visited Dec. 11, 2015).
- <sup>5</sup> *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.drugs.com/news/fda-public-health-advisory-sepsis-medical-abortion-update-1762.html> (last visited Nov. 7, 2016).
- <sup>6</sup> Association of Reproductive Health Professionals, *What You Need to Know: Mifepristone Safety Overview*, (April, 2008), at <http://www.arhp.org/uploadDocs/mifepristonefactsheet.pdf> (last visited Nov. 7, 2016).
- <sup>7</sup> *Id.*
- <sup>8</sup> PHYSICIANS' DESK REFERENCE (65th ed. 2011). 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, "sweating" was not cited, with cited percentage reflecting more serious side effects that would have been comparable to those possible with ingestion of mifepristone.
- <sup>9</sup> GlaskoSmithKline, *Full Prescribing Information: Advair Diskus* (Apr. 2016), at [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Advair\\_Diskus/pdf/ADV AIR-DISKUS-PI-MG-IFU.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Advair_Diskus/pdf/ADV AIR-DISKUS-PI-MG-IFU.PDF) (last visited July 25, 2016).
- <sup>10</sup> GlaskoSmithKline, *Full Prescribing Information: Wellbutrin* (Apr. 2016), at [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/W](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/W)

*Notes, cont.*

- [ellbutrin SR/pdf/WELLBUTRIN-SR-PI-MG.PDF](#) (last visited July 25, 2016).
- <sup>11</sup> Pfizer Inc., *U.S. Physician Prescribing Information: Xanax* (Sept. 2013), at <http://labeling.pfizer.com/ShowLabeling.aspx?id=547> (last visited July 25, 2016).
- <sup>12</sup> Pfizer Inc., *U.S. Physician Prescribing Information: Lipitor* (Mar. 2015), at <http://labeling.pfizer.com/ShowLabeling.aspx?id=587> (last visited July 25, 2016).
- <sup>13</sup> Merck & Co., Inc., *Full Prescribing Information: Clarinex-D 12 Hour* (Mar. 2014), at [http://www.merck.com/product/usa/pi\\_circulars/c/clarinex\\_d\\_12/clarinex\\_d\\_12\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/c/clarinex_d_12/clarinex_d_12_pi.pdf) (last visited July 25, 2016).
- <sup>14</sup> Pfizer Inc., *U.S. Physician Prescribing Information: Celebrex* (May 2016), at <http://labeling.pfizer.com/ShowLabeling.aspx?id=793> (last visited July 25, 2016).
- <sup>15</sup> GlaskoSmithKline, *Full Prescribing Information: Imitrex Tablets* (Nov. 2013), at [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Imitrex\\_Tablets/pdf/IMITREX-TABLETS-PI-PIL.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Imitrex_Tablets/pdf/IMITREX-TABLETS-PI-PIL.PDF) (last visited July 25, 2016).
- <sup>16</sup> GlaskoSmithKline, *Full Prescribing Information: Flonase Nasal Spray* (Jan. 2015), at [https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing\\_Information/Flonase/pdf/FLONASE-PI-PIL-COMBINED.PDF](https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Flonase/pdf/FLONASE-PI-PIL-COMBINED.PDF) (last visited July 25, 2016).
- <sup>17</sup> AstraZeneca Pharmaceuticals LP, *Full Prescribing Information: Nexium* (Jan. 2016), at <http://www.azpicentral.com/nexium/nexium.pdf> (last visited July 25, 2016).
- <sup>18</sup> Forest Pharmaceuticals, Inc., *Full Prescribing Information: Monurol* (Sept. 2014), at [http://pi.actavis.com/data\\_stream.asp?product\\_group=1934&p=pi&language=E](http://pi.actavis.com/data_stream.asp?product_group=1934&p=pi&language=E) (last visited July 25, 2016).
- <sup>19</sup> Allergan, *Full Prescribing Information: Botox* (Jan. 2016), at [http://www.allergan.com/assets/pdf/botox\\_pi](http://www.allergan.com/assets/pdf/botox_pi) (last visited July 25, 2016).
- <sup>20</sup> Pfizer Inc., *U.S. Physician Prescribing Information: Zithromax* (May 2016), at <http://labeling.pfizer.com/ShowLabeling.aspx?id=512> (last visited July 25, 2016).
- <sup>21</sup> Merck & Co., Inc., *Full Prescribing Information: Singulair* (June 2016), at [http://www.merck.com/product/usa/pi\\_circulars/s/singulair/singulair\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/s/singulair/singulair_pi.pdf) (last visited July 25, 2016).
- <sup>22</sup> Novartis Pharmaceuticals Corp., *Full Prescribing Information: Ritalin* (July 2015), at [https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin\\_la.pdf](https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/ritalin_la.pdf) (last visited July 25, 2016).
- <sup>23</sup> Almatica Pharma, Inc., *Full Prescribing Information: Naprelan* (May 2016), at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2016/020353s031s032lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020353s031s032lbl.pdf) (last visited July 25,

*Notes, cont.*

2016).

<sup>24</sup> U.S. Food and Drug Administration, *Mifepristone U.S. Postmarketing Adverse Events Summary through 04/30/2011*

(Apr. 30, 2011), at

<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf> (last visited Nov. 7, 2016).

<sup>25</sup> Centers for Disease Control and Prevention, *Medication Safety Program: Adults and Older Adult Adverse Drug Events* (Oct. 2, 2012) at [http://www.cdc.gov/MedicationSafety/Adult\\_AdverseDrugEvents.html](http://www.cdc.gov/MedicationSafety/Adult_AdverseDrugEvents.html) (last visited Nov. 7, 2016).

<sup>26</sup> Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical Overdose Deaths, United States, 2010. *JAMA*. 2013;309(7):657-659. doi:10.1001/jama.2013.272.

<sup>27</sup> Centers for Disease Control and Prevention, *Medication Safety Program: Adults and Older Adult Adverse Drug Events* (Oct. 2, 2012) at [http://www.cdc.gov/MedicationSafety/Adult\\_AdverseDrugEvents.html](http://www.cdc.gov/MedicationSafety/Adult_AdverseDrugEvents.html) (last visited Nov. 7, 2016).

<sup>28</sup> *Id.*

<sup>29</sup> H. Boonstra, *Medication Abortion Restrictions Burden Women and Providers—and Threaten U.S. Trend Toward Very Early Abortion*, *GUTTMACHER POL. REV.*, Winter 2013, Vol. 16, No. 1, at <http://www.guttmacher.org/pubs/gpr/16/1/gpr160118.pdf> (last visited Nov. 7, 2016).

<sup>30</sup> *Study: Off-label drugs often prescribed*, *USA TODAY*, May 8, 2006 at <http://consumer.healthday.com/general-health-information-16/misc-drugs-news-218/off-label-prescription-drug-use-common-532598.html> (last visited Nov. 7, 2016).

<sup>31</sup> Judith G. Edersheim, *Off-Label Prescribing*, *Psychiatric Times*, April 14, 2009 at <http://www.psychiatristimes.com/display/article/10168/1401983> (last visited Dec. 11, 2015); National Abortion Federation (NAF), *Pharmacological Approaches to Early Abortion* (2010) at [http://www.prochoice.org/online\\_cme/m1pharma.asp](http://www.prochoice.org/online_cme/m1pharma.asp) (last visited Nov. 7, 2016); 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);

<sup>32</sup> Consumer Report Best Buy Drugs, *Shopper's Guide to Prescription Drugs: "Off-Label Drug Use* (2007) at <http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/money-saving-guides/english/Off-Label-FINAL.pdf> (last visited Dec. 11, 2015).

<sup>33</sup> *Study: Off-label drugs often prescribed*, *USA TODAY*, May 8, 2006 at [http://www.usatoday.com/news/health/2006-05-08-offlabel-drugs\\_x.htm](http://www.usatoday.com/news/health/2006-05-08-offlabel-drugs_x.htm) (last visited Nov. 7, 2016).

<sup>34</sup> Reproductive Health Technologies Project, *Mifepristone*. Hard copy on file at NARAL offices.

*Notes, cont.*

- <sup>35</sup> Phillip G. Stubblefield & David A. Grimes, *Septic Abortion*, 331 NEW ENG. J. MED. 310 (1994).
- <sup>36</sup> Sonia Gamble et al. , Centers for Disease Control & Prevention, *Abortion Surveillance – United States, 2005*, 57 MORBIDITY & MORTALITY WEEKLY REP. 13, tbl. 19 (2008).
- <sup>37</sup> The estimated number of deaths per year from illegal abortion services (e.g. 5,000) has been derived from the findings of several studies. The following is a summary of these studies: “Difficulty as it is to accumulate statistics in this area, a surprising similarity has been noted in various studies independently made within the last thirty years. If general trend observed is accepted, without becoming sidetracked in disputes over exact numbers of methodology, we must consider the probability that more than one million criminal abortions will have been performed in the United States in 1962, and more than five thousand women may have died as a direct result.” Zad Leavey & Jerome M. Krummer, *Criminal Abortion: Human Hardship and Unyielding Laws*, 35 S. CAL. L. REV. 124 (1962) (citing to Gebhard, et al, PREGNANCY, BIRTH AND ABORTION 136-137 (1958); Frederick Taussig, ABORTION SPONTANEOUS AND INDUCED: MEDICAL AND SOCIAL ASPECTS 25 (1936); Marie Kopp, BIRTH CONTROL IN PRACTICE 222 (1934); Stix, *A Study of Pregnancy Wastage*, 13 MILBANK MEMORIAL FUND QUARTERLY 347, 355 (1935); MODEL PENAL CODE § 207.11, comment, p. 147 (Tent. Draft No. 9, 1959.). “It has been estimated that as many as 5,000 American women die each year as a direct result of criminal abortion. The figure of 5,000 may be a minimum estimate.” Richard Schwarz, SEPTIC ABORTION 7 (1968) (citing to Taussig, 23-28, which discusses the original mathematical formula used for determining that somewhere between 8,000 and 10,000 women died each year from illegal abortion.); “One recent study at the University of California’s School of Public Health estimated 5,000 to 10,000 abortion deaths annually.” Lawrence Lader, ABORTION 3 (1966) (also citing to Edwin M. Gold et al, *Therapeutic Abortions in New York City: A Twenty-Year Review*, in New York Dept. of Health, Bureau of Records and Statistics (1963), which discussed Dr. Christopher Tietze’s estimate of nearly 8,000 deaths from illegal abortion annually in the United States. The estimate was based on the number of illegal abortions in New York City, the only major municipality keeping abortion statistics.); “[M]ore than five thousand women may have died as a direct result [of criminal abortion in the United States in 1962].” Zad Leavy & Jerome M. Kummer, *Criminal Abortion: Human Hardship and Unyielding Laws*, 35 S. CAL. L. REV. 123, 124 (1962); “Taussig and others have concluded that the abortion death rate during the late 1920s was about 1.2% and amounted to over 8,000 deaths per year.” Russell S. Fisher, *Criminal Abortion*, in Harold Rosen, THERAPEUTIC ABORTION, MEDICAL PSYCHIATRIC, LEGAL, ANTHROPOLOGICAL, AND RELIGIOUS CONSIDERATIONS 8 (1954).
- <sup>38</sup> Concerned Women for America, *About CWA*, at <http://www.cwfa.org/about/> (last visited Nov. 7, 2016).
- <sup>39</sup> Concerned Women for America, *Contraception or Deception* (Aug. 22, 2002) (on file with NARAL Pro-Choice America).