

The Special Treatment of RU-486

by Nick Frase

September 28th marks the ten-year anniversary of the FDA's approval of RU-486 which invites the opportunity to step back with a decade's experience and consider the drug's embattled history. Billed as a safe non-invasive alternative to surgical abortion, this *abortifacient* (abortion-producing) pill's early supporters touted RU-486's potential to change the landscape of the abortion industry in America. The widespread ease and relative privacy in which a pill could be administered would, it was believed, relieve the social stigma many women felt from having an abortion. This left some to hope that it would defuse the abortion conflict more generally. One advocate described it thus: "Abortion in the U.S. is this degraded, shameful, violence-surrounded thing. ...It's not like that in Europe. So that makes our context for medical [e.g., RU-486] abortion unique."¹

The FDA expedited RU-486's approval under their Subpart H regulations, a process designed to fast track life-saving and otherwise vital drugs. The FDA argued they possessed wide discretion to make this decision—but as to the wisdom, the decision left many concerned whether the FDA did not also possess ulterior motives. Senator DeMint has criticized the FDA's actions for being disingenuous, "Defining pregnancy as a life-threatening illness was a thoroughly political, not scientific, decision."²

To date, eight women in the U.S. have died and thousands more have suffered severe adverse effects due to complications arising from RU-486.³ Even abortion providers have approached the non-surgical method with hesitancy as it's *10 times* more likely to end in death than surgical methods, begging the question what clinical benefits if

any RU-486 offers.⁴ Many drugs have been removed from the market for far lesser reasons than the known risks assumed with taking RU-486. This has some health advocates wondering if the drug is not somehow receiving special treatment over and above its track record.

In recent days the diabetes drug, Avandia, has been removed from shelves due to its link with increased risk of stroke. In fact, a survey of the last decade reveals a myriad of drugs whose uses have been significantly curtailed or have been removed outright from sale for side-effects comparable to, if not more benign than, those shown to be associated with RU-486: *(N.B. The following information has been excerpted from a Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Subcommittee on Criminal Justice, Drug Policy and Human Resources (May 16, 2006) (on file with Subcommittee. The additional references are simply cross-referencing.)*

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| NeutroSpec (Appendicitis and infections) |
| December, 2005 – Palatin Technologies voluntarily suspended sales and marketing of NeutroSpec. No definitive determination was made regarding the relationship between NeutroSpec and reported adverse events. ⁵ |
| Tysabri (M.S. and Crohn’s Disease) |
| February, 2005 – Biogen voluntarily suspended marketing of the drug as well as its use in clinical trials until more detailed information could be gathered on one death and one other adverse event. ⁶ |
| Palladone (pain killer, stronger than morphine) |
| July, 2005 – Purdue Pharma agreed to voluntarily suspend sales and marketing of Palladone in the U.S. Withdrawal was triggered by a company study that showed potentially serious or even fatal consequences if a person abusing the drug also drank alcohol. Neither the company nor the FDA reported any instances of the problem among the 11,500 people who have been prescribed the drug. ⁷ |

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| Rezulin (Type 2 Diabetes) |
| March, 2000 – Manufacturer agreed to withdraw Rezulin after the drug showed it was more toxic to the liver than two other drugs. ⁸ |
| Orlaam (detoxicant used in treatment clinics) |
| August, 2003 – Roxane stated that it was discontinuing the sale and distribution of the product after current inventory was depleted following reports of severe cardiac-related events among opiate-addicted patients. ⁹ |
| Vioxx (Osteoarthritis and menstrual cramps) |
| September, 2004 – Merck voluntarily withdraws Vioxx from U.S. market. FDA was in the process of reviewing the cardiovascular events to determine whether labeling changes were warranted when Merck decided to withdraw it. ¹⁰ |
| Baycol (cholesterol) |
| August, 2001 – Bayer Pharmaceuticals voluntarily withdrew the product after FDA received reports of 31 deaths associated with the drug. ¹¹ |
| Raplon (muscle relaxer) |
| March, 2001 – Organon announced it was voluntarily withdrawing the drug after several serious adverse events, including bronchospasm and unexplained fatalities, were reported during postmarketing surveillance. ¹² |
| Lotronex (IBS in women) |
| November 2000 – Glaxo Wellcome informed FDA it was voluntarily withdrawing Lotronex, In just eight months on the market, Lotronex was linked to 54 cases of a severe and potentially fatal abdominal problem called <i>ischemic colitis</i> , and 20 more possible cases, including five deaths, listed in so-called "adverse event" reports submitted to the FDA. ¹³ |
| Cylert (stimulant for ADHD) |
| May 2005 – Abbott chose to stop sales and market on Cylert. FDA was aware of 12 reports of liver failure resulting in liver transplant or death, the reporting for liver failure is 4 to 17 times greater than the background rate of liver failure in the general population. NOTE: RU-486 is 10 to 14 times more lethal to the mother than surgical abortion during |

the first 49 days of gestation when RU-486 is used in chemical abortions.¹⁴

Trovan (bacterial infections)**

June 1999 – FDA issued a public health advisory when it received over 100 reports of patients who were ill with symptoms of liver toxicity. FDA was aware of 14 cases in patients whose livers actually failed.¹⁵

The FDA continues to maintain that RU-486's benefits outweigh its risks, but just exactly what those benefits are and, more importantly, whether or not they have been determined independently of a political or social agenda, strictly on the basis of health concerns, seems doubtful.¹⁶ This is especially evident when RU-486 is compared to other drugs that have been removed from the market. Has RU-486 received special treatment?

Not every drug is analogous, that is understandable, and a comparison may be overly simplistic. Each drug serves to treat a different ailment, each with varying risk factors with the ultimate goal of preserving and fostering life. It is probable that RU-486 has received special treatment because, after all, it is indeed a "special" drug.

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¹ Margaret Talbot, "The Little White Pill," *New York Times Magazine*, July 11, 1999, quoting Carole Joffe, professor of sociology, University of California-Davis.

² "Legislation will Suspend FDA's Approval of RU-486; Review FDA's Approval Process for Drug," <http://www.aaplog.org/position-and-papers/mifeprex/legislation-will-suspend-fdas-approval-of-ru-486-review-fdas-approval-process-for-drug/> (Accessed Sept. 27, 2010).

³Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Subcommittee on Criminal Justice, Drug Policy and Human Resources (May 2, 2006) (on file with Subcommittee).

⁴ Gardiner Harris, "Some Doctors Voice Worry Over Abortion Pills' Safety," *The New York Times*, <http://www.nytimes.com/2006/04/01/health/01abort.html> (Accessed Sept. 27, 2010).

⁵ "FDA Issues Public Health Advisory On Use of NeutroSpec," *FDA*, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108536.htm> (accessed Sept. 27, 2010).

⁶ "MS Drug, Tsyabri, Suspended," *Medicare Advocacy*, http://www.medicareadvocacy.org/news/Archives/MS_TsyabriSuspended.htm (accessed Sept. 28, 2010).

⁷ Marc Kaufman, "Painkiller Palladone Pulled Over Alcohol Risk," *Washington Post*, <http://www.washingtonpost.com/wp-dyn/content/article/2005/07/13/AR2005071302286.html> (accessed Sept. 28, 2010).

⁸ "Rezulin," *FDA*, <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173081.htm> (accessed Sept. 28, 2010).

⁹ "Orlaam," *FDA*, <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm153332.htm> (accessed Sept. 28, 2010).

¹⁰ "Merck Announces Voluntary Worldwide Withdrawal of Vioxx," *Merck*, http://www.merck.com/newsroom/vioxx/pdf/vioxx_press_release_final.pdf (accessed Sept. 28, 2010).

¹¹ Gina Kolata, "Anticholesterol Drug Pulled after Link with 31 Deaths," *NYT*, <http://www.nytimes.com/2001/08/09/us/anticholesterol-drug-pulled-after-link-with-31-deaths.html> (accessed Sept. 28, 2010).

¹² "Raplon," *FDA*, <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm172580.htm> (accessed Sept. 28, 2010).

¹³ "Drugmaker Pulls Lotronex," *CBS News*, <http://wap.cbsnews.com/site?sid=cbsnews&pid=sections.detail&catId=TOP&storyId=252951&viewFull=yes> (accessed Sept. 28, 2010).

¹⁴ "Cylert Discontinuation Letter," *FDA*, <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/ucm086047.pdf> (accessed Sept. 28, 2010).

¹⁵ "Questions and Answers on Trovafloxacin Public Health Advisory," *FDA*, <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/PublicHealthAdvisories/UCM053104> (accessed Sept. 27, 2010).

¹⁶ Janet Woodcock, "Mifepristone: Approval Process and Postmarketing Activities," *FDA Testimony*, <http://www.fda.gov/NewsEvents/Testimony/ucm112562.htm> (Accessed Sept. 27 2010).