



NARAL
Pro-Choice America

Legislation Pulling Mifepristone Off the Market Is Unprecedented Political Intrusion Into Drug-Approval Process

After eight years of clinical trials and tests, and approximately two decades of use in other countries, the Food and Drug Administration finally approved mifepristone (originally known as RU 486) in September 2000 for use as a non-surgical, early abortion option. The drug represents a significant step forward in American women's reproductive health. Now, having failed to block mifepristone's approval, anti-choice lawmakers and advocates have mounted a multi-front campaign against the drug.

It is very clear that these efforts are driven by a desire to outlaw all forms of abortion. Understanding that the majority of Americans supports a woman's right to choose, anti-choice activists have chosen to frame their attacks on mifepristone deceptively, in terms of "health" or "scientific" concerns.

Until recently their strategy has included anti-choice federal and state legislation to impose unnecessary and burdensome conditions on the drug's prescription, a public-relations offensive calculated to misinform and scare American women and doctors, and anti-choice petitions to the FDA demanding the drug's withdrawal. During the 2000 presidential campaign, candidate George W. Bush contributed to the cause by, among other things, boasting of his willingness to restrict mifepristone. (This promise was subsequently downplayed when it was observed that a president may lack the authority to pull drugs off the market. It should be noted, however, that a president may sign legislation imposing restrictions on a drug or withdrawing it from the market.)

As president, Bush has attempted to restrict medical abortion by making a number of hostile executive-branch appointments to key committees overseeing women's reproductive health, most notably naming W. David Hager to the FDA advisory panel that was influential in mifepristone's approval. In 2001, Hager, an avowed opponent of legal abortion and common forms of contraception, helped the anti-choice Christian Medical Association spearhead a "citizen's petition" calling on the FDA to reverse its position and revoke mifepristone's approval.

Now, anti-choice lawmakers are stepping up the pace. Willing to exploit the very rare adverse events associated with mifepristone (as there are for every medication), Rep. Roscoe Bartlett (R-MD) has launched a frontal attack on the drug. His bill, the RU 486

Suspension and Review Act (H.R.63), would pull mifepristone off the market altogether and demand a “study” into the FDA’s approval of the drug.

The Bartlett bill is an unprecedented intrusion of politics into science.

Congress wisely created the FDA to serve as the repository of scientific expertise and impartiality about drugs and medical devices. Politicians have no direct role in the drug-approval process – nor should they. If Congress stepped in to override the FDA’s determination of a drug’s safety and efficacy – or to add new, political criteria to these well-established standards – it would be taking an unprecedented step into science and public health.

Such a move would also signal to the FDA – and the public – that scientists’ work could be nullified at any time by Congress’ political whims, calling the whole drug-approval process into question. PhRMA, the trade association representing the country’s leading pharmaceutical and biotechnology companies, states clearly: “The U.S. system of new drug approvals is perhaps the most rigorous in the world.” In attempting to override the FDA’s approval of mifepristone, anti-choice members of Congress are threatening the very integrity of the FDA and its scientific approval process.

Moreover, what other drugs or devices might next fall into politicians’ sights? Contraceptive technologies? Fertility drugs? Discoveries made from our investment in biomedical research using fetal tissue or embryonic stem cells? If politics are allowed to enter the realm of drug approvals, the list could be endless.

Mifepristone is a proven safe and effective drug.

Anti-choice claims about mifepristone are wildly inaccurate.

- It has been in use for approximately two decades and is available to women in 36 countries, including France, the United Kingdom, Sweden, Austria, Belgium, Denmark, Finland, Germany, Greece, Norway, Switzerland, Luxemburg, China, Israel, the Netherlands, Russia, Ukraine, and Spain.
- It is safe. Side effects are like those common to a natural miscarriage and, in the rare case when the abortion is incomplete, the remedy is the very common and safe procedure of dilation and curettage (D&C).
- Patient satisfaction rates are very high. According to a recent study, 96 percent of women who have used mifepristone would recommend the medication to others considering abortion care.

- More than 800,000 American women have used the drug since its approval in 2000.

In spite of this proven record of safety and efficacy, anti-choice politicians and activists are, unfortunately, apparently willing to exploit rare tragic adverse effects associated with mifepristone – as there are for every drug and medical device – for their own political purposes. It is wrong for them to do so. The broad problem of adverse-drug reactions is real, but it exists for every drug and medical device. As Dr. Janet Woodcock, 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."

In fact, contrary to anti-choice claims, medical evidence indicates that mifepristone is as safe or safer than other commonly used medications. The number of adverse effects associated with mifepristone is less, for example, than for such common medications as Viagra and Tylenol. If anti-choice lawmakers were truly committed to improving public health, they would examine this broad problem rather than single out for special scrutiny a drug that has been safely used by millions of women around the world.

Their apparent disinterest in doing so betrays their real motives. In fact, some lawmakers openly admit their real agenda; when a reporter asked bill sponsors whether they intend to suspend and investigate every drug with an adverse-event report, anti-choice Rep. Bartlett responded. "This is fundamentally different," he said. "RU 486 kills babies ..."

Clearly, supporters of the Bartlett legislation are not concerned about drug safety; they are opposed to the right to choose in all circumstances. Recriminalization of abortion takes America back to the dark days of back alleys and illegal, unsafe procedures – clearly the most dangerous option of all for women.

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