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When Politics Defeats Science

By Susan F. Wood

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Since my resignation six months ago as assistant commissioner of women's health at the Food and Drug Administration, I have been traveling around the country meeting with men and women, fellow scientists and health care professionals. I have shared my concerns that our federal health agencies seem increasingly unable to operate independently and that this lack of independence compromises their mission of promoting public health and welfare.

At every stop I am reminded that whether it is the environment, energy policy, science education or public health, the American public expects our government to make the best decisions based on the best available evidence.

Yet, at a recent hearing of the House Appropriations subcommittee on labor, health and human services, we saw once again that this is not happening. Reps. Sam Farr (D-Calif.) and Rosa DeLauro (D-Conn.) questioned FDA acting commissioner Andrew C. von Eschenbach about the delay in approving the application to make Plan B emergency contraception available over the counter to women 17 and older. Von Eschenbach responded that the agency was carefully reviewing the thousands of comments received in response to last-minute concerns raised about the feasibility of making the same product available over the counter for most women but keeping it on prescription for young teens. This exchange confirmed my suspicion that, like his predecessor, von Eschenbach is unable or unwilling to let the science and the scientists guide FDA policy and decisions, and that the real answer as to whether the FDA will allow Plan B over the counter for those 17 and older is no.

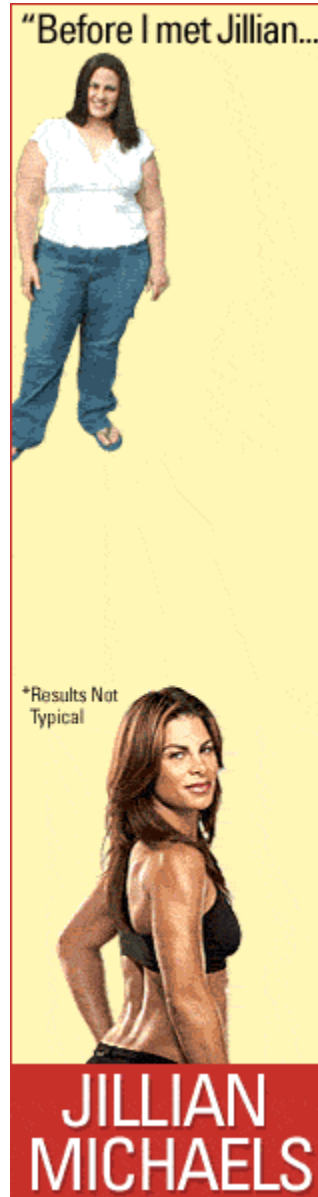
Time and again in my travels I am asked, "What happened to derail Plan B?" I have to answer honestly that I don't know. The manufacturer agreed to take the "controversial" issue of young teens' access to emergency contraception off the table in 2004; now we are talking only about adult access to safe and effective contraception. Over 98 percent of adult women have used some form of contraception. So what is the objection?

Perhaps it is that posed by a small but vocal political minority that insists on labeling emergency contraception as abortion, or at least confusing the two. One of the main questions I hear is, "Does this pill cause an abortion?" In fact, the only connection this pill has with abortion is that it has the potential to prevent the need for one. Emergency contraceptive pills work exactly the same way as other birth control pills, and they do not interfere with or harm an existing pregnancy. Emergency contraception is simply a higher dose of daily birth control pills; it is not RU-486, the "abortion pill." Indeed, emergency contraception has been used as a method to prevent unintended pregnancies for decades by women who had physicians advise them on how many pills in their regular pill pack to take. So people who are comfortable with oral contraceptives as methods of contraception should be just as comfortable with emergency contraception.

Having spent 15 years working for the federal government, nearly five of which were at the FDA, I care deeply about what's happening in the federal agencies, particularly our health agencies. Nearly 25 cents of

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every consumer dollar is spent on products regulated by the Food and Drug Administration. We count on the FDA for the safety and effectiveness of our medicines, vaccines and medical devices, and for the safety of the blood and food supply. The American public does not want to -- nor should it -- have to think twice about the quality and reliability of information it is getting from the FDA. Its reputation as the international gold standard for regulatory agencies, and as a body that sets the bar very high when it comes to scientific evidence and integrity, is being put at risk over adult access to contraception. Why would the administration risk such a reputation over this?

Von Eschenbach could demonstrate his commitment to the FDA's independence and scientific integrity and help restore staff morale and waning public credibility by stopping the rulemaking process and approving access to Plan B for women 17 and older. Instead, he continues to hide behind a wasteful and pointless bureaucratic process. Congress needs to step in and restore the FDA's independence and its ability to make decisions based on the evidence.

It's been nearly three years since the first application came in to make Plan B emergency contraception available over the counter, so that women, including rape victims, could have a second chance to prevent an unintended pregnancy and the need for an abortion. How many chances have we missed? I still can't explain what is going on here, and why women 17 and older are still denied this product in a timely way. When did adult access to contraception become controversial? And why have we allowed it to happen?

The writer is a former assistant commissioner of the Food and Drug Administration and is a senior policy adviser to the Reproductive Health Technologies Project.

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