FDA ducks decision on emergency contraceptive

Janice Hopkins Tanne looks at why emergency contraception is proving so controversial in the United States, even though it is now available without prescription in nearly 40 countries

A furore has erupted in the United States after the announcement by Dr Lester Crawford, commissioner of the Food and Drug Administration (FDA), that he was going to postpone indefinitely a decision to make emergency contraception available over the counter, even though two FDA committees have recommended such availability (*BMJ* 2005;331:532, 10 Sep).

An assistant commissioner at the FDA resigned over the issue, and 13 senators asked the independent Government Accounting Office to accelerate the investigation of the FDA's actions, which the senators had requested in June 2004.

Major newspapers from coast to coast castigated the FDA; almost none spoke in its support.

The consensus was that the FDA had abandoned science and was knuckling under to political pressure from conservatives who oppose abortion and confuse emergency contraception with abortion.

Susan Wood resigned as assistant commissioner for women's health and director of the FDA's Office of Women's Health, saying that the FDA was no longer making decisions on scientific grounds.

Dr Wood, who had just completed eight months in the UK Department of Health on a fellowship, said that Dr Crawford's decision to postpone making a decision had nothing to do with the safety or the efficacy of the drug, Plan B, made by Barr.

"It was approved for women of all ages," she said. The FDA approved availability of Plan B by prescription in 1999. In December 2003 the FDA committees on reproductive drugs and over the counter use overwhelmingly recommended that Plan B be made available to women of all ages over the counter.

In the UK and Europe, Dr Wood said, drug approval boards similar to the FDA hold

Dr Susan Wood said the FDA was no longer making decisions on scientific grounds

closed meetings, which allow for more frank discussion. They also have more binding authority than the FDA's advisory committees. FDA committee meetings are public and include comments from interested members of the public. One public comment on Plan B was that it would be used by men who raped teenage girls and forced them to take emergency contraception.

Dr Wood said she was astounded that emergency contraception had been caught up in the abortion debate. "I thought approval would be an easy thing. But a small group argues that it's an abortifacient. It's not, but they say it is."

Plan B comprises two pills, each containing 0.75 mg of levonorgestrel. A woman takes one pill as soon as possible after unprotected sex, preferably within 24 hours, and the second pill 12 hours later. Emergency contraception is available either over the counter or on request to a pharmacist in nearly 40 countries, according to the International Consortium for Emergency Contraception. It is

available on request to a pharmacist in several US states.

After questions were raised about whether young teenagers would understand the instructions on using Plan B—a point that Dr Wood says was never raised with any other over the counter drug—the manufacturer proposed that the drug be made available over the counter to women aged over 16 but on prescription only for younger teenagers. The FDA promised a decision, and then Commissioner Crawford announced that he was postponing a decision because he said the FDA had never before faced a situation where a drug was available over the counter and by prescription only at the same dosage. He said there would be 60 days of public comment and that a decision would be made in the future.

In the US drugs are usually available either over the counter or are prescription only. A few states allow pharmacists to dispense emergency contraception without a prescription after talking with the woman—a situation similar to that in the UK.

Although many people have blamed the FDA's failure to make a decision on conservative politics stemming from the White House, no "smoking gun" has been identified.

Alastair Wood, chairman of the FDA's advisory committee on non-prescription drugs and professor of medicine and pharmacology at Vanderbilt University in Nashville, Tennessee, said, "In the absence of evidence, I assume it's meddling. The committee and commissioners received letters from congressmen not to approve Plan B. Science is being ignored in the case of Plan B. Plan B never killed anybody. If the FDA is worried about teenagers understanding drug labels, they ought to restrict purchase of aspirin and other drugs."

One committee member who voted against giving the drug over the counter status is W David Hager, who was a controversial appointee of the Bush administration to the committee but who is no longer a member. Dr Hager, a part-time professor of obstetrics and gynaecology at the University of Kentucky, is a "pro-life" doctor who has published several books, including *As Jesus Cared For Women*.

Dr Hager said that he felt the committee did not have enough long term data about possible

adverse effects among young users of emergency contraception. As for an age limit, he said, "I did not feel it was appropriate that emergency contraception could be bought by an 8 year old or a 25 year old."

Vivian Dickerson, a past president of the American College of Obstetricians and Gynecologists and an associate professor at the University of California in Irvine, who testified in favour of making Plan B available over the counter, said, "We're not encouraging sex in young teenagers, but it's far safer for a 13 year old to take Plan B than to carry a pregnancy to term."

The issue in dispute is when pregnancy begins. The American College of Obstetricians and Gynecologists says that pregnancy begins when a fertilised egg is implanted in the uterus. The US government has accepted that definition in a number of rules and regulations. UK law also defines implantation as the beginning of pregnancy, said Ann Furedi, chief executive of the British Pregnancy Advisory Service. However, several US states and many anti-abortion groups believe that pregnancy begins when sperm meets egg.

Emergency contraception, according to Plan B's manufacturer and the International Consortium for Emergency Contraception, works mainly by inhibiting ovulation or by preventing sperm and egg from uniting, or else by altering the endometrium so it is less receptive to a fertilised egg. The anti-abortion movement has grasped that last possibility and consequently labelled the drug as an abortifacient.

Michael Mennuti, president of the American College of Obstetricians and Gynecologists, said, "Unplanned pregnancy remains a major public health issue in the US. Emergency contraception offers a safe and effective way to prevent [it]."

The American Medical Association, the American Academy of Pediatrics, and about 70 other professional groups also endorsed availability of Plan B over the counter. Ms Furedi said that in the UK, "Emergency contraception was endorsed as a very, very safe method. It's strange that the US FDA is turning itself inside out to resolve a huge dilemma. It didn't happen in the UK."

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