FDA appointment is stalled as revelations emerge over Plan B

Janice Hopkins Tanne *New York*

The nomination of Andrew von Eschenbach as permanent commissioner of the US Food and Drug Administration continues to be blocked by two senators. The senators are blocking the nomination in protest at the FDA's three year delay in approving the sale over the counter of the emergency contraceptive known as Plan B.

Plan B is a two pill, high dose regimen of the oral contraceptive levonorgestrel. The drug is not currently approved for over the counter sale in the United States, although it is available from pharmacists in some states and is approved for over the counter sale in about 40 countries. Plan B is opposed by conservatives in the US, who say that it is an abortifacient not a contraceptive.

Dr von Eschenbach's nomination has become entangled in revelations from the Center for Reproductive Rights, a non-profit organisation that uses the law to advance reproductive freedom, about political pressure on the FDA to delay approval of the over the counter sale of the drug.

In an apparent reversal the FDA suddenly decided to reconsider the application for over the counter status of Plan B on 31 July, the day before Dr von Eschenbach was to face a Senate committee reviewing his nomination. The FDA asked to meet the manufacturer within a week to reconsider the application.

The FDA has lacked a permanent commissioner for most of George Bush's presidency. Dr von Eschenbach, formerly head of the US National Cancer Institute, was nominated as acting head of the FDA by President Bush in 2005. He was nominated immediately after Lester Crawford abruptly resigned after only two months as permanent commissioner. Dr Crawford, who had been with the FDA for

30 years, had delayed approving the over the counter sale of Plan B (*BMJ* 2005;331:713).

To become permanent Dr von Eschenbach's nomination must be approved by the Senate's Health, Education, Labor, and Pension Committee and then by the full Senate.

In December 2003 two FDA advisory committees recommended approval of over the counter sale of Plan B to women of all ages, and the FDA's professional staff agreed. The FDA staff considered that the drug should be sold over the counter to women aged 17 years or older but that it should be available only by prescription to younger women. Dr Crawford postponed approval because of perceived problems with simultaneous prescription and over the counter status.

Because of the FDA's delay the two senators, Patty Murray of Washington state and Hillary Rodham Clinton of New York, both Democrats, placed a "hold" to block a vote by the Senate to approve Dr von Eschenbach's appointment as permanent commissioner of the FDA until the FDA reached a decision on Plan B.

Meanwhile the Center for Reproductive Rights filed two lawsuits regarding the FDA's delay. Last week it posted sworn pretrial depositions from several FDA scientists on its website (www.crlp.org) and subpoenaed White House documents and emails regarding Plan B. The depositions carry allegations that FDA staff members were under political pressure not to approve the over the counter sale of Plan B.

In last week's hearings of the Senate committee Dr von Eschenbach was asked about the FDA's sudden turnaround in considering the over the counter sale of Plan B. He said it was because of "medical ideology"

President Bush listens as Dr Andrew von Eschenbach speaks at a White House ceremony in 2001

not "political ideology."

Senators Murray and Clinton said, "The administration is continuing to play a game of smoke and mirrors ... [This] is nothing more than another delay tactic ... We will maintain our hold on Dr von Eschenbach's nomination until a decision is made."

However, the Senate went into August recess last week. President Bush could make a "recess appointment" naming Dr von Eschenbach as permanent commissioner. His appointment would then need to be confirmed by the Senate before the end of its next session. An acting commissioner or one with a recess appointment has less credibility than one confirmed by the Senate in the usual way.

In a letter sent to Plan B's manufacturer on 31 July Dr von Eschenbach called for restrictions on the sale of Plan B—even to women aged 18 or older. The

drug should "not be available at gas stations, convenience stores, etc, but only to those pharmacies agreeing to (1) keep the OTC [over the counter] version of the drug behind the pharmacy counter and (2) dispense the drug only upon the production of a valid photo identification card establishing the age of the consumer." The manufacturer would have to monitor pharmacies for compliance.

If the FDA found that the company's programme was not "sufficiently rigorous" it would maintain the prescription only status of Plan B for all women.

In an editorial the *New York Times* warned that the new approach "does open a loophole for the agency to block non-prescription use once again, by finding fault with the company's plans" (www.nytimes.com, 2 Aug. "New day for morning-after pill?"). □