Susan Wood

When US Food and Drug Administration (FDA) official Susan Wood resigned over foot-dragging on Plan B, she found herself at the center of a maelstrom concerning political interference in agency decision-making.

Susan Wood did not think quitting the FDA in August 2005 over the agency's handling of the Plan B birth control product would garner much notice. She'd been with the FDA for five years and was the director of the Office of Women's Health, but she assumed her departure would get only "a little attention, a mention inside *The Washington Post* or something," she says.

But it got more than that, mainly because around that time the Bush administration's performance was already at the forefront of the public's mind: the US National Oceanic and Atmospheric Administration had been under fire for downplaying global warming, the FDA had already caused a stir over its prolonged deliberation for the contraceptive Plan B (levonorgestrel) and the US Federal Emergency Management Agency was in the midst of bungling its response to Hurricane Katrina. Indeed, Wood's departure was "one little story," she says, "but it tied in with bigger issues."

To some observers, Plan B had come to represent the rudderless FDA, as well as the 'ideology trumps science' policy of the socially conservative White House, which feared that an over-the-counter (OTC) contraceptive, designed to prevent pregnancy if taken within 72 hours after unprotected sex, would encourage promiscuity in young, unmarried women. "The FDA was without leadership for most of the time that Bush has been in office," says Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development in Boston. "So it was much more susceptible to political whims. The FDA became a pawn in an ideological chasm."

The history of Plan B at the FDA suggests as much. In 2003, an FDA advisory panel voted to give Plan B OTC status, and the drug had been available by prescription since 1999, distributed by Duramed Pharmaceuticals, a subsidiary of Barr Pharmaceuticals, of Pomona, New York. But the FDA's top brass and its commissioner at the time, Lester Crawford, blocked approval anyway, telling Barr in 2004 that the agency was concerned about adolescent use. Barr submitted a revised application, asking for approval for women 16 and older, but even that filing languished.

"The rationale for [the original] rejection had no bearing on the medical issues of the product," says Kaitin. "The FDA deals with safety and efficacy, not issues of promiscuity." Furthermore, "there was no transparency in how the FDA made the Plan B decision. Like everyone else, I have a lack of real information about what was going on in the FDA at the time."

Wood, at her FDA post, shared Kaitin's frustration. Although Wood comes from an academic background—studying basic biology at Johns Hopkins University in Baltimore and biochemical transduction pathways at the Marine Biological Laboratory at Woods Hole, Massachusetts—she also is steeped in policy. At Woods Hole she had helped to organize a seminar series that would in many ways define her future work: "Science and a Social World." She'd also earned an American Association for the Advancement of Science fellowship in 1990 that brought her to Congress, eventually leading her to FDA. But the policy issues she confronted over Plan B went beyond rational argument, she says.

"My office couldn't any longer explain, as an insider, what had happened," she says. "Can a woman of adult age have access to safe and effective contraceptive? It was a no-brainer science-wise. As the head of women's health, how was I supposed to go out there and explain it to colleagues and the public? It wouldn't have been possible to stay silent in the agency, and I couldn't, as part of the agency, [publicly] say they made the wrong decision."

So she quit, writing in correspondence to colleagues she could "no longer serve as staff" when scientific and clinical evidence has been overruled. And even though she "is not a sensationalist," as acknowledged by Vivian Pinn, director of the Office of Research on Women's Health at the National Institutes of Health (NIH), who had worked with Wood on women's health initiatives, her resignation caused a sensation nonetheless.

Able to talk freely after leaving, Wood found a public eager to listen. She hit the speaker circuit, telling scientific, legal, policy and women's groups about her experience, and warning that it wasn't just about Plan B, but also about the overall integrity of the FDA. Among her messages: "If government agencies are not given the support to do jobs properly, they won't draw people in that can do the jobs." Wood is now a research professor at the School of Public Health and Health Services at George Washington University in Washington, DC.

Since Wood's departure, there have been changes at the FDA. There is a new commissioner, Andrew C. von Eschenbach, and in August 2006, Plan B received OTC approval for women 18 and older. "Nobody was more surprised than me by von Eschenbach's path to approval for 18 and over," says Wood. "The decision was not because there was new evidence or interpretation of evidence." And, others say, it was not because of an ideological shift in the administration. Rather, Senators Hillary Rodham Clinton and Patty Murray threatened to block von Eschenbach's confirmation as new FDA commissioner unless the Plan B issue was resolved.

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A confirmed commissioner helps increase transparency at the FDA, says Kaitin, and should decrease the influence of politics at the agency. Still, there was talk of a $1.2 million budget reduction to the FDA's Office of Women's Health, a significant chunk of an overall $4 million budget, which was "viewed by people in the FDA as payback for an office that was very vocal on Plan B," says Ira Loss, senior health policy analyst at the investment research firm Washington Analysis in DC.

The suggested budget cut was met with a chorus of criticism and eventually scuttled, and the FDA has suggested a plan for curbing the influence industry has with scientists, but Wood says the FDA will be shaped significantly by what happens with the Prescription Drug User Fee Act (PDUFA). The act collects fees from industry for reviewing drug applications and is up for reauthorization.

No one is suggesting all those changes are due to Wood quitting, but she serves as a reminder about social responsibility.

"People should not just lock themselves up in their labs and assume all will go well," she says. There's "an imperative that researchers engage in discussion."

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