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Women's Health and the FDA

[Perspective]

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Science commits suicide when it adopts a creed.

-Thomas Henry Huxley ([1])

On August 31, 2005, I resigned my post of assistant commissioner for women's health and director of the Office of Women's Health at the Food and Drug Administration (FDA). The agency leadership had chosen to delay indefinitely a decision about switching emergency contraception to nonprescription status. I believed that in doing so, they were disregarding the scientific and clinical evidence and the established review process and were taking an action that harms women's health by denying them appropriate access to a product that can reduce the rate of unplanned pregnancies and the need for abortions.

Both the relevant advisory committees and the professional review staff at the FDA's Center for Drug Evaluation and Research had strongly recommended that nonprescription status be granted to Plan B emergency contraception (levonorgestrel), given its safety and the need for timely access for optimal efficacy. The FDA had rejected the status change in 2004 on the basis of the stated concern that there were inadequate data showing comprehension and proper use by young teens, and it proposed making the product available over the counter only to women over a certain age; it has now delayed a decision, however, so that the difficulties raised by its own unprecedented proposal may be assessed. [2]

These actions should be examined in the broader context of the FDA's policies and programs for women's health. Women's health issues have been deeply entwined with the history of the agency. Congress's granting of the legal authority to the FDA to ensure that products are safe and effective was often driven by tragedies associated with women's health - often reproductive health, in particular. In 1962, when the Kefauver-Harris Amendments were added to the Food, Drug, and Cosmetic Act in response to the thalidomide tragedy, for example, the FDA gained critical authority, including the mandate to ensure that drugs were effective before being marketed and to require that manufacturers report unexpected adverse events. Thalidomide was denied approval for use in the United States; the evidence of its teratogenicity also led to the establishment, in 1977, of FDA guidelines calling for the exclusion of women of childbearing potential from phase 1 and early phase 2 studies - a policy that was not reversed until 1993.

In 1976, after the Dalkon Shield intrauterine device injured many women, Congress passed the Medical Device Amendments, strengthening the FDA's ability to regulate medical devices. In 1992, the FDA was given the responsibility of setting standards for and inspecting mammography facilities.

The agency's growing role in providing information has also been tied to women's health issues. In 1970, the FDA developed its first package insert for patients in response to calls from women's health advocates and the public for more consumer information about oral contraceptives. Such package inserts are now an important way of getting patients information on a wide variety of medicines. The discovery of a link between toxic shock syndrome and tampon use led to the provision of relevant information in tampon packaging. Recently, in response to new data, Congress called on the FDA to be the source of unbiased information about the risks and benefits of hormone therapy in menopause.

But women's health has meant more at the FDA than just reproductive health or women-specific health concerns. The key focus since 1993 on including women in all phases of clinical studies and evaluating the resultant data for differences according to sex and other demographic variables has affected all the products that come before the FDA - ensuring that studies explore the potential for sex differences in safety and efficacy and that data are collected rigorously enough to permit such evaluation. This issue was the primary reason for the formation, in 1994, of the FDA's Office of Women's Health. Current research and outreach activities of this office focus on coronary heart disease in women; other programs have targeted diabetes, pharmacokinetic and pharmacodynamic studies of medications used during pregnancy, and safe medication use. The office has also funded data-mining analyses of adverse drug events, as well as the development of systems for tracking the demographic characteristics of study subjects and analyzing data for significant sex differences.

The Office of Women's Health, which is part of the Commissioner's Office, is not in the usual decision-making chain for the approval of products at the FDA. But its staff members are often called on by the review centers to provide consultation, serve on working groups, or provide a broad perspective on women's health, particularly when a product under review has a clear link to women's health needs. The common threads in all our work have been the development of policy and programs for the benefit of the public health and a reliance on sound science for decision making.

Scientists and others sometimes raise questions about whether the FDA's decisions are in fact being guided by the available data, and vigorous and healthy debate over an agency decision is not unusual. Recent debates have focused on concerns about product safety and the structure of decision making with regard to safety labeling, and the Office of Women's Health played an appropriate role in these debates, as we did in the early discussions about Plan B.

The FDA holds dear its sometimes controversial prerogative to make decisions independent of its advisory committees, and there have been cases in which not accepting an advisory committee's recommendations has resulted in good decisions. But recommendations of an advisory committee that are strongly supported by the FDA's review staff have rarely, if ever, been overturned at the highest level of the agency, as they were both in the decision to reject nonprescription status for

Plan B and in the most recent decision to delay through rule making. The first of these decisions, including the suggestion of possible dual status, overturned the recommendations of all the lower review levels in the Center for Drug Evaluation and Research. I disagreed with that 2004 decision, because such dual status has never been required for other over-the-counter products sold to adolescents and because the proposal was not based on concerns about safety or efficacy. Yet I and other staff members remained hopeful that this was indeed a path toward some form of approval.

But on August 26, 2005, the process appeared to have gone off track. The unusual decision to seek public comment and to begin the probable development of a new regulation to permit and govern such dual status - that is, to launch a rule-making process - came as a surprise to most of the agency. None of the senior members of the professional and scientific staff who would normally have participated in making a decision about nonprescription status for Plan B (all of whom had recommended approval) seemed to be aware of what the decision was going to be until shortly before it was announced. The staff members I spoke with indicated that they had not recommended this process, which can take years, as a needed step. The decision, which left women of all ages without appropriate and timely access to emergency contraception, was a clear rejection of recommendations that had been based on extensive review and evaluation of the pertinent data.

Recently, the commissioner of the FDA, Dr. Lester Crawford, stepped down; this will be the first test of whether a new commissioner will be able to ensure that science is the driving force in the agency. If the FDA is to continue to fulfill its important role in public health, both in the United States and internationally, its professional scientific and clinical staff must maintain its independence and thus its scientific credibility. In compromising these values and ignoring the expertise within the agency, the FDA's leadership has compromised the health of women and families. As a scientist, as a career FDA employee, and as the director of the Office of Women's Health, whose mission is to be the champion for women's health at the FDA, I could not sanction this action by remaining at the agency.

REFERENCES

1. Reflection #71. In: Aphorisms and reflections - from the works of T.H. Huxley, selected by Henrietta A. Huxley. London: MacMillan, 1907. [\[Context Link\]](#)
2. Wood AJJ, Drazen JM, Greene MF. A sad day for science at the FDA. N Engl J Med 2005;353:1197-9. [Ovid Full Text](#) | [Bibliographic Links](#) | [Library Holdings](#) | [\[Context Link\]](#)

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