

SUSAN F. WOOD

The Boston Globe

Back to science at the FDA

By Susan F. Wood | November 11, 2006

SCIENTISTS AT the US Food and Drug Administration have reported that morale is at an all-time low because they are not allowed to do their jobs properly. But the FDA today is suffering from more than morale problems. It also suffers from a lack of independent leadership, clear legal authority, and adequate resources.

The problems at the FDA have an effect on us all. We count on the FDA for medicines -- for both ensuring their safety and effectiveness before they come on the market and for assuring their quality and long-term safety once on the market. We count on the FDA for vaccines and a safe blood supply, and for medical devices, from implants to mammography facilities. We count on the FDA for a safe food supply, except for meat and poultry. This is just the short list of all the responsibilities that we place on the FDA's shoulders. Yet the current vision for addressing the problems at the FDA is shortsighted.

FDA leadership demonstrated its lack of independence over the last several years when it continually delayed the approval of emergency contraception as a nonprescription drug, despite the medical evidence and the recommendations of all the scientific staff there. The FDA's recent partial approval of Plan B (without a prescription for those 18 and older) was not made on the basis of new information or new understanding, but due to the fact that people across the country kept insisting that the FDA stick to the science. The acting head of the FDA, Dr. Andrew von Eschenbach, came to the realization that he would not be confirmed by the Senate unless he let the FDA at least approve it for adults. But his limited action shows that the science is still not driving the FDA's decisions.

The Institute of Medicine studied some of the problems with the drug safety system and proposed some solutions. They identify problems with the culture of the FDA, the need for better scientific tools, more legal authority, and better communication with the public. But unfortunately, not even these limited proposals are being seriously considered by the Senate as it takes up new drug safety legislation and the reauthorization of one of the major FDA laws on drug approval, much less more sweeping reforms.

The FDA needs to be transparent, accountable, and independent. It will take specific and far-reaching action by Congress.

How can a strong, independent, and science-based FDA get back on track?

First, Congress should consider making the FDA an independent agency, similar to the National Science Foundation or the Social Security Administration. It should also consider giving the FDA commissioner a fixed term so the commissioner will have some protection from inappropriate political interference.

To improve accountability and transparency, there must be a public way for scientific disagreement within the FDA to be voiced, heard, and responded to in a systematic way. The FDA needs real authority in labeling and in requiring studies from industry sponsors.

Proposals that would establish a new outside entity that could respond in real time to product safety concerns -- similar to what the National Transportation Safety Board has -- need to be examined seriously. Truly ensuring that the members of FDA Advisory Committees do not have financial conflicts of interest can be accomplished by actively reaching out to the research community that is publicly funded by the National Institutes of Health.

Saying that all good scientists have financial conflicts is a red herring, and we need to move forward in strengthening the Advisory Committee system.

The amount and source of funding for the FDA greatly shapes what work is done and what priorities are set. Now that much of the FDA's budget comes from industry, it is critical that FDA scientists be able to use that funding for the right priorities: promoting and protecting the public health.

Current law restricts these funds to speeding the review of products; this needs to be changed to allow funding of post-market research and surveillance, enforcement, and oversight of advertising. Equally as important is getting an increase in public dollars to support the FDA in carrying out all of its responsibilities -- right now FDA is stretched too thin. Proposals to expand funding -- such as a consumer fee of several cents per prescription filled -- need to be

seriously debated. Investment in the FDA is worth it.

Congress will be taking up FDA legislation this month, but the legislation lacks the vision and depth needed for a real return to a science-based FDA. In particular, the Senate bill introduced by Senators Edward M. Kennedy of Massachusetts and Mike Enzi of Wyoming needs to take advantage of this rare opportunity to strengthen the FDA. The public depends on it.

Susan F. Wood is a research professor at the George Washington University School of Public Health and Health Services Project on Scientific Knowledge and Public Policy and former assistant commissioner for women's health at the FDA US Food and Drug Administration. ■

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