

# FDA Science Base Badly Eroded But Will Congress Provide Urgent New Funding?

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The scientific mesh used by the Food and Drug Administration (FDA) to sift through new drugs has more holes than the U.S. border with Mexico. And given the cascading headlines accorded to big-name drugs with big-time problems, the FDA's serious scientific shortcomings may become almost as huge a political concern as immigration.

Politicians in Washington are already making rhetorical hay out of the new report from the FDA Science Board: *FDA Science and Mission at Risk*.<sup>1</sup> But whether those same politicians will appropriate the major increases in funding that the FDA clearly needs to close those scientific holes, well ... just don't bet your 401K on it.

The "science" gap comes to the fore after Congress in 2007 plugged the "regulatory" gap at the FDA by passing the FDA Amendments Act (FDAAA) of 2007. But now, it now turns out, according to the FDA Science Board report, which was the subject of congressional hearings in late January, the FDA has much larger problems: its scientific resources are falling far short of what is needed to determine whether drugs, food, and cosmetics ought to be on the market in the first place.

For purposes of metaphor, the FDA's regulatory problems that were exposed last year were blemishes on the apple's skin. In *FDA Science*,<sup>1</sup> the Science Board subcommittee, which wrote the report, said, in effect, that the apple is rotten to the core.

Gail H. Cassell, MD, Vice President of Scientific Affairs and a distinguished research scholar for infectious diseases at Eli Lilly, chaired the Science Board subcommittee. She said at hearings in the House Energy and Commerce Committee in late January:

It became rapidly apparent that the FDA suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities. It is agency-wide, i.e., not limited to a single program or center.

Garret FitzGerald, MD, Professor of Medicine and Chair of Pharmacology at the University of Pennsylvania, expanded the indictment. He said both an earlier Institute of Medicine (IOM) report<sup>2</sup> and the *FDA Science* report<sup>1</sup>

have identified in plain terms a disturbingly systemic set of problems in the agency. ... These include the politicization and instability of leadership, attrition of manpower, poor morale, structural and organizational inadequacies, depleted infrastructure and—most importantly—critical gaps in scientific expertise and technology, as emphasized in our Science Board report.

The IOM report paints a wide and disturbing picture, indicting the information technology resources at the agency, the quality of its scientific staff, and the quantity of research the agency funds. For example, it mentions the need to fund research in "emerging science" and refers to, by way of citing examples at other federal agencies, investments made in genomics by the Federal Bureau of Investigation for the purpose of establishing its felon database or the National Institute of Health's investment in a new genomic institute.

The IOM report in August 2007<sup>2</sup> indicated that a new science program at the FDA could require \$15 million a year. Janet Woodcock, M.D., Deputy Commissioner and Chief Medical Officer at the FDA's Center for Drug Evaluation and Research (CDER), as quoted in that report, said that less than a few million dollars a year is available to CDER to study such topics as predictive safety biomarkers, drug toxicology, and tailored therapy, all at the top of the FDA's wish list.

Although the FDAAA addressed regulatory gaps primarily, it did establish a

new Reagan-Udall Foundation to raise private money to fund the FDA's Critical Path Initiative. Dr. Woodcock had promoted this initiative, but the FDA has essentially put it on hold since 2004 for lack of funds. The FDAAA authorized \$1.25 million in fiscal year 2008 from FDA funds marked for administrative startup to get the Foundation up and running before it had a chance to solicit the private funds on which it will have to depend in the future. However, Representative Rosa DeLauro (D-Conn.), Chairperson of the House Appropriations Subcommittee with the authority to determine the FDA budget, inserted a provision in the FDA appropriations bill for 2008 prohibiting the use of agency funds for the Foundation, which has been paralyzed as a result.

However, that did not prevent Ms. DeLauro from issuing a press release after President Bush published his federal budget proposal for fiscal 2009 on February 5. The budget proposed to increase the CDER budget from \$680.3 million in fiscal 2008 to \$738.7 million in fiscal 2009, a 7.8% increase. Of that \$68 million increase, \$26 million would come from increased drug company user fees—that money is dedicated to new drug review activities. The rest would ostensibly come from a higher congressional appropriation. But that extra money would be spent on many CDER activities.

It is not clear from the President's budget how much of the \$42 million extra for CDER in 2009 would go for "science" investments or—more importantly—whether Congress would provide the extra \$42 million. There is no mention in the FDA's narrative that accompanies the 2009 budget proposal of any new investments in science, much less the Reagan-Udall Foundation.

## REFERENCES

1. *FDA Science and Mission at Risk*. Report of the Subcommittee on Science and Technology, November 2007.
2. Institute of Medicine. *Challenges for the FDA: The Future of Drug Safety*. Workshop Summary, Washington, DC: National Academies Press, August 2007. ■

