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February 29, 2008

HEALTH ALERT

FOOD AND DRUG ADMINISTRATION: SHOW ME THE MONEY

On February 4, the president issued his proposed fiscal year (FY) 2009 budget for the Food and Drug Administration (FDA). The administration proposed a $130 million increase in FDA funding, which it said provided a 5.6 percent increase from last year's FDA budget. A closer look at the administration's proposal, however, shows only a $51 million increase – less than a 2.9 percent increase. What happened to the rest of the $79 million? The administration proposed user fees paid by industry that would require a separate congressional review process.

FDA's funding problems are well-documented and supported. By the end of 2007, the Institute of Medicine, the Government Accountability Office, the Health and Human Services Inspector General and the FDA's Science Advisory Board all reached the same conclusion, the "FDA can no longer fulfill its mission without substantial and sustained additional appropriations."[1] Based on these assessments, Congressman John Dingell, chairman of the House Energy and Commerce Committee, which has authorizing and oversight responsibilities over the FDA, wrote off the president's budget request for the FDA and asked the FDA's Science Advisory Board to provide him with a more accurate funding request that would get the FDA back on track. The Science Board responded on February 26 that the FDA needs almost $325 million more than the administration requested for FY 2009.

At this point, even the administration's top appointee at the FDA agrees. On February 27 FDA commissioner Andrew von Eschenbach, in a visible and unusual break with the administration, stated, "I think to do what we need to do requires substantially more dollars than what has been invested in FDA thus far."

Stakeholders in the FDA share concern that the agency could fall behind in its role as the world's premier consumer protection agency. While the FDA regulates 25 cents of every consumer dollar expended in the country, its budget is smaller than the Montgomery County, Maryland School District, where FDA's headquarters is located. Lawmakers continue to add and expand FDA's responsibilities without providing the agency with funding increases. Specifically, over the last 14 years, more than 100 laws have been enacted that either further define or expand the FDA's responsibilities.[2] During that same time period, FDA's resources have not commensurately increased. In fact, FDA's funding has not even kept pace with

[1] FDA Subcommittee on Science and Technology, *FDA Science and Mission at Risk* (Nov. 2007), available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html.
[2] Gardiner Harris, "For F.D.A., a Major Backlog Overseas," *The New York Times*, Jan. 29, 2008.

inflation, causing the agency to lose full-time employee slots, specifically at the Center for Food Safety & Applied Nutrition and the Office of Regulatory Affairs.

What are the practical effects of the lack of resources at the FDA? One problem is the FDA does not have the capacity to inspect and control FDA-regulated products imported into the country.

For example, the FDA inspected less than 2 percent of all food imports from China, and, whereas in 1973 the agency performed over 34,000 food inspections, only 7,000 plus inspections occurred in 2006.[3] Another significant outcome of inadequate funding is the impact on innovation. Last year, the FDA approved only 19 medications – the lowest number since 1983.[4] Patient and industry groups argue that increased funding will help the FDA develop tools to better review products and understand complex new technology, such as nanotechnology.

The FDA's funding failures affect every stakeholder both large and small – from pharmaceutical companies to the local pharmacist and grocer to the average consumer. Consumer, patient and industry groups all agree that funding shortfalls translate into less innovation and less consumer confidence in the agency. This will be even more evident with responsibility placed on the agency through last year's Food and Drug Administration Amendments Act.[5] This legislation places new mandates on the agency, including implementation of enhanced post-market surveillance, enhanced direct-to-consumer advertising reviews and clinical trials registration.

How can this problem be fixed? One coalition, the Alliance for a Stronger FDA, has already begun to advocate for more resources at the FDA and it is beginning to make a difference.[6] The Alliance is a broad-based, bipartisan organization, comprised of over 170 organizations, including non-profit and industry groups, former FDA commissioners, and former HHS secretaries. This organization has been successful in calling the public's attention to the FDA's funding crises. In turn, congressional hearings on the FDA's funding deficiencies have increased and for what it's worth, the FDA was one of the few agencies in the president's FY 2009 budget where there was any increase requested at all.

The bottom line is that the FDA itself is not broken, rather, its funding is broken. It will take a serious commitment from Congress and the administration to get the FDA where it needs to be. Until such a commitment can be made, the health care industry should prepare for a challenging environment at the FDA, and at the same time, become more engaged on the FDA's funding crisis.

To learn more about the Alliance, please call Akin Gump partner and Alliance executive director, Ladd Wiley, at 202.887.4083 or see the Web site at: www.strengthenfda.org.

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[3] Editorial, "Condition Critical at the FDA," *Boston Globe*, Feb. 3, 2008; Gardiner Harris, "For F.D.A., a Major Backlog Overseas," *The New York Times*, Jan. 29, 2008.
[4] Justin Blum, "FDA Accepted 19 Drugs in '07, Fewest it has OK'd Since '83," *Arizona Daily Star*, Jan. 10, 2008.
[5] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85 (Sept. 27, 2007).
[6] See www.StrengthenFDA.org. At the end of last year, the Coalition for a Stronger FDA and the FDA Alliance merged to form the Alliance for a Stronger FDA.