American Medical Women's Association

The Honorable Harold Rogers
Chairman
Committee on Appropriations
United States House of Representatives
Washington, DC 20510

May 27, 2011

Dear Chairman Rogers:

The Patient, Consumer, and Public Health Coalition adamantly opposes the $285 million (11.5%) cut to the Food and Drug Administration's Fiscal Year 2012 budget.

We understand that budget cuts are necessary in many important federal programs. However, cutting the FDA budget is like robbing Peter to pay Paul—the result will cost the federal government much more than it saves, because of increased costs of Medicare, VA medical care, medical care for our armed services, Medicaid, and other federally-supported health care programs. In addition, the delays in getting FDA approval and the recalls that will become necessary because of unsafe food and medicine will cost companies in every state in our nation billions of extra dollars each year.

The FDA is responsible for the safety of more than $2 trillion in products.[1] Lives depend on its performance, whether it is approving life-saving new medical products in a timely manner or protecting our family members and our pets by ensuring safe food and safe medical products. FDA's costs increase every year, driven by the globalization of medical products and the increased complexity of medical devices and medicines such as biologics. And, when the FDA isn't able to do its job well, it hurts all of us. An FDA without adequate resources will harm patients and consumers and add billions to the cost of medical care and to the expenses of the companies that the FDA regulates.

Globalization

More than 200,000 foreign companies sell food, cosmetics, and medical products in the U.S.[1] Even before the proposed budget cuts, the FDA did not have the funds to adequately inspect foreign facilities. For example, the FDA estimated that it was inspecting foreign medical devices establishments every 6 years for high-risk devices, and every 27 years for moderate-risk devices.[2] With the proposed budget cuts, it will be much more likely that we will see more contaminated medical products, such as the blood thinner Heparin that killed patients and added enormous medical costs to those who were harmed through no fault of their own or their doctors.

Increased Complexity

Biologic drugs and medical devices are much more complex than they were even a few years ago, and that increased complexity means that it takes more FDA time and expertise to determine whether or not the products are safe and effective. Cutbacks in the FDA's budget will either result in longer delays before products are approved, or products that won't be carefully reviewed due to the need to meet performance goals with limited resources. That can be deadly as well as enormously expensive to Medicare, the VA, insurance companies, and all taxpayers.

Food Safety

Budget cuts will make it more difficult to implement the recently passed Food Safety Modernization Act, designed to prevent contaminated foods such as salmonella-contaminated peanut butter from ending up in our children's sandwiches. The budget cuts will negatively affect the FDA's ability to identify risks and enforce basic preventive controls. That means more Americans will get sick from and die from tainted foods. Currently, "about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases," according to Centers for Disease Control and Prevention data.[3]

False savings

Today, there is a backlog of nearly 2,000 generic drug applications waiting for approval. With the large budget cuts proposed by the Appropriations Agriculture Subcommittee, these backlogs will get worse.

Generic drugs are used to fill two-thirds of prescriptions in the U.S.,[4] saving consumers and government programs $750 billion over the past decade.[5] By cutting the FDA's budget, the Agriculture Subcommittee has effectively shifted costs—and may actually increase costs—to other federal agencies such as the Center for Medicare and Medicaid Services and the U.S. Department of Veterans Affairs.

User Fees
User fees already provide a large proportion of FDA funding but there is a limit to how much companies will be willing or able to pay. This is especially true for the small businesses that currently pay much smaller user fees and provide jobs in your district and all over the country. Additionally, a GAO report highlighted concerns about the inherent problems with user fee programs. In the report, FDA officials noted that user fees have "seriously limited the agency's ability to fulfill its oversight responsibilities in some areas, particularly those not funded with user fees."[6] This is why it is vital that the FDA be adequately funded by Congressionally appropriated dollars.

In 2009, FDA Commissioner Margaret Hamburg said that one of the FDA's biggest challenges was "its limited resources."[7] The budget cuts have turned a challenge into an obstacle. Commissioner Hamburg recently said that the FDA's job is to "promote health, prevent illness, and prolong life."[8] The FDA cannot do that with an inadequate budget, such as the one the Appropriations Agriculture Subcommittee has proposed.

Sincerely,

American Medical Women's Association
Annie Appleseed Project
Breast Cancer Action
Center for Medical Consumers
Consumers Union
GAP
National Consumers League
National Physicians Alliance
National Research Center for Women & Families / Cancer Prevention and Treatment Fund
National Women's Health Network
Our Bodies Ourselves
THE TMJ Association
Women Heart
WoodyMatters

For additional information contact Paul Brown at 202-223-4000 or pb@center4research.org

[1] Hamburg MA, Sharfstein JM (June 11, 2009). The FDA as a Public Health Agency. *The New England Journal of Medicine* (Perspective).
[2] Government Accountability Office (June 2009). Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments. Statement of Marcia Crosse before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives.
[3] U.S. Food and Drug Administration (2011). Background on the FDA Food Safety Modernization Act (FSMA). Web site accessed May 24, 2011.
[4] U.S. Food and Drug Administration, Federal Register [Docket no. FDA-2010-N-0381] (August 9, 2010). Generic Drug User Fee; Public Meeting; Request for Comments.

[5] U.S. Food and Drug Administration (February 18, 2010). Commissioner Margaret Hamburg's speech to the Generic Pharmaceutical Association's Annual Meeting in Naples, Florida.
[6] Government Accountability Office (June 2009). FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs.
[7] Smith, L (July 6, 2009). Commissioner Margaret Hamburg: Moving FDA Beyond A Regulatory Agency. *The Pink Sheet.*
[8] U.S. Food and Drug Administration (2010). Remarks of Margaret A. Hamburg, M.D. Commissioner of Food and Drugs to AdvaMed 2010: The MedTech Conference.