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Before the

Science Board of the U.S. Food and Drug Administration

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Good afternoon and thank you for the opportunity to address the FDA Science Board.

My name is Diane Dorman and I am President of the Alliance for a Stronger FDA, as well as Vice President for Policy at the National Organization for Rare Disorders. The Alliance is a 200-member coalition of all FDA's stakeholders—consumers, patients, health professionals, trade groups and industry. Our sole purpose is to advocate for increased appropriated resources for the FDA.

When we started in 2006, FDA appropriations stood at slightly less than $1.5 billion for an agency tasked with overseeing 100% of drugs, vaccines, medical devices, and personal care products and 80% of our nation's food supply. Altogether, the products and industries regulated by FDA account for nearly 25% of all consumer spending in the United States.

In short, FDA was the victim of decades of underfunding. It was quite small, despite its vital, complex world-wide responsibilities. Presidents weren't asking for nearly enough money for FDA and Members of Congress were responding by giving the bare appropriations that had been asked for.

The Alliance's goal was to change this situation by galvanizing the FDA's broad stakeholder community to focus attention on the consequences of underfunding. We never doubted the accuracy of our analysis or the importance of our cause.

Nonetheless, it was immensely helpful when--18 months after our founding--the FDA Science Board released its own report in November 2007. As the media described it---the FDA's own Science Board evaluated the agency's capacities and responsibilities and declared that the agency's mission was "at risk." The word "crisis" was often used and was an appropriate description of the situation.

Subsequently—and with the Alliance's broad stakeholder advocacy—the prospects for FDA improved. Policymakers acknowledged the underfunding and acted aggressively to reverse it.

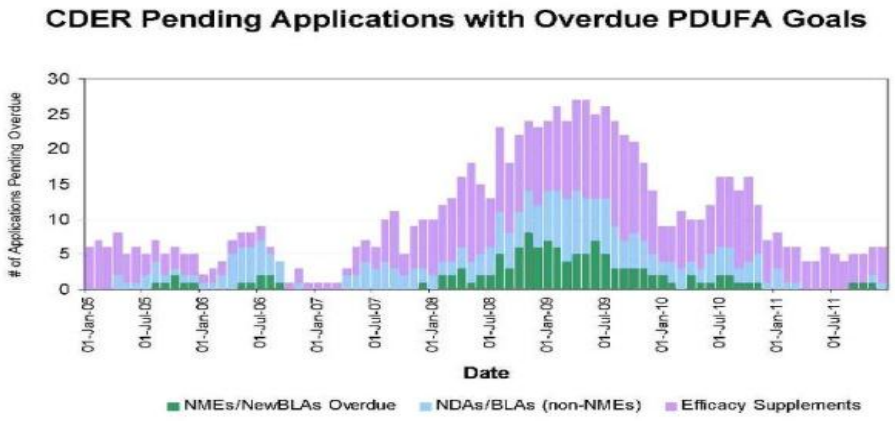
Today, in FY 13, the FDA receives slightly more than $2.5 billion in appropriated funding. *This amount, might have met the FDA's funding needs in late 2007 when the Science Board report was issued…BUT NOT NOW.*

Today, $2.5 billion is dramatically less than the amount the FDA needs. For reasons I will describe in my testimony, the agency's mission is again "at risk." Even without the possibility of funding cutbacks, the American people will lose if FDA does not receive increased funding.

FDA Responsibilities Grow Each Year Because Congress Enacts New Laws

Two months before the Science Board declared FDA to be "an agency at risk," the FDA Amendments Act of 2007 was signed into law, renewing the prescription drug and medical device user fee programs. It added a slew of new responsibilities, notably in food and drug safety, regulatory science, clinical trial registries, and establishment of a program for risk evaluation and mitigation strategies for new drugs.

The new responsibilities--combined with delays in funding of existing and new programming--had severe consequences. For example, FDA's efforts in the critical area of drug reviews and approvals were slowed substantially for nearly two years, as demonstrated by this CDER chart.



CDER data as of 11/30/2011. Figures reflect the number of NDAs, BLAs and efficacy supplements pending and overdue on their PDUFA goal date, evaluated on the first day of each month.

The message from this experience is clear, albeit not surprising: new laws take enormous resources to implement. Once implemented, they permanently increase agency responsibilities.

Since 2007, Congress has identified a number of new needs that fall within FDA's jurisdiction. At least six new laws have been passed in the intervening five years:

- Family Smoking Prevention and Tobacco Control Act (2009)
- Biologics Price Competition and Innovation Act (2010)
- Secure and Responsible Drug Disposal Act (2010)
- Combat Methamphetamine Enhancement Act (2010)
- Food Safety Modernization Act (2011), and
- FDA Safety and Innovation Act (2012), including re-authorization of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act

This is hardly the end of it. Congress is already looking at a number of legislative initiatives for 2013, covering topics such as:

- Bio-security
- Track and trace/counterfeit products,
- Drug compounding, and
- Drug shortages.

In addition, this year's legislative requirement--renewal of two Animal Drug User Fees--is widely seen as a vehicle for other legislative mandates that FDA will need to implement.

The problem is not solely Congress' urge to legislate. While some of our Alliance members may quibble with some of the new programs and requirements, overall I believe there is strong public and stakeholder support for Congress addressing unmet needs and emerging challenges. We all want safe foods and safe and effective medical products.

Ultimately, the real problem is Congress' failure to acknowledge FDA as a funding priority despite the austere budget environment. Transforming FDA's mission and responsibilities needs to be met by the necessary resources to do the job well. The current appropriations level is totally inadequate to make up for decades of underfunding AND all of the new laws enacted since 2007.

FDA Responsibilities Grow Each Year Because of Globalization and Scientific Complexity

Even were Congress not active in legislating new mandates for FDA, the agency's mission and responsibilities would grow enormously each year for reasons unrelated to new laws. While the list is long, my remarks will concentrate on two: globalization and increasing scientific complexity.

One of FDA's highest priorities since the Science Board report has been to re-align to adjust for the accelerating globalization in all product categories overseen by the agency. While there is no one way to fully convey the enormity of this shift and the resources required, I offer the following sample of key facts:

- **Food Imports are growing 10% annually.** Altogether, 10-15% of all food consumed in the U.S. is imported. This includes nearly 2/3 of fruits and vegetables and 80% of seafood.
- **Device Imports are also growing about 10% annually.** Currently, about 50% of all medical devices used in the US are imported.
- **Drug Imports are growing even more quickly, about 13% annually.** Approximately 80% of active pharmaceutical ingredients (API) are manufactured abroad, as are 40% of finished drugs.

Inspections at U.S. ports-of-entry are critical, but ultimately less than 2% of shipments can be inspected. The better alternative--the one encouraged by Congress and chosen by FDA--is to increase foreign inspections and to establish foreign offices to work globally to improve the standards and quality of products entering the U.S.

The value of this approach cannot really be quantified. We know that the cost of illness, death and lost markets--from just a single bad actor in a single food category--can cost as much or more than the entire investment we put into FDA's food safety activities. Drugs and devices are harder to track for a variety of reasons, but there is no reason to doubt a similar effect.

In contrast to globalization, greater scientific complexity is diffused into every part of the agency and its mission. That makes dealing with it less visible, but doesn't make it any less costly.

FDA has adopted several approaches, many from the FDA Science Board Report. These include creation of a commissioner-level science office, investment in regulatory science, expanded and more intensive training, changes in time and manpower allotments for complex assignments, and significant reworking of the drug and medical device approval pathways.

Specifically, we have identified five areas that FDA is working on to improve the review process and respond to more complex science. Each comes at a cost in additional dollars and manpower:

- Sponsors Need More Meeting Time and Other Feedback from FDA
- Product Applications Require More Patients, Study Sites and Analysis
- Enhanced Timeliness and Consistency of Product Review is Paramount
- Expansion of Pre-and Post-Market Safety is Essential
- Sustain and Increase Core Programs That Enhance Innovation, Speed Approvals

Further, safety inspections have also become more complex—requiring more scientific training, more preparation and, often, more time during the inspection itself.

FDA: An Agency Still Very Much "At-Risk" for Lack of Adequate Funding

It is important to recollect that FDA is a staff-intensive organization. More than 80% of its budget is devoted to staff-related costs. Of the remainder, rent and utilities are fixed costs that must be paid first. There is little grant and contracting to cut.

Sequestration is the most immediate threat to the FDA's already-inadequate funding. Just a few days from now, the agency faces a loss of 5.1% of its FY 13 (current year) budget. This is the nominal rate. The Alliance's analysis, confirmed by OMB testimony, is that the actual impact will be close to 9%.

Even if sequestration is avoided, FDA faces challenging funding battles in FY 14 and beyond.
If cuts occur now or in FY 14—or even if the agency budget stalls and fails to grow over the next few years:

- food will be less safe and consumers put at risk,
- drug and device reviews will be slower, conflicting with promises made to consumers and companies,
- problems with imports and globalization will become more numerous, and
- critical efforts to modernize the agency and improve its support for innovation will stall.

Is FDA's mission again at risk? Absolutely, yes.

And those who have the most to lose are the American people.

FOR MORE INFORMATION: www.StrengthenFDA.org or contact Steven Grossman of the Alliance staff at (301) 539-9660, sgrossman@strengthenfda.org.