

**Congress of the United States**  
**Washington, DC 20515**

August 4, 2010

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Ave, SW  
Washington, DC 20201

Dear Madam Secretary:

The demands placed on the Food and Drug Administration (FDA) in recent years have never been greater. Continuing innovation has led to a growth in both volume and complexity of FDA regulated products. Advances in the science of early detection of risky products have made available new ways for FDA to prevent problems from occurring. Globalization has prompted an upsurge in the number of imported FDA-regulated products. Congress has also ordered FDA to take on new responsibilities—over 125 new statutory requirements in the past two decades alone.

There have been several high-profile illustrations of the fact that the FDA is not always able to successfully meet these demands. The heparin contamination and the many food safety outbreaks are some of the more notorious examples. Unfortunately, FDA has become an agency that has been reduced to “management by crisis,” continually forced to address the most recent crisis instead of preventing the next one.

There is no doubt that the chronic lack of resources at FDA has been a primary cause of these regulatory failures. A series of expert reports from the likes of the Government Accountability Office, the Institute of Medicine, and even the FDA's own Science Board, have documented the serious funding deficits facing the FDA. These experts all agree that the FDA's current resource levels are wholly inadequate to allow the Agency to keep pace with the ever-increasing number of demands on the Agency. After years of inadequate budgets, FDA finally received real increases in fiscal years 2008, 2009, and 2010, which enabled FDA to restore the staffing losses incurred since the early 1990s. However the FY 2011 budget for FDA barely kept up with inflation, and the agency is faced with far more problems and challenges than it had in 1994.

We recognize that there is little that you, as Secretary, can do to stem the influx of demands placed on the Agency.

There is, however, much that you can do to strengthen the Agency so that it is prepared to meet these challenges: it is incumbent on you to request—and to demand—that FDA receive the resources it needs to do its job and to do it well. Congress needs to hear from you, as the leader of this critically important Agency, what the FDA requires to allow it to protect American consumers from unsafe foods, drugs, and medical devices.

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We have seen in recent months how regulatory failures can be catastrophic, both in impacts on our citizens and economic costs to our nation. Three recent foodborne disease outbreaks alone, for example, have sickened or killed scores of our citizens and been estimated to cost over a billion dollars. These are graphic illustrations of what will continue to happen if we do not give FDA the resources to set modern food standards and inspect the facilities that manufacture our food. We also are concerned that such problems could cause the public to view FDA as a failed agency – not because the agency isn't doing its best, but because FDA simply doesn't have the resources to be fully effective.

Therefore, we urge you to ensure that your FY 2012 budget request will reflect the urgency of the findings of our Nation's experts by setting forth a funding level that will allow the Agency to fulfill its vitally important public health mission. Your team at FDA is demonstrating a strong commitment to public health, but we must support them with the necessary resources to be successful.

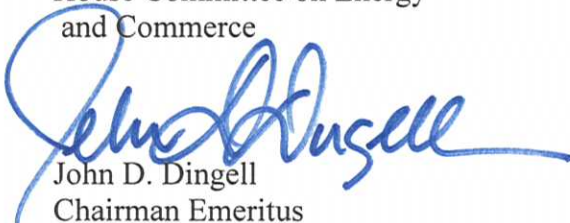
Sincerely,



Henry A. Waxman  
Chairman  
House Committee on Energy  
and Commerce



Tom Harkin  
Chairman  
Senate Committee on Health,  
Education, Labor & Pensions



John D. Dingell  
Chairman Emeritus  
House Committee on Energy  
and Commerce



Frank Pallone  
Chairman  
Subcommittee on Health  
House Committee on Energy  
and Commerce



Bart Stupak  
Chairman  
Subcommittee on Oversight  
and Investigations  
House Committee on Energy  
and Commerce