

ONE HUNDRED TWELFTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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**Opening Statement of Rep. Diana DeGette**  
**Ranking Member, Subcommittee on Oversight and Investigations**  
**“Import Safety: Status of FDA’s Screening Efforts at the Border”**  
**Subcommittee on Oversight and Investigations**  
**April 13, 2011**

Mr. Chairman, I am pleased that we are holding today’s hearing on the safety of imports regulated by the U.S. Food and Drug Administration. FDA plays a vital role in protecting the health and security of Americans, and Congress should be vigilant in examining ways to ensure that FDA is best equipped to carry out its mission.

I am deeply disappointed, however, that for the third time in the last month, the majority has denied the minority a hearing witness. This approach is inconsistent with the practice in all other Subcommittees regarding minority witness requests and flies in the face of the bipartisan spirit we should maintain toward oversight.

In the case of today’s hearing, we requested testimony from Allan Coukell, Director of the Pew Prescription Project. Mr. Coukell is an expert on issues raised by the influx of imported drugs and other medical products, and his testimony would have enhanced the Subcommittee’s understanding of this matter. I ask unanimous consent that Mr. Coukell’s written testimony he prepared be included in the record.

Over the past decade, imports of FDA-regulated products have grown at an astronomical pace. In 2004, FDA oversaw the entry of 12 million shipments of products like food, pharmaceuticals, and medical devices. In just six years, the number of imports nearly doubled, reaching 21 million shipments by 2010. And the number of imports is expected to grow. Unfortunately, FDA faces resource constraints that pose significant challenges to the Agency’s ability to keep the food and drug supply safe. For example, FDA is able to physically inspect less than 2% of imported shipments.

In the face of such challenges, FDA has worked hard to become more efficient. One example of this is the creation of the PREDICT database system. This system enables FDA to target higher-risk shipments for inspection, enhancing FDA’s ability to ensure the safety of imported food and drugs at ports of entry into the United States.

The system is currently in use in New York, Los Angeles, Seattle, and San Francisco, and it will soon be implemented nationwide.

Given the increasing number of imports and the resource constraints facing FDA, it is difficult to understand the recent efforts by my colleagues on the other side of the aisle to cut FDA funding.

In H.R. 1, the majority's opening salvo in the budget debate, Republicans proposed cutting FDA's budget by \$241 million. The Republicans' FY 2012 budget, recently introduced by Rep. Paul Ryan, calls for massive reductions, rolling back agency funding to 2008 levels. In FDA's case, this would mean a budget cut of over \$600 million, a nearly 20% reduction in the agency's total budget.

Make no mistake – a cut of this size would have a significant impact on FDA's ability to keep the food and drug supply safe. The House will be voting on this budget this week, and I hope that my Republican colleagues will reconsider these devastating FDA budget cuts. In the last Congress, we took an important step forward regarding food safety, passing the bipartisan Food Safety Modernization Act to give FDA new tools to protect the safety of the nation's food supply.

We now have a similar opportunity to provide FDA with the additional resources and authorities it so desperately needs for pharmaceuticals. Nearly 40% of pharmaceuticals are imported, and up to 80% of the active pharmaceutical ingredients in drugs come from foreign sources.

The Drug Safety Enhancement Act, introduced yesterday by Mr. Dingell, will hold manufacturers responsible for the safety of their entire pharmaceutical supply chain, including components produced in foreign countries. And it will give FDA tools it needs to enforce these requirements. This is good legislation that deserves bipartisan support.

There is a lot of ground to cover in today's hearing, and I appreciate Commissioner Hamburg coming today. I'm looking forward to hearing about FDA's efforts on imports, its work to implement the new food safety law, and its views on the Drug Safety Enhancement Act. And I hope Commissioner Hamburg can help convince my Republican colleagues to reconsider their proposed cuts to the FDA budget.