

Statement By

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Before the

Subcommittee on Health

Committee on Energy and Commerce

U.S. House of Representatives

Washington, DC

September 26, 2007

## **INTRODUCTION**

Mr. Chairman and members of the Committee, I am William K. Hubbard. Before my retirement after 33 years of Federal service, I served for many years with the U.S. Food and Drug Administration, and for my last 14 years was an FDA Associate Commissioner responsible for, among other things, FDA's regulations and policy development. Although I have remained retired since my departure from FDA in 2005, I provide advice to The Coalition for a Stronger FDA, an organization comprised of patient, industry, and public interest groups whose mission is to urge that FDA's appropriations be increased. I will be providing comments on FDA's resource constraints on behalf of the Coalition, but my comments on specific legislative changes do not necessarily reflect the Coalition's views and are solely my own (as the Coalition does not take positions on non-appropriations issues). During my career at FDA, I was deeply involved in seeking improvements in FDA's ability to assure the safety of foods, drugs, medical devices and other products that are imported into the United States from around the world. Accordingly, I wish to thank the Committee for moving quickly this year to consider legislation that would strengthen FDA's ability to oversee imports of food and other products from other countries.

## **BACKGROUND**

This committee has often raised concerns about our nation's vulnerability to unsafe foods and drugs imported from abroad, and illustrated those concerns with examples of illegal pesticides on fruit from Latin America, deaths associated with raw drug ingredients from China, and other instances of unsafe goods produced in developing countries. FDA's

scientists have agreed with you that imports were a growing concern, as they noted with increasing alarm the volume of imports moving from a trickle to a stream to a flood, with no new resources or authorities to deal with the problem. Perhaps the events of this year – the deadly pet food ingredients, toothpaste tainted with antifreeze, seafood laced with illegal drugs, and other examples of dangerous imports—will serve as the national wake-up call that is sometimes needed to get our institutions moving toward effective solutions. And solutions are indeed needed, for, Mr. Chairman, there can be no doubt that our current system for overseeing food and drug imports is broken, and therefore cannot protect us as it is currently structured.

### **THE CURRENT FDA IMPORT SAFETY SYSTEM**

As was noted in July's Oversight and Investigations Subcommittee hearing on imports, the current FDA system predates the creation of the Food and Drug Administration. First established in 1896, the system was designed to authorize Federal inspectors to open and examine (and sample, if necessary) foods and drug imported into the United States. It was folded into the original Food and Drug Act that established the FDA in 1906. And when the current statute authorizing FDA to protect our foods and drugs was enacted by Congress in 1938, the import provision was the only one of the original 1906 authorities that were believed to have worked well (and were thus continued in the Food, Drug and Cosmetic Act that remains FDA's principal legal authority). Congress' judgment at the time was correct, as most imports were foods and FDA inspectors could generally oversee imports via technology of the early and mid-20<sup>th</sup> century—tools such as visual

inspection, a well trained sense of smell, microscopic examination, and laboratory analysis. But as we neared the end of the century, it became increasingly apparent that changes in the nature of imports were overwhelming the ability of the FDA to assure their safety, namely:

- A huge increase in volume, for instance, from 2 million shipments of imported products regulated by FDA in 1993 to a level approaching ten times that today.
- A tremendous surge in foods, drugs, medical devices, cosmetics, animal foods, and dietary supplements from developing nations that have little or no established regulatory authorities overseeing production of those commodities.
- A shift in the types of commodities from “finished” products ready for consumption toward components that are used to make finished products in the United States, such as the active ingredients for our drugs from India and many of our basic food ingredients from China.
- A greater range of risks, such as new pathogens in food unknown to science in past years, and the intentional but dangerous addition of industrial chemicals and cancer-causing drugs in products produced overseas.

### **AN AGENCY OVERWHELMED**

Several times in recent years, examinations by Congressional committees, the Government Accountability Office, the National Academy of Sciences, and other expert panels have concluded that FDA’s ability to protect us from unsafe foods and

drugs has been steadily deteriorating. No better example of that erosion exists than in the import area. Let me give you just a few measures of how FDA's capacity lines up with its responsibilities for imports:

- The volume of imports, as I noted earlier, has grown to the point that it is nearing 20 million annual shipments of foods, drugs, medical devices and other FDA-regulated products. Yet the number of import inspectors has not been increased, and today the agency has only 450 inspectors to cover this massive inflow of products, which means that less than 1% of imports receive Federal inspection.
- Imports of FDA-regulated products enter the United States at many ports of entry. [Depending on how one counts a "port," between 300 and 400.] But inspector staffing is so low that they can man only about 40 ports, and many of those only part time.
- Despite the fact that there are thousands of facilities overseas making products for our medicine cabinets and dinner tables, the number of FDA inspections of those facilities is tiny. For example, only 125 inspections of foreign food manufacturers were conducted last year, and that was down from only 209 in 2001. This year, the agency will do even less, about 100. And for other products the numbers are even more dismal—2 dietary supplement foreign inspections last year, zero animal food inspections, and zero cosmetics inspections.
- FDA's information systems, particularly those focused on imports, are old and out of date. They cannot interact directly with other agencies' systems, such as those at Customs, and cannot even distinguish imports of road salt from table salt.

- FDA inspectors lack modern scientific tools to make rapid assessments of imported goods for contaminants such as bacteria, viruses, heavy metals and industrial chemicals. They must undertake an expensive and time consuming process of collecting a sample and sending it to laboratory for analysis, often having to wait days for results.
- With so few inspectors, FDA's laboratories cannot be adequately used, and the agency has attempted to close some for that reason. The result is that only a small number of products even receive laboratory analysis. For example, only 20,000 samples of imported foods were sent for laboratory analysis last year, out of about 10 million shipments. There were about 200,000 shipments of food from China last year, for example, so if ALL of the laboratory analyses were directed toward China alone, FDA would have been able to analyze just 10% of those imports.
- All in all, the parts of FDA that do not receive user fees (for new drug and medical device review) have been growing steadily weaker over the past decade, as the agency has lost a thousand scientists and inspectors who would have been protecting us from products on the market and those being imported from overseas.

### **A BROKEN PARADIGM**

If the signs of FDA's failure to adequately oversee imports are so clearly evident, then what can we say about how we got to this point? There are, in my opinion, two principal reasons for our current dilemma, both revolving around the paradigm that current exists for imports – namely, FDA inspection, at the border, to “catch” problems before they make it into our homes.

First, FDA's budget has not kept pace with its growing responsibilities. The agency has sustained either a flat appropriation or actual cuts in their budgets for more than a decade, at a time in which new problems and new regulatory challenges have been thrown steadily at the agency. The food safety program is a good example. It was almost half of FDA's budget in the 1970s, but today is only about one quarter.

Let me give you a more recent example. FDA's food safety budget was \$407 million in 2003. If the agency had received sufficient funding since then just to stay even with inflation, the food safety appropriation for this year would be \$626 million. But it was actually \$450 million, which means that the agency lost \$176 million in buying power for food safety in recent years. The result has been a loss of 20% of its food scientists, and over 600 inspectors, during that time.

One would think that with a growing domestic food industry, soaring imports of food from other countries, numerous new technologies (such as biotechnology) being used to produce food, an increase in food borne disease outbreaks associated with foods regulated by FDA, and declining public confidence in FDA, our leaders would be anxious to assure that the regulatory structure would be strengthened.

Similar analyses can be done for other FDA programs, such as drug and medical device safety, dietary supplements, and animal foods and drugs. These trends are alarming, and underscore the reasons for the creation of The Coalition for a Stronger FDA. While the

Coalition's members often disagree on policy outcomes with respect to regulation, they are all concerned that a weak FDA is detrimental to domestic business, international trade, and, most importantly, public safety.

The second reason for our current vulnerability with respect to imports is that the regulatory paradigm for those products simply does not work in the 21<sup>st</sup> century. It is a system fraught with flaws in today's world:

- It is a reactive system that looks for problems in foods and drugs after they've arrived in the United States, rather than preventing the export of contaminated products at their source
- It would need massive new resources to be significantly improved, requiring hiring thousands of new inspectors at a cost of billions of dollars, and even then may not be able to meet our expectations
- It continues to place all of the burden of assuring safety on this one small agency – the FDA – rather than requiring accountability by those who produce and import these commodities,
- It provides little incentive for foreign governments and foreign producers to be vigilant in producing safe goods for sale to the United States, and
- It does not take into account modern principles of product quality assurance that have recently been developed and proven to work effectively in the production of food and other products.

In sum, Mr. Chairman, I believe we must re-engineer our system of import oversight in ways that will not only strengthen the FDA but also bring our trading partners and their producers into a comprehensive safety assurance system.

### **BUILDING QUALITY IN**

Let me give a brief history that I believe will illustrate the concept of building safety into our food and drug supply. Many Americans do not know the name F. Edward Deming, but he is revered in Japan as one of the leaders in their post-World War II effort to rebuild their economy. Deming convinced the Japanese that traditional production methods, which relied on post-production inspection, would not assure product quality, and advocated instead a process whereby defects in a product's manufacturing are prevented from ever occurring. The Japanese embraced the concept and began a transformation in their production of automobiles, electronics and other consumer products that enabled Japan to shift from an image of a producer of cheap, shoddy products --some would say analogous to China today -- to an economic superpower with a reputation for product quality. American manufacturers eventually adopted Deming's quality assurance philosophy, which has been credited with improving quality in recent years of a host of U.S.-produced consumer products.

This quality assurance concept was implemented for food by the Pillsbury Corporation in 1960, when they were tasked by NASA to develop food for the U.S. manned space program. A food borne illness resulting in vomiting or diarrhea could be catastrophic in the weightless space environment, so Pillsbury developed a food production process to

ensure that no contamination could occur as the food was being produced, thereby “building safety in” to the food as it was produced. This concept, known by the acronym “HACCP” (for Hazard Analysis Critical Control Points) was quickly used by FDA to solve a series of contaminations in the 1960s in canned foods, then used more recently to improve the safety of seafood and juice. Meanwhile, the Agriculture Department adopted the concept for improving meat safety in the United States, and the European Union has legislated HACCP into its food safety laws. FDA also developed regulations, utilizing the same quality control concept, for drugs and medical devices, to minimize production defects in those products.

### **AN EMERGING CONSENSUS ON A SOLUTION – BUILD SAFETY IN**

As dismaying as the recent contaminations of seafood, pet food, toothpaste and other commodities have been, they have focused the various stakeholders in ways that would not have been likely a few months ago. I believe, Mr. Chairman, that we are seeing the development of the elements for needed change in the regulation of imports that could be a wonderful, even historic, opportunity to “fix” imports for the foreseeable future.

Two weeks ago, the Interagency Working Group on Import Safety created by the President this summer released a “strategic framework” that emphasizes a “life cycle” approach to the management of imports that builds prevention in upstream from the FDA. Last week, the Grocery Manufacturers Association/Food Products Association issued its “Four Pillars” for import safety, which emphasizes the need for all parties in the production and sale of imports to be accountable for the safety of foods. Consumer

groups have long urged that a system of continuous quality controls over food production be adopted to reduce food borne disease. And your Committee's draft import bill includes provisions that emphasize the need for safety assurance across the supply chain.

My point is that I believe you are all saying fundamentally the same thing—that the answer for import safety is a system based on prevention that requires producers, exporters, importers, U.S. purchasers –everyone in the chain of supply – to take greater responsibility for the safety of imports, and give FDA the authority and resources to implement and oversee such a system.

### **A SYSTEM BASED ON PREVENTION**

I urge you to accept this emerging consensus among the various stakeholders as a sign of a tremendous opportunity to re-engineer our import safety system in ways that will save lives, reduce illnesses, enhance our citizens' confidence in their government, and perhaps even improve some of our trade relationships. The elements of legislation that would focus on a system of prevention could include:

- O An express requirement for a foreign supplier quality assurance program that importers would implement to provide greater assurance of the safety and quality of imported food products and ingredients;
- O Enhanced international standard setting, for better consistency in safety standards across the globe;

- O Agreements with exporting countries that would improve their capacity and willingness to better oversee producers within their borders;
- O Procedures to assure that verification is made that safety standards are being followed, and
- O A strengthened FDA, with resources to strengthen the agency's scientific base; to gather and utilize new technologies for screening imports; to create modern IT systems to track the movement of imports; and to recruit and train inspectors to oversee the new system -- both by better, risk-based inspections at the border and by more frequent inspections of foreign facilities.

## **CONCLUSION**

I believe it is entirely possible for the Congress to bring together the disparate interests involved in import safety and, keying off of the very basic concept of prevention throughout the supply chain, craft legislation that could be accepted by consumers, the industry, and the current Administration. Obviously, there would be many details to consider, but, in the end, the goal of a better, more effective import screening system is achievable. And, of course, there are other authorities that members of Congress have considered in the past, such as country of origin labeling, new recall authority and more. But those additional authorities would not, in my view, address the fundamental problem of why FDA cannot assure the safety of imports. Thus, I urge the Committee to consider making a system of prevention your primary objective, and I thank you for allowing me to express my views on this subject.