

Statement By

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Coalition for a Stronger FDA

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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 have agreed to provide advice to a remarkable group of patient, public interest, and industry groups that have recently formed themselves into a Coalition for a Stronger FDA (whose mission is to urge that FDA's appropriations be increased). Throughout my career at FDA, I was deeply involved in seeking improvements in one of FDA's most important functions—the safety of our food supply, with particular concern for the massive increase in foods being imported into the United States from around the world. Accordingly, I wish to thank the Committee for inviting me to testify on that subject today.

BACKGROUND

As you know, Congress established the Food and Drug Administration in 1906 as a result of concerns about the safety of our food supply. In those days, it was common for foods to be subjected to all manner of problematic practices—filthy, unsanitary conditions were common in food processing facilities; talcum powder, sawdust and many other contaminants were added to deceptively increase the weight or value of foods; and chemical preservatives were used in food that were untested and often highly toxic. As

the 20th Century progressed, FDA's scientists and those in the emerging food processing industry slowly built a food safety infrastructure for the United States that enabled us to claim that we had the safest food supply in the world. And the standards established by the FDA for the production of safe foods became the model for protection around the globe. But I believe those accomplishments are at great risk today, and I would like to use my testimony at this hearing to describe why I think FDA is no longer able to provide the assurances of safe food that were once taken for granted in this country. While food safety domestically is a major concern, I will focus my comments today on the problems posed by foods imported from other countries.

FDA'S STATUTORY CONSTRUCT FOR IMPORTS

FDA's authority over imported foods actually pre-dates the agency, as the original statutory construct was created in 1896, and allowed Federal inspectors to examine foods as they passed through U.S. ports. That authority was included in the Pure Food and Drug Act of 1906, which established the FDA, and again authorized port inspectors to open food cargo containers and examine their contents. In those early days, it was a fairly simple process. Most imported foods were staple goods, such as flour and molasses, and a visual inspection was often the appropriate means to assure that the food did not contain mold, insect parts, or other visible contaminants. When Congress radically revised FDA's authorizing statute in 1938 to create the modern FDA, it discarded all of the provisions of the 1906 Act, which it concluded were inadequate, except for the import provision, which appeared to have worked well up to that date. Thus, FDA's statutory authority over imported foods remains essentially the same as it

was in that much earlier, simpler day. The authority, embodied in Section 801 of the Food, Drug and Cosmetic Act, permits FDA to examine foods, drugs, and other FDA-regulated products when they arrive for entry into the United States. If the product appears to be in violation of U.S. standards, it can be refused admission. Unlike the Department of Agriculture's meat inspection program, FDA cannot require the exporting country to make assurances that it applies an equivalent safety standard to exported foods, cannot pre-certify foreign food processors, cannot designate the U.S. ports at which the food can be entered, and cannot remove the exporting country from a list of authorized exporters if it fails to maintain U.S. standards. So, the burden is primarily on the FDA to find a problem in an imported food and deny its admission into this country. . And, as I will discuss later, the agency has few resources with which to effectuate that authority.

GLOBALIZATION AND THE FDA

As I have noted, FDA's import screening process was designed for an earlier era, and there is ample evidence that it is not adequate in today's world. The changes wrought by a globalized economy are stark, and even alarming, in the context of FDA's responsibility to assure the safety of our food:

- First and foremost, there is the matter of volume. Whereas imports of FDA-regulated products from other countries were about 10,000 in 1920, by 1993 they were up to 2 million, to 9 million only a decade later, and are approaching 20 million today. In any given year, about 65% of such imports are food; but, of course, FDA is responsible as well for screening the

millions of shipments from abroad of pharmaceuticals, medical devices, dietary supplements, cosmetics, animal feeds, microwave ovens, and other consumer goods under its regulatory purview.

- Second, the nature of imports has changed. The staple goods of a century ago have expanded to every conceivable commodity – fresh fruits and vegetables, canned and other processed foods, food preservatives, emulsifiers and stabilizers, seafood, apple juice, cheeses and many more.
- Third, the threats to food have increased greatly since the turn of the century. Pesticides, industrial chemicals and heavy metals often contaminate imported foods, either as result of intentional acts, such as appears to be the case with the recent melamine contamination, or via environmental pollution that is commonplace in some exporting countries. Also, disease-causing pathogens, such as E Coli 0157:H7, which were unknown in nature a century or even a few years ago, can infect food and present life-threatening risks, especially to children and the elderly.
- And finally, so much of our food is coming today from developing countries, which have weak regulatory systems and that simply cannot assure the safety of food exported from producers within their borders.

FOODS FROM CHINA AND THE DEVELOPING WORLD

The exporting country most in the public eye today in relation to contaminated food is, of course, China. FDA has long identified problems with food imported from China, but in the past it was often with “ethnic” foods and other low-volume commodities, many of

which would seem strange to the average American's palate. A favorite example of mine was a product known as Gecko-On-A-Stick, a dried lizard impaled on a wooden skewer that one would dip into hot water to make a presumably flavorful tea. It was heavily infested with mold and bacteria and, of course, denied admission to the United States.

But today, products from China fill our supermarkets. Whole foods such as apple juice, garlic, honey, mushrooms and several types of seafood frequently are of Chinese derivation. And it appears that many, in some cases a majority, of the ingredients American food manufacturers use to make our processed foods are purchased from China – constituents such as wheat and corn gluten, rice protein concentrate, soy lecithin, ascorbic and citric acid, and xanthan gum. In fact, U.S. food processors report difficulties in even identifying sources of some ingredients outside of China.

Chinese food imports are increasing at a rate exceeding the rapid increase in imports generally. In 2002, 82,000 food shipments were presented to FDA inspectors, yet last year the number was 199,000, and it will likely be at 300,000 in another year or two. The foods appear to be coming from an enormous network of food producers across China, a large percent of which are farmers deep in the Chinese provinces. Indeed, estimates of the number of Chinese food producers are as high as 1.5 million, and the Chinese government has acknowledged its difficulties in reaching into their country's hinterlands to regulate such a vast cottage industry.

With such a huge, fragmented food production system, in a nation rapidly developing, it is no surprise that we see examples of food processing mistakes that border on horror stories – poultry cages suspended over fish farm tanks, so that the fish will consume the bird droppings; substitutions of safe and approved pesticides and food additives with chemicals known in the West to be hazardous; polluted water used in food production; and reports of filthy processing conditions that would be alien to most American food manufacturers. I recall an FDA inspector’s story of his visit to a Chinese herbal tea manufacturer, where the normal process for drying the leaves was laying them out in the sun. But the firm’s desire to speed production caused them to spread the leaves out on the concrete floor of a huge warehouse, over which large trucks would be driven, using the exhaust to hasten drying. The trucks used leaded gasoline and did not have catalytic converters, so lead and other heavy metals were being spewed directly onto the leaves.

These concerns are not just our view of the problems. Chinese food safety officials have publicly acknowledged that the reports of substandard foods and improper processing methods are “not isolated cases,” to quote a Chinese food safety official, and that 75% of that nation’s food processors are small, privately-owned entities over which the central government has exerted little regulatory control. Chinese regulators announced in late June that a recent investigation of processing facilities had found 23,000 food safety violations, including the use of industrial chemicals, banned dyes, and other illegal ingredients in food.

Despite the widespread publicity associated with Chinese imports, it should be recognized that FDA commonly finds problems with foods from many other countries as well, especially less developed nations. Raspberries from Guatemala, catfish from Vietnam, melons from Mexico, and other products from countries such as India, Malaysia, Thailand, Pakistan, the Dominican Republic and the Philippines have often been found in violation of FDA's food safety standards. Indeed, Mr. Chairman, one of our most common confectionary and soft drink ingredients, gum Arabic, comes often from Sudan and Somalia, countries with arguably no functioning government, and thus no discernible food safety system.

In a world in which global trade is an acknowledged fact, I believe we must accept the reality that foods will be imported into the United States from countries that simply do not have the regulatory infrastructure, industry resources or scientific expertise to be a model of safe food production. One recent study, for example, concluded that China alone must invest \$100 billion in its food safety system in order to bring it up to Western standards. That analysis, by the global management consulting firm A.T. Kearney, noted, for instance, that China must insure against food spoilage by better refrigerating products during shipment, but found that the entire country possessed only 30,000 refrigerated trucks and 250 million cubic feet of cold storage (yet that it would need 365,000 such trucks and 5 billion cubic feet of cold storage). For its part, the Chinese government has said it intends to improve its food safety procedures and has suggested that it may be able to have better functioning rules in place by 2012.

FDA'S CAPACITY TO OVERSEE IMPORTED FOOD

Although it has become somewhat of a cliché, let me describe the emerging problems with food imports as a “perfect storm” – a scenario in which the United States is flooded with an enormous volume of food from abroad, where the risks to food are greater than ever before, and at a time in which FDA’s ability to protect our food supply is growing ever weaker. I have described the first two parts of that scenario; now, let me elaborate on the third.

When I began service in the Federal government, in 1971, FDA’s food program comprised almost half of the agency’s total budget. Today, it is about a quarter. During the intervening years, there has been a dramatic drop in FDA’s oversight of the food supply. One stark example domestically is the drop in FDA inspections of food processing facilities, from 35,000 in the early 1970s, to fewer than 8,000 today.

More recently, FDA’s budgets have been particularly alarming for their effects on food safety. On first blush, it appears that FDA’s budget has been rising, but that is due to increased user fees paid principally by drug firms for the review of new drugs. Those funds cannot be used for programs such as food safety. The appropriations for FDA have been inadequate to fund even the staffing level that the agency had in the early 1990s. Thus, the agency has lost 1,000 people over the last decade in non-user fee programs such as the food program. [The attached graph illustrates the drop in non-user fee staffing.] Why has this severe drop in staff occurred?

In most FDA budgets since the mid-1990s, the Administration's annual budget request for appropriations for FDA has not included the inflation "catch up" that Federal agencies routinely expect. Thus, the agency must absorb each year's inflation-driven costs, and if any new funds are requested, they must go to offset the additional costs of employee pay, building rent, and other expenses—which for FDA have averaged about 6% in recent years. This means that the food program, in particular, has undergone steady budget cuts: the staff of FDA's headquarters food program has been reduced from almost a 1000 scientists to fewer than 800 in just five years; and FDA's field force, which includes its inspectors and import staff, has dropped during that period from over 4000 to about 3300 today. Of course, this is at a time in which the problems are growing and food imports are skyrocketing. The current budget request for Fiscal Year 2008 is a good example of the recent trends. Although the official budget request states that it includes an "additional" \$10 million for food safety, the food program's inflation needs are not covered by the request, so the practical effect of that budget is a 3% (or \$14 million) decrease (even with the \$10 million "increase").

How does this effect FDA's import coverage? This year, FDA has 450 inspectors to cover more than 400 ports at which imported foods can enter the United States. With those 450 inspectors, they are asked to screen almost 20 million imports of food, drugs, and other products, which average a staggering 44,000 shipments per inspector. I suggest to you, Mr. Chairman, that no "efficiencies," "better management" or "working smarter" -- all solutions suggested for FDA -- will significantly improve this picture. The agency needs to open and examine a significant portion of these food containers, send samples to

laboratories for analysis, and refuse entry to those foods deemed unsafe – and only people can do that.

Perhaps another China example will be helpful in understanding the workload dilemma. Last year, 199,000 food imports from China arrived at U.S. ports. Also last year, FDA was able to take 19,000 samples of imported food for laboratory analysis. So, if the agency had sampled only Chinese food imports – and none from more than 130 other countries – it would have been able to sample and test only 10% of those imports. And, of course, one could easily argue that, given the large number of Chinese imports turned away for violations, far more than 10% should be analyzed.

A HISTORY OF FAILURE

It has been suggested, Mr. Chairman, that FDA's inability to protect our citizens from contaminated imports is a failure on FDA's part. That may be true, but I suggest that there is ample evidence that the cause of that failure lies beyond that agency. Let me support that contention that by describing a recent pattern of events:

- In the mid-1990s, FDA, USDA, and EPA began a major initiative to identify threats to our food supply, improve our scientific knowledge of foodborne threats, and act against them in a coordinated, aggressive fashion. It was called a "Farm to Table" approach intended to "fix" food safety both

domestically and in terms of imported foods. Despite a promising beginning, it eventually withered away due to lack of funding.

- In 1999, with no prospect for additional funds for food imports and a rising tide of incoming products, the agency drafted a legislative proposal that would have given FDA authority to require foreign countries to take more responsibility for the foods they send to us. It would have allowed FDA to embargo a given food from a given country if there were repeated instances of that food being found contaminated when it arrived here. Countries that sent safe food would have no reason to be concerned, as they would be unaffected. But countries that demonstrated a pattern of disregard of U.S. safety standards would have to step up their oversight of food exported from their country. Congress did not accept the recommendation; indeed, no hearings were ever scheduled.
- In 2002, with statutory change and funding denied, the agency formulated a thorough reinvention of its import program—to rely more on modern risk assessment procedures, to develop better intelligence about foreign food processing practices, and to design a sophisticated computer data base to make the few inspections that could be done more targeted and thus more effective. Result: denied due to even the fairly minimal funding it would have required.

- Just this year, FDA's food safety scientists proposed to the Administration new rules for fresh fruit and vegetable production that promised perhaps a 50% reduction in foodborne disease from domestic and imported produce. Despite the support of such rules from the produce and food manufacturing industries, the proposal was denied.
- And during this entire period, FDA officials repeatedly pointed out to officials in the Clinton and Bush Administrations that food safety should be a priority, that imports were reaching alarming dimensions, and that the agency's food safety program was severely under funded.

FDA has seen the problem, proposed several different solutions, tried to raise an alarm, and been met with relative indifference at higher levels. Therefore, Mr. Chairman, I believe that it is fair to conclude that FDA has not failed us so much as we have failed the FDA.

OPTIONS FOR THE FUTURE

We have all heard the story of the English livery stable owner, Mr. Hobson, who gave everyone who hired a horse his option of whichever horse he wished, so long as it was the one nearest the door. Unfortunately I believe that we are faced with a series of Hobson's choices in the case of food safety – in other words, no real choice at all. Banning food importation is obviously not a serious option, nor is authorizing FDA to implement a USDA-like program that would require the agency to certify hundreds of countries and hundreds of thousands of food processors. Demanding that FDA “do

better” and solve the problem without new resources sets vastly unrealistic expectations. And country of origin labeling is, in my opinion, neither practical nor a substitute for safe food. I suggest to the Committee that the only effective option is to give FDA the resources to design and implement an effective food safety program. The Coalition for a Stronger FDA is recommending an initial increase of at least \$450 million, but it is likely that more would be needed to be truly successful.

The default, of course, is to do nothing, which means that imports will continue to soar, foreign exporters will believe they can send food of any quality to our nation’s dinner tables with impunity, we will continue to blame FDA for problems they cannot fix, U.S. food processors will bear an ever larger burden of concern and liability for food ingredients they purchase on the world market, and Americans’ confidence in our food supply – and in their government’s willingness to protect them -- will deteriorate further.

I urge the Committee to find ways to help the agency solve this dilemma. When similar problems have occurred in the past – drug deaths in 1937 and 1962, pesticide fears in 1955, medical device failures in 1975, counterfeit drugs in 1985, and many other times – this Committee has come to FDA’s rescue. I hope that this will be another of those times when you bring to bear your determination to correct a problem that threatens us all.

Thank you for inviting me to give my views on this subject.