AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2011

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

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NOTE: Under Committee Rules, Mr. Obey, as Chairman of the Full Committee, and Mr. Lewis, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

MARTHA FOLEY, LESLIE BARRACK, ALEXANDER GILLEN, and MATT SMITH,
Staff Assistants

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2011

THURSDAY, MARCH 11, 2010.

GLOBAL FOOD SECURITY

WITNESS

THOMAS MELITO, DIRECTOR, GAO; INTERNATIONAL AFFAIRS AND TRADE

MS. DELAURO OPENING REMARKS

Ms. DELAURO. The hearing will come to order. First of all, our apologies to you, but we just concluded voting on the floor of the House and got here as quickly as we could. So I appreciate your forbearance—to our guests, and also to our guests who are here for the hearing.

What we want to do is to, first, to welcome you and to say thank you for coming here, Thomas Melito, director of the General Accounting Office's international affairs and trade team. Mr. Melito is here to present the report, which I had requested, and that GAO is releasing today at this hearing, on our government's current approach to international food aid and food security. So, again, we thank you for being here.

The funding of international food aid is another of the fundamental responsibilities of this subcommittee. I am very proud of the fact that, together, Democrats and Republicans have both worked to increase funding for the Food for Peace program, P.L. 480, by 38 percent in last year's appropriations bill. And, thanks to Republican champions of food aid like Representative Jo Ann Emerson, we also more than doubled funding for the McGovern-Dole program, including funding for pilot programs and fortified food that will improve nutrition for the recipients of this aid.

So, I am proud of what we have accomplished in this arena so far. Nonetheless, because of higher food prices and global economic uncertainty, the number of undernourished people has increased by over 150 million over the past 2 years. And now, for the first time ever, over a billion souls on our planet go hungry or are ill-fed. Every six seconds a child in this world dies because of hunger or hunger-related causes.

If that statistic were not, in and of itself, horrible enough, that's just the hunger side of the ledger. We also know that malnutrition causes all kinds of lingering problems for the underfed. Research

shows that children's mental and physical development are stunted by inadequate nutrition, that women are more likely to suffer from conditions like obstetric fistulas, and that people's immune systems across the board are all adversely affected by malnourishment.

I believe, and I know many here agree, that the continued existence of such famine in our day and age is a moral outrage. We have the resources and the ability to confront this kind of suffering in our world, and it behooves us to act when and where we can put a stop to it.

You know, even if you do not share the sense of moral obligation, however, global hunger is a national security issue. We know for a fact that hunger, gnawing, unyielding, forces people into desperate acts and dangerous pacts. Famine and starvation create the conditions for militant extremism around the world, the very extremism that we fight right now in Iraq and in Afghanistan.

Simply put, international food aid is not only an important aspect of our diplomacy, it's a crucial aspect of our current efforts to combat global terror. We fight hunger, and we undercut the recruiting base of those who would threaten us. As a former national security advisor, Sandy Berger wrote in the Los Angeles Times last year, "Ensuring that no child goes to school hungry is the single greatest investment we can make in building prosperous, healthy, and stable societies."

This is one reason why I am concerned about the flat funding levels in the USDA's proposed budget for the P.L. 480 Title II program and the McGovern-Dole program. Now, when the world needs our help and is looking to us for moral leadership, now is not the time to forsake our commitment to funding food aid. After all, it is no hyperbole to say that helping to feed the world in this manner also helps to keep our troops safe.

Of course, we must make sure that our food aid is distributed effectively and efficiently, and that the money we are spending on these programs is getting to the people who desperately need it, as the single comprehensive food safety agency.

Based on the report that we have, it seems that we may face a predicament in our current approach to global food security. We now have 10 agencies that have jurisdiction over our international food commitments. And again, perhaps this is an arena where some streamlining and consolidation of our global food security apparatus would benefit everyone involved, not the least all of the hungry that we are trying to help.

Let me just indicate to you that this is not a new concept for me, in trying to get to one single agency that has to deal with food safety. There are 15 at the moment. In my view, there are 14 too many. So we seem to have a number of agencies that are engaged in this effort, as well.

In any case, I look forward to hearing what the GAO report has ascertained about our current multi-faceted food security strategy, and I hope and I expect that today's testimony will help to illuminate the path ahead, as we consider these issues on the subcommittee.

So, thank you once again for joining with us today, Mr. Melito, and let me now recognize my colleague, Congressman Kingston, for any opening remarks that he may have.

MR. KINGSTON OPENING REMARKS

Mr. KINGSTON. Thank you, Madam Chair, and thank you for having this hearing. I know that this is a great passion for all three of us that are here—in fact, the whole committee and most Members of Congress. Yet, at the same time, my perspective might be a little bit different than my two colleagues up here, from a number of points of view that I want to just talk about briefly.

Number one, very important, do you know what the deficit was last month? $223 billion. One month's deficit. One month. The deficit projection for this year is $1.6 trillion, about 37 percent of our entire budget.

Now, I just heard a Republican colleague of mine, Bob English, say—and I'm not sure if this is accurate; I'm going to check it out—he said, "Basically, we have enough money that comes in to pay for Medicare, Social Security, and most of the entitlement programs. Everything else that the Federal Government spends money on is actually borrowed money or printed money. It's deficit spending." Sobering thought.

The Republican conference just voted to not do any earmarks this year, just sort of as a show. And now we all, as appropriators, think that the Administration actually does need our input on their budget, and so that's not necessarily a position of everybody's here, because if you do not earmark the budget or change it, you're essentially agreeing with the executive branch, which the legislative branch would not want to do. But I think there is the theme that the budget issue is huge. And for too long we have chosen to ignore it, both parties.

A second concern of mine is that—and I think you're addressing this, it's just the lack of comprehensive data on the funding on what are we doing. You know, it's amazing that every generation thinks they've discovered something new, food aid being one of them, as if we weren't in many of these countries for decades already.

I was recently in Ethiopia. And one of the food aid—we went to a food aid program, which I enjoy doing immensely when I go to other countries. I want to see the plate in the child's hand. Sometimes that's hard to do, by the way. The international communities resist you going out and doing site inspections. But I don't stop until I see the plate in the kid's hand. And one of the workers said to me, "You know, this might be"—and the kind of, I'd say, self-dramatization of many aid workers—"This child might only have this plate of food today." I talked to a local who said, "That's not true at all."

Case in point. I lived in Ethiopia in the 1950s. The population was around 12 million to 13 million people. Today it's 80 million people. Now, they have had all kinds of problems with their government, as you may know, all kinds of problems with droughts, and so forth. Yet, somehow, they are getting food, because their population has gone up so much. It could not have done—it could not have happened.

International aid—and food aid included in that—in Africa has been just churning for years. Very few bright spots in it. You get a country like Botswana, that's making a lot of progress, but we

don't allow U.S. developmental aid. And so here is a country that, if you will, has kind of graduated from the primary care stage, needs technical assistance, but because they're prosperous they don't get it any more. And to me, that's an inconsistency.

Switching back to Ethiopia, what's interesting, as we were going outside of Addis Ababa to visit this village and this school that had a program, we actually had some down time in which we saw another school. And I said, "Well, let's stop at this school." Both schools, concrete or dirt floor. No electricity, no insulation. The kids all sharing a desk, kind of a plank table—you've seen those before. But one school gets the aid, the other one doesn't. Don't know why. I mean, we can say, "Well, it's lack of resources," but what was the decision that chose one over the other? Where was the decision-making in that?

Another concern of mine is how much of this is skimmed off by corrupt governments? In Zimbabwe, the aid is led by the host country. Is that a great idea, with the Mugabe Government? Probably not.

Another issue which I think is very important—and I actually think food aid is ahead of most aid on this—is using the host country resources. You know, we want to employ as many people on the ground as possible for the manufacturing and for the distribution. And I think food aid actually is moving in that direction, more than some of the other aid. But that's something that we need to address.

And so, I am very interested in this, very committed to it, and very curious about it. But, you know, people who are on the ground who would give food aid an A plus, I don't know what their grade scale is. I think absolute A plus for compassion, absolutely A plus for purity in heart and idealism. But in terms of delivery, in terms of long-term results, in terms of helping impoverished countries so that they don't need aid, it's a C minus, at the best.

So, I am looking forward to your testimony, looking forward to a relationship, and working with you in the long term.

Ms. DELAURO. Thank you very much, Mr. Kingston. Mr. Melito, you are now free to engage in testimony, and the full report of your testimony will be on the record. And you are free to summarize or to characterize your remarks. Thank you.

MR. MELITO OPENING STATEMENT

Mr. MELITO. Thank you. Madam Chairwoman and members of the subcommittee, thank you for the opportunity to discuss our work on U.S. agencies' progress toward the development of a government-wide strategy to address global food security.

Global hunger continues to worsen, despite the world leaders' 1996 pledge, reaffirmed in the year 2000 and again in 2009, to halve hunger by 2015. The Food and Agriculture Organization recently reported that more than one billion people were undernourished, worldwide. In 2009, major donor countries pledged about $22 billion for agriculture and food security in developing countries, of which the U.S. share is at least $3.5 billion.

Since assuming office, the President and the Secretary of State have each stated that improving global food security is a priority of this Administration. Consistent with the recommendation in our

2008 review of food and security, U.S. agencies have launched an effort to develop a government-wide strategy to combat global hunger.

My statement is based on our report released today on government-wide efforts to address global food insecurity. I will focus on two topics: first, the types and funding of U.S. global food security programs; and second, progress in developing an integrated U.S. government-wide strategy, and its potential vulnerabilities.

Regarding the first topic, we found that the U.S. Government supports a wide variety of programs and activities for global food security, but it lacks comprehensive data on funding. As a result, it is difficult to determine the full extent of such programs and activities, and to estimate precisely the total amount of funding that the U.S. Government, as a whole, allocates to global food security.

In response to GAO's data collection instrument, seven agencies reported funding for global food security in fiscal year 2008. USAID and USDA reported the broadest array of programs and activities, while USAID, MCC, and Treasury reported the highest levels of funding.

The seven agencies together directed at least $5 billion in fiscal year 2008 to global food security, with food aid accounting for about half of that funding. However, the actual total is likely greater for two reasons.

First, the agencies lack a commonly accepted operational definition of global food security programs and activities. Such a definition would enable U.S. agencies to apply at the program level for planning and budgeting purposes.

Second, some agencies' management systems are inadequate for tracking food security funding data comprehensively and consistently. Most notably, USAID and State fail to include a very large amount of food aid funding in a database they both use to track foreign assistance.

Regarding our second topic, the Administration is making progress toward finalizing a government-wide strategy, but its efforts are vulnerable to data weaknesses and risks associated with the strategy's host country-led approach. The Administration has established inter-agency coordination mechanisms at headquarters. In addition, it is finalizing an implementation document and a results framework, both of which are expected to be released shortly.

However, the lack of comprehensive data on funding levels may deprive decision-makers of information on available resources and a firm baseline against which to plan. Furthermore, the host country-led approach, although promising, has three key vulnerabilities.

First, the weak capacity of host governments can limit their ability to sustain donor-funded efforts. For example, the multilateral development banks reported relatively low sustainability of agriculture-related projects in the past.

Second, a shortage of expertise in agriculture and food security at U.S. agencies could constrain efforts to help strengthen host government capacity. In 2008, 3 former USAID administrators reported that the agency had only 6 engineers and 16 agricultural experts at that time.

And, third, policy differences between the United States and host governments may complicate efforts to align our assistance with

their strategies. For example, Malawi's strategy of providing subsidized agricultural inputs to farmers runs counter to the U.S. approach of encouraging the development of agricultural markets, and linking farmers to those markets.

In the report issued today, we recommend that the Secretary of State work with other agencies to develop an operational definition of food security, establish a methodology for consistently reporting comprehensive data, and periodically inventory food security-related programs. We also recommend that the Agency specify measures to mitigate the risks associated with the host country-led approach. The agencies concurred with our recommendations.

Madam Chairwoman, this concludes my statement. I would be pleased to respond to any questions that you or other members of the subcommittee may have. Thank you.

[The information follows:]

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, House of Representatives

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GLOBAL FOOD SECURITY

Progress toward a U.S. Governmentwide Strategy Is Under Way, but Approach Has Several Vulnerabilities

Statement of Thomas Melito, Director
International Affairs and Trade Team

March 2010

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-10-494T, a testimony before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, House of Representatives

GLOBAL FOOD SECURITY

Progress toward a U.S. Governmentwide Strategy Is Under Way, but Approach Has Several Vulnerabilities

Why GAO Did This Study

Global hunger continues to worsen despite world leaders' 1996 pledge—reaffirmed in 2000 and 2009—to halve hunger by 2015. To reverse this trend, in 2009 major donor countries pledged $22 billion in a 3-year commitment to agriculture and food security in developing countries, of which $3.5 billion is the U.S. share. This testimony addresses (1) the types and funding of food security programs and activities of relevant U.S. government agencies and (2) progress in developing an integrated U.S. governmentwide strategy to address global food insecurity and the strategy's potential vulnerabilities. This statement is based on a new GAO report being released at today's hearing (GAO-10-352).

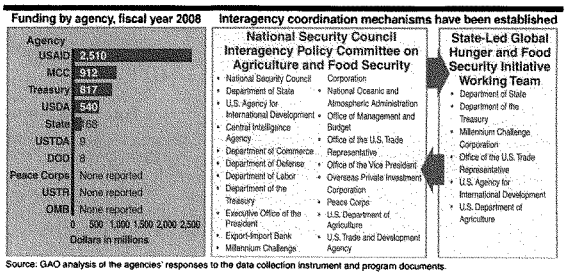
What GAO Recommends

The related GAO report recommends that the Secretary of State (1) develop an operational definition of food security that is accepted by all U.S. agencies and establish a methodology for reporting comprehensive data across agencies; and (2) collaborate with other agency heads to finalize a governmentwide strategy that delineates measures to mitigate the risks associated with the host country-led approach. The Departments of State, the Treasury, and Agriculture (USDA), and the U.S. Agency for International Development (USAID) generally concurred with the recommendations.

View GAO-10-494T or key components. For more information, contact Thomas Melito at (202) 512-9601 or melitot@gao.gov.

What GAO Found

The U.S. government supports a wide variety of programs and activities for global food security, but lacks readily available comprehensive data on funding. In response to GAO's data collection instrument to 10 agencies, 7 agencies reported funding for global food security in fiscal year 2008 (see figure below) based on the working definition GAO developed for this purpose with agency input. USAID and USDA reported the broadest array of programs and activities, while USAID, the Millennium Challenge Corporation, Treasury, USDA, and State reported providing the highest levels of funding for food security. The 7 agencies together directed at least $5 billion in fiscal year 2008 to global food security, with food aid accounting for about half of that funding. However, the actual total level of funding is likely greater. GAO's estimate does not account for all U.S. government funds targeting global food insecurity because the agencies lack (1) a commonly accepted governmentwide operational definition of global food security programs and activities as well as reporting requirements to routinely capture data on all relevant funds; and (2) data management systems to track and report food security funding comprehensively and consistently.



Source: GAO analysis of the agencies' responses to the data collection instrument and program documents.

The administration is making progress toward finalizing a governmentwide global food security strategy—expected to be released shortly—but its efforts are vulnerable to data weaknesses and risks associated with the strategy's host country-led approach. The administration has established interagency coordination mechanisms at headquarters in Washington, D.C., (see figure above) and is finalizing an implementation document and a results framework. However, the lack of readily available comprehensive data on current programs and funding levels may deprive decision makers of information on available resources and a firm baseline against which to plan. Furthermore, the host country-led approach, although promising, is vulnerable to (1) the weak capacity of host governments, which can limit their ability to sustain donor-funded efforts; (2) a shortage of expertise in agriculture and food security at U.S. agencies that could constrain efforts to help strengthen host government capacity; and (3) policy differences between host governments and donors, including the United States, which may complicate efforts to align donor assistance with host government strategies.

Madam Chairwoman and Members of the Subcommittee:

Thank you for the opportunity to discuss our work on U.S. agencies' progress toward the development of a governmentwide strategy to address global food insecurity. Global hunger continues to worsen despite world leaders' 1996 pledge—reaffirmed in 2000 and 2009—to halve hunger by 2015.[1] In 2009, the Food and Agriculture Organization (FAO) reported that more than 1 billion people were undernourished worldwide. The food and fuel crisis of 2006 through 2008 and the current global economic downturn exacerbated food insecurity in many developing countries and sparked food protests and riots in dozens of them. However, official development assistance for agriculture declined from the 1980s to 2005. To reverse this trend, in 2009, major donor countries pledged $22 billion, in a 3-year commitment, for agriculture and food security in developing countries, of which the U.S. share is at least $3.5 billion. Various legislative proposals introduced in 2009[2] call for action to improve global food security.[3]

Since assuming office in January 2009, the President and the Secretary of State have each stated that improving global food security is a priority for this administration. Consistent with one of our recommendations in our

[1]At the 1996 World Food Summit, world leaders set a goal to halve the *total number* of undernourished people worldwide by 2015 from the 1990 level. However, in 2000, the first of eight UN Millennium Development Goals (MDG), referred to as MDG-1, was defined as a commitment to halve the *proportion* of undernourished people. Both goals apply globally as well as at the country and regional levels. MDG-1 has two targets: first, between 1990 and 2015, to halve the proportion of people whose income is less than $1 a day and second, between 1990 and 2015, to halve the proportion of people who suffer from hunger. The second target is measured by two progress indicators: (1) the prevalence of underweight children under 5 years of age on the basis of United Nations Children's Fund and World Health Organization data and (2) the proportion of the population below the minimum level of dietary energy consumption. In this report we focus on the latter indicator, which is based on FAO's World Food Summit goal estimates.

[2]These include S. 384, *Global Food Security Act*, introduced on February 5, 2009; HR 2795, *Roadmap to End Global Hunger and Promote Food Security Act of 2009*, introduced on June 10, 2009; and HR 3077, *Global Food Security Act of 2009*, introduced on June 26, 2009.

[3]FAO defines food security as a condition that exists when all people, at all times, have physical, social, and economic access to sufficient, safe, and nutritious food to meet their dietary needs and food preferences for an active and healthy life. Specifically, food security includes three elements: (1) food availability, (2) access, and (3) utilization. The declaration approved at the World Summit on Food Security in November 2009 expanded FAO's definition to include stability as a fourth element. This fourth element was added after we completed our data collection and analysis. However, the FAO's definition does not include an operational definition that would indicate which programs and activities it covers.

2008 review of food insecurity,[4] U.S. agencies have launched a global hunger and food security initiative, and in April 2009 the administration renewed efforts to develop a governmentwide strategy. The National Security Council (NSC) Interagency Policy Committee on Agriculture and Food Security and a Department of State-led Global Hunger and Food Security Initiative (GHFSI) working team are responsible for these efforts. In September 2009, the Department of State (State) issued a consultation document that delineated a comprehensive approach to food security based on host country- and community-led planning whereby recipient countries decide on their own needs, solutions, and development strategies on the assumption that the most effective food security strategies come from those closest to the problems.

My statement is based on our report—issued today—on U.S. governmentwide efforts to date to address global food security.[5] I will focus on two topics. First, I will discuss the types and funding levels of global food security programs and activities of relevant U.S. government agencies. Second, I will discuss progress in developing an integrated U.S. governmentwide strategy to address global food insecurity, as well as potential vulnerabilities of that strategy.

To address these objectives in our report, we administered a data collection instrument to the 10 U.S. agencies that are engaged in global food security activities[6] and participated in the Food Security Sub-Policy Coordinating Committee on Food Price Increases and Global Food Security (Food Security Sub-PCC) of the NSC in 2008. The 10 agencies are the U.S. Agency for International Development (USAID), Millennium Challenge Corporation (MCC), Department of the Treasury (Treasury), U.S. Department of Agriculture (USDA), State, Department of Defense (DOD), U.S. Trade and Development Agency (USTDA), Peace Corps,

[4]GAO, *International Food Security: Insufficient Efforts by Host Governments and Donors Threaten Progress to Halve Hunger in Sub-Saharan Africa by 2015*, GAO-08-680 (Washington, D.C.: May 29, 2008).

[5]GAO, *Global Food Security: U.S. Agencies Progressing on Governmentwide Strategy, but Approach Faces Several Vulnerabilities*, GAO-10-352 (Washington, D.C.: Mar. 11, 2010).

[6]In the absence of a commonly accepted governmentwide operational definition of food security, we developed a working definition for our data collection instrument based on a broad framework we established in an earlier report (GAO-08-680), prior GAO work on international food security, and our interactions with the agencies. This working definition is based on existing definitions used by FAO, the World Food Program, and some U.S. agencies.

Office of the U.S. Trade Representative (USTR), and Office of Management and Budget (OMB). In addition, we conducted fieldwork in Bangladesh, Ethiopia, Ghana, Haiti, and Malawi on the basis of multiple ongoing programs addressing food insecurity, the proportion of the chronically hungry in these countries, and geographic coverage of U.S. efforts in Africa, the Western Hemisphere, and Asia. In these countries, we met with U.S. mission staff and host government, donor, and nongovernmental organization (NGO) representatives. We also visited numerous project sites funded by the U.S. government and other donors. In addition, we attended the 2009 World Food Summit as an observer and met with Rome-based United Nations (UN) food and agriculture agencies—namely FAO, the World Food Program (WFP), and the International Fund for Agricultural Development (IFAD)—as well as the U.S. Mission to the United Nations and representatives of other donor countries. We conducted this performance audit from February 2009 to March 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The U.S. Government Supports a Broad Array of Programs and Activities for Global Food Security, but Lacks Comprehensive Funding Data

While the U.S. government supports a wide variety of programs and activities for global food security, it lacks comprehensive data on funding. We found that it is difficult to readily determine the full extent of such programs and activities and to estimate precisely the total amount of funding that the U.S. government as a whole allocates to global food security.

In response to our data collection instrument to the 10 agencies, 7 agencies reported providing monetary assistance for global food security programs and activities in fiscal year 2008, based on the working definition we developed for this purpose with agency input. Figure 1 summarizes the agencies' responses on the types of global food security programs and activities and table 1 summarizes the funding levels. (The agencies are listed in order from highest to lowest amount of funding provided.)

Figure 1: Summary of the 10 Agencies' Responses on the Types of Programs and Activities for Global Food Security, Fiscal Year 2008

Types of activities	USAID	MCC	Treasury[a]	USDA	State	USTDA	DOD	Peace Corps	USTR	OMB[b]
A. Food aid										
Emergency food aid	●			●	●		●			
Nonemergency food aid	●			●	●					
B. Nutrition										
Supplementary feeding and micronutrient supplementation	●									
Nutritional education, counseling, and assessment	●			●				●		
Assistance focusing on especially vulnerable groups	●			●				●		
C. Agricultural development										
Agricultural technologies	●	●		●	●	●				
Farming techniques and agricultural inputs	●	●		●	●	●		●		
Agricultural value chains, including investments in food processing and storage	●	●		●		●				
Agricultural market development	●	●		●		●				
Agricultural risk management	●	●		●	●	●				
Agricultural research and development, education, and training	●	●		●	●		●	●		
Irrigation and watershed management	●	●		●		●	●	●		
Maintaining the natural resource base	●	●		●	●	●		●		
D. Rural development										
Land tenure reform	●	●								
Rural infrastructure	●	●		●		●	●			
Microlending and access to other credit	●	●		●		●		●		
E. Safety nets	●				●					
F. Policy reform										
Government food security-oriented policy reform	●		●	●	●	●				
Encouraging private sector investment	●		●	●	●				●	
Strengthening national and regional trade and transport corridors	●		●	●	●	●			●	
G. Information and monitoring	●			●			●			
H. Other types of food security assistance	●			●	●	●				
I. Future challenges to food security	●	●	●	●	●		●			

Source: GAO analysis of the agencies' responses to the data collection instrument.

[a]Treasury reported that its involvement in food security is in the area of policy reform and through its participation as the U.S. representative at multilateral development institutions, which support a range of global food security activities, such as agricultural and rural development.

[b]OMB is not an implementing agency for global food security activities and, as such, does not have programs and activities to report.

Table 1: Summary of Global Food Security Funding by Agency, Fiscal Year 2008

(Dollars in millions)

Agency	Reported funding
USAID	$2,510
MCC	912
Treasury	817
USDA	540
State	168
USTDA	9
DOD	8
Peace Corps	None reported
USTR	None reported
OMB	None reported
Approximate total[a]	**$5 billion**

Source: GAO analysis of the agencies' responses to the data collection instrument.

[a]We present a rounded total of $5 billion because the agencies used different measures to report data, which made it difficult to arrive at a precise estimate. USAID reported on planned appropriations; State provided appropriations, obligations, and expenditures data; DOD, MCC, USDA, and USTDA reported obligations data; and Treasury's funding is a GAO estimate based on Treasury data for agricultural development funding of multilateral development institutions and U.S. participation in these institutions.

USAID and USDA reported providing the broadest array of global food security programs and activities. USAID, MCC, Treasury (through its participation in multilateral development institutions), USDA, and State provide the highest levels of funding to address food insecurity in developing countries. In addition, USTDA and DOD provide some food security-related assistance. These 7 agencies reported directing at least $5 billion in fiscal year 2008 to global food security, with food aid accounting for about half of this funding. However, the actual total level of funding is likely greater.

The agencies did not provide us with comprehensive funding data due to two key factors. First, a commonly accepted governmentwide operational definition of what constitutes global food security programs and activities has not been developed. An operational definition accepted by all U.S. agencies would enable them to apply it at the program level for planning and budgeting purposes. The agencies also lack reporting requirements to routinely capture data on all relevant funds. Second, some agencies' management systems are inadequate for tracking and reporting food security funding data comprehensively and consistently. Most notably,

USAID and State—which both use the Foreign Assistance Coordination and Tracking System (FACTS) database for tracking foreign assistance—failed to include a very large amount of food aid funding in that database. In its initial response to our instrument, USAID, using FACTS, reported that in fiscal year 2008 the agency's planned appropriations for global food security included about $860 million for Food for Peace Title II emergency food aid. However, we noticed a very large discrepancy between the FACTS-generated $860 million and two other sources of information on emergency food aid funding: (1) the $1.7 billion that USAID allocated to emergency food aid from the congressional appropriations for Title II food aid for fiscal year 2008,[7] and (2) about $2 billion in emergency food aid funding reported by USAID in its *International Food Assistance Report* for fiscal year 2008. USAID officials reported that USAID has checks in place to ensure the accuracy of the data entered by its overseas missions and most headquarters bureaus. However, the magnitude of the discrepancy for emergency food aid, which is USAID's global food security program with the highest funding level, raises questions about the data management and verification procedures in FACTS, particularly with regard to the Food for Peace program.

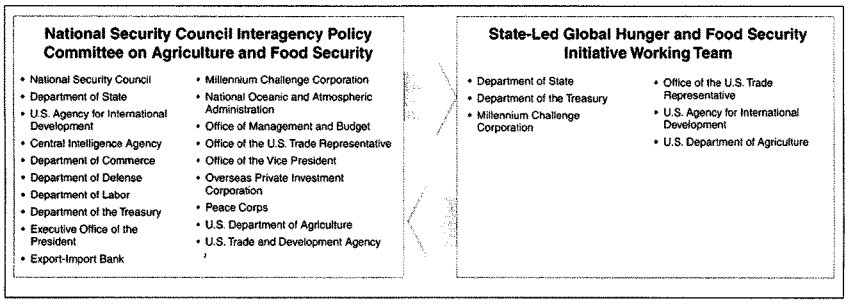
The Administration Is Developing a Governmentwide Global Food Security Strategy, but Efforts Are Vulnerable to Data Weaknesses and Risks Associated with the Host Country-Led Approach

While the administration is making progress toward finalizing a governmentwide global food security strategy through improved interagency coordination at the headquarters level, its efforts are vulnerable to weaknesses in data and risks associated with the host country-led approach called for in the strategy under development.

Two interagency processes established in April 2009—the NSC Interagency Policy Committee on Agriculture and Food Security and the GHFSI working team—are improving headquarters coordination among numerous agencies, as shown in figure 2.

[7]These include the regular appropriations (Pub. Law No. 110-161) of $1.2 billion and the supplemental appropriations (Pub. Law No. 110-252) of $850 million in Food for Peace Title II funding for fiscal year 2008.

Figure 2: Interagency Coordination Mechanisms for Addressing Global Hunger and Food Insecurity Have Been Established



Source: GAO presentation based on State data.

The strategy under development is embodied in the Consultation Document issued in September 2009, which is being expanded and as of February 2010 was expected to be released shortly, along with an implementation document and a results framework that will include a plan for monitoring and evaluation. In the fiscal year 2011 Congressional Budget Justification for GHFSI, the administration has identified a group of 20 countries for GHFSI assistance, including 12 countries in sub-Saharan Africa, 4 in Asia, and 4 in the Western Hemisphere.

However, the administration's efforts are vulnerable to weaknesses in funding data, and the host country-led approach, although promising, poses some risks. Currently, no single information database compiles comprehensive data on the entire range of global food security programs and activities across the U.S. government. The lack of comprehensive data on current programs and funding levels may impair the success of the new strategy because it deprives decision makers of information on all available resources, actual costs, and a firm baseline against which to plan. Furthermore, the host country-led approach has three key vulnerabilities, as follows:

- First, the weak capacity of host governments raises questions regarding their ability to absorb significant increases in donor funding for agriculture and food security and to sustain donor-funded projects on their own over time. For example, multilateral development banks have reported relatively low sustainability ratings for agriculture-related projects in the

past. In a 2007 review of World Bank assistance to the agricultural sector in Africa, the World Bank Independent Evaluation Group reported that only 40 percent of the bank's agriculture-related projects in sub-Saharan Africa had been sustainable. Similarly, an annual report issued by the International Fund for Agricultural Development's independent Office of Evaluation on the results and impact of the fund's operations between 2002 and 2006 rated only 45 percent of its agricultural development projects satisfactory for sustainability.

- Second, the shortage of expertise in agriculture and food security at relevant U.S. agencies can constrain efforts to help strengthen host government capacity, as well as review host government efforts and guide in-country activities. For example, the Chicago Council on Global Affairs noted that whereas USAID previously had a significant in-house staff capacity in agriculture, it has lost that capacity over the years and is only now beginning to restore it.[8] The loss has been attributed to the overall declining trend in U.S. assistance for agriculture since the 1990s. In 2008 three former USAID administrators reported that "the agency now has only six engineers and 16 agriculture experts."[9] According to USAID, a recent analysis of direct hire staff shows that the agency has since increased the number of its staff with technical expertise in agriculture and food security to 79. A USAID official told us that the agency's current workforce plan calls for adding 95 to 114 new Foreign Service officers with technical expertise in agriculture by the end of fiscal year 2012.

- Third, policy differences between the United States and host governments with regard to agricultural development and food security may complicate efforts to align U.S. assistance with host government strategies. For example, Malawi's strategy of providing subsidized agricultural inputs to farmers runs counter to the U.S. approach of encouraging the development of agricultural markets and linking farmers to those markets. Since 2005 and 2006, the government of Malawi has implemented a large-scale national program that distributes vouchers to about 50 percent of the country's farmers so that they can purchase agricultural inputs—such as fertilizer, seeds, and pesticides—at highly discounted prices. USAID has supported operations that use targeted vouchers to accelerate short-term relief operations following conflicts or disasters. However, according to

[8]The Chicago Council on Global Affairs, *Renewing American Leadership in the Fight Against Global Hunger and Poverty: The Chicago Initiative on Global Agricultural Development* (Chicago, IL: 2009).

[9]J. Brian Atwood, M. Peter McPherson, and Andrew Natsios. "Arrested Development: Making Foreign Aid a More Effective Tool." *Foreign Affairs*, vol. 87, No. 6, p. 127 (2008).

USAID, the provision of cheaper fertilizer and seeds does not address the fundamental problem—that poor farmers cannot afford fertilizer on their own and, furthermore, without improvements in irrigation, investments in fertilizer would not pay off in drought years in a country like Malawi, where agriculture is mainly rain-fed.

Conclusions

In the face of growing malnutrition worldwide, the international community has established ambitious goals toward halving global hunger, including significant financial commitments to increase aid for agriculture and food security. Given the size of the problem and how difficult it has historically been to address it, this effort will require a long-term, sustained commitment on the part of the international donor community, including the United States. As part of this initiative, and consistent with a prior GAO recommendation, the United States has committed to harnessing the efforts of all relevant U.S. agencies in a coordinated and integrated governmentwide approach. The administration has made important progress toward realizing this commitment, including providing high-level support across multiple government agencies. However, the administration's efforts to develop an integrated U.S. governmentwide strategy for global food security have two key vulnerabilities: (1) the lack of readily available comprehensive data across agencies and (2) the risks associated with the host country-led approach. Given the complexity and long-standing nature of these concerns, there should be no expectation of quick and easy solutions. Only long-term, sustained efforts by countries, institutions, and all relevant entities to mitigate these concerns will greatly enhance the prospects of fulfilling the international commitment to halve global hunger.

GAO Recommends That Agencies Address Data Weaknesses and Mitigate Risks Associated with Host Country-Led Approach

In the report issued today, we recommended that the Secretary of State (1) work with the existing NSC Interagency Policy Committee to develop an operational definition of food security that is accepted by all U.S. agencies; establish a methodology for consistently reporting comprehensive data across agencies; and periodically inventory the food security-related programs and associated funding for each of these agencies; and (2) work in collaboration with relevant agency heads to delineate measures to mitigate the risks associated with the host country-led approach on the successful implementation of the forthcoming governmentwide global food security strategy.

Four agencies—State, Treasury, USAID, and USDA—provided written comments on our report and generally concurred with our recommendations.

With regard to our first recommendation, State and USAID agreed that developing an operational definition of food security that is accepted by all U.S. agencies would be useful. With regard to our second recommendation, the four agencies noted that the administration recognizes the risks associated with a host country-led approach and that they are taking actions to mitigate these risks.

Madam Chairwoman, this concludes my statement. I would be pleased to respond to any questions that you or other Members of the Subcommittee may have.

GAO Contact and Staff Acknowledgments

Should you have any questions about this testimony, please contact Thomas Melito at (202) 512-9601, or melitot@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals who made key contributions to this statement include Phillip J. Thomas (Assistant Director), Joy Labez, Sada Aksartova, Carol Bray, Ming Chen, Debbie Chung, Martin De Alteriis, Brian Egger, Etana Finkler, Amanda Hinkle, and Ulyana Panchishin.

Ms. DELAURO. Thank you very much for your testimony. Let me just start right in.

I am troubled by the discrepancy that you found in the data that USAID reported for Title II of P.L. 480, which, as you know, is one of the most popular and most effective international food aid programs. You report that the Foreign Assistance Coordination and Tracking System, the database that's used by both the State Department and USAID, included a number that was over $1 billion short of the actual 2008 appropriation of $2.1 billion—a significant discrepancy.

Mr. MELITO. Yes.

Ms. DELAURO. Troubling, also, that USAID was unaware of the mistake until you brought it to their attention.

Your report also suggests the database was not immediately corrected after the mistake was discovered.

Equally troubling is your conclusion that USDA has no established mechanism for reporting data on food security programs, and that several different conflicting estimates were provided to you after several inquiries.

Why do you think USAID and USDA had so much difficulty in reporting accurate data? What effect is this likely to have on the food aid programs at these agencies? How do USDA and USAID compare with the other agencies that you reviewed?

Mr. MELITO. Thank you. The situation with USAID was that they had a fairly—actually, they had a very accurate number for the initial appropriation. Where it broke down was on the supplemental. They included a couple of supplemental items, but they didn't include the very large Title II supplemental item, which was very large and, obviously, very clear to us, when we compared it to the IFAR and other documents, including the budget.

We did bring that to their attention, and they did tell us, "Yes, you used a larger number." Where there seems to be some discrepancy——

Ms. DELAURO. Was there any reason why they didn't include it?

Mr. MELITO. They didn't seem to have a good process for updating——

Ms. DELAURO. I got it, okay, okay.

Mr. MELITO [continuing]. After the budget was supplemented.

Ms. DELAURO. Okay.

Mr. MELITO. Where we're a little confused is in their agency comment letter. They have—they're not seeming to indicate that that's a problem. Although, informally with us, they agree it was a problem. And they ultimately included the number in the official number that we have here. So we're still in dialogue with them——

Ms. DELAURO. Okay.

Mr. MELITO [continuing]. About exactly what processes they will have in place, and thus, our recommendation.

Regarding USDA, I would say that the issue was stovepiped within the organization, that there really was no good way of cutting across different parts of USDA to see across—for something which touches a number of different programs. Also, I don't think they initially assigned it to someone at a high enough level for them to actually help us with this.

That all said, I think ultimately we have a pretty good USDA number. But it took a lot of work with us to work with them.

We consider all of this to be a problem, though, because this strategy is an attempt to be a whole-of-government approach. And they're going to be needing—or they're going to say they need resources. And we think you can't really give a good number on what resources you need unless you know what resources you already have. So, this is an attempt by GAO—we're working with the agencies to create as good a baseline as possible.

That said, we know in our report this is an understatement. There are a number of categories—there is over $800 million of USAID funding which overlaps with other programs, such as health and such, that we know there is a food security component, but we couldn't tease it out. If they had a better definition, AID ultimately could tease it out——

Ms. DELAURO. Well, that's what—we will get to those questions.

Mr. MELITO. Right, yes.

Ms. DELAURO. But I—just quickly, USDA, USAID, a comparison to other agencies that you reviewed, or are these the two major pieces that——

Mr. MELITO. Those are the two largest discrepancies. State Department, we had a lot of problems early on with State Department, separate from the issue with the supplemental. Their initial number didn't include their contribution to the Food and Agriculture Organization, their initial——

Ms. DELAURO. Oh, okay.

Mr. MELITO [continuing]. Which is $100 million a year.

Ms. DELAURO. Sure, sure, sure.

Mr. MELITO. And we sat down with them and ultimately——

Ms. DELAURO. And said, "You've got to"——

Mr. MELITO. Yes, then——

Ms. DELAURO. That fits. That fits. Okay.

Mr. MELITO. We thought we had pretty good numbers with MCC. The other large player was Treasury.

Ms. DELAURO. Yes.

Mr. MELITO. There, the numbers were fine. The question was the methodology. How do you attribute our contributions to a multilateral organization? And I think we came up with a mutually agreeable methodology between GAO and Treasury on how we're scoring that.

Ms. DELAURO. I think your point is well taken. I have one more question in regard to that before—I know my time is going to be up.

But it would appear to me that what we're talking about is—rather than substance—is process here, in terms of getting to figuring out how much there is, what a definition is, and what gets allocated. It is really the process and not, if you will again, the substance of the commitment to doing that, or to getting the food——

Mr. MELITO. That's exactly right. That's a separate consideration.

Ms. DELAURO. That's a separate consideration.

Mr. MELITO. Yes.

Ms. DELAURO. Just quickly, have you seen specific improvements with either agency since your initial review? And what is your current assessment of—your assessment of the current capabilities of

USDA and USAID to collect and to report data for food security programs?

What specific steps should each agency take to correct the problems?

Mr. MELITO. I would say our story is the current story, because we were making adjustments based on dialogue with them through the end of February.

Ms. DELAURO. Got you.

Mr. MELITO. So—but I—they concurred with our recommendations.

Ms. DELAURO. Okay, okay.

Mr. MELITO. So I think they do agree they can do better. And I think we've given them a path to that.

Ms. DELAURO. Okay. Okay, and you've laid out—the specifics are laid out in your recommendations?

Mr. MELITO. Yes.

Ms. DELAURO. My time has expired. Thank you very much. Mr. Kingston?

Mr. KINGSTON. Mr. Melito, if I am kind of listening to you correct, you're the—kind of the bean counter of the operation, the cold-hearted accountant guy, right? Do you think they're going to listen to you? Do you think Congress or the agencies will?

Mr. MELITO. Well, I can only go by what they currently said, which is they do agree they need something, a good comprehensive number, for planning purposes.

They have yet to come out with their official strategy. And that official strategy should start having some budget numbers, going forward. That will be, I think, the first test. And that should be in the next couple of months, whether or not they actually will act on GAO's recommendation.

Mr. KINGSTON. You know one of the things that's interesting to me? I deal a lot with USDA employees. And I think they're, on the whole, a very, very good group of people, very dedicated. And the ones that are international are among the sharpest people I've ever met. And you know, you just—it's incredible, how smart some of these people are.

In the planning, are they ever included in the strategy, in terms of, "Okay, what do you need to get out of there in five years?"

Mr. MELITO. For this particular assignment, we looked at the State Department effort right now to create a government-wide strategy. USDA is an important part of the strategy.

Mr. KINGSTON. But are the people in the field given input?

Mr. MELITO. You highlight an important issue. We were very careful in the report to talk about this as a headquarters effort. We were silent on what this will mean on the field, because we don't know yet.

In the past, these kind of efforts have broken down when you've gone from headquarters to field. We hope and don't know that's true, but that will be one of the important implementation steps, which GAO would like us to look at, six months or a year from now.

Mr. KINGSTON. You know, people who spend their lives in third-world countries who could make more back home and live more comfortably back home and be with their families back home,

they're pretty dedicated people. They're very interested in what they're doing, not just passionately, but they have an understanding and a sense of, "I want to get something done." And I think we're remiss in not listening to them, and drawing them into the process more.

A problem we have politically is—we're looking at international aid, including food aid—is the State Department vote rating system. Are you familiar with that?

Mr. MELITO. Just very little——

Mr. KINGSTON. Well, I'm not an expert on it. But as I understand it, maybe 20 or 30 years ago, Congress mandated that the State Department rates UN voting, and there is a sample of 13 different votes which the State Department deems important. And then they publish once a year to Congress how these countries have—how every country that's in the UN votes, in terms with us. Israel, Great Britain are, you know, in the 70s, the 90s. South Korea is in the 70s.

But then, it just falls. And so many of the countries that we give aid to have very, very low rating systems. So when our constituents are looking at international aid, foreign aid, which generally isn't the most popular thing on the budget, and they look at that, then they say, "Look, look at all the money we're giving to people who vote with us 10 or 15 percent of the time."

Now, that's an outrage, and I like to bring it up when I'm on these international meetings. But the truth of the matter is, if it was voting—if I was doing the voting, or with my colleagues to my right and left, philosophically and spatially, they would not have 100 percent, either. Because the votes are all about the Middle East, Israel, Cuba boycott, and the death penalty. I mean they're just, frankly, stupid votes. And yet, that's what our constituents are going to use as a gauge to if a country is an ally or not.

What we, I think, need to do is look at the broader context. Take a country like Nigeria, which is very helpful, in terms of, you know, looking at Abdulmutallab, The Underwear Bomber, you know, the investigation of him trying to tap down local dustups in that area of Africa, they are a good ally of us, but they don't vote with us in the UN, necessarily.

So, we need to, I think, change that voting sample to give a truer picture. Because it is really detrimental, if you are trying to give food aid to people. And, you know, it's so easy for us to grandstand. And somebody like Ms. Emerson, who has dedicated so much of her life to it, we're pulling out the rug from under the efforts.

And I'm talking to you only because you go in these circles, and you can talk to people. But it's something that we should say, "You know what? It's probably proper for us to look at UN voting, but not these votes." And it's also not proper to end it at voting, because if they're sending people to Afghanistan, or they're helping with local skirmishes in their part of the world, we need to give them some credit for that beyond it, so that Members of Congress can go back to their folks and say, "Look, these people are allies, they're helpful." You know, there is a case for it.

So, I know I'm out of time, and we will look forward to more questions.

Ms. DELAURO. Ms. Emerson.

Ms. EMERSON. Thanks, Madam Chairwoman. Dr. Melito, thanks for being here.

Mr. MELITO. Sure.

Ms. EMERSON. And thanks for doing this study, which is quite interesting. And I am hopeful it will be quite helpful.

I do want to concur with my chairwoman about the need to streamline things. It would just be so much simpler just to have one place where everything was done. And that way you could monitor it, we would know how much money we were spending, we could perhaps figure out if we were doing any good a lot easier than we are now.

I also want to say I share your view that we shouldn't expect any easy solutions here, and we're dealing with a long-term sustained effort that is going to be necessary, I think, by every single person, every single government agency, every country involved in trying to ensure that we can feed those people who otherwise are unable to do so for themselves.

But let me ask you, just—you know, one of the things that is concerning—and I think this plays off of what Jack was saying—we really somehow, if you want to look at it from the military perspective, we've got to be able to show that there is a strong and vested coalition of nations in the fight against global hunger, and not just us.

But—so while you raise the concerns that we lack data across agencies, did you look at any opportunities to improve data across nations, or efforts to improve international coordination of aid efforts?

Mr. MELITO. We wholeheartedly agree that this coordination and integration effort has to be much larger than the U.S. That said, this U.S. Government effort was much more difficult than my team and I ever anticipated it was going to be.

Ms. EMERSON. I think if you probably did that for every single piece of the government you would probably say the same thing.

Mr. MELITO. It took almost a year. And it was really difficult to get the agencies engaged. And once they engaged, it became very difficult to get them to coordinate and align, and what not. But there probably needs to be a similar international exercise, which I think would help. But I guess one battle at a time.

Ms. EMERSON. Yes, precisely.

Mr. MELITO. Yes.

Ms. EMERSON. No, it is interesting, though. Hopefully, by having engaged all of the agencies, somehow you made them start thinking about perhaps we ought to keep better track, or try to at least have some cost-benefit analysis done for the work that they're doing.

I also understand your concern about a country-led approach. And, you know, obviously it would go without saying that the American taxpayer does expect competent and honest governments and NGOs with whom to partner.

But you know, I was reading the discussion that you wrote about in Malawi. And it's just interesting, because I happen to know the nephew of the president of Malawi, and I know that they're trying to do some different things there. Obviously, their approach to add-

ing value, if you will, to the producers' labor—actually creating subsidies, which is a bad word—I think that that is helpful.

But there is obviously some pushback by some of our government agencies about the way that they are helping their farmers, and therefore we should take a step back. I would be interested just—and your thoughts a little bit more about that.

And, I don't know, I don't know how to fix this, or try to——

Mr. MELITO. Right.

Ms. EMERSON [continuing]. Go on the path to make us be efficient and streamlined, and be able to help more people. If we could just somehow better direct resources.

Mr. MELITO. Malawi was a carefully chosen example. Because, if you look at it, you can see that they both have somewhat of a credible argument to make. Malawi is a pretty good performer, and they're actually meeting the pledge that—they've already provided more than 10 percent of their budget towards agriculture. But the U.S. has a long-running reason for wanting to mark markets.

So, we chose that example because the host country-led approach is going to create conflict and difficulty for agencies a number of ways. And this one would be one where, basically, two different philosophies, which may have justification, are going to clash.

I mean, we could chose examples where one side looks—The policy is not correct.

Ms. EMERSON. Right.

Mr. MELITO. This one, it's debatable policy. So I don't think, actually, I can tell you how the U.S. Government is going to approach this. We just want them to basically begin thinking about this. They're going to be confronting it a lot, probably, as they deploy lots of money right now, and think about basically reinvigorating U.S. food security approaches.

Ms. EMERSON. Yes, it's going to be—it is going to be interesting——

Mr. MELITO. Yes.

Ms. EMERSON [continuing]. Once this whole strategy is finalized, I guess, is the best way of putting it. But it is, in my opinion—I mean there are great challenges. But, then again, there is also an understanding—at least I can understand, given that I come from an ag district—that you want to help your farmers be able to create some sustainable lifestyle.

So, my time is up. I will wait and ask another question. Thanks. Thanks, Dr. Melito.

Ms. DELAURO. Dr. Melito, let me try to get to the issue of the definition of global food security.

Mr. MELITO. Sure.

Ms. DELAURO. And that—one of your findings in the report suggested a cause of incomplete funding is the lack of a commonly accepted government-wide definition of global food security.

And you further posit that, without that understanding or that definition, many agencies will submit inaccurate funding data by defining the term too broadly or too narrowly.

What you did was you used a working definition of global food security, based on your prior work with and in consultation with agencies. You included programs, as I understand it, containing elements such as food aid, nutrition, agriculture development, rural

development, safety nets, policy reform, market intelligence and monitoring, and future challenges to food security. This strikes me as a broad definition. Why did you include, for instance, elements such as rural development?

My further question is here—is how do we get to an acceptable global food security definition, if that is fundamental to our being able to calculate what it is that we are—you know, what is it we're doing, and what kind of resources we have, and how we can monitor those resources? Why rural development, first.

Mr. MELITO. Well, it's a broad category, but it's not everything in rural development. But the infrastructure of rural areas, most especially the roads, has been pointed out in many studies as an enormous impediment to being able to effectively take advantage of surpluses.

So, if you actually do the good work of increasing yields and surpluses, but you can't then bring it to the market, then your efforts are going to fail.

Similarly, the issues of microcredit in the rural areas is something which—it's often very difficult for the farmers to take advantage of new technologies without some kind of credit system.

So, those are two areas. But it's not all the elements of rural development, but those are two vital areas which are directly linked to ag security.

You mentioned that our definition is broad. It's broad because this is an interactive process. You mentioned correctly that we had—in a previous report, our 2008 report——

Ms. DELAURO. Right.

Mr. MELITO [continuing]. We also had nine different focus groups with experts and with practitioners in the field——

Ms. DELAURO. Okay.

Mr. MELITO [continuing]. So we refined what we had in the—for our report, based on that. But then—that became the basis for our data collection instrument with the 10 agencies. Then we basically went back and forth with the agencies.

So, some of that will get added—got added—because the agencies made a compelling case that we should also add this category. So the broadness was also a product of the dialogue that we had with the agencies.

But we also pushed back in places where we thought that was—"Your link to food security is way too indirect." We're not saying these aren't important things, but basic education spending is just—you know, obviously, it's a vital development goal, but it's not directly related to food security.

Ms. DELAURO. So help me. So that would include, if you're looking at transportation—and I understand that—so then it is the amount of resources that we provide that help to build roads, deal with reconstruction efforts, and—

Mr. MELITO. Road building is probably the single biggest expense there, for that category, although there are other—some subcategories, as well. But yes, it's ways of trying to improve the marketing of ag products through rural infrastructure. And this is done by a number of U.S. agencies, as well as the World Bank and others will also work in that area.

Ms. DELAURO. Now, I'm not—I'm just——

Mr. MELITO. Yes.

Ms. DELAURO. You then multiply the various, you know, sources of funding, if you will, in terms of these—you know, these efforts, which is—I mean, look, the delivery system is important to this.

I need to think about that, in terms of, you know, how do you then do get to this definition of what it is. And if you make it so broad, are we ever going to get to a conclusion, whereas we're delivering a food product and—because that—these are categorized as international food aid.

And to go back to what my colleague was saying, it's food aid. And if we're dealing with all these other pieces in a number of ways, it gives you a false view of what we are providing to a country in direct food aid, so that you run the risk of constituencies who say, you know, "What are you doing here," and it's not just the food aid that you're doing, but you've got all these other pieces that are linked to it.

I will be very honest with you. There are a whole lot of folks in the U.S. who are not terribly concerned about us building roads and reconstructing, you know, countries and communities, et cetera. They—I would—I believe I'm standing on 100 percent solid ground when I say giving food to people who are hungry and who are starving, you bet. You bet they're there. But—and so you begin to mix up a process here.

I need to think about it, because I understand what you're saying, but I——

Mr. MELITO. Let me just say this is the kind of thing we're struggling with. But we are differentiating in our work, and it is also being differentiated in the strategy, between humanitarian assistance and development assistance.

Ms. DELAURO. That's right.

Mr. MELITO. So, the humanitarian assistance is the direct intervention on the part of the U.S. and other donors to mitigate a serious immediate food crisis. The development purpose is to try to get ahead of the crises, to try to improve their own——

Ms. DELAURO. I understand that.

Mr. MELITO. Yes.

Ms. DELAURO. But we have two pieces here. One is the humanitarian, the other is the developmental. And, quite frankly, developmental funding has dropped substantially.

Mr. MELITO. You're telling me.

Ms. DELAURO. Substantially, worldwide. And we now just respond to emergencies. So we don't have a balance.

Now, that's where—but you look at another—you look at other portions of our budget, and the USDA budget, which we have jurisdiction over, where you can look at developmental efforts to deal with productivity. You've got the foreign operations subcommittee, which deals with that effort, as well. But by commingling them in some way here, it may be some false impressions about what's happening with the humanitarian side of food aid.

I will leave it at—my time is well over.

Mr. MELITO. Okay.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. I think the chairwoman has really touched something very important to all of us. Because, in my experiences going

to Rwanda, people are collecting water. Every house has a banana plant and a water vat, and—for the rainy season. You go to a place like Senegal, where I went in Dakar, they don't have it.

And so, that's a developmental issue. You say, "Okay, come on now. Look, guys, you've got to collect your water." And that is basic. But the chair is correct. You start getting into things where our constituents back home are saying, "Well, you're building water—you're building dams and ponds and irrigation over there? Hmm, we don't have it in our own farms back home." And so that is really a challenge.

And here is a frustration that I have, as well. I would like to know, by your rating system, what works and what doesn't. I notice that you did have water here checked off by a number of the groups that are involved in it, which is a good thing, because you have to have water, and you have to be a good water steward.

But I was in Afghanistan this weekend. And what the—and Pakistan. What the Pakistanis and the Afghan folks say is, "Look. We are trying to close the gap between military victory and civilian stability," civilians coming in and taking over.

The biggest cash crop in Afghanistan is poppies, $100 million a year. And it would be so great if we could say, "Hey, you know what worked in some country somewhere is that USDA program or the USAID program that we can—we're going to take that and we're going to put it in Afghanistan right now," because that's the key to winning the war.

Secretary Vilsack was here two weeks ago, and requested that we go from 14 to 64 USDA employees in Afghanistan. We're all going to support that.

I had a briefing while I was over there, which I haven't had a chance to tell you about. It was a really good briefing. And, again, very sharp people on the ground over there.

But what I would love to know is, you know, if we could have something that we knew would work, because——

Mr. MELITO. Right.

Mr. KINGSTON [continuing]. To get them away from poppies, it is one of the most—it just doesn't seem like it could be so complicated, but it is real complicated. But you can't substitute something with nothing. You have to have a program that will really help these folks. And with all of our foreign aid around the world all these years, you would think there would be five or six surefire programs that could be helpful.

Mr. MELITO. Unfortunately, in the area of ag development and food security, the success rates are generally lower than other development projects. And, for that reason, assistance—development assistance to this area actually dried up heavily. It reached its peak in the mid–1980s, and then it steadily fell until it was a very low part of development assistance by the mid-part of the last decade.

Ms. DELAURO. Mr. Kingston, would you mind if I asked——

Mr. KINGSTON. Sure, sure.

Ms. DELAURO [continuing]. Why the food assistance is in a——

Mr. MELITO. It's multifaceted, why there is a problem. But World Bank did an excellent study in 2008, where it looked backwards and did its own mea culpa. And I don't think they gave a real satis-

fying reason. I think everyone is appealing right now to an evaluation, as we really need to really understand better what's working.

But the point, though, was by—in the process of pulling out of investing in ag sectors, hunger got worse. And the instance of emergencies got more frequent.

Ms. DELAURO. That's right.

Mr. MELITO. So, there is no easy answer here. So we are faced with a very difficult development option. But if we don't, we know that hunger is going to get worse. So——

Mr. KINGSTON. Well, you know, getting back to my point on the budget—and I really think we're sitting on the cusp of a big taxpayer backlash, and foreign aid is going to be out there.

And so, the question is, which NGOs are the most effective?

Mr. MELITO. I don't have that——

Mr. KINGSTON. But could we ask you to give us an evaluation? Which ones are really out there, and which ones aren't?

Rosa, this was interesting. Several years ago I was in Tajikistan with Chairman Kolbe, when I served on the foreign operations committee. And many of the women—excuse me, it was Uzbekistan—but many of the women run the village, because the men go to Russia to work. I think the population is five million, and one million people go to Russia, looking for work.

And so, we went into this house, and it's, you know, a one-room, two-room kind of house, and they don't have beds, they all sit up on things, a table, and then it's a bed at night. And we sat with the village mayor, if you will, and about five or six women, poor as they could be, beautifully dressed, nice as they could be, serving us some kind of a native food.

And so, here we were, richest nation in the world facing the poorest nation in the world, ambassador-to-ambassador, if you will. And we asked them, "What can we help you with? What do you need?"

And they talked amongst themselves for a few minutes, and then the mayor came back to us and she said, "Our village really needs three more cows."

And now, we never heard of Heifer International, but I was—we actually came back, passed the hat, and bought them three or four cows, you know. But it was the only way to get there. And I was just thinking, this is just so—there has got to be a better way to fill the micro and the macro big picture.

Mr. MELITO. I think the focus—the new focus on global food security is a good thing. We need to, though, learn lessons of the past, and learn what is and is not working. You're asking me excellent questions about who is more productive, who is doing it better. I actually don't think that data exists yet, and I think it's vital that we make sure that we do collect it.

Mr. KINGSTON. I'm wondering if we could ask you to collect it. And I don't know the—but because it would just be so helpful. I know there are so many good-hearted groups in America who want to do things and can't get overseas. And if we could say, "Look, here are some really good ones. Now, these ones talk a good game, they've got great advertising, they've got movie stars. But these are the ones on the ground that know what's going on."

Ms. DELAURO. Ms. Emerson.

Ms. EMERSON. Actually, playing off that, it would be really nice to know precisely how many NGOs there are in the food security, and then the developmental side.

I actually have a friend who is working—has been working on this project kind of on the side of the World Food Program, US-based, to try to do a surveillance, I mean seriously, to put together the list and figure out who is doing what where.

But it seems to me that if there is any way that that information could be collected, and instead of having a lot of overlap, that we're actually leveraging and maximizing our opportunities, you know, with who specializes here and who specializes there, and then we do this, and somebody else does—I mean, to me, that seems like the most logical, common-sense way to do it. I realize that, in reality, that doesn't exist.

But it would be helpful, because we don't have infinite——

Mr. MELITO. Right.

Ms. EMERSON [continuing]. Resources, that we take advantage of every opportunity.

Mr. MELITO. I have done some work on AID's data systems, and I don't think they are equipped to easily give this answer to themselves or to anyone else. They are supposed to improve their data systems. I mean this is getting into the contracting databases——

Ms. EMERSON. Right.

Mr. MELITO [continuing]. How you can actually aggregate up. There is a lot of weaknesses in the contracting databases. They have—it's recognized by—they've got this new system called GLAAS, which they have been working on, which aspires to reach a level where you can do this. But I think they're quite a ways away from implementing that.

Ms. EMERSON. Well, it's just worrisome. Based on what you say, it's really hard to know what—the right hand doesn't know what the left hand is doing.

I mean, you know, in a—how do I want to say this nicely? It doesn't matter. It's just—it seems to me that if we could get our arms around this, we could certainly reach more people and better utilize the resources that we have right now.

Mr. MELITO. Right.

Ms. EMERSON. And, you know, I think it's important, because you know, I love the—I have, up in my office, you know, the wheat bags and the rice bags with the red, white, and blue, and the USA, whether it went to Cuba or whether it's gone, you know, to Africa or sub-Saharan Africa, wherever. And that's been a lot of—there has been a lot of goodwill given to us for that.

I wonder if—you know, is anybody paying attention to this whole goodwill that we are doing? I mean, are we—how do we fix—how do we create, you know, this global strategy and still allow us to get some credit for it? I mean the taxpayers are going to continue to demand more and more——

Mr. MELITO. Right. Whether or not the U.S. is getting sufficient credit for its effort, the U.S. is, by far, the most generous country when it comes to providing food assistance. And we have been the most generous for 50 years.

Ms. EMERSON. Right.

Mr. MELITO. We provide, at varying points, half of the amount of assistance of the world. And everyone else is the other half. So we have got a lot to be proud of. We have taken a vital leadership role. This has been a bipartisan commitment to food assistance.

Ms. EMERSON. Absolutely.

Mr. MELITO. So I don't know if the State Department or AID, or whoever is doing—in terms of advertising that, but there is a good story to tell.

Ms. EMERSON. Yes, and I mean, you know, it is—I mean, hunger, we know, is—knows no politics. So——

Mr. KINGSTON. And if the gentlewoman will yield?

Ms. EMERSON. Sure.

Mr. KINGSTON. I think, in a lot of instances, the people like us. Their governments might not, but people-to-people, the relationships, I think we do get goodwill.

Ms. EMERSON. Right.

Mr. KINGSTON. It might not be reflected in the government.

Ms. EMERSON. Thanks, Dr. Melito.

Mr. MELITO. Sure.

Ms. DELAURO. Dr. Melito, there was—I think an interesting point in your report is that, according to FAO, from 1990 to 2004, 2006, there was actually a decline in the percent of undernourished people in key areas. Sub-Saharan Africa down from 34 percent to 30 percent, South Asia down from 25 percent to 23 percent, Haiti down from 63 percent to 58 percent.

You do note, however, during this period the number of undernourished people increased. I presume this was because of population growth.

Mr. MELITO. Right.

Ms. DELAURO. Still, I would just say this. It was encouraging that some progress was made. Can you speak to what worked during those years in reducing the proportion of undernourished persons?

Also, you have a number of observers who believe that the worldwide economic decline in the last two years or so, accompanied by steep increases in food prices, could undo progress that has been made. And do you share that view? What worked in those years?

Mr. MELITO. Well, I would be very hesitant to say anything "worked." It gets into a couple of problems that we have discussed—we only allude to it in this report, we discuss it more fully in our 2008 report—and that comes down to how they're measuring the prevalence of hunger, and also problems with FAO's own methodology. But it just comes down to how they're measuring.

The 1996 original pledge was an absolute number.

Ms. DELAURO. Right.

Mr. MELITO. They wanted to reduce hunger——

Ms. DELAURO. By 2015.

Mr. MELITO. In terms of the number of people. The pledge thing got changed in the year 2000—well, they never actually rescinded the other pledge, so they're side-by-side. But the 2000 pledge became a proportion pledge.

So, the progress, for the most part, especially when you look at the poorest countries, in Africa and in Haiti, it's due to population growth. So you're having the denominator growing faster than the

numerator is growing. The numerator is growing, which is the number of hungry people.

Ms. DELAURO. Right.

Mr. MELITO. The places where there has been success has been Asia, and it's mostly China and India. There you have absolute numbers of people going down, as well as, you know, the proportion. But in terms of Africa, the absolute numbers of hungry people have steadily risen over this period of time.

So, what you were looking at there was the proportion of hungry people went down. But that's mostly driven by population growth.

Ms. DELAURO. But still, you know, what allowed for that to happen?

Mr. MELITO. Right.

Ms. DELAURO. I mean, I understand what you're saying.

Mr. MELITO. Right.

Ms. DELAURO. You know, I believe we're all here on the first goal, which is to end hunger. But something happened that allowed for a decrease here.

Mr. MELITO. I would not characterize this as any success, though. I mean, yes, population growing is actually a sign that there are some good things going on.

Ms. DELAURO. Right.

Mr. MELITO. I mean let's not understate that. But that is not—those numbers are not being used as an indicator of success.

Ms. DELAURO. Okay.

Mr. MELITO. And even in——

Ms. DELAURO. By you, or by FAO?

Mr. MELITO. By FAO. We're not the arbiters of this, okay?

Ms. DELAURO. No, I understand, right.

Mr. MELITO. So, yes.

Ms. DELAURO. Okay. A shortage of expertise at agencies——

Mr. MELITO. Yes.

Ms. DELAURO [continuing]. Which you also make reference to, USAID, you note in-house expertise in agriculture has declined over the years. Efforts need to be made to add foreign service officers with technical expertise in agriculture.

You talk about USDA with oversight of food aid programs and recipient countries. FAS regional office is engaged in that effort. It is a little troubling, with regard to FAS, because they don't maintain nearly 100 offices around the world with their efforts.

What specific effects has this shortage of expertise had on programs? Let's just start there.

And with respect to FAS, is one of the problems the fact that overseas FAS staff has focused too much on trade and not on food assistance?

And is there a clearly differentiated role between USAID agriculture staff abroad and FAS agriculture staff abroad, or are we duplicating the same work?

So, three questions.

Mr. MELITO. Those are three good questions.

Ms. DELAURO. Specific effects of the——

Mr. MELITO. Right.

Ms. DELAURO [continuing]. Shortage of expertise.

Mr. MELITO. In our 2007 food aid report, where we raised concerns about the efficiency and effectiveness of food aid, we demonstrated that both the AID and USDA had almost no monitors. So that's getting even away from providing technical assistance. They didn't have any of the expertise of people to actually know that the food was going to the right people in the right amounts, and that it was having the impact they were looking for.

We are, in this report, highlighting that if you are actually going to pursue actively this host government approach, you have to recognize that these governments have very weak technical capacities on their own.

So, you are putting in their hands the responsibility of running what is, in many ways, a technical exercise without them having the technical expertise. We have a responsibility, in that case, to assist them. And if we have—we don't have technical experts in the field, that's going to be very, very difficult to do.

Ms. DELAURO. And we don't, in terms of your view.

Mr. MELITO. And we don't——

Ms. DELAURO. We don't have the experts in this area. I mean, I understand——

Mr. MELITO. Right.

Ms. DELAURO [continuing]. About monitors. But your view is that we don't have——

Mr. MELITO. Right. So I'm going with two different things, but they both impact the way these programs work.

Ms. DELAURO. Okay.

Mr. MELITO. AID—you know, you had that star quote from the former AID director in 2008. They have done a lot of hiring in 2009.

Ms. DELAURO. Yes.

Mr. MELITO. But—so they're recognizing and they're acting. They are nowhere near where they want to be, but they are acting on it.

FAS has traditionally been very interested in market promotion.

Ms. DELAURO. Trade.

Mr. MELITO. Trade. And they won't deny that. But market promotion and development assistance are two very different things.

Now, they are talking about invigorating and adding to development assistance, and they're talking about bringing somebody to Ethiopia for the first time, and that makes sense. Ethiopia is one of the largest recipients of USDA resources. This is—needs to be seen. They are making a verbal commitment; we would like to see it actually be deployed.

Ms. DELAURO. Well, so FAS has spent most of its time and its resources with regard to market promotion, is that correct?

Mr. MELITO. There aren't that many USDA people in the field, to begin with.

Ms. DELAURO. No, I understand.

Mr. MELITO. Very small numbers——

Ms. DELAURO. I am just trying to get it, because——

Mr. MELITO. We're getting this from—my team goes to Africa regularly on this, and they meet with the USDA representatives. And they come back with stories about, basically, the person has

done very little on the development side, because his portfolio is active on the marketing side.

Ms. DELAURO. Right.

Mr. MELITO. Yes.

Ms. DELAURO. That's what I'm trying to get at. The portfolio is on the market promotion side——

Mr. MELITO. Yes, yes.

Ms. DELAURO [continuing]. And not on the food assistance side, or the development side.

Mr. MELITO. Right, yes.

Ms. DELAURO. Now, and you just mentioned that your understanding is that they are going to try to move in this area. I must tell you—and we will go back and check—their budget doesn't reflect what you are talking about. But we will get to asking——

Mr. MELITO. That's an important point. That's an important point.

Ms. DELAURO. We will go back to ask that question.

Mr. MELITO. Yes.

Ms. DELAURO. Again, then are we looking at—USAID and FAS and that staff that's on the ground, are we doing different work or are we doing the—duplicating efforts between these two agencies?

Mr. MELITO. Well, we start with the premise that, up until now, very little has been happening.

Ms. DELAURO. I'm there. But——

Mr. MELITO. But moving——

Ms. DELAURO. But whatever little is happening——

Mr. MELITO. Right, right.

Ms. DELAURO [continuing]. Tell me about it.

Mr. MELITO. I think, moving forward——

Ms. DELAURO. Yes.

Mr. MELITO [continuing]. If we actually—and this is—I want to say "if," I want to put two underlines on the word "if."

Ms. DELAURO. Right, right.

Mr. MELITO. If they actually successfully start coordinating at the head, they are going to confront the challenge of coordinating at the field level. They are going to have to confront that.

We look for opportunities of leveraging. Do they need to have the same people in the same places? They probably do not.

I guess this is going to be something that has to happen over time, as they recognize that maybe they have shortage of resources, they can deploy them in ways which may take advantage of opportunities, and they may not need to be in the same place.

Ms. DELAURO. I understand the limitations. I understand that. As of this moment, today, now, with regard to on the ground, are we more duplicating functions or are we dealing with separate functions here and now at the present moment?

Mr. MELITO. We are talking about very few people. I think there has been——

Ms. DELAURO. Of the two people there, are both of them doing the same thing or two different things?

Mr. MELITO. They are doing two different things, but the USDA person for the most part is doing market promotion.

Ms. DELAURO. The USDA person is doing market promotion. Thank you. My time has long expired.

Mr. Kingston.

Mr. KINGSTON. The questions just keep coming. I hope you brought dinner. [Laughter.]

The 1949 foreign aid original concept was spreading some goodwill around the world in the Cold War context. That was number one. Number two, development of underdeveloped countries who needed help with science and investments to overcome poverty.

Number three was dealing with our surplus for our own farmers because of our great new production technique, and then number four was the leg of developing markets.

It would appear to me that the answer to the Chairwoman's questions should really be at the USDA in Washington, D.C. where somebody says okay, any given country, tell us where we are in these four areas.

It is shocking to me that you are saying there is not really an answer. I am not picking on you. I am not picking on anybody.

Here is where my question is, can you tell me ten success stories? What do we have, 168 countries around the world that we have given aid? What are some of the hey, this is where we made a difference?

Mr. MELITO. My team has traveled extensively to Africa. They went to Bangladesh. They went to Haiti. They came back with a number of success stories, but they are success stories at a very localized level.

We at GAO are looking at systems. We are looking at processes. We know that yes, this particular version of the program seems to be doing well here, but we also see weaknesses there. Then we comment on the overall working of the program.

Mr. KINGSTON. You are saying maybe in a given region of a country, you had success?

Mr. MELITO. Yes. A particular orphanage, a particular school district.

Mr. KINGSTON. That success would be measured by?

Mr. MELITO. It's tricky. We have concerns with how they do monitoring and evaluations. Then it really comes down to more ad hoc.

Mr. KINGSTON. Switching lanes for a minute, one of the things about micro credit, and I traveled to Africa twice with the Banking Finance Committee, and one of the things I have learned is micro credit, when everybody says let's get a 94 percent pay back record, one reason is they keep lending money to people, so it is not that.

If it was that good of an investment, the private sector would be there.

A lot of it, you have to keep asking and asking questions to really find out, and that is why when you say we have had success in an orphanage, the add on question is tell me about it, are these people out being productive and doing great things.

Mr. MELITO. We hesitate to declare any of the projects we look at as going well in GAO. We witness things which are not working well. We hesitate to call that a "failure." Again, those are just data points to what we were trying to get at a larger level.

Our biggest concerns in terms of effectiveness is there is not really a good way for USAID and USDA right now to tell you how their programs are working. They do not collect data well. They do not do a good job of monitoring and evaluation.

Ms. DELAURO. We do not have a definition of what this issue is, and we do not have a structure that allows us to——

Mr. KINGSTON. I think some of the finest people that I have met in Government are involved in this program.

I want to ask you this. You just said half of the world food aid comes from America. I have heard that statistic. In reading your testimony, you said $22.7 billion with America doing $3.5 billion, which is not half.

What is that?

Mr. MELITO. That is a commitment for new money for food security. We are counting food aid as well as part of the budget. We are very hesitant to comment on that $22 billion number and the $3.5 billion number because we have not quite seen exactly how the details are going to work on that.

There is always the risk there is double and triple counting going on.

Mr. KINGSTON. Japan is number two?

Mr. MELITO. For food aid, I believe so. EU as a whole is number two.

Mr. KINGSTON. It might be good if you could rattle off that, because one of the things that really shocked me is in the Middle East with all the oil rich countries, they do not seem to do much, or if they do it, it is all spent locally.

Mr. MELITO. The Middle East countries have a large role in IFAD, but I agree, they are not one of the major players in food aid. They are not.

Mr. KINGSTON. People flying around in gold plated jets, it is kind of interesting you do not see much coming from them.

Why did not the Administration get OMB to conduct the crosscut rather than GAO?

Mr. MELITO. They did not get GAO. GAO got requested by the Chairwoman, and we did the exercise.

OMB, fortunately, after they really recognized what we were doing, saw that they themselves could do something like this. They could make this call.

I do not know why they have not yet been asked. We made a point of putting in our report that they say they can do this. I think that is an important part of how the Administration moves forward.

Mr. KINGSTON. Would it be helpful for us to insist or write a letter? It seems to me that you are actually doing something that they do normally.

Mr. MELITO. We recognize that what we did there was probably something which was a little non-standard, but it could have been very easy for us to write a report to say the data was bad, and we really wanted to understand why the data was bad and to understand how to make the data better.

It now needs to be the Administration's exercise moving forward and OMB is clearly a vital player, and congressional support and pressure is probably a good idea.

Mr. KINGSTON. I think Secretary Vilsack would be on the same sheet, too.

Ms. DELAURO. Let me talk a little bit about food quality control and nutrition. In your 2007 report, you concluded that "U.S. agen-

cies were not coordinating adequately to respond to food quality and delivery problems."

You said that "Various agencies involved different tracking systems and were not able to effectively monitor and resolve problems that occurred. In some cases, agency country offices were unclear about their role in tracking food quality."

You concluded that "USAID and USDA had no central process for updating food aid products, specifications or nutritional standards."

You recommended that "USAID and USDA establish a coordinated system for tracking and resolving food quality complaints and develop an inter-agency mechanism to update food aid specifications and products."

In your September 2009 report, you concluded "The agencies have implemented" your 2007 recommendations on food quality control and nutrition.

Can you just walk us through the improvements that USDA and USAID made in nutrition and food quality since your 2007 report and what effect are the improvements likely to have on the delivery of food aid?

Mr. MELITO. In the case of both recommendations, we wanted them to establish processes. Processes have been established. I will not go beyond that and say now that means it is working.

We do have a request that we have just gotten recently where we are being asked to look at both the changes on the nutrition side and the changes on the food quality side. We were going to be launching that as soon as this study ended.

We have reasons to believe in the case of nutritional quality, they are working with Tufts University and NGO, SUSTAIN. They have some ongoing studies going on.

The great frustration we had in 2007, and I am still not yet convinced this particular thing is overcome, so that is why our new job is going to be important, even when the science is clear and even when the interest and desire is there, there seems to be bureaucratic inertia to actually get it rolled out.

This is a relatively inexpensive way of greatly improving the effectiveness of U.S. food aid. It will not cost a lot of money and can have actually a dramatic impact on nutrition.

I think our next study is going to be vital.

Ms. DELAURO. What would be the timing on that next study?

Mr. MELITO. Probably early next year. We have to work with the agencies. We have to go and look in the field for what they say they are doing. That is usually the hardest part, the field work.

Ms. DELAURO. The Chicago Council, can I talk about them for a second here? The Chicago Council on Global Affairs, they have been a major contributor on key global policy issues.

I asked them a while ago, and it was not in relationship to this hearing, to get me a memo that raised some of the possible areas for our work on this subcommittee and what we could do in these areas under our jurisdiction. We like to stretch our jurisdiction like any other committee as far as it can go, but we do have to move within our jurisdiction.

One idea was to ask GAO to focus just on USDA's work in international agriculture. There is, of course, a lot of expertise at the

USDA. The thought would be to look at just how to leverage its resources to support the work of State and USAID.

This would drill down into their activities in a much more intense way than this report. Let me get your thoughts on that, then I have a follow up question.

Mr. MELITO. I think there is clearly great opportunities for the USDA to play a much larger role here in many ways.

Their letter and the report that you requested makes the compelling argument that in terms of technical expertise, they probably are the best in the U.S. Government, in terms of their association with the extension programs and the universities. They have a lot of national and domestic experts on ag.

There needs to be a way of integrating that into the international effort. They make a compelling argument both in the letter and also in our conversations with them, but I do not know if they have figured out a way yet to do that in practice.

Ms. DELAURO. That gives us some guidance there.

Another idea was to do more oversight on the food and agricultural organization of the U.N., the FAO. The Council believed that its effectiveness has been limited in recent years and that perhaps USDA could engage more actively in reviewing its capacity, management, strategy and policy making and program evaluation.

One, would that be useful? Do you have any sense of the work USDA currently does with the FAO right now?

Mr. MELITO. Yes, without a doubt. FAO, its reason to be is food security. FAO is the food security agency. It is striking that they are not a major player right now.

They are, I think, trying very hard to ramp up in certain areas like in data collection and really monitoring of food crises, but the FAO has a long way to go. I do not have a good sense of USDA's involvement in oversight of FAO. I hesitate to say anything other than yes, oversight of FAO is a good thing.

Ms. DELAURO. Jack, let me just ask one more question in conjunction with this. Is it a question of resources at FAO? Is it a question of statute within the U.N. framework? Is it just lack of——

Mr. MELITO. FAO is a complicated organization. It is very old, in terms of U.N. organizations, it is over 50 years old. It has a large budget, but I think they would make a compelling case that they need more money.

Ms. DELAURO. Where does the money come from?

Mr. MELITO. This is an organization where members are assessed.

Ms. DELAURO. Members of the U.N. are assessed.

Mr. MELITO. They also get bilateral contributions from some other members. They had their own internal review last year, I believe. They came up with a lot of management weaknesses at FAO. That actually gives a starting point for whether or not they are taking that review seriously and making those changes.

Ms. DELAURO. Thank you very much.

Mr. KINGSTON. Do you not think it is going to be hard to get the FAO to kind of change their culture?

They have a very lofty definition of "food security," "When all people at all times have physical, social, economic access to suffi-

cient, safe and nutritional food to meet their dietary needs and food preferences," that means chocolate ice cream, "for an active and healthy life."

USDA has a different definition of "food security." Yet it would appear that the definition of FAO can almost make it harder for the United States to be seen to have a long-term sustained commitment to food and global security.

It would appear to me at some point we are just going to have to agree to disagree with them.

Mr. MELITO. Those definitions are really more the goals. Ultimately, those goals are fairly compatible with each other. FAO also has a particular operational goal which gets into minimum caloric levels. That, I think, could be overcome.

FAO should be the agency that has the expertise on Africa, for example, ag development problems. They should be either a repository of what works and what does not work and that should be the go to agency, and they need to get to that place.

Mr. KINGSTON. Do we have a definition of "food security" that we would measure?

Mr. MELITO. When we talk about an operational definition in our report, we are not actually talking about the goal. They are saying basically everyone has a sufficient amount of food.

We are talking about something a little bit more green eye shaded in what we are talking about here, where you have these budget categories and you have these processes and programs that the U.S. Government has, and they aspire to do five things.

It is getting them to really sit down and say okay, this is related, this is not related. This sounds boring but really, we are trying to be efficient in the U.S. Government and we are trying to deploy our resources.

How do we know what resources we have to deploy? The answer is we do not know what resources we have to deploy.

I find a planning and strategizing exercise where you actually do not know what you have to be somewhat bizarre.

Mr. KINGSTON. On the host country situation, you are saying it is very awkward but then you also say it is promising. I think you are darned if you do and darned if you do not.

There still should be some measurement of host country cooperation, you know, we are going to do it your way, but inasmuch as we are donating so much, we have to have certain results and it has to be moving in a certain direction or we are out of here.

Mr. MELITO. Yes. That is to be expected. What we are doing is trying to anticipate some of the likely conflicts and make sure there is a process in place to deal with it.

Some countries like Ghana, I think they have a pretty healthy relationship between the donors and the country. I think there are some models they can use, but it is going to be case by case, country by country.

Ms. DELAURO. Mr. Kingston, because I was going there next, let me just add a couple of points. I think a number of the agencies involved in this report indicated in their comments that they believed you leaned too heavily toward the downside of a country-led approach. They indicated their plan is to do this in two phases,

doing a lower level of funding initially and reviewing it before moving forward.

Does that sound like a sound approach to you and are there other steps that the agencies are taking to minimize this risk? What steps should they be taking? It is a conflict.

Mr. MELITO. That is clearly one of the important steps. That, I think, helps GAO with the first issue which is the sustainability of projects, the capacity of the host governments themselves. Some of them are just not ready yet. Some are ready and some are not ready yet, and to differentiate, not to treat them the same is the right way to go.

It does not address the lack of expertise within the U.S. Government. That is something we have to do ourselves.

To try to create some sort of process or sophisticated internal dialogue about when we disagree, when is it material and when is it not material, a successful process is going to have disagreement.

If you are really going to energize the host governments, they are going to come up with home-grown approaches which at times we are not going to approve of.

What are we going to do about that? You do not want to necessarily pull the rug out every time that happens.

They are correct in saying they are starting to approach this but we have not seen the final document and we really want to make sure they stay on top of this.

Mr. KINGSTON. One of the questions I had is there is not a consistent goal for food aid that we have, correct?

Mr. MELITO. The goal of food aid is emergency food assistance, to mitigate the crisis in a relatively brief period.

Mr. KINGSTON. That is emergency food aid.

Mr. MELITO. Eighty percent is emergency. Twenty percent of food aid has development purposes.

Mr. KINGSTON. We do not just stick with a natural disaster or war.

Mr. MELITO. Sure.

Mr. KINGSTON. The next question is the State Department has a FACTS Book that has incomplete data. Is it called the "Green Book?" USAID has U.S. overseas loans and grants.

Mr. MELITO. "FACTS" is an acronym they use for their database, Foreign Assistance Coordination Tracking System, FACTS.

Mr. KINGSTON. What does that track? What is included in that?

Mr. MELITO. It aspires to be what you would want right now. It aspires to comprehensively show U.S. international development efforts across many different categories across the U.S. Government.

The database itself is currently only populated by the State Department and USAID, and then they have resolved some ambiguities in terms of how to characterize things, but a lot of the ambiguities, they have not, and then we highlight also they do not necessarily have a great process for keeping it up to date.

Mr. KINGSTON. If I were to look for the ten best case scenarios, would it be in that book?

Mr. MELITO. That does not provide you with performance, but it can give you pretty detailed expenditure information.

Mr. KINGSTON. It appears to me that we ought to have this is the case. Today on television, I saw something called the Urban

Prep Academy in Chicago where four years ago or five years ago, a very small percentage of the kids even graduated from high school. Today, something like 100 percent go to college. It is the story everybody is looking to find.

I want to hear that on food aid. Are there not some really bright spots?

Mr. MELITO. This is a drum that I keep beating and I am going to keep beating it. We do not have a good monitoring and evaluation process.

GAO did a report that came out at the end of September which looked at USAID's ag development efforts and found that while certain efforts are monitored in certain ways, they really do not do good lessons learned, they do not have a good approach for then taking the lessons learned and integrating it back into how the program works.

Mr. KINGSTON. Is that in your report here or recommendations?

Mr. MELITO. That is in our report that came out in September.

Mr. KINGSTON. Could you make sure that I have a copy of that?

Mr. MELITO. Certainly.

Mr. KINGSTON. In your observation, and you are not going to be comfortable answering this, meeting State Department kind of diplomacy people on the ground, USDA people, PEPFAR people, USAID folks, there is a culture within each agency.

Who do you think is the most effective or the most entrepreneurial in terms of look, we are going to get this thing done and we are going to cut some corners?

I do not want you to really answer that.

Mr. MELITO. Thank you.

Mr. KINGSTON. You are way too young to involuntarily retire.

Mr. MELITO. That is exactly right.

Mr. KINGSTON. It does appear to me that there are different cultures. I have been impressed with PEPFAR but I have been impressed with USAID on the ground and USDA.

Mr. MELITO. I can easily tell you I do work with multiple international agencies of the U.S. Government and I have found good people in all of them.

Mr. KINGSTON. I have, but I know good people can be constrained by bureaucracy. If the bureaucracy is a little bit more flexible—I heard a great summary of communism in China, and that is what works. They just want to do what works. That is what I would kind of look for on the ground, what works. Just do it.

I want the person in Ghana to say hey, we got it done.

Ms. DELAURO. Just a footnote. It does not come under our jurisdiction but State is asking for $14 million for the monitoring and evaluation of their global food security initiative. That is in the 2011 budget. I think that is very, very positive.

Mr. MELITO. I agree.

Ms. DELAURO. Obviously, we will wait to see what happens. I think we ought to encourage the Appropriations Committee responsible for that to move forward.

Maybe Mr. Kingston, the two of us could write to that subcommittee and indicate the necessity for this as we try to move forward.

Let me just ask a question. In the letter that I wrote in December talking about a request for the report, I commented that from the 2008 report, the GAO had recommended that a coordinated and integrated government-wide U.S. global food security strategy is necessary to address many of the underlining factors that cause food insecurity.

GAO also recommended that the Administrator of the USAID program prepare and submit an annual report to Congress on progress toward implementation of the first recommendation here, which was that GAO found the efforts to reduce global food security have been hampered by fragmented and uncoordinated nature of U.S. assistance efforts.

Did we ever get a report from that recommendation and is that recommendation a part of the current report if we did not get one?

Mr. MELITO. The answer to your first question is no, you did not get a report. We consider those two recommendations to not yet be closed. We think the current effort is a possible means to create that strategy, but there is not any vehicle yet for them to report regularly to Congress, and we think that is essential.

Ms. DELAURO. I would concur. Let me ask a question about food aid in Haiti. GAO visited Haiti as part of your field work effort for this report. Haiti is so close to the United States, and as your report points out and I quote "It is the least developed country in the western hemisphere and one of the poorest countries in the world."

You note that the number of undernourished people in Haiti ranges from 4.5 to 5.4 million and will probably grow due to the recent earthquake.

I have three questions in this regard. Would you share with us GAO's observation from that trip? Were you able to assess food aid efforts in Haiti during the trip, and can you suggest steps that could be taken to improve Haiti's food security?

Mr. MELITO. I was not part of that trip but my team had an excellent visit to Haiti. We were looking at ag development projects. This is again a case where they came back with some good stories and some not so good stories. Again, we try to look above that to try to understand systems.

The team did have a strange encounter with a Government official in Haiti in terms of monetization of food aid. We were surprised to learn that actually Haiti had a Bureau of Monetization, which its sole purpose was implementation of monetization of U.S. food assistance. We would like to look closer at that. We actually are going to do some monetization work in the future.

What is surprising about Haiti is for a western hemisphere country, it has a hunger rate that is among the worse in the world. It is over 50 percent. That stands out among some of the worse cases in Africa.

Ms. DELAURO. It did not get to that point because of the earthquake.

Mr. MELITO. No, not at all. I hesitate to give you a quick and easy answer. I believe there is governance issues. This is not something that is in my expertise. I have sent teams to Haiti several times. GAO has done Haiti related work a lot. We are actually going to do probably a large reconstruction based on the earthquake.

I do not know how you differentiate the difficulties of development from the difficulties of Haiti. It seems like everything is magnified when you talk about Haiti.

Ms. DELAURO. Mr. Kingston.

Mr. KINGSTON. I know we are kind of going over and over again on this important accountability, but it is important.

You did list in your report the numerous agencies that work on global food security, but did you say what kind of food aid is most effective?

Mr. MELITO. As I mentioned earlier, I do not think anybody knows yet.

Mr. KINGSTON. Would you ponder that issue?

Mr. MELITO. Yes. I want to address something which Chairwoman DeLauro mentioned earlier, which was the letters from the agencies said we might have been too harsh about the country-led approach.

We are not too harsh. As the letters came in, we added a little more positive language to make sure we are not saying it is wrong.

The donor-led approach to food assistance did not work. That is mostly what is preexisting. Telling the governments to do X, Y and Z did not seem to have any long-term effect.

Engaging the governments in that as a partner is the sense that maybe this can have some long-term effects, but really we are embarking on that path now. That is for the future.

Ms. DELAURO. Just a quick follow up on that. Does that mean we are dealing with different levels of abilities, stabilized nations, we are dealing with a whole variety of countries which have a whole different set of circumstances that they are engaged in?

In terms of looking at the approach you are talking about, what you are saying is there needs to be involvement with the host government, so we are clear up front as to what we may confront in that effort, we are going to work, there may be two steps forward and a step backward, we are trying to calibrate how we work together or in some instances, are we likely to look like we have not done the right thing?

Mr. MELITO. That is beautifully stated. I could not have said it better than you just said. I would only add success is going to be a slow, grinding long-term effort.

Ms. DELAURO. That success is going to take trying of some things that may in fact not be successful and instead of saying we are done, we are finished, it is over, that we try to figure out another way to integrate the systems.

Mr. MELITO. To give you a sense on the same observation. The Gates Foundation has made food security one of its top priorities. They are spending as much as 20 percent of their budget on monitoring and evaluation because they recognize they went in using a private sector business model, and I do not know, meaning "I" the organization, do not know what works and does not work.

What do I do now? I better be spending a lot on R&D. I better really create a body of knowledge that we can build from. That is their approach. I think we should be taking the same approach.

Ms. DELAURO. Thank you.

Mr. KINGSTON. Let me ask you this. A donor-led, is not Food for Education donor-led?

Mr. MELITO. Food for Education has a donor involvement. I would not necessarily say "donor-led." We are actually going to be looking at the program as well in the months ahead, so we will see exactly how the rhetoric and policies are working. There is donor involvement.

Mr. KINGSTON. You are not sure how effective it is; right?

Mr. MELITO. I do not think there has been yet a systematic evaluation of the effectiveness of that program. There has been a lot of anecdotal success stories on that program.

Mr. KINGSTON. How about a farmer-to-farmer approach?

Mr. MELITO. We have not looked into that at all. That is a very small program.

Mr. KINGSTON. I know it is small but that might be a small bright shining light.

When would we get this follow up on the report back, which you just mentioned to the Chairwoman? When would we get some more info from you in terms of this getting better and would you recommend that we bring the Gates Foundation in here and ask them the same type of questions we have been asking you in terms of their monitoring?

Mr. MELITO. The answer to your second question first, I think you would find discussion with the Gates Foundation group quite rewarding. We met with the Gates Foundation, high level officials including Mr. Shah, when he was there. It was a very stimulating afternoon that we had with them.

They are providing lots of resources. This is not a small effort. They are providing tens of millions of dollars for food security.

Ms. DELAURO. It is overwhelming.

Mr. KINGSTON. Another thing, should there not be a graduation kind of idea/concept to this food aid?

Mr. MELITO. The humanitarian assistance is situational.

Mr. KINGSTON. I understand that.

Mr. MELITO. On the development side, that is almost what they are doing with the tiering, the two tiers. There are countries that are performing well and countries that are not performing well.

In the back of their own minds, I think, the best performance eventually will be no longer need assistance, but they are obviously working currently with those countries that need assistance.

I think successful development requires graduation.

Mr. KINGSTON. I think so. Who is your Congo expert?

Mr. MELITO. Actually, I think none of my current team have gone to the Congo. We have people who have gone to the Congo back at headquarters.

Mr. KINGSTON. Do you have any comments on it?

Mr. MELITO. Sad. It is a very discouraging situation.

Mr. KINGSTON. Under the topic of roads, that is one of the biggest challenges.

Mr. MELITO. Yes, it is an enormous country.

Mr. KINGSTON. It is very big. Madam Chair, I have about five kind of wrap-up questions which are just sort of for the record, if you are ready to wrap it up.

Ms. DELAURO. I am. I would just say to you with regard to your comment on graduation, Mr. Kingston, I think one of the strengths of the McGovern/Dole program has been countries do graduate,

they become donor countries, but then they become countries that provide resources in order to assist in this project.

Mr. Kingston knows, I am a strong proponent of the McGovern/Dole program. I think it does not get its just due. That is not just with regard to resources, which it does not get, but in terms of its success rate, and that is particularly true with women and girls. I think we need to do some investigating of that program and how that can be utilized to do some other things.

Mr. Kingston.

Mr. KINGSTON. I just wanted to give some closing remarks, some closing thoughts, that are just reiterations.

I would be very interested in your rating of NGOs, who is effective and who is not, and I would be interested in going to a source who could give me that if you are unable to, and if we need to come back to you and task that or whatever way we could get there.

And why again, because as in my opening comments, I am just convinced there is going to be a real budget fury coming up more and more in the years ahead, and foreign aid people back home do not consider it their top priority, so the more we know about what works, the better.

The other thing is the U.N. rating system. If anybody has any ideas about that who wants to weigh in on it, it is something that I am trying to figure out. It is just such an awkward system.

Number three, poll your folks on the ground. I feel a real sensitivity that is what you are doing, you are aware of that, but I want to make sure that in Washington, D.C. they are listening to the people who really have country expertise.

It would be so good if we had five or ten great success stories that say okay, here is a country, here is a region that really turned around because this was U.S. aid at its finest. We certainly owe it to ourselves and the taxpayers on that.

You have given us some reform ideas, but there are a lot more that I feel you know that could be done. We would like to work on that.

The Chairwoman and I, the opportunity you have is whenever I vote "yes," she votes wrong and votes "no" when we are up on the House Floor.

You have two people who are really philosophically at different ends of the spectrum, but we both stand for so much in common when it comes to trying to do it right and get reform.

If you could get the two of us, there are a lot of people in between. Things we could live with.

Again, just coming back from Afghanistan, whatever you can add would be so important to the war effort. There is just so far that the men and women in uniform can take this thing. Victory in Afghanistan is more in the hands of civilians than military at the moment.

Mr. MELITO. That is true.

Ms. DELAURO. Thank you. When we do both get to the Floor, I vote in the correct way and my colleague votes wrong. It is a "yes/yes" and "win/win" on this issue.

We are really committed to this. That is why we are interested in some of the reforms that you proposed. We are interested in following up on this evaluation and monitoring of the agencies that

have the responsibility, and those that have a prime responsibility, and we are trying to work within the jurisdiction of this committee, which as it affects this issue I think is significant in where we can have a role.

I know we will follow up on how we leverage the work of USDA and how we take a look at FAO and what opportunities are there.

Jack has done a lot more traveling in this regard than I have and has seen the hunger. We are also experiencing domestic hunger at this juncture.

I think we both at our core believe that we have a moral responsibility to be engaged in this effort, and as I said about Afghanistan, if the Taliban is providing food for your children, I do not care who you are, and you cannot take care of your children, you will accept food, and you will swear allegiance.

This is a national security issue. The more we make that reality known to our colleagues and to the people we represent, I think the more buy-in we have on this issue.

Thank you so much for being here. Thank you for the report. We appreciate it.

I think I have to formally close the hearing.

THURSDAY, MARCH 25, 2010.

FARM AND FOREIGN AGRICULTURAL SERVICES

WITNESSES

JIM MILLER, UNDER SECRETARY, FARM AND FOREIGN AGRICULTURAL SERVICES
JONATHAN COPPESS, ADMINISTRATOR, FARM SERVICE AGENCY
JOHN BREWER, ADMINISTRATOR, FOREIGN AGRICULTURAL SERVICE
WILLIAM MURPHY, ADMINISTRATOR, RISK MANAGEMENT AGENCY
SCOTT STEELE, BUDGET OFFICER, U.S. DEPARTMENT OF AGRICULTURE

MS. DELAURO OPENING REMARKS

Ms. DELAURO. The hearing is called to order. Let me begin by welcoming Jim Miller, the Under Secretary for Farm and Foreign Agricultural Services. He is joined by Jonathan Coppess, John Brewer, William Murphy, Administrators of the Farm Service Agency, the Foreign Agricultural Service, and the Risk Management Agency, respectively; and Scott Steele, Budget Officer. Thank you all for being here today with us.

This is one of the most important budget hearings that this subcommittee convenes each year, because of the enormous portfolio that is covered among the agencies before us today. Everything from farm assistance to food aid to exports and that's why we rescheduled the hearing from earlier this week on the day that the President signed the health care legislation that we just passed. We want to try to give the subject the attention that it deserves.

The Farm Service Agency, as you know, administers farm credit, commodities, emergency assistance, some conservation programs for farmers and ranchers. And through its network of county offices, it is, as under secretary Miller notes in his testimony the agency that the majority of farmers and ranchers interact with most frequently.

First, I want to congratulate FSA on what appears to be a swift and efficient implementation of the 2008 Farm Bill. I see from today's testimony that FSA has provided nearly $6 billion in direct and counter-cyclical program payments, $1.7 billion in conservation reserve program payments, and over $318 million for the Livestock Indemnity Program, Livestock Forage Disaster Program, and the Supplemental Revenue Assistance payments, the SURE program.

I am particularly impressed with how quickly the agency set up the Dairy Economic Loss Assistance Payment Program that we established in last year's appropriations. Within three months of the passage of the program, it already issued $270 million to struggling dairy farmers, and I and they thank you for the competent implementation of this program. It was really a matter of survival for so many of the dairy farmers.

What I would like to do is to urge the Under Secretary and Mr. Coppess to continue to work in every possible way to ensure that the civil rights violations that occurred at FSA as well as other USDA agencies are remedied and that they don't occur again. I am glad that the government has reached an agreement with African-American farmers who were discriminated over the years.

However, remedies for other groups on the receiving end of what was systematic USDA discrimination such as Hispanics, women, Native American farmers, remain to be provided. We need to provide assistance there, and I ask you for your help and your assistance with those groups as well.

Just as a note, Congresswoman Eshoo and myself have introduced legislation providing a process by which women farmers who were victims of discrimination can make claims against a compensation fund appropriated by the Congress. It also requires USDA to institute some reforms. One of the issues facing the FSA in the past several years as we all know is the severe deterioration and the consequent performance problems of its IT infrastructure, and I know you know that.

If this year's budget request is met, Congress will have appropriated $250 million to fix this, so it is important that the subcommittee gets an accounting for our investment. In addition, crop insurance is an area that should be and is a great interest to this subcommittee, particularly given the concerns about the potential fraud in the program. This hearing provides us an opportunity to ask RMA what they are doing to combat wasteful spending in the crop insurance program.

Switching gears, I am also very concerned about the flat funding of P.L. 480, the Title II program, the McGovern-Dole program in the 2011 budget at a time when we have over a billion people who are now going hungry or who are ill-fed, and the world is looking to us for some kind of moral leadership. I do not believe we should be turning away from our strong, bipartisan commitment to international food aid.

So, Mr. Brewer, I would say to you I'll be curious to hear your thoughts about these funding levels. The flat funding of food aid is in marked contrast to the substantial funding increases for programs under the title of the National Export Initiative. I share the President's desire to increase U.S. agricultural exports, and we will be holding a hearing on how trade agreements affect the public health in the near future. And, as an aside, it seems to me that if we really want to increase our agricultural exports, one of the easiest ways to do it would be to open trade with our neighbor, Cuba.

Fifty years, 11 Presidents after setting up an embargo policy that has failed to change the political dynamic there, it seems to me that it's time to shift U.S. policy toward greater engagement and a greater opportunity for our export markets and a greater opportunity for our farmers. So a number of wide-ranging issues on our plate this morning as befitting the considerable diversity of responsibilities that are handled by these agencies, I look forward to hearing from you today on how we can continue to refine, to improve our performance in these areas to make good on our commitments to Americas farmers and ranchers.

Thank you very much for being here this morning.

We look forward to hearing your testimony, and with that, Mr. Kingston, I'd like to yield to you for your comments.

MR. KINGSTON OPENING REMARKS

Mr. KINGSTON. Thank you, Madam Chair. It's great to have all you guys here, and Scott Steele's there would never be a hearing here without you being present, and you get to hear so much of us. So this is the way the chair and I like this, by the way, when no members show up so we get the microphone time. [Laughter.]

Ms. DELAURO. That's right. We can do all that.

Mr. KINGSTON. This is going to be a good hearing. We are eager to hear what you have to say, a couple things I want to mention.

While the chair and I disagree on Cuba, I think certainly she has made a good point in terms of trade and opportunities for our farmers; and that's why I'm astounded, absolutely astounded that this President keeps talking about the South Korean trade agreement and the Columbian Trade Agreement without moving forward to it. In fact, I don't even know who the USTR is these days.

You know, it used to be a household name under President Clinton, President Bush, somebody who was dynamic out there explaining markets and opportunities. And I'm being serious. You can say, well, that's your fault, but I can tell you that the Clinton and the Bush USTRs were far more active, and so we have opportunities for agreements with Panama, Columbia, and South Korea. South Korea was one; and Mr. Brewer you know well having your AIG days look to global threats what a great ally that is in the Pacific Rim. And for us to be ignoring that, it's to me unbelievable.

The Foreign Market and Development Cooperation Program—I'd like to know about the overlap with MAP and what your thoughts are what we should do about that. I'd like to hear some success stories with the technical assistance and specialty crops in terms of trade, and we hear a lot from MAP and some of the other ones, and be interested in that.

Another thing that I'm very, very interested in having served on the Defense Committee and recently gone to Afghanistan and gotten briefed by some of your folks over there, we have some—not really opportunities, but absolutely must-do assignments in terms of getting Afghanistan off of the poppies. And I think it's something like 200 million in cash crops with everybody in Afghanistan getting some form of the benefits from there.

I'm not sure how we do it. I will tell you that I have asked top military leadership what are we doing about the poppies, and I cannot get a good answer from them. They absolutely, all, everybody agrees it's a huge problem that kind of the culture, it's like a toxic to all of them. So we've got to come up with some things, and I'm hoping USDA might be able to bring some new angle or fresh thinking that the military has not been able to capture in our eight years there.

And then, Mr. Brewer, kind of going back to you in terms of P.L. 480 or whatever the food aid programs are—and we're not asking questions right now, but Paul Theroux, who as you now is a traveling journalist, lived in Africa about 40 years ago. He's recently written a book that I'm reading called "Dark Star Safari," where

he talks about how despite many years, four decades of food aid—not food aid, but all aid—that so many countries have not made any progress whatsoever, no permanent progress or benefited from it.

So you have a lot of familiarity from the private sector and from what you're doing now, and I'd like to hear what are some of the success stories that we've had, so a lot of good stuff. I've talked and I'll yield the floor, madam chair, and again welcome all of you.

Ms. DELAURO. Thank you very much. And Mr. Secretary, Mr. Miller, if you will proceed with your testimony, the testimony in its entirety will be part of the record and you are free to summarize it any way you would like. Thank you.

UNDER SECRETARY'S OPENING STATEMENT

Mr. MILLER. Well, thank you very much, Chairwoman DeLauro, Ranking Member Kingston. It's a real pleasure to appear before the Committee today to present the 2011 budget proposals for the Farm and Foreign Agricultural Services at the Department of Agriculture.

You have already acknowledged the three administrators representing the agencies within our mission area as well as Scott Steele with our Office of Budget and Program Analysis, and I am very appreciative of these gentlemen participating in this hearing with me. With your permission I would like to summarize the statement that I have submitted for the record. And following my remarks, we are certainly happy to respond to any comments or questions that you may have.

First, let me thank the Subcommittee for the support you have provided to our mission area and its programs in the past. The President's 2011 budget provides the resources needed to meet our mission area's priorities next year, and so I'd like to begin with the Farm Service Agency. As you noted, the Farm Service Agency is the lead agency for delivering farm assistance to our producers throughout the country.

The 2011 budget request for FSA funds essential program delivery expenses. For FSA salaries and expenses the budget provides $1.7 billion, a net increase of about $116 million over the 2010 enacted level in order to sustain essential program delivery. This total includes about $95 million to fund our IT modernization projects, which we'll discuss further, I'm sure, during the questioning period.

The Committee is aware of FSA's longstanding need to upgrade its aging technology and we certainly thank you for providing $117 million through the Recovery Act as well as the 2010 annual appropriations to engage in these activities. This funding will enable us to continue our modernization efforts. After severe performance problems a few years ago, and while challenges certainly remain in order to complete this task, important steps are in fact under way to transition FSA to a modern, centralized, web-based IT system. Continuation of these efforts is our top priority in our 2011 budget request.

FSA also plays a very critical role for agriculture producers by providing direct and guaranteed credit for farm families who would otherwise be unable to obtain the financing they need for their op-

erations. The 2011 budget proposes a total program level of about $4.7 billion for these programs. Of this total, over $1.5 billion is requested for direct loans and nearly $3.2 billion for guaranteed loans offered in cooperation with private lenders.

Turning to the Risk Management Agency, as you are well aware, it administers the Federal Crop Insurance Program, which is our primary risk management mitigation program for our producers. Our current projection for 2011 shows the value of insurance coverage will remain relatively constant with what we have seen in recent years at about $84 billion of liability, while insuring over 260 million acres.

The 2011 budget request of $83 million for discretionary administrative expenses for RMA includes additional funding for pay cost and for the maintenance of the RMA IT system. The 2011 budget also includes a mandatory request reflecting estimated placeholder savings of $8 billion over 10 years resulting from changes to the terms in the Standard Reinsurance Agreement with our private insurance providers. That agreement is currently under negotiation with our private insurance company partners, and we expect to complete those contract negotiations by June 30th of this year.

The RMA IT modernization project is in its third year. To date, approximately $35 million of the $54 million four-year project provided in the 2008 Farm Bill has been obligated under a two-phase approach. Phase 1 will conclude this summer. Phase 2 is scheduled for production next year.

The Foreign Agriculture Service is the lead agency for the department's international activities, and it is at the forefront of our efforts to expand agricultural trade and enhance global food security. Let me begin by expressing my appreciation to the Committee for providing additional 2010 funding for the Foreign Agriculture Service that has helped address the financial concerns experienced by the agency in 2009.

For the 2011 budget we are proposing FAS have resources that represent American agriculture on a global basis and create new overseas market opportunities. The budget provides a program level of $265 million, an increase of $78 million over the 2010 enacted level. This includes $54 million for increased export activities as part of the President's National Export Initiative. $10 million of this funding will support expansion of several FAS export promotion activities. A portion will also be used to meet higher, nondiscretionary operating expenses at the agency's overseas posts, and the initiative also includes over $34 million to double the funding for our Foreign Market Development Cooperator Program.

In addition, the initiative provides an increase of $9 million for the Technical Assistance for Specialty Crops Program, which doubles overall funding available for TASC in 2011. The increased funding for TASC reflects the importance of specialty crops in our export strategy moving forward and the need to resolve barriers that restrict the trade in those crops.

For the Cochran and Borlaug fellowship programs, the budget includes increased funding of $1.5 million. These programs provide important training and collaborative research opportunities in the United States for our trade partners in order to advance food security and to address U.S. trade policy objectives. In addition, fund-

ing of $14.6 million is requested for FAS in recognition that it has assumed full management of USDA's reconstruction and stabilization activities, including the provincial reconstruction teams in Afghanistan and Iraq. Of this amount $13 million is moved from Department Management where it was funded in this year's Appropriations act.

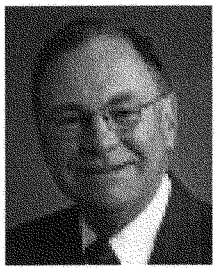
For the McGovern-Dole Program, as well as for Food for Peace Title II assistance, the budget provides funding at the 2010 enacted level of $210 million and $1.7 billion respectively. These funding recommendations represent sizeable increases over the 2009 levels for both programs. In conclusion, I would like again to express our appreciation to the Subcommittee for the support it has provided our mission area and programs.

We look forward to working with you as you review our 2011 budget proposal, and we will be pleased to provide whatever assistance you may require as you review this proposal. Thank you very much.

[The information follows:]

Jim Miller

Under Secretary for Farm and Foreign Agricultural Services



Jim Miller is USDA's Under Secretary for Farm and Foreign Agricultural Services. Before joining USDA, from September 2008 until he was confirmed by the U.S. Senate for this position, Miller served as chief of staff for the National Farmers Union, based in Washington, DC. He worked as the senior analyst for agriculture and trade on the U.S. Senate Budget Committee from 2004-08. From 1999-2004 he was the chief economist for the National Farmers Union.

Miller served as president of the Washington, DC-based National Association of Wheat Growers in 1987, and was its vice president for government relations from 1995-99. From 1994-95 he served as co-chair of the Canada-U.S. Joint Commission on Grains, a federal commission established to resolve grain trade issues between those two countries. For over 20 years, from 1974-95, he operated his family farm--a fourth-generation family farm---located in Garfield, Wash.

Statement by James Miller
Under Secretary for
Farm and Foreign Agricultural Services
United States Department of Agriculture
Before the House Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Madam Chairwoman and Members of the Committee, I am pleased to be with you today to present the 2011 budget and program proposals for the Farm and Foreign Agricultural Services (FFAS) mission area of the Department of Agriculture (USDA). Accompanying me are the Administrators of the three agencies that comprise our mission area: Jonathan W. Coppess, Administrator of the Farm Service Agency; William J. Murphy, Administrator of the Risk Management Agency; and John Brewer, Administrator of the Foreign Agricultural Service. Scott Steele, Director of the Department's Office of Budget and Program Analysis, is with us as well.

Statements by each of the Administrators providing details on the agencies' budget and program proposals for 2011 have already been submitted to the Committee. My statement will summarize those proposals, after which we will be pleased to respond to your questions.

Madam Chairwoman, the FFAS mission area carries out a diverse array of programs and delivers services that support a competitive agricultural system and provide the foundation for prosperity throughout rural America. We believe the 2011 President's budget provides the resources needed to meet our mission area objectives, including essential administrative expenses. At the same time, it also contributes to the Administration's objectives of improving the delivery of our services and restoring fiscal discipline to the Federal budget.

Farm Service Agency

The Farm Service Agency (FSA) is the lead agency for delivering farm assistance. It is the agency that the majority of farmers and ranchers interact with most frequently. FSA provides producers with access to farm programs such as direct and counter-cyclical payments, commodity marketing assistance loans, farm ownership and operating loans, disaster assistance, and certain conservation programs, such as the Conservation Reserve Program.

The 2011 budget request for FSA provides a fiscally responsible approach to funding essential program delivery expenses, including critical information technology (IT) operational expenses and long-term investments.

We know the Committee is aware of FSA's long-standing need to upgrade its aging technology and would like to thank you for providing $117 million through the Recovery Act and 2010 annual appropriations. This funding will enable us to continue our modernization efforts. We appreciate the support the Committee has provided, particularly in view of the challenges the Committee faces during these times of fiscal constraints.

FSA has been attempting to improve the quality of its service to its clientele in recent years with some success, although additional improvements are needed and many challenges remain. Since enactment of the 2008 Farm Bill, FSA has rapidly implemented newly authorized farm programs, including complex new programs, such as the Average Crop Revenue Election (ACRE) and Supplemental Revenue Assistance Payments (SURE) programs. Many of these activities were effectively carried out with very few additional resources.

However, the agency's progress in implementation and delivery of these complex new programs in a timely, secure, and customer friendly manner has become increasingly difficult to ensure without significant progress in modernizing our business processes and IT systems, as discussed with this Committee previously. Important steps have been taken as a result of recent appropriations, and continuation of these efforts is our highest priority for the 2011 budget request.

Information Technology Systems

The role of IT is crucial for FSA's capacity to continue to deliver adequate services to its farm clientele. After suffering from severe performance problems several years ago, the IT infrastructure supporting the delivery system has been stabilized and set up to transition to a 21st century IT environment, but this transition is far from complete and more funding is required. Therefore, the 2011 budget requests an increase of about $95 million for implementation costs of these IT system modernization efforts. This funding will build on the IT investments made in recent years and will go a long way toward achieving the program delivery goals of improved quality of service, operational efficiency, and greater accountability.

The short-term stabilization efforts used to correct the most urgent deficiencies in FSA's IT network infrastructure have been successful in averting crippling breakdowns of the sort experienced two or three years ago. However, it is still essential that FSA program delivery be transitioned to a modern, centralized web-based system in order to meet minimum expectations for reliable, timely, and accountable program delivery in the future. This is the principal goal behind the agency's Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) initiative.

FSA has established a Program Management Office (PMO) to manage the day-to-day operations and provide the capability to acquire, manage risk, and deploy the MIDAS system. The budget request includes $1 million to support 10 additional staff years for the PMO. The PMO is a critical component of our effort to ensure that funding provided by this Committee is used effectively and efficiently.

FSA, in coordination with the General Services Administration (GSA), recently completed the largest and most significant vendor contract for the completion of MIDAS. As this Committee might be aware, a bid protest was filed with the Government Accountability Office shortly after that contract was awarded. Due to the joint efforts of GSA and the PMO, that bid protest has been withdrawn, allowing FSA to move forward with the MIDAS acquisition.

Salaries and Expenses

The budget provides $1.7 billion for FSA salaries and expenses, including credit reform transfers, for a net increase of about $116 million over the 2010 enacted level. The request reflects increases in pay-related and non-pay-related costs to sustain essential program delivery. The majority of the increase consists of about $95 million to fund critical IT replacement and modernization projects essential to viable future operations.

The budget, which assumes the current level of program workload, provides support for approximately 5,100 Federal staff years and 9,425 non-Federal staff years, which are the same as the 2010 levels aside from 10 additional staff years for MIDAS. Temporary non-Federal staff years are maintained at 650.

Farm Loan Programs

FSA plays a critical role for our Nation's agricultural producers by providing a variety of direct loans and loan guarantees to farm families who would otherwise be unable to obtain the credit they need to continue their farming operations. By law, a substantial portion of the direct and guaranteed loan funds are reserved each year for assistance to beginning, limited resource, and socially disadvantaged farmers and ranchers.

The 2011 Budget proposes a total program level of about $4.7 billion, reflecting credit usage forecasts at the time the budget was developed. Of this total, over $1.5 billion is requested for direct loans and nearly $3.2 billion for guaranteed loans offered in cooperation with private lenders. While the total request is slightly below the amount available in 2010, it generally reflects actual usage in recent years.

For direct farm ownership loans, we are requesting a loan level of $475 million to extend credit to about 2,800 small and beginning farmers to purchase or improve a family farm. For direct farm operating loans, we are requesting a program level of $900 million to provide production loans to approximately 15,000 family farmers. Over the past several years, demand has been high for direct operating loans made to beginning farmers. Many beginning farmers are minimally capitalized and, as a result, they cannot obtain commercial credit to finance annual crop and livestock production expenses.

For guaranteed farm ownership loans, we are requesting a loan level of $1.5 billion to provide about 4,300 farmers the opportunity to acquire their own farm or to preserve an existing one. For guaranteed farm operating loans, we propose a loan level of approximately $1.6 billion to assist over 7,500 producers in financing their farming operations. The guaranteed loan programs enable private lenders to extend credit to farm customers who otherwise would not qualify for a commercial loan.

Risk Management Agency

The Federal crop insurance program represents the main risk-mitigation program available to our Nation's agricultural producers. It provides risk management tools that are

compatible with international trade commitments, creates products and services that are actuarially sound and market driven, harnesses the strengths of both the public and private sectors, and reflects the diversity of the agricultural sector.

In 2009, the crop insurance program provided about $90 billion in protection on over 265 million acres. Our current projection is that indemnity payments to producers on their 2009 crops will be about $4.7 billion on a premium volume of over $8.9 billion. Our current projection for 2011 shows the value of protection will remain relatively steady at about $84 billion. This projection is based on the Department's latest estimates of planted acreage and expected changes in market prices for the major agricultural crops.

The 2011 budget requests an appropriation of "such sums as are necessary" as mandatory spending for all costs associated with the program, except for Federal salaries and expenses. This level of funding will provide the necessary resources to meet program expenses at whatever level of coverage producers choose to purchase. For discretionary administrative expenses of the Risk Management Agency (RMA), $83 million in discretionary spending is proposed. The request includes additional funding for pay costs and maintenance of the RMA IT system. Staffing for RMA is projected to remain at the same level as 2010.

Standard Reinsurance Agreement

The 2011 budget includes a mandatory request that reflects estimated savings of $8 billion over 10 years through changes to the terms in the agreement RMA has with reinsured companies that sell and service crop insurance, the Standard Reinsurance Agreement (SRA). The savings estimate included in the budget reflects a placeholder for savings we hope to achieve in the negotiation process. RMA is in the process of negotiating a new SRA with the reinsured companies that will be effective for the 2011 reinsurance year. We expect to complete the process by June 30, 2010, before the July 1 start of the 2011 reinsurance year.

On February 23, 2010, RMA released a second draft of the proposed new agreement. This second draft reflects many of the comments and concerns raised by insurance companies, agents, and Members of Congress over the past several months.

The proposed new SRA includes six primary objectives that will (1) maintain producer access to critical risk management tools; (2) realign administrative and operating subsidies paid to insurance companies closer to actual delivery costs; (3) provide a reasonable rate of return to the insurance companies; (4) equalize reinsurance performance across States to more effectively reach under-served producers, commodities, and areas; (5) enhance program integrity; and (6) simplify provisions to make the SRA more understandable and transparent.

These objectives align with RMA's primary mission to help producers manage the significant risks associated with agriculture. By achieving these six objectives, the new SRA will ensure financial stability for the program and the producers it serves, while increasing the availability and effectiveness of the program for more producers and making the program more transparent. The new agreement will also provide insurance companies with greater flexibility for their operations and financial incentives to increase service to underserved producers and areas, while ensuring that taxpayers are well-served by the program.

Information Technology

The RMA IT modernization (ITM) project is in its third year, since funding was provided in the 2008 Farm Bill. To date, approximately $35 million of the $54 million 4-year project has been obligated under a two-phase approach.

Phase I includes all processes needed to implement rate and price development and filing of insurance offers, edit and validation of data submitted by approved insurance providers (AIP), and enhanced reporting capabilities. Phase I development will be completed around June 2010 and will support implementation of the Combination (COMBO) policy for the 2011 crop year.

Phase II will include accounting, exception processes, and the remainder of the corporate reporting system, and is scheduled for production in 2011. RMA has strengthened information security to protect producer and corporate information. Significant security enhancements implemented include data encryption for all RMA laptops, more secure

remote access into RMA networks, additional policies and security controls, and working with AIPs to protect critical information throughout the insurance process.

Combination Policy (COMBO)

The Federal Crop Insurance Corporation (FCIC) published a Proposed Rule in the *Federal Register* in 2006 to amend the Common Crop Insurance Regulations, Basic Provisions, Small Grains Crop Insurance Provisions, Cotton Crop Insurance Provisions, Coarse Grains Crop Insurance Provisions, Malting Barley Crop Insurance Provisions, Rice Crop Insurance Provisions, and Canola and Rapeseed Crop Insurance Provisions to provide both revenue protection and yield protection. However, the regulatory process was halted because the aging IT infrastructure could not support the COMBO policy. With the imminent completion of Phase 1 of the ITM project, the COMBO regulation is currently under review and is expected to be published early in 2010 for implementation for the 2011 crop year. The amended provisions will replace the Crop Revenue Coverage, Income Protection, Indexed Income Protection, and the Revenue Assurance plans of insurance.

When implemented, producers will have a choice of revenue protection (protection against loss of revenue caused by low prices, low yields, or a combination of both) or yield protection (protection for production losses only) within one policy. This will reduce the amount of information producers must read to determine the best risk management tool for their operation and to improve the prevented planting and other provisions to meet the needs of insured producers better. This combined policy is expected to cover nearly $76 billion of the nearly $84 billion of FCIC's total liability and 94 percent (approximately one million policies) of all policies earning premiums.

Foreign Agricultural Service

Agricultural trade makes a critical contribution to the prosperity of local and regional economies across rural America through increased sales and higher commodity prices. USDA estimates that every $1 billion of agricultural exports generates $1.4 billion in economic activity throughout the American economy. Therefore, the Department, with the FFAS mission area in the forefront, has an important role to play in removing agricultural trade barriers, developing

new markets in both the near and long term, and enhancing the competitive position of U.S. agriculture in the world marketplace.

The Foreign Agricultural Service (FAS) is the lead agency for the Department's international activities and is in the forefront of efforts to expand trade and foster global food security. FAS carries out its work through its network of nearly 100 overseas offices and its headquarters staff in Washington. With its overseas presence, FAS represents U.S. agricultural interests throughout the world.

The 2011 budget is designed to ensure that FAS has the resources needed to continue to represent and advocate on behalf of American agriculture on a global basis and to create new market opportunities overseas. The budget provides a program level of $265 million, an increase of $78 million above the 2010 enacted level. In particular, increased funding is provided to expand export promotion activities, maintain the agency's overseas presence at current levels, and improve information technology network support at its overseas offices.

The budget includes $53.5 million of discretionary funding for export expansion activities as part of the government-wide National Export Initiative. Of this, $10 million will support expansion in a variety of FAS export promotion activities, including exporter assistance, trade missions, in-country promotions, and trade enforcement efforts to remove non-tariff barriers. A portion will also be used to meet higher, non-discretionary operating expenses at the agency's overseas posts.

The initiative also includes $34.5 million to supplement funding for the Foreign Market Development (Cooperator) Program. With this increase, overall funding available to the program will double to $69 million in 2011. The additional funding will broaden the opportunity for program participation by traditional cooperators and for small- and medium-sized enterprises that seek to become exporters and will support new, innovative program activities, such as promoting broader international acceptance of the products of biotechnology.

In addition, the initiative proposes an increase of $9 million for the Technical Assistance for Specialty Crops (TASC) Program, which will double overall funding available for TASC in 2011 to $18 million. Increased funding for TASC reflects the growing importance of specialty crops for U.S. agricultural export growth and the contribution the program has made in resolving numerous trade barriers that have restricted trade.

For the Cochran and Borlaug Fellowship Programs, the budget includes increased funding of $1.5 million. These programs provide training and collaborative research opportunities in the United States to advance U.S. government food security and trade policy objectives.

The budget also provides an increase of $3.4 million for higher payments to the Department of State for administrative services provided at FAS overseas posts. In addition, an increase of $4 million is provided for FAS to contract with the Department of State for overseas IT network support and maintenance to take advantage of the secure information system that the State Department operates.

Agricultural Reconstruction and Stabilization

Funding of $14.6 million is requested for FAS to manage and support the Department's participation in reconstruction and stabilization activities, including Provincial Reconstruction Teams (PRTs) in Afghanistan and Iraq. Of this amount, $13 million is moved from Department Management where it was funded in this year's appropriations act. This reflects the fact that FAS has assumed full management of the operational and policy components of USDA's reconstruction and stabilization activities during the past year. Transferring the funding for these activities to FAS provides for more efficient operations and is consistent with how the Department is now managing them. The overall level of funding for these activities is increased by $1.6 million over the 2010 level to provide for an expansion of activities in Afghanistan and to meet higher operating costs.

As the Committee is aware, the Department has greatly expanded its activities in Afghanistan this past year and is committed to placing 64 agricultural advisors in Afghanistan, who will serve on the PRTs and similar teams throughout the rural areas, and serve as advisors to the Ministry of Agriculture, Irrigation, and Livestock in Kabul. Their work is essential to stabilizing strategic areas of the country, building government capacity, ensuring the successful management of assistance programs, and addressing food insecurity.

International Food Assistance

The United States plays a leading role in global efforts to alleviate hunger and malnutrition and enhance world food security through international food aid programs. USDA contributes to these efforts by carrying out a variety of food aid programs that support economic growth and development in developing countries.

For the McGovern-Dole International Food for Education and Child Nutrition Program, the budget provides funding at the 2010 enacted level of $209.5 million. Last year, the Administration proposed a substantial increase in appropriated funding for the program in order to support additional school feeding and child nutrition programs and to bolster the Department's contribution to supporting economic development and food security in developing countries. We are pleased Congress endorsed the increase in the 2010 appropriations bill. This level of funding is expected to support assistance for an estimated 5 million women and children during 2011.

The budget provides funding of nearly $1.7 billion for Food for Peace Title II grant food assistance, which is unchanged from the 2010 enacted level. Last year's budget increased base funding for Food for Peace grants by 38 percent over the previous year in order to bolster resources available for emergency needs, enhance global food security, and restore U.S. leadership in global development efforts. The 2011 budget maintains funding at that level to further support those objectives.

Madam Chairwoman and Members of the Committee, this concludes my statement. The Administrators and I would be pleased to answer any questions you and other Members of the Committee may have.

FARM SERVICE AGENCY
Statement of Jonathan W. Coppess, Administrator
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Madam Chairwoman and Members of the Subcommittee, I appreciate this opportunity to discuss Farm Service Agency (FSA) issues and funding. Our fiscal year (FY) 2011 budget emphasizes improved program delivery by focusing on support for our county office staff and investments in crucial information technology (IT) modernization priorities, while funding critical program levels within an environment of constrained discretionary spending.

AGENCY OPERATIONS

FSA carries out many of the programs authorized by the 2008 Farm Bill as well as programs under other authorities. We deliver these programs through approximately 2,248 county level USDA Service Centers, 50 State offices, and an office in Puerto Rico. FSA has headquarters offices in Washington, DC, two field offices in Kansas City, an office in Salt Lake City, and a field office in St. Louis servicing farm loan programs.

At the end of FY 2009, the Service Centers were staffed by a total of 8,757 non-Federal and 2,223 Federal FSA employees, who are the public face of the agency, working directly with producers. Nationwide during 2009, FSA averaged 1,400 payment transactions and $1.8 million per county office employee, while educating producers about complex new programs and handling countless questions, concerns and needs for guidance and information.

Working together at all levels, FSA provided an estimated $4.5 billion in loans to over 33,000 farmers and ranchers across the country – the highest levels since 1984 – while decreasing loan processing times, managing significantly increased demand, and providing increased lending to beginning farmers and ranchers and socially disadvantaged farmers and ranchers. FSA also made USDA the first to provide American Recovery and Reinvestment Act funding to Americans by obligating loans totaling over $170 million in less than 48 hours.

FSA continued implementation of the 2008 Farm Bill, issuing an impressive volume of payments. By early in FY 2010 we had delivered assistance of over $318 million to farmers and ranchers through the Livestock Indemnity Program (LIP), the Livestock Forage Disaster Program (LFP), and the Supplemental Revenue Assistance Payments (SURE) Program. We issued Direct and Counter-Cyclical Program (DCP) payments of nearly $6 billion via over 2.4 million transactions, and provided over 920,000 Conservation Reserve Program (CRP) payments for approximately 31 million acres, totaling $1.7 billion. We also provided over $40 million to individuals delivering biomass to facilities using it to produce renewable energy and products.

We had also signed up over 1.5 million producers for DCP payments and 130,000 for the ACRE program, as well as many thousands more for Milk Income Loss Contract, LIP, LFP, and Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP) assistance. We entered into 758,000 CRP contracts on 424,000 farms. We registered over 300 biomass conversion facilities and thousands of individuals to deliver biomass to them.

In addition to Farm Bill implementation, FSA has taken swift action to expedite implementation of the Dairy Economic Loss Assistance Payment (DELAP) Program established by the FY 2010 Agriculture Appropriations Act, enacted on October 16, 2009. By December 24, FSA had published regulations and begun making payments, and by January 20 nearly $270 million had been issued. The remaining funds are being held for producers whose production records were not already on file and who consequently had to submit an application for the program.

These accomplishments represent only a portion of what FSA has achieved. With activities of this scope and complexity, it is clear that continued top-notch performance depends not only upon an adequate number of motivated, well-trained staff, but also upon sound business processes and reliable, modern IT resources.

Business Processes

FSA is continuing work on the "MIDAS" (Modernize and Innovate the Delivery of Agricultural Systems") initiative, which is a comprehensive project to streamline the existing complicated business processes that have been used to administer mandated farm programs. Reengineering of the legacy processes is necessary in concert with the design of a modern, web-based IT infrastructure that will ensure efficient and reliable service to FSA's customers.

We have already completed a similar effort in the farm loan area in conjunction with the development of the web-based Farm Loan Program Information Delivery System (FLPIDS). As a part of this endeavor we were able to dramatically reduce the number of pages of regulations and significantly simplify program instruction manuals.

Information Technology

As you know, FSA farm programs rely on one of the oldest information technology systems, both hardware and software, within the Department of Agriculture. The Committee has provided $117.3 million through the Recovery Act and the FY 2010 regular appropriation to enable us to continue our modernization efforts. We appreciate this support, particularly in view of the challenges the Committee faces during these times of fiscal restraint.

We have made some solid progress. At the end of the past crop year, FSA implemented the National Receipts and Receivables System (NRRS), a web-based application for managing payments for various farm programs. Designed to eliminate improper and inaccurate payments, reduce administrative resources, and speed payments to producers, this modernization initiative streamlined three previously separate legacy system processes, allowing more effective disbursement of CRP and DCP payments.

We have also made progress on the MIDAS project. In FY 2009 we awarded several project management contracts designed to reduce overall project risk, meet Earned Value Management requirements of the Office of Management and Budget, and ensure good overall contract oversight. In December 2009, the largest contract needed to support MIDAS was

awarded. Valued at $500 million over a 7-year period, this contract provides for modern, off-the-shelf software applications to be integrated into the FSA system. While MIDAS is the primary beneficiary of this agreement, it can also be used throughout USDA to address other Departmental IT initiatives.

The FLPIDS modernization effort will complete the transition to a web-based platform later this spring. It was this web-based system that enabled us to expeditiously deliver Recovery Act funds to farmers with pending loan applications.

Performance and Accountability

FSA has also made progress in resolving an issue that has been of concern to the Committee. Together with the Natural Resources Conservation Service, we have entered into an agreement with the Internal Revenue Service (IRS) to establish an electronic information exchange to verify compliance with the adjusted gross income requirements of programs administered by both USDA agencies. While providing ample protections for producers' information – for example, no actual tax data will be provided to USDA – the process will flag possible violations of the income limits. Producers in question will have the opportunity to present additional information. This cooperative effort with the IRS will reduce fraud in the farm programs and enhance program integrity.

PROGRAM UPDATES

2008 Farm Bill Implementation

At the outset of this statement I provided a snapshot of some of FSA's accomplishments in implementing the 2008 Farm Bill. Now I would like to supply additional detail on the status of some of the major Farm Bill programs.

Disaster Assistance

Regulations for the Supplemental Revenue Assistance Payments (SURE) Program were published December 28, 2009, and the signup began January 4, 2010, for losses during the 2008

crop year. Within the first 3 weeks, payments of over $870 thousand were issued, and to date we have made payments of over $40.6 million.

In 2009, FSA implemented the Livestock Indemnity Program (LIP) and Livestock Forage Disaster Program (LFP) to aid livestock producers affected by 2008 and subsequent natural disasters, issuing a combined total of over $276 million for losses of livestock under LIP and grazing losses under LFP.

Signup for the 2008 and 2009 Emergency Assistance for Livestock, Honeybees, and Farm-Raised Fish Program (ELAP) has ended and payments will be made shortly. Signup for the 2010 ELAP is ongoing.

Regulations for the Tree Assistance Program are being developed and should be published this spring.

Biomass Crop Assistance Program

In June 2009, FSA issued a Notice of Funds Availability for matching payments for the collection, harvest, storage, and transportation of eligible biomass materials sold to qualified biomass facilities for the Biomass Crop Assistance Program (BCAP), with the first payment issued in August. On February 3, 2010, we published a proposed rule with a 60-day comment period to fully implement the second phase of BCAP, which includes establishment and annual payments.

Conservation Reserve Program

As of December 31, 2009, total Conservation Reserve Program (CRP) enrollment stood at 31.2 million acres under 758,000 contracts, of which 4.4 million acres under 391,000 contracts are for practices under continuous signup. We anticipate enrollment of about 31.4 million acres at year end. For FY 2011, the budget projects enrollment of about 30.2 million acres. Because CRP participation is driven by economic considerations such as producer expectations about future commodity prices and rental rates, the amount of land they are willing to offer varies as

circumstances change. FSA intends to use all available authorities to encourage enrollment as authorized by the 2008 Farm Bill.

We plan to publish an interim rule for the Voluntary Public Access Program, to encourage owners and operators of private farm, ranch, and forest land to make that land publicly accessible for hunting, fishing, or other wildlife-related recreation under programs administered by the State or Tribal governments.

In addition to our Farm Bill implementation activities, in January 2010 USDA announced the issuance of more than $950 million to quota holders and producers for the Tobacco Transition Payment Program.

BUDGET REQUESTS

Commodity Credit Corporation

The FY 2011 budget estimates largely reflect supply and demand assumptions for the 2010 crop, based on November 2009 data, and primarily reflect current law, with some modifications for proposed legislation. CCC net expenditures for FY 2011 under current law assumptions are projected at $11.4 billion, down from approximately $12 billion forecast for FY 2010 and a record high of $32.3 billion in FY 2000. Commodity prices are expected to remain relatively robust into FY 2011, leading to a continuation of fairly level outlays comprising primarily direct payments.

CCC is authorized to replenish its borrowing authority, as needed, through annual appropriations up to the amount of realized losses recorded in CCC's financial statements at the end of the preceding fiscal year. For FY 2009 losses, CCC will be reimbursed $15.1 billion in FY 2010.

Appropriated Programs

For Farm Loan Programs, the Budget proposes a total program level of about $4.7 billion – over $1.4 billion for direct loans and nearly $3.1 billion for guaranteed loans. These levels reflect credit usage forecasts at the time the Budget was developed.

For direct farm ownership loans we are requesting a loan level of $475 million to extend credit to about 2,800 small and beginning farmers to purchase or improve a family farm. In accordance with legislative authorities, FSA has established annual participation targets for members of socially disadvantaged groups based on demographic data. Also, 70 percent of direct farm ownership loan funds are reserved for beginning farmers; over the past several years, all of the reserved funds have been used for beginning farmer loans. For direct farm operating loans we are requesting a program level of $900 million to provide production loans to approximately 15,000 family farmers. The Agency also targets a portion of direct operating loan funding to members of socially disadvantaged groups based on demographic data, and 35 percent of the funds are reserved for beginning farmers. Over the past several years, loans made to beginning farmers have exceeded the amount of funds reserved for them.

For guaranteed farm ownership loans in FY 2011, we are requesting a loan level of $1.5 billion to provide about 4,300 farmers the opportunity to acquire their own farm or to preserve an existing one. One critical use of these loans is to allow real estate equity to be used to restructure short-term debt into more favorable long-term rates. For guaranteed farm operating loans we propose an FY 2011 program level of approximately $1.64 billion to assist over 7,500 producers who would not otherwise qualify for commercial loans and would be forced to seek direct loans from FSA.

In addition, our budget proposes program levels of $2 million for Indian tribe land acquisition loans and $60 million for boll weevil eradication loans. For emergency disaster loans, our budget does not request an appropriation since disaster needs are unpredictable.

The 2008 Farm Bill provides two new programs: conservation loans, and loans to purchase highly fractionated Indian land. Direct and guaranteed conservation loans provide funding for construction or establishment of conservation structures, forest and permanent cover, or other projects. Priority is given to qualified beginning farmers, ranchers, socially disadvantaged farmers or ranchers, owners or tenants who use the loans to convert to sustainable

or organic agricultural production systems, and producers who use the loans to build conservation structures or establish conservation practices. The requested FY 2011 program level for direct and guaranteed conservation loans is $75 million each. The Indian Highly Fractionated Land Program is a direct loan program which provides authority to make and insure loans to eligible purchasers of highly fractionated land under the Indian Land Consolidation Act. The requested FY 2011 program level is $10 million.

For State Mediation Grants the FY 2011 budget requests $4.369 million, the same as the FY 2010 appropriation, for grants to 35 or 36 States to assist in operating alternative dispute resolution programs that deal with disputes involving a variety of agricultural issues.

For the Dairy Indemnity Program the Budget requests "such sums as may be necessary", as provided in the last two appropriations acts, to compensate dairy farmers and manufacturers when, through no fault of their own, their milk or milk products are removed from commercial markets due to residues of certain chemicals or other toxic substances.

Since it is impossible to predict natural disasters and difficult to forecast an appropriate funding level for the Emergency Conservation Program, the FY 2011 Budget does not include a request for this program.

Administrative Support

The FY 2011 Budget requests $1.69 billion from appropriated sources including credit reform transfers, for a net increase of about $116 million over the FY 2010 enacted level. The request reflects an increase of approximately $20.6 million for Federal and non-Federal pay costs and operating expenses, and about $95.3 million to fund critical IT replacement and modernization projects essential to support core agency operations. The IT request includes $38.3 million to continue the MIDAS project, $1 million to fund an additional 10 staff-years in support of MIDAS, $20 million to convert essential program delivery software from the obsolete mainframe system to the new web-based system, and $36 million to support the Department's

efforts to modernize and upgrade the Common Computing Environment for the Service Center agencies.

FSA has taken aggressive action over the past several years to reduce discretionary administrative expenditures and operate within available funding. The FY 2011 budget assumes that the agency will continue that trend of fiscal restraint.

The FY 2011 S&E request reflects a total of 5,104 Federal staff-years, an increase of 10 over the FY 2010 level, and 9,425 non-Federal staff-years, unchanged from FY 2010. As I noted earlier, the additional 10 staff-years would support the MIDAS initiative. Temporary non-Federal county staff-years will remain at the projected FY 2010 level of 650. These staffing levels are essential to enable FSA to handle the workload associated with the broad array of complex programs entrusted to us.

Madam Chairwoman, this concludes my statement. I will be happy to answer your questions and those of the other Subcommittee Members.

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FOREIGN AGRICULTURAL SERVICE

Statement of John D. Brewer, Administrator
Before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Madam Chairwoman and Members of the Subcommittee, I appreciate the opportunity to review the work of the Foreign Agricultural Service (FAS) and to present the President's budget request for FAS programs in FY 2011.

Introduction

FAS is a vital component of the U.S. Department of Agriculture's (USDA) effort to improve foreign market access for U.S. products, build new markets, improve the competitive position of U.S. agriculture in the global marketplace, and provide food aid and technical assistance to foreign countries. FAS has primary responsibility for USDA's international activities—market development; trade agreements and negotiations to gain, retain, and re-open market access; and the collection and analysis of statistics and market information. FAS also administers USDA's export credit guarantee and food aid programs, and helps increase income and food availability in developing nations by mobilizing expertise for agriculturally led economic growth.

FAS has an unmatched global network of agricultural economists, marketing experts, and negotiators. With more than 90 overseas offices covering 154 countries, FAS' employees identify problems, provide practical solutions, and work to advance opportunities for U.S. agriculture overseas.

In FY 2009, U.S. agricultural exports reached $96.6 billion, despite the significant impact of the global economic downturn. The outlook for FY 2010 is that export sales will reach $100 billion, the second highest level ever.

Market Access

Greater access to foreign markets for U.S. agricultural products requires an aggressive trade policy to lower tariffs, reduce non-tariff barriers, eliminate export subsidies, and reduce trade-distorting domestic subsidies. FAS works with other USDA agencies, the United States Trade Representative (USTR), and others in the U.S. government (USG) to negotiate new trade agreements and to monitor and enforce existing trade agreements.

Notable achievements in these areas in FY 2009 include implementation of Free Trade Agreements with Costa Rica, Peru, and Oman; attaining greater access to the European Union (EU) for U.S. high-quality beef; and protecting over $1 billion of U.S. specialty crops exports to Asia.

Trade Development

In his State of the Union address in January, President Obama called for a government-wide National Export Initiative to help farmers and small businesses increase their exports, expand their markets, and grow the Nation's economy. This initiative sets a goal of developing exports over the next 5 years and supports 2 million jobs. FAS supports U.S. industry efforts to build, maintain, and expand overseas markets for U.S. food and agricultural products. FAS administers several market development programs including the Foreign Market Development (Cooperator) Program (FMD), Market Access Program (MAP), Technical Assistance for Specialty Crops (TASC) Program, Quality Samples Program (QSP), and Emerging Markets Program (EMP). These programs provide matching funds to U.S. organizations to conduct a

wide range of activities including market research, consumer promotion, trade servicing, capacity building, and market access support. Working with the State Regional Trade Groups and other industry organizations, FAS also encourages outreach efforts that focus on facilitating export readiness for U.S. exporters.

FAS' Export Credit Guarantee Program (GSM-102) provides credit guarantees to encourage financing of commercial exports of U.S. agricultural products, while providing competitive credit terms to buyers. Under this program, FAS guarantees credit extended by private banks in the United States (or less commonly, by the U.S. exporter) to approved foreign banks using dollar-denominated, irrevocable letters of credit for purchases of U.S. food and agricultural product by foreign buyers. In FY 2009, the program provided credit guarantees that facilitated sales of a near record $5.3 billion, up significantly from $3.2 billion in FY 2008.

In FY 2009, in response to poor domestic market conditions and the reintroduction of dairy export subsidies by the EU, FAS reactivated the **Dairy Export Incentive Program (DEIP)**. DEIP helps U.S. dairy exporters meet prevailing world prices and encourages the development of international export markets in countries or regions where U.S. dairy products are not competitive due to subsidized dairy products from other countries. On May 22, 2009, USDA announced DEIP for the July 2008 through June 2009 year. On July 6, 2009, the initial tranche for the July 2009 through June 2010 year was announced. As of January 13, 2010, USDA had awarded bonuses for 37,228 metric tons of nonfat dry milk; 17,470 metric tons of butterfat; and 1,843 metric tons of cheese.

Food Security and Agricultural Development

Food insecurity affects over 1 billion hungry people worldwide. The problem is exacerbated by the current global economic downturn. Food aid alone is not enough –

availability is also about increasing trade and in-country production. The biggest contributing factors to insufficient in-country production are chronic under-investment in agriculture, inefficient inputs and markets, and poor governance.

Foreign Food Aid

The Food for Progress (FFPr) Program provides for the donation or credit sale of U.S. commodities to developing countries and emerging democracies that have made commitments to introduce and expand free enterprise in their agricultural economies. FFPr activities have included improvements to agricultural techniques and marketing systems, providing education to farmers, helping to develop cooperatives, supporting agribusiness and microcredit enterprises, and building the capacity to trade. FFPr funding provided over 267,000 metric tons of agricultural commodities valued at $117.2 million, and $98.6 million of transportation and other non-commodity costs in FY 2009.

The McGovern-Dole International Food for Education and Child Nutrition (FFE) Program supports preschool and in-school food for education programs and nutrition programs for women, infants, and children in foreign countries. FAS programmed over 126,500 metric tons of commodities through the FFE program to support programs implemented by the World Food Program and private voluntary organizations (PVO) in FY 2009. About $168.5 million of assistance was made available through this program, benefitting more than 4.2 million children and mothers.

The Local and Regional Procurement Pilot Project was authorized as a pilot program under the 2008 Farm Bill. The primary objective of the project is to use local and regional purchasing to help quickly meet urgent food needs due to food crises and disasters. In FY 2009, $4.75 million was allocated for programming in three countries, Malawi, Mali, and Tanzania.

Trade Capacity Building and Development

The Cochran Fellowship Program (CFP) provided short-term training in the United States for 395 international participants from 73 countries in FY 2009. Cochran participants meet with U.S. agri-businesses, attend policy and food safety seminars, and receive technical training related to short- and long-term market development and trade capacity building.

In its fifth year of existence, the **Norman E. Borlaug International Agricultural Science and Technology Fellows Program (BFP)** continued to expand, training 89 Fellows in FY 2009. The BFP offers agricultural research fellowships for scientific training in the United States to individuals from eligible countries. The program helps developing countries strengthen agricultural practices through the transfer of new science and agricultural technologies, including those related to production, processing, and marketing.

Agricultural Development in Afghanistan and Pakistan is a critical part of the Administration's strategy toward these countries. The primary non-security issue facing the region's stability is reconstructing the agricultural economy in Afghanistan and the border region to provide the people of both countries with legitimate means to earn a living. In Afghanistan, agricultural development plays an enormous role in economic development, as more than 80 percent of Afghanistan's population relies on agriculture to earn a living with much of it in poppy production. There is significant need for technical assistance to provide competitive alternatives to illicit crops, strengthen sustainable agricultural production, and address food insecurity in the region. USDA, working closely with the U.S. Agency for International Development, the State Department, and other USG agencies, is playing a critical role in the effort to rebuild the Afghan agricultural economy, to help provide sustainable economic development in the long term.

Another activity meant to bolster a strong regional economy for both Afghanistan and Pakistan is the Agricultural Trilateral sessions. In January 2010, in Doha, Qatar, the countries of Afghanistan, Pakistan, and the United States met for the first-ever series of Trilateral meetings on agriculture. More than 50 representatives worked over 3 days to outline plans in three specific areas: food security, water management, and trade corridors.

Budget Request

Madam Chairwoman, our FY 2011 budget proposes a funding level of $265 million in salaries and expenses and 1,006 staff years, an increase of $78 million above the FY 2010 enacted level. The budget has been developed to ensure the Agency's continued ability to conduct its full array of activities and provide services to U.S. agriculture, enhancing export opportunities and global food security.

The budget proposes an increase in discretionary spending of $53.5 million as part of the National Export Initiative. This initiative has the primary goals of spurring economic growth and employment opportunities. The future of U.S. agriculture is tied to trade, as agricultural trade is an important generator of output, employment, and income in the U.S. economy. This initiative includes supplemental funding of $34.5 million for the Cooperator Program, increasing the funding to $69 million in FY 2011. Also, the TASC Program will increase by $9 million, doubling overall funding available for TASC to $18 million. The National Export Initiative also includes a funding increase of $10 million to expand FAS exporter assistance, trade missions, and in-country promotion activities and trade enforcement efforts to remove non-tariff barriers, and for higher operating costs at FAS overseas posts.

FAS overseas offices are critical to carrying out the Agency's mission and provide essential support to U.S. exporters, as well as to the wide range of international activities carried

out by USDA. The FAS overseas office network is affected by macro-economic events and developments that are beyond the agency's control, but which increase operating costs. These budget increases are necessary to maintain FAS' overseas presence during FY 2011 so that our representation and advocacy activities on behalf of U.S. agriculture can continue.

The FY 2011 increase also includes:

- $3.4 million for increased payments to the State Department for International Cooperative Administrative Support Services (ICASS) for FY 2011. State provides common administrative services at more than 200 diplomatic and consular posts overseas that FAS and other foreign affairs agencies help to pay for through the ICASS system. Major factors contributing to higher ICASS costs in FY 2011 are increased pay allowance for State staff for danger pay and high threat posts, rapidly increasing costs of operating New Embassy Compounds, growth in ICASS direct hire positions, increased compensation for locally employed staff providing ICASS services, overseas comparability pay for Americans providing ICASS services, and other increased State personnel costs.
- $1.5 million to expand the Borlaug and Cochran Fellowship Programs. This funding will improve the U.S. government's ability to provide technical assistance and capacity building programs, including in-country, third-country, and U.S.-based training programs as appropriate. These programs are critical to ensure that trade systems are science-based and that countries have the capacity to establish the basic institutions required to open their markets to trade. They also assist fragile market states with the access, availability, and utilization issues that affect food security for their population. This increase will allow for additional training in support of food security objectives in sub-Saharan African

countries, as well as Haiti. Under our proposals, as many as 680 individuals will be able to participate in and benefit from these fellowship programs.

- $4.0 million for the costs of transferring all overseas IT network support and maintenance responsibilities to the State Department by FY 2011. Strong security for FAS IT systems is essential because of the sensitive information handled by the agency. For example, an estimated 34 percent of U.S. agricultural pricing data is derived from information and support provided by FAS. This transfer will allow FAS to take advantage of the secure information system infrastructure that is operated and maintained by the Department of State.
- $14.6 million to fund agricultural reconstruction and stabilization activities, of which $13 million is moved from Departmental Management where it was funded in the FY 2010 appropriations act. Funding for these activities is increased by $1.6 million over the FY 2010 level to provide for an expansion of activities in Afghanistan and to meet higher operating costs. FAS coordinates USDA's efforts to assist in reconstruction and stabilization activities, primarily in Afghanistan and Iraq, and assumes full management of the operational and policy components of such activities.
- $1.4 million to cover higher personnel compensation costs associated with the anticipated FY 2011 pay raise. Pay cost increases are mandated and must be funded by the agency. Without the requested increase, FAS would have to reduce agency personnel levels. This would significantly affect FAS' ability to carry out its agency mission to link U.S. agriculture to the world to enhance exports and global food security.

Export Programs

Madam Chairwoman, the FY 2011 budget includes approximately $6.1 billion for

programs administered by FAS that are designed to promote U.S. agricultural exports, develop long-term markets overseas, and foster economic growth in developing countries.

Export Credit Guarantee Programs

The budget includes a projected overall program level of $5.5 billion for export credit guarantees in FY 2011, of which $5.4 billion will be made available under the GSM-102 program. As in previous years, the budget estimates reflect the level of sales expected to be registered under the programs and can change depending on world financial market conditions, program demand, and other relevant factors during the course of the year.

Market Development Programs

Funded by CCC, FAS administers a number of programs in partnership with private sector cooperator organizations to promote the development, maintenance, and expansion of commercial export markets for U.S. agricultural commodities and products. For FY 2011, the CCC estimates include a total of $216 million for the market development programs.

The FY 2011 budget proposes a series of adjustments in the funding levels for these programs to reflect the changing nature of agricultural trade competition. The budget increases funding for the Cooperator program to $69 million in FY 2011. This includes an additional $34.5 million of discretionary funding to be provided in the FAS salaries and expense account as part of the National Export Initiative. The budget includes a total of $18 million for the TASC program, consisting of $9 million of CCC funding and an additional $9 million of discretionary funding provided in the FAS salaries and expense account. Similar to the Cooperator Program, funding for TASC will be increased in FY 2011 as part of the National Export Initiative. Although the FY 2011 MAP funding level is reduced from FY 2010, it still provides a program level that is nearly 80 percent above FY 2001. Funding for the Quality Samples Program and

Emerging Markets Program remain at the FY 2010 level.

Foreign Food Aid

The United States continues to play a leading role in global efforts to alleviate hunger and malnutrition and enhance global food security through international food aid activities. USDA carries out a variety of food aid programs which support economic growth and development in recipient countries. In this regard, the FY 2011 budget includes an overall program level for U.S. foreign food aid of $2.1 billion consisting of:

- $1.7 billion for Food for Peace Title II Grants. Emergency food aid is provided through the Title II Grants program, which is administered by USAID.
- $146 million for the CCC-funded Food for Progress program projected to support approximately 170,000 metric tons of commodity assistance.
- $209.5 million for the McGovern-Dole program which will assist an estimated 5 million women and children in FY 2011.
- $25 million for the Local and Regional Commodity Procurement Pilot Program. The 2008 Farm Bill authorizes and provides CCC funding for a limited, field-based pilot program of local and regional procurement of food aid commodities for distribution overseas. Grants are provided to PVOs, cooperatives, and the World Food Program that undertake procurement activities.

This concludes my statement, Madam Chairwoman. I will be pleased to answer any questions.

RISK MANAGEMENT AGENCY
FEDERAL CROP INSURANCE CORPORATION

Statement of William J. Murphy, Administrator
before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Madam Chairwoman and members of the Subcommittee, I am pleased to present and discuss the fiscal year (FY) 2011 budget for the Risk Management Agency (RMA). This budget reflects a conservative funding level - - and minor increases - - for both the discretionary Administrative and Operating (A&O) Expense Account and mandatory Federal Crop Insurance Corporation (FCIC) Fund. The mandatory request also reflects estimated savings of $8 billion over 10 years because RMA is actively pursuing changes to the terms in the agreement it has with reinsured companies that sell and service crop insurance, the Standard Reinsurance Agreement (SRA).

The progress of the Federal crop insurance program may be measured in several ways. In crop year 2009, there were more than 1.1 million polices written with over $8.9 billion in premium. Federal crop insurance was available for approximately 350 different commodities in over 3,141 counties covering all 50 States and Puerto Rico. Roughly 265 million acres of land were insured and $83.9 billion in risk protection was provided. A participation rate of nearly 81 percent was maintained for the ten principal crops.

In order for the Federal crop insurance program to support risk protection coverage of $83.9 billion in 2011, the funding level proposed for the FCIC Fund is $7.6 billion, and for the A&O Expense Account, $83.1 million.

ADMINISTRATIVE EXPENSES

RMA's FY 2011 request of $83.1 million for discretionary administrative expenses includes an increase of $2.7 million. Of this increase, $739,000 will cover pay costs for essential staff and allow the Agency to continue successfully operating the Federal crop insurance program. The budget request also includes $2.0 million for information technology (IT) operations and maintenance, which are systems without other mandatory funding sources. Specifically, the additional IT funding will provide resources that are critical for RMA to properly exchange data with private insurance partners, interface with industry representatives and other government entities, confirm and assure optimal program performance, and develop, deliver, or monitor the risk management program. The Agency will also be able to sustain its 24x7 operating environment and continue to support hardware, software, and network upgrades.

FCIC FUND

The FY 2011 budget proposes under current statute that "such sums as may be necessary" be appropriated to the FCIC Fund. This ensures the program is sufficiently funded to meet estimated growth based on the latest program indicators. The basis for premium subsidy, delivery expenses, and excess capital stems largely from USDA's latest projections of participation and expected higher market prices.

We anticipate that $5.5 billion will be needed for premium subsidy in FY 2011. Without subsidized crop insurance premiums, many producers, especially minority and limited-resource farmers and ranchers, likely will opt not to participate in the crop insurance program due to financial hardship, or they will reduce coverage levels; leaving them inadequately protected in the event of a crop loss.

The FCIC Fund budget estimate also includes $1.7 billion to reimburse the reinsured companies for delivery expenses associated with selling and servicing crop insurance products and another $1.2 billion in underwriting gains. However, because this company subsidy is excessive, and the government should be able to offer the same program at less cost, RMA has included anticipated program savings of approximately $782 million in FY 2011 - - and $8 billion over 10 years. As I mentioned earlier in my testimony - - changes to the SRA proposed by the Administration will allow these savings to materialize. Due to the preliminary state of the negotiations, however, we did not attempt to apply the savings to individual budget line items at this time. A second draft of the revised agreement was released February 23 and is available on the RMA website (http://www.rma.usda.gov/news/2010/02/223sra.pdf).

Also included in the budget is $26.2 million for excess capital due to timing of fiscal year premium and loss payments and a total of $59.7 million of expected carryover from FY 2010 will be applied to program costs in FY 2011. Federal Crop Insurance Act (FCIA) initiatives total $74.5 million, from which program outreach and risk management education (RME) activities are funded. In FY 2009 alone, FCIC approved 65 outreach projects - - totaling $7.1 million - -

targeting women and small limited resource farmers and ranchers. An additional $6.4 million was spent on RME related commodity partnership agreements, including small sessions focused on specialty crops.

PROGRAM MANAGEMENT

The following is an update on accomplishments and ongoing operations that reflect major program management activities to support our strategic goal:

IT Modernization Project (ITM)

The RMA ITM project is in its third year, since funding was provided in the 2008 Farm Bill. To date, approximately $35 million of the $54 million 4-year project has been obligated under the two phased project approach.

Phase I includes all processes needed to implement rate and price development and filing of insurance offers, edit and validation of data submitted by approved insurance providers (AIPs), and enhanced reporting capabilities. Phase I development will be completed around June 2010 and will support implementation of the Combination (COMBO) policy for the 2011 crop year.

Phase II will include accounting, exception processes, and the remainder of the corporate reporting system, and is scheduled for production in 2011. RMA has strengthened information security to protect producer and corporate information. Significant security enhancements

implemented include data encryption for all RMA laptops, more secure remote access into RMA networks, additional policies and security controls, and working with AIPs to protect critical information throughout the insurance process.

SRA Negotiations

RMA recently met with industry representatives and presented findings on company profitability. The Agency has received, reviewed, and considered recommendations and comments from the insurance industry, analyzed various Office of General Counsel and Office of Inspector General reports, and briefed Congress. RMA finalized and released the first draft of the 2011 SRA on December 4, 2009 - - the second draft was released on February 23, 2010. SRA negotiations are an iterative process of draft documents, explanatory meetings, comment periods and document revisions. The process must be completed by June 30, 2010 to be in effect for the 2011 reinsurance year beginning July 1, 2010.

COMBO Regulations and Provisions

FCIC published a Proposed Rule in the Federal Register to amend the Common Crop Insurance Regulations, Basic Provisions, Small Grains Crop Insurance Provisions, Cotton Crop Insurance Provisions, Coarse Grains Crop Insurance Provisions, Malting Barley Crop Insurance Provisions, Rice Crop Insurance Provisions, and Canola and Rapeseed Crop Insurance Provisions to provide both revenue protection and yield protection. FCIC also proposed to amend the Common Crop Insurance Regulations, Basic Provisions to incorporate changes resulting from input and

recommendations by the Prevented Planting Work Group. The final rule is expected to be published early in 2010 for implementation for the 2011 crop year. The amended provisions will replace the Crop Revenue Coverage, Income Protection, Indexed Income Protection, and the Revenue Assurance plans of insurance.

When implemented, producers will have a choice of revenue protection (protection against loss of revenue caused by low prices, low yields, or a combination of both) or yield protection (protection for production losses only) within one Basic Provision and the applicable Crop Provisions. This will reduce the amount of information producers must read to determine the best risk management tool for their operation and to improve the prevented planting and other provisions to better meet the needs of insured producers. This combined policy is expected to cover nearly $76 billion of the nearly $84 billion of FCIC's total liability and 94 percent (approximately one million policies) of all policies earning premium.

Compliance Activities

Through combined efforts between RMA, the Farm Service Agency (FSA), and approved insurance providers, program compliance and integrity activities continued to improve through: 1) data reconciliation and matching for disaster program payments; 2) evaluating and amending procedures for referring potential crop insurance errors or abuse between FSA and RMA; and 3) creating anti-fraud and loss adjustment training packages as required by FCIA. FCIC continues to improve efforts to integrate other data mining projects; explore avenues to expedite the processing of sanction requests; and implement the new Compliance Activities and Results System for case management, tracking, and reporting compliance findings.

The formalized alliance with FSA, along with data mining and analysis, greatly improved referral activity to and from the Agency. This is attributable to the greater emphasis placed upon deterrence and prevention efforts.

CONCLUSION

This concludes my statement, Madam Chairwoman. I would be pleased to answer any questions that you and other members of the Subcommittee may have. Thank you.

FSA IT STABILIZATION AND MODERNIZATION

Ms. DELAURO. Thank you very much, Mr. Secretary. Let us begin here. As you pointed out this is with regard to the Farm Service Agency. The budget requests an additional $59 million for the agency's ongoing IT stabilization and modernization initiative. As I said in my opening remarks, if we move in this direction, we will have seen about $250 million spent in this effort.

Let me just ask you this, because as I again pointed out, there is a growing bipartisan concern about how long this is taking and what more is needed to complete it. On the first question, when will the project be completed?

Mr. MILLER. Jonathan, would you like to give a specific answer?

Mr. COPPESS. Sure. Thank you. And we anticipate if the funding continues that the last contracts will be let out in 2013 and that the bulk of this project will complete in 2014. So we're looking at three and a half, four years, to get through the modernization part of this.

Mr. MILLER. Madam Chairwoman? If I might, let me point out that progress is being made in a very significant way and we expect ongoing improvements. For instance, the Farm Loan Program delivery system has lowered the loan processing time from 41 days to 25 days. Our National Receipts and Receivables System is finally beginning to speed payments to producers, and we expect after some glitches this year in the transfer that that system will be much improved in this interim period.

Ms. DELAURO. I don't mean to be flip about this. I think people were concerned that we were going to put an entirely new healthcare system together between now and 2014. We haven't been able to get this system up and running for a number of years now, so, let me follow-up with a question that I have.

Quite frankly, we have not been able to get clear answers from FSA about how much additional funding is needed to finish the project, which is of concern. We are told now that the funds we provided specifically for stabilization and modernization are being used for other purposes and are not remaining in the base for use just for this initiative. We did run numbers ourselves.

Committee staff did that for me and we are assuming that the total cost of the project as projected by FSA is about $454 million. If we provide your 2011 funding request and if previously appropriated funding remains in the base for this initiative, then you need only about $15.3 million in fiscal year 2012 to reach full funding. Alternatively, if you don't keep the previous funding in the base and you spend it on other things, that will mean another $203 million, or you'll fall short by that much.

There's a difference of $188 million, and we just don't have that kind of money. So we need a commitment from you today that funding provided for this initiative will be kept in the base for this initiative and nothing else, and it will only be used for this initiative. And I'm going to ask you for your commitment today on that.

Mr. COPPESS. And my understanding is the number on MIDAS, about $305 million for this whole project, has been consistent, that that is the estimate for the full project. And our commitment is to absolutely use this funding to modernize our systems, our processes

around those systems, and get it completed as soon as we can. As the Under Secretary mentioned, the National Receivables System that we started using this year is a big step forward, and we are learning the problems as we go with that. So we're committed to putting this funding to that.

FUNDING COMMITMENT

Ms. DELAURO. But I want a commitment that the funding that we provide is not used for anything else, that the base number stays the same and we build on it. And then we just don't add to it. That is essentially, and again, we've had a difficult time getting the answers. I don't know what it's going for. If you know where it's going to, but money is not staying in the base account and it's being used for other things. So we can't allow that to happen here.

Mr. COPPESS. I understand.

Ms. DELAURO. Because the money is just, you know, just can't be filling the gap—and you using money to go someplace else. So do we have your commitment?

Mr. COPPESS. Yes. We're not moving that money around.

Mr. MILLER. Chairwoman DeLauro, there are two critical elements to this project that I know you're very much aware of. One is to stabilize the existing system so we can continue to deliver programs under the agency. The other is to create the modernization, which is both a software and hardware issue, so we can get the advantages of these new efficiencies.

Those projects are, in fact, moving forward and it is our top priority. We are committed to utilizing the funding that is made available to the agency to ensure that we can move ahead with this project and that we can complete it and deliver the benefits to our stakeholders.

Ms. DELAURO. I understand that. The commitment for this committee is imperative, and this is on the bipartisan basis. We've been asking this question for, you know, last year, the year before. And there's a January report that was due to lay out where the money is, and to my knowledge we do not have that report yet. So we would like to get that report and we would like that commitment that says this money is here. It's going nowhere else.

Mr. MILLER. Let me make sure that we get that report to you as soon as possible. I believe the report is, if not concluded, is very close to conclusion and then we will be very happy to come up and speak to you.

Ms. DELAURO. Because the next one is due April 1st, and, Mr. Secretary, your commitment on not moving the money out of the base.

Mr. MILLER. No, you have that commitment.

Ms. DELAURO. Fine, thank you. Thank you very much. Let me go ahead and yield to my colleague. Start with another question.

Mr. KINGSTON. Thank you, Madam Chair.

Mr. Coppess, I just want to say that I think this goes back to Henry Bonilla, maybe even Joe Skeen. I was chair of the Leg. Branch Appropriation Subcommittee when we were building the CVC project that was supposed to be like $260 million, take one or two years, maybe three, and it ended up taking seven years. It is really, truly not even completed, and it is well over, I think, $650

million. And the only way we got any progress out of him was just somebody has to be the mean SOB. Is that you? You don't look like one, you know? [Laughter.]

Mr. COPPESS. I tried to be too mean.

Mr. KINGSTON. Well, Scott's pointing at you. And maybe Rosa and I together can constitute a two-headed monster, but really and truly, it's just one of those things where nothing has happened. Every year we could practically record your testimony and play it back through all the other Administrations and people have sat in your seat, and we've been hearing it. And so you've inherited a long legacy of this is going to happen.

Mr. COPPESS. Yeah, there's a few of those, and I want to echo the commitment that we're putting behind this to get this moving, simply because as I've come onto this job and gone through and met county offices and see what's going on, it is absolutely vital that we get this system up and running in the modern environment. I mean we cannot continue to serve farmers and ranchers if we don't do it. So I'm committed to it, and it's absolutely something we want to complete and complete on time.

Mr. KINGSTON. And the other thing that you're facing as you know is the technology vision of three to four or five years ago is obsolete. Things are changing so rapidly these days that, you know, you're now building a system that was yesterday's system. So, you know, you have to cajole. You have to embarrass. You have to fire some people. I mean you just have to get in there and get it done.

AFGHANISTAN

Let me switch to the Secretary. Are you familiar with our military strategy in Iraq that is a "Shape, Clear, Hold, Build and Transfer"?

Mr. MILLER. Very roughly, sir.

Mr. KINGSTON. Okay, well those are the five buzz words that we are hearing over and over again from our military commanders. And, of course, Shape would be identify your next area, which is Kandahar, that we are going to take over. And then Clear is the military; Hold; and then you come in, really, the last two phases, which would be to Build and then Transfer. And then actually you're staying there once the transfer happens. And as you also know we have four ambassadors in Afghanistan. The reason is to sort of offset the military presence with the diplomatic presence and make sure, you know, the two and three stars have kind of the civilian equivalent in the State Department, but also with USDA.

And I would like to make sure that, number one, if you guys don't feel you're getting enough love from the military-State Department side, if you let our committee know. Mr. Boyd and I serve on the Defense committee, and they don't listen to us any more than they listen to anybody else.

I think they might listen to him, but, you know, we want to make sure USDA is in the forefront of thought when it comes to the build and transfer side of the phase. But I would also like to see from you what your plan is, because when I was in Afghanistan on the 8th talking to your folks over there, and I felt that they were very competent, but we're still giving technical assistance and

it's very hard to get things up and running when, you know, the big money is in poppies.

So what I would like to see, if possible, is if you could tell us kind of what you're going to do about poppies, because I am just not getting an answer from the military. And then what is your plan, as well, because we want to be able to support you. You are going to have in this budget, which I will support, I think, all Republicans on this side are going to. You are increased from 14 to 64 people.

And as I understand it, in order to get the USDA people there, you basically have to double their salary when it comes to costs and expenses. Because it is a voluntary thing and they are leaving their home—leaving, you know, their families—and they're going into a war zone, so, you know, that sort of thing is to be expected. But we want to make sure that while they're on the ground they're doing a good thing. So I guess my quick question is could you give us periodic reports, maybe even a quarterly update on what USDA is doing in Afghanistan, how you identify the problems and how you're going to attack them.

And I want to say, because I am absolutely convinced we can have military victory, but it's not going to mean anything unless we can grow the civilian part of that government; and, as you know, it's a very tough part of the world.

Mr. MILLER. Well, Mr. Kingston, let me respond this way. Certainly the attitude of Secretary Vilsack in the Department of Agriculture, and I believe the attitude across government is second to the outstanding job that our men and women in uniform are doing in Afghanistan. I think we recognize that if we are going to be able to declare real success at some point in that part of the world, we have to ensure that the Afghan government is capable of governing the country. And that means it has to find ways to get more support out in the countryside, and we have to ensure that there is economic stability and opportunity for the Afghan people in the countryside.

AGRICULTURAL ISSUES IN AFGHANISTAN

You raised the poppy issue. Certainly, shifting the agricultural production in—Afghanistan historically has been a significant agricultural producer prior to all the turmoil that it's been engaged in. Shifting the focus from poppies to other commodities, creating market opportunities, and that's more than just raising crops. That's providing infrastructure.

That's providing the opportunity for them to export to what had been some traditional markets that had been abandoned for years. It's a critical objective for our success. As you indicated, USDA is planning on increasing the number of individuals that will participate in our Provincial Reconstruction Teams in Afghanistan, up to 64.

Many of those people will be going out into the country into the provinces of Afghanistan working in cooperation with the locals, first to identify what do they need in order to be successful. It does very little good for us to try to impose something on them, so it is really a question of finding ways to work with the people, find out what they need to rebuild their communities, to rebuild their agri-

cultural economy, and then finding the wherewithal in initial phases.

That certainly is technical assistance, but find the wherewithal to work with the Afghan people in their government, to rebuild that country and create the stability we all would like to see. We are happy to provide regular reports to the subcommittee in terms of our progress in that areas, because I think our work in cooperation with U.S. AID, State Department and Department of Defense is a very positive story in a very troubled area. Thank you.

[The information follows:]

The first report on Afghanistan is expected to be provided in the fourth quarter of FY 2010, with subsequent reports on a regular basis. The reports will include information on the status of our funding and programs for Afghanistan.

Ms. DELAURO. Mr. Boyd.

AGRICULTURAL POLICY

Mr. BOYD. Thank you, Madam Chairwoman. And I want to start by associating myself with the remarks that you made relative to the modernization of the technology.

I guess many know that I have had a lot of experience as a customer dealing with Farm Service Agency offices, and certainly understand that there are some issues there that we need to resolve.

Secondly, Madam Chair, I want to say for the record in this committee that in the last couple of years we've seen significant attention given to a couple of severe problems in this country. Summer of 2008, we had gasoline, because of the rising cost of oil, go to $4.25, $4.50 a gallon, one of the largest single factors that put this country in a recession in the summer of 2008.

Now we are in the middle of a very heated polarizing debate on another issue that is gripping this country in terms of its costs and effectiveness, and that is its health care system.

I want to remind the Committee members and everybody in this room that of all the public forums I have attended—over the hundreds of public forums I have attended over the years, I have never heard a constituent come to me and complain about the lack or access to quality, affordable food supply on the shelves of our supermarkets.

I say that because I hear a lot of people fussing about our national agricultural policy, that we have had a policy that has worked well for this country for years and years and years.

I just wanted to go on the record, Madam Chair, as supporting that policy, and warning folks about being too aggressive in changing significantly that policy.

FSA AND NRCS COUNTY OFFICES

Having said that, I will move to a quick question, and that question, I think, Mr. Under Secretary, either you or Mr. Coppess could answer it, has to do with the workings of the FSA and NRCS Offices, and those two systems, it appears to me, work separately.

I always thought or at least the people around me, the folks who use those offices, believed the FSA Office works from the bottom up, that is from the farm advisory committees up, and the NRCS Offices worked from the top down.

There has been a lot of talk over the last number of years by a lot of folks, including folks in Congress, about a way to modernize the way those offices worked together.

My question really is, I understand a legislative change is not necessary to shift administrative work entirely into FSA, so that NRCS can get back to doing what they are best at, which is technical expertise, technical advice.

Is this something that you consider or you think the USDA should consider doing?

Mr. MILLER. Mr. Boyd, let me respond this way and then I will ask Mr. Coppess if he wishes to provide any more specific comments in terms of the interaction that his agency has with NRCS.

I believe that over the last year, there has been a dramatic change in the way the Department is interacting with a variety of agencies that exist down there.

This is something that Secretary Vilsack has been very insistent upon, and I think the relationship, the breaking down of barriers or stovepipes, whatever you may wish to characterize them, has changed significantly.

We cooperate with our colleagues at NRCS on a day-to-day basis while we implement a wide range of assistance programs for farmers. We are also engaged through the Conservation Reserve Program and in some ways through the new BCAP in conservation program administration through FSA as well.

All of these programs really become interrelated at the farm level, as you very well know. We believe it is imperative that we have a good working relationship.

It is interesting that in many of our county offices, NRCS and FSA are co-located. They are just down the hall.

We are working hard both here in Washington, D.C., as well as out in the country to ensure that there is greater collaboration between the two agencies to ensure that the programs that are available, that the benefits that are available, and as you note, the important technical assistance that can be made available, is in fact being delivered to the producers.

Also, I should point out that I think as we resolve this IT problem, that is going to in a lot of ways improve our ability to interact with other agencies within USDA. Just our ability to share information and share databases is extremely important. Quite frankly, right now, FSA, RMA, NRCS, we are all working off different databases.

Mr. BOYD. Mr. Under Secretary—if I could follow up briefly, Madam Chair—I hear what you say. Just being co-located down the hall, and I am sure many offices are, I am sure most of them are, but if the customer has to go to the two separate offices to do the administrative work, the administrative procedures are different in one office than they are in another, being co-located really does not give you much advantage.

FSA AND NRCS OPERATIONS

My question really goes to how they work and how they operate. NRCS is best at technical supervision. I have said this before in this meeting.

I have a farm that I can show you pictures of coming out of the Depression that you would not believe is the same farm that it is today.

Much of that is a result of the work that NRCS helped with, with technical advice, and the FSA, then called something else, helped us implement.

My question really is administratively, is this doable, that we can shift most of that administrative burden into FSA, which they seem much better at—you seem much better at than NRCS. That is really the gist of my question.

Mr. MILLER. Again, I think your point is well taken in terms of we have to get better at ensuring that we are providing an improved level of service to our farmers, that we make it as easy and convenient as possible, and to the extent possible, that functions between various agencies utilize similar forms and other administrative tools.

I cannot suggest at this point that FSA is willing to assume all of those functions from NRCS other than the technical assistance, but I do believe it is entirely possible for us to develop a much closer working relationship where we can streamline processes and make it easier for our stakeholders.

Jonathan, do you have any additional comments?

Mr. COPPESS. I think you have made pretty much all the main points. Certainly, Chief White and I have talked many times and are continuing to push in an effort to make our coordination better for things like land coming out of CRP and going into other programs.

I think both agencies have incredible resources and the ability to work together is the first and most important step, and as the Under Secretary mentioned, I think as we get ourselves in this modern environment—we cannot share oftentimes across counties—so to be able to share from a centralized database information and work that way in better cooperation with other agencies is going to be a big part of it.

Mr. BOYD. Thank you, Madam Chair.

SUPPLEMENTAL REVENUE ASSISTANCE PROGRAM (SURE)

Ms. DELAURO. Thank you. Let me ask you, Mr. Coppess, I want to turn to the FSA's implementation of the SURE program. As I again mentioned in my opening statement, it is encouraging that the regulations were published at the end of last year and the payments have been going out.

I am concerned that it is 2010. The payments that are going out are for 2008 losses. That is a long time for these folks to have to wait for assistance.

By the way, the 2008 Farm Bill, this was to be the permanent disaster fund, and what Congress did was to say let us have a permanent disaster fund so that we do away with this ad hoc disaster program.

2010, we are dealing with losses in 2008. When the Secretary appeared before our subcommittee last year, he said he would see if there was any way the process could be accelerated.

Can you give us an update on the implementation of the program? When do you expect the payments for the 2009 losses to begin going out? Why has the process taken so long?

Mr. COPPESS. Thank you. Certainly, we expedited this process when we came on board to move things up. I agree with you completely that it is very difficult for farmers who had losses in 2008, and a bill that passed in 2008, to just now be getting payments.

We expedited that and put a lot of effort behind that—in fact, in front of software issues—so that we are actually calculating these in the offices and getting the payments out.

Farmers began signing up for the 2008 losses this January, and we have paid out, I believe, over $2 million to date for 2008. 2009 will begin this year.

One of the things about SURE is because we have to wait until the crop year is done and calculate the national prices and everything in the statute, it will not be sort of a realtime disaster response.

It is a supplemental program. You have to have NAP or crop insurance. That is sort of closer to the disaster part of the safety net. Then we calculate that after the crop year is over and then know the prices, know what all the pieces of that calculation will be, and then it will generally pay out a year to 18 months after the disaster.

Ms. DELAURO. Are there other steps that we can take to accelerate the process?

Mr. MILLER. Let me just remind the Chairwoman of a couple of things and then let's discuss how we might be able to solve this problem.

If you recall, it took three years before disaster payments began to be calculated in the last ad hoc programs.

Ms. DELAURO. I am aware. We made some promises to people and quite frankly to ourselves because we are going to be continuing to do this, but also to continuing to look at ad hoc disaster relief programs because people cannot wait as long. You will then see supplementals continuing to do this.

The goal was to have a permanent disaster relief fund. I am well aware. As I say, I applaud what you have done but I have been out there and I have heard people talk about how difficult it is for them, some of the small folks, they cannot survive if they have to wait all this time.

Mr. MILLER. As you have noted, we do have the program out. Quite frankly, the development of the crop disaster program did not really begin until the new team at USDA was in place, less than a year ago.

As Jonathan indicated, this became the top priority for FSA.

I do expect within the requirements of the statute, and that is for crop losses, that we need to have the average market year prices in order to calculate the payment, but we will be getting payments out more quickly in the future now that the program——

Ms. DELAURO. The program is up and running.

Mr. MILLER [continuing]. Is up and running. It is still going to be at the end of the marketing year, not directly associated with the production year.

In terms of the other elements of the disaster program, however, we are able to make those payments, again, because of the provisions in the statute, much more quickly—the livestock indemnity program, as well as the livestock forage program. Those payments were implemented earlier and payments began to flow to producers who were eligible much earlier.

It is a range, but yes, we have this issue in terms of timing, primarily because we are complying with the statutory requirement.

SURE PAYMENT PROCESS

Ms. DELAURO. Is there anything we can do to accelerate it? Anything that we can help with? Is there anything else you need or are there any tools that you need that could help accelerate this process?

Mr. MILLER. If it is the desire of Congress to find a way to accelerate the process, there are a couple of things that could be considered. I am not advocating them. I am providing some technical guidance.

One, you could consider that we develop a way to provide advance payments. That would be a partial calculation of what an estimated disaster payment would be.

Another is to potentially reconsider what we are going to use for the pricing of these commodities. Right now, we are waiting until the end of the marketing year. We are calculating prices based on average prices received by producers consistent with the statute. That is an element that Congress could potentially review if the goal is to find a way so we can make these calculations and thereby deliver assistance sooner.

All of those are going to come at some cost, as you are well aware.

Ms. DELAURO. Thank you very much. Mr. Kingston.

FOREIGN AID

Mr. KINGSTON. Thank you, Madam Chair.

Mr. Brewer, I wanted to talk to you a little bit about the foreign aid and the effectiveness of it as much as anything else.

I want to preface that by something that I have learned recently, that revenues in our budget cover Social Security, Medicaid, Medicare, interest on the national debt, and then essentially we borrow about 37 cents on the dollar that we spend, which would include agriculture, military, education, transportation.

That is not a political statement. I would attribute that to both parties.

The twist in here, the irony, is that we are borrowing money for foreign aid, including borrowing money to give some to China, and we are borrowing money from China, which I think has a certain twist.

Again, I am not trying to be political. I am just saying this is reality and both parties have dug this hole, but we are in it.

That is statement one. Statement two, I was watching Morning Joe today. They had an excellent show on education. They had Mayor Bloomberg and Al Sharpton, and kind of a star studded bipartisan eclectic group of people who were there, who said the new mantra of New York City is actually to challenge the status quo.

They were really emphasizing charter schools, saying they have 10,000 kids in charter schools, 30,000 on the list.

It is kind of an interesting type dialogue that we need to see more of in public policy.

SUCCESS STORIES

My question to you on foreign aid and with your private sector background, where do you see the success stories? Where are we moving the best on alleviating food insecurity? Talk to me about U.S. food aid versus host country food aid.

Let me just ask you the big picture philosophical questions on that.

Mr. BREWER. Congressman Kingston, thank you for this opportunity to talk to you about it. The way you posed your question really is very expansive, but let me bring it down——

Mr. KINGSTON. You have two minutes. [Laughter.]

Mr. BREWER. A couple of our programs—I think where you will see the success stories for us will be in our programs of McGovern-Dole as well as Food for Progress.

Let me say how much we appreciate the Congress' efforts to work with us to provide budget authority and increase those programs by $500 million in 2010. We appreciate that. We are working hard to make those funds effective.

MCGOVERN-DOLE PROGRAM

As you know, with the McGovern-Dole program, that is linked to education. We work very hard to make sure that program is going to bring this year, we anticipate it will help feed up to five million women and children. That McGovern bill was definitely a success story.

Mr. KINGSTON. Just in terms of our dialogue, and if we go over, I intend to come back to you and give you more time on this, and this is a long discussion, I am aware, but just because we are feeding that many people, that does not necessarily mean success.

To me, another question would be well, what else are we doing for them in order to help them help themselves. Not that that is the focus of the program per se, but I am kind of talking to you philosophically.

Again, thinking about Morning Joe and this group and they are putting their best thoughts together, that is what I am trying to get to.

Mr. BREWER. Again, I apologize if I cannot go as philosophical as you want. With regard to McGovern-Dole, it is not just that we are feeding people. It is the innovation. We are linking it to education. That education is the innovation and the success story. It is the manner in which we are providing that food that is leading to education, which we all believe is the foundation for success and innovation.

FOOD FOR PROGRESS PROGRAM

Also, with regard to our Food for Progress program, again, the way in which we provide our assistance, we are doing that through the providing of commodities, which those countries then are able

to sell in an effort to provide economic development, economic development opportunities for investment, et cetera.

At the philosophical level that you are talking about, it is the way in which we are managing our programs.

One thing I do want to add is remember in the area of food aid, we are part of a whole Government effort. We are working with partners in USAID and State. That whole Government approach is again an innovative way in which we are providing—we are complementing each other's programs.

I think the way we link our aid to certain areas which lead to economic development and advancement of countries as well as our comprehensive and collaborative approach are where we are making progress in the area you are referring to.

Mr. KINGSTON. I am out of time now. I will yield some more time to you on my next round. In the next round, one of the questions I would like to ask you is what are some of the countries that you see with your background in Africa that are moving forward, where we are more successful and where we are not making progress.

Thank you, Madam Chair.

Ms. DELAURO. Thank you, Mr. Kingston. I, too, have questions with regard to our food aid programs.

I am glad to say, Mr. Brewer, I think we share the experience of going to the London School of Economics; some of the best years of my life was at the LSE.

Mr. BREWER. I am sorry Congressman Bishop is not here, after Morehouse, it is the best.

NATIONAL EXPORT INITIATIVE

Ms. DELAURO. I will tell him. Let me ask about the Export Initiative. Fifty-three and half million dollars is the increase for the National Export Initiative. It was included as the USDA component of the President's initiative, and doubling the exports in five years, which is the goal, and to support two million jobs.

To fund the initiative, the budget request increases for FAS exporter assistance and in-country promotion activity, the Foreign Market Development Program and the Technical Assistance to Specialty Crops Program.

That is $53.5 million in discretionary increases. That would be in addition to $43.5 million in mandatory funding, which will also be provided for two of the programs, the Foreign Market Development and the Technical Assistance for Specialty Crops.

It is about $97 million. What data, and I think my colleague, Mr. Kingston, mentioned this earlier, what data do you have showing the impact that these programs have had on exports to date and how will you measure the success of this initiative? How will we know if it is working? What are the standards that we have now that intimate that these programs are working?

What data do you have showing the impact these programs have had on exports to date?

Mr. BREWER. The data we have been primarily using particularly with TASC and FMD has been the metrics we have been using to justify what we have been doing with these programs that are currently existing, the FMD program and TASC program are currently funded through CCC funding.

Ms. DELAURO. That is mandatory funding.

Mr. BREWER. Yes, ma'am. That is mandatory funding that we are talking now. The NEI program or the proposal doubles those current mandatory programs.

Ms. DELAURO. I know that. What I want to find out is how do we know, tell me about how we have expanded this export capacity and how an additional $53.5 million is going to further expand that capacity for exporting? I do not have a sense of that.

Mr. BREWER. Let me answer that question through some of the success stories that were referred to earlier.

In the area of TASC, in 2009, using TASC funds, our cooperators, our partners, were able to open up the market for U.S. seed potatoes in Thailand. That led to an additional potential of $1 to $3 billion in additional export sales. That assisted the States of Washington, Idaho, Oregon, and California.

We also used TASC funds to assist us in opening a market in Mexico for stone fruit, which was very useful to the stone fruit producers in California.

Our efforts to open up markets and those success stories are just two examples of the metrics we use or the way in which we determine that these programs are useful.

There are other success stories that I would be happy to provide.

PROGRAM PERFORMANCE CRITERIA

Ms. DELAURO. I think it is important to deal with the success stories. I would like to see what we view, when we are looking at goals that we are trying to reach, how is this additional $53.5 million going to deal with our part, ag's part, of contributing to doubling the exports, two million jobs.

I would like to know what the criteria are that we measure the success of these programs with. As I said earlier, I want to increase our ability to export, but I want to know if what we are doing now is successful, what are the measures that calculate that success. I also mentioned, and I will come back again on this, opening up a market to Cuba. We refuse to open up a market to Cuba, for a whole variety of reasons, which could increase our exports, but we are going to look at $53.5 million to expand programs.

What I do not have, and I do not know that the Committee has, is any way of judging the use of the current funds, both the mandatory funds and discretionary funds, that allow us to get to that goal.

If you can provide us with that, the criteria, we will let you know what it is specifically that we would like to have in order to look at how we try to treat the $53.5 million for the next year.

[The information from USDA follows:]

The Foreign Agricultural Service (FAS) uses an Internet tool called the Unified Export Strategy (UES) that is designed to coordinate and manage complementary programs. Applicants for the Market Access Program (MAP), Foreign Market Development Program (FMD), Technical Assistance for Specialty Crops program (TASC), Quality Samples Program (QSP), and Emerging Markets Program (EMP) submit a UES document which can serve as the application for any or all five programs, as well as the organization's activity plan. This allows applicants to identify market constraints (or opportunities), strategies to mitigate (or exploit) them and request program resources to implement the strategies. The UES allows FAS to see all programming requests at the same time and how they relate to one another. This system ensures coordination of resources. Each UES is reviewed by FAS Office of Trade Programs as well as by FAS Field Offices.

Each recipient of program funding is obligated to annually report results against the performance measures established in their UES. FAS staff evaluate reported results. Reviewing all UES results in 2003, participants met about 30 percent of their stated goals. By 2008, participants met about 58 percent of their performance measure goals. Reaching about 60 percent on this measure reflects both sufficiently challenging goals and a meaningful level of results.

The National Export Initiative (NEI) would double the amount of funding for TASC as well as FMD. To ensure the effectiveness of TASC, FAS currently conducts a thorough review of proposals to determine their likelihood of success and the potential value of return. The proposals are initially reviewed to determine if each proposal is eligible for TASC funding according to the program regulations. If a proposal is eligible for funding, relevant FAS Washington program areas and overseas posts review the proposal. In addition, FAS seeks input and expertise from the Animal and Plant Health Inspection Service (APHIS). Applicants must include project objectives and corresponding performance measures in their application. Each reviewer examines the importance of the phytosanitary concern, the ability of the applicant to implement the activity, and the value of the activity in helping mitigate the issue.

TASC participants are required to submit a progress report, at least on an annual basis. A final report is also required, which reports results against the performance measures presented in the approved TASC proposal. In addition, all TASC projects are subject to review by the FAS Compliance, Security, and Emergency Planning Division, to assure program funds were managed properly and in accordance with program regulations.

Since 2005, FAS has tracked a number of different types of program metrics: UES performance measure results, industry contributions, total exports in countries and product lines where MAP or FMD funds are expended, various measures related to small company participants (i.e. number of companies making their first sale), and an export multiplier. FAS has moved away from using an export multiplier, towards program cost-benefit analysis, as a better measure of program success.

Market development programs contribute to FAS' agency goal to help "U.S. farmers, ranchers, and agricultural industry maintain and expand exports." FAS commissioned a cost-benefit analysis in 2007 with an independent economic analysis firm, Global Insight Inc., and recently received the results of an update of that study. The study analyzed the impact of the increase in foreign market development investment that took place under the 2002 Farm Bill through 2009. It concluded that every dollar of increased investment in the MAP and FMD resulted in $35 in exports. It also reported that U.S. agricultural exports were up $6.1 billion in 2009, compared to what they would have been without the increased investment in market development.

Additional commodity specific studies highlight the beneficial economic impact of market development programs. The U.S. Grains Council annually assesses their market development program's trade impact; this study is conducted by Informa Economics LLC. In July 2009, the study concluded that the Council's market development program accounts for $395 million in U.S. exports of the targeted commodities on an annual basis. These exports increased U.S. producer incomes annually by $915 million. This is a return of $50 for each dollar of industry and U.S. government funds invested in market development. The U.S. Wheat Associates' market development program cost-benefit study concluded that …" U.S. wheat export promotion had a large and beneficial impact for producers and the economy that far exceeded its cost." The overall average net producer revenue, derived from the combined producer and FAS market development expenditures, was estimated to be about $117 for each dollar spent.

To achieve the objectives of the NEI, the proposed $34.5 million increase in the FMD budget, which has remained relatively constant since the early 1980s, will augment ongoing efforts to address long-term barriers to export growth and allow organizations to conduct new activities in existing markets and to target new markets. Increased funding will also provide new opportunities for participation and innovative activities, such as promoting broader international acceptance of the biotechnology products and combating persistent sanitary barriers to U.S. red meat and poultry. Addressing these long-term barriers will maintain market share in developed markets and allow for expansion in others.

The $9 million increase proposed for TASC will add impetus to actions to address unique barriers that prohibit or threaten exports of U.S. specialty crops. The proposed increase in TASC reflects the growing importance of specialty crops for U.S. agricultural export growth and the contribution the program has made in resolving trade barriers.

The additional $10 million provided to the FAS will enable an expansion of export assistance efforts, in-country promotions and trade enforcement activities to remove non-tariff trade barriers. These funds would facilitate the participation of a greater number of small- and medium-sized enterprises (SMEs) at foreign and domestic trade shows, increase the number of trade missions, and increase the number of foreign buyers at U.S. trade shows.

Mr. Kingston.

FOOD ASSISTANCE

Mr. KINGSTON. Mr. Brewer, I do want to emphasize that I do think we are very interested in which ones are more effective and which ones are not.

One of the things—MAP, for example, has been described as corporate welfare in the past, so we do need to be able to get back to people and say look, this is where the dollar invested brings a dollar return.

I wanted to go back to you on the food assistance in Africa and some other places, on which countries does it seem to be working the best and what is our progress, and then anywhere else around the globe.

I know you have a pretty big world vision.

Mr. BREWER. Thank you, Congressman. A couple of places, and again, I want to expand this a little bit beyond food aid, again, we are in this whole of Government approach. I will expand it a bit further just to aid in general.

I think Botswana is certainly a country that has, in part through U.S. assistance, has moved from a position of being one of the poorest nations on the continent to one that is in the middle tier, middle income tier.

Mr. KINGSTON. I want to mention, right now, they cannot get developmental aid because they actually have done so well. They are working on a huge water project in the north of the country and they cannot get any of our aid on it.

I raised that question with Secretary Vilsack. You and I may want to pursue that. Sorry to interrupt.

Mr. BREWER. No, that is quite all right.

Again, Botswana would be one. Just to kind of reach out, I will expand a little beyond Africa and go to Indonesia, certainly a country which started off as one of the poorer nations and has moved forward. Lebanon.

When we are dealing with a situation as we often are of having scant resources or limited resources and a lot of demand, we really have to kind of set some criteria, and one of the criteria we do use is trying to determine where are countries within the income spectrum.

As I say, Botswana, Lebanon and Indonesia are clearly countries that start off needing and receiving a great deal of assistance and have now gotten to a level, an income level, where that U.S. assistance is not needed as much, so we are able to try again to focus our assistance in areas where we can work effectively with our partners and get the best bang for our buck.

Mr. KINGSTON. There are so many other countries that are out there.

Mr. BREWER. A great deal.

Mr. KINGSTON. I think we are giving them aid but there is no real rhyme or reason where we are going with it or why we are going there or whatever.

NON-GOVERNMENTAL ORGANIZATIONS

I know in Haiti, the USDA put out a request recently, this week maybe, on aid for Haiti, to NGOs.

Which NGOs do you think are the best ones?

We always kind of shy away from that. I know they all mean well, but certainly, just like with basketball teams and corporations and politicians, you got some who are better than others. I think it is time that we start talking in terms of what NGOs are really good and effective and not just good P.R. people and not just good politicians, but who actually are making something happen.

Mr. BREWER. Congressman, the best way I could answer that one now, quite frankly, is I will refer you to the process we use. When we are out trying to identify our partners in Haiti and in whatever countries we work with and use non-profits as partners in those countries, we have a very vigorous compliance as well as application process of how we identify our partners.

If they are successful in our very vigorous process to become a partner for us, we see them as a valuable and effective partner.

I think I will leave it there. I do not want to name names.

Mr. KINGSTON. Someone could hit a grand slam in one area and strike out in another country, and that is actually to be expected.

I think what would be good in-house is for you with your business background to take country-by-country looks. In some areas, host countries are probably going to be the best way to go, and in others, they are not.

You know, kind of figure out what is working and what is not. I think we give foreign aid maybe to too many countries too efficiently, and maybe we should every three years take a look at the whole thing from ground zero, which ones did it really make a difference and were we making progress.

Mr. BREWER. We are certainly taking steps to do that, Congressman. One of the things we are doing and certainly paying a great deal of attention to is our monitoring and evaluation efforts, our compliance efforts, so we have a program certainly of compliance and monitoring and evaluation.

It is not as strong as we want it to be, but we are certainly taking steps to do that. We certainly agree with you wholeheartedly, what you are suggesting, and we are in the process of doing that. We are doing that and seeking to improve it. Again, not only within USDA and our food aid programs, but whole Government wide, working closely with our partners, again to collaborate, monitor and evaluate our programs.

We are right on the same page with that.

Mr. KINGSTON. Thank you.

Ms. DELAURO. Mr. Latham.

Mr. LATHAM. Thank you very much. I apologize for being a little late. I had another hearing going on this morning.

CROP INSURANCE

Mr. Murphy, I just wanted to ask you, I know you are in negotiations, I think, as far as contracts with the crop insurance folks, and I guess rather than get into specifics about where you are, unless

you want to comment, what do you see long term as far as where the Department wants to go?

We have seen the Federal Government take over direct student loans, huge expansion of a lot of different areas of Government takeover.

Do you see it remaining in the private sector? What is your long-term plan?

Mr. MURPHY. Yes, I think myself as well as everybody in the Administration I have dealt with would like to see it stay in the private sector, sir; yes. It has been a very efficient system.

The participation numbers are at some 80 percent participation, very high levels of coverage. It has been due to the private agency system, I think.

Mr. LATHAM. There is no discussion of——

Mr. MURPHY. There are always people who have different ideas of delivery systems. There always has been. What has been a concern lately has been the increasing cost of delivery, which is expressed in the administrative and overhead subsidy, as well as the underwriting gains.

In 2006, those costs combined were $1.8 billion. This year, 2009, it is just short of $4 billion.

I think the primary concern of everybody is trying to get a handle on the costs while ensuring that the program continues to be delivered in a very efficient manner across the country.

Mr. LATHAM. Okay. Do you have any update about where you are?

STANDARD REINSURANCE AGREEMENT

Mr. MURPHY. Yes. We just issued the second draft late February. We are currently meeting with the companies this week in Kansas City. Next week, here in Washington, D.C. That is getting their input on the second draft.

We are going to break out into smaller groups. We just agreed with the industry to put together some four or five small groups to try to take care of low hanging fruit, where there is some minor disagreements. That is going to occur in early April.

We expect to have the final agreement out on the street at the end of April, that is what we are looking at now.

LEGISLATIVE PROPOSALS

Mr. LATHAM. Thank you. I am not sure who to direct this to, probably FSA. In the budget request, there is talk again about limiting farm payments, storage payments on cotton and peanuts, of course, more taxes for businesses in the form of new fees.

Can I just ask, is there specific legislation you propose to change the current Farm Bill that is not that old to begin with? The request is going to have to go to the authorizing committee to make those kinds of changes. Are you proposing anything?

Who wants that? Probably nobody. [Laughter.]

Mr. MILLER. Congressman, thank you. Yes, sir. There are a number of proposals in the budget. I think as you will note, compared to last year's budget, the suggestion concerning payment limitations is significantly different than what was included last year.

We believe this is certainly consistent with what the President had talked about throughout the campaign and since he has been in office. This is an issue that has already been discussed at various times by the authorizing committee.

It is a way, we believe, to more clearly target the limited resources that we have for commodity program payments to those most in need and reducing the number of producers based on an adjusted gross income calculation from being able to receive full benefits under the commodity program.

There are a number of other, as you suggest, revenue proposals in terms of fees. This Administration has reviewed those options and we have looked at what other Administrations have proposed in that regard as well.

We believe this represents reasonable fees for the services that the Federal Government is providing.

We are happy to work with the authorizing committees. We have indicated to them our willingness to work with them as we find ways to deal with ensuring we can move ahead with a very solid foundation in terms of our farm programs and domestic assistance to producers while at the same time recognizing the fiscal situation that we currently find ourselves in.

Mr. LATHAM. I see I am out of time. If I could follow up here just for a second.

Ms. DELAURO. Yes.

Mr. LATHAM. Thank you. I guess the frustration you are going to see, you know the authorizing committees have not just said no, they said hell, no. They are never going to adopt this kind of stuff.

Knowing that, why do you continue to make these kinds of requests? It is not going to happen. You know that.

Mr. MILLER. First of all, we are not convinced it is not going to happen.

Mr. LATHAM. Have you spoken to the chairman over there?

Mr. MILLER. We believe that it is an appropriate approach to the farm programs, and quite frankly, there was substantive change in the payment limitation regime contained in the 2008 Farm Bill.

We believe it should go somewhat further. It is not like we are suggesting that the commodity payment programs be eliminated, but we are suggesting some additional movement in that regard.

Mr. LATHAM. Unless you have a news flash, it ain't happening. Thank you.

FOOD AID AND DEVELOPMENT ASSISTANCE

Ms. DELAURO. Thank you. Mr. Brewer, earlier this month, the Subcommittee heard testimony from GAO. This was on a new report of evaluating the Government wide global food security strategy.

One issue that was identified in the report was a shortage of expertise at USDA. GAO found that FAS generally oversees food aid programs from its headquarters and regional offices. The report cited a USDA review of staffing that concluded that additional positions are required to support food security priorities.

The witness from GAO also indicated that in reality, FAS had been all about trade, not development assistance and food aid. He said when his staff visits FAS, staff in the field, and this is a quote,

"They come back with stories about basically the person has done very little on the development side because his portfolio is on the marketing side." That is from the GAO.

Given the conclusions in the GAO report, why is it your budget does not propose to hire any new staff?

Mr. BREWER. Although USDA does not have development—dedicated foreign service staff, our foreign service officers in the field have the ability to employ the significant technical expertise residing in other mission areas in USDA as well as in our U.S. land grant university system when we have issues of development going on, as well as, again, going back to our collaborative work with AID. We—so we have—while that assistance can—does not—or that expertise does not sit in our offices, per se—and I question the extent of the GAO report.

I think our people through just the work that they have to do, particularly in particular countries, they have a knowledge and a working understanding of development issues. But that certainly can be supplemented by our contacts and relationships within our land grant university system as well as our partners in AID. So I think more collaboration, more effective use of that.

Ms. DELAURO. Do you see your role or the role of the agency as to be focused on the marketing and the trade side, versus the oversight of the—if you will, of the food aid side and that effort.

Mr. BREWER. No, ma'am.

Ms. DELAURO. Where do you see your priorities?

Mr. BREWER. I see our priority as both. I think that we have a responsibility, and our mission is to open export promotion and the management of food aid. So our priority is both, and I believe we are doing both, but can effect—can certainly do it more effectively by our—the relationships that we are building and the contacts that we have among our partners in government and outside of government.

FAS STAFFING

Ms. DELAURO. I understand Land Grant and USAID. There is nothing in the budget that shows an increase in staff for work on hunger security. And then you've got an increase of $53.5 million for an export initiative, but you actually have no staff attached to that as well. It looks as if the FAS budget shows no increase in staffing over 2010. Is that inaccurate?

Mr. MILLER. Madam Chairwoman, let me respond. I think you've raised a couple of issues here. First of all, in terms of the food aid or more broadly speaking, the food security initiatives, as Mr. Brewer has pointed out, we're now looking at a whole of government approach. Just last month, the Secretary appointed within his office a food security coordinator who will be working with our folks at FAS that are directly engaged in food aid, food security and capacity building initiatives. And we do have a rather robust program there, and we do have a group of people that are dedicated to those activities. The purpose of the food aid security coordinator in the Secretary's office is in fact to ensure that we are coordinating our activities with our other partners in this, which are primarily State and USAID. We believe there are significant synergies that can be developed by that kind of coordination. So

that we avoid the possibility of duplicating activities, we work together to more clearly identify many of the areas where we believe we can achieve success, as Mr. Kingston suggested we should be doing. And so we are already dedicating personnel to this effort.

In terms of additional personnel, at this point we believe that with the assistance of the Secretary's office and the other agencies involved, that we can satisfy those needs and actually be more efficient and more effective at ensuring that our food assistance and food security dollars are achieving the results that we all would like to see.

Ms. DELAURO. I—I'm sorry, Mr. Brewer. I didn't mean to——

Mr. BREWER. I'm sorry, Madame Chairwoman, if I could just add to——

Ms. DELAURO. Sure. Sure.

FAS STRATEGIC RE-ENVISIONING

Mr. BREWER [continuing]. What the Under Secretary said, as well as your question about additional staff. One thing that we are doing currently underway in FAS is our re-envisioning effort. That is an effort to restructure the agency more efficiently and effectively. Part of that effort is to also make sure that we are staffed at the appropriate levels. So we are underway. That's been going on for the last year, and the effort of looking at the way we're structured, our personnel in our various program areas. And we are addressing our staffing issues through that initiative as well. So we are looking at and paying attention to whatever we're asking for within our program areas and with our—in our export initiative we are certainly making sure that we have the proper staff levels to do that, so that's being handled on an ongoing process. We're hiring now and have been doing that, and see through that process to continue to do that.

Mr. MILLER. Could I follow up with one more comment?

Ms. DELAURO. Sure, sure.

Mr. MILLER. We focused this in terms of our budget for next year and looked at it in terms of what we are doing just within the U.S. government and how we deliver on these programs and try to achieve success. I also want to point out that this is an international effort now, and I think Secretary Clinton's initiative supported by Secretary Vilsack suggests that there is new emphasis on greater international coordination and collaboration in this effort. Quite frankly, I think we all recognize that efforts in the past have certainly not met the expectations of the United States or other developed countries who are very interested in this. I see now a much greater effort in again ensuring that we have a collaborative process, that we can do things better maybe in the United States in some aspects. Other countries bring other things to the table. We've got to find a better way to coordinate that effort.

COORDINATION OF TRADE AND DEVELOPMENT PROGRAMS

Ms. DELAURO. I understand that, and I think that that's—and I really do, I applaud the initiatives in this area. But I will also say I think you do have to come to grips with what the GAO said, and it would appear that the people who are on the ground in these

areas view their portfolio and their mission as one that is market oriented, trade oriented and not oversight of food aid programs.

I would also suggest that—and in keeping with something that my colleague Mr. Kingston has talked about, I think in terms of coordination, we need to take a look at the coordination of the trade promotion programs and have a coordinator that's looking into those and see where duplication is occurring or not occurring. Because we are—and I want to promote trade, but it would appear to me just on the surface, and we haven't examined that, that we're looking at serious duplication in these programs, and we're not looking at—we are—and we will continue to do it, emergency aid.

But part of the mission is to look at development, development of these—of agricultural development here and—so that you allow these people to be able to produce, produce better, get better yield, better crops, to be able to deal with their own economic security, rather than us just providing emergency aid. And I see, quite frankly—this is not you. I mean, this is historically here. I see very little emphasis on the development side. And not only from the United States.

But overall, if you take a look at the Chicago Council's report, they have said that development assistance from not only the United States, but more broadly, internationally, has seriously declined over the last several years or the last decade, putting these countries in the position of just being—asking for a handout in order for them to be able to survive, which ultimately causes us a national security threat. Because if they can get food from elsewhere, they're going elsewhere, to whomever it is. And what we need to be doing, and I take it—you take it seriously—I do, the mission of the USDA is to build on the side of production and the development of their capacity to be able to grow food and to be able to be sustainable. There's—and I think we share that mission, though I don't see a document or a budget review that gets—moves us in that direction. Sorry, Mr. Kingston. It's——

INTERNATIONAL FOOD AID

Mr. KINGSTON. Well, thank you, Madam Chair. I wanted to say also, you know, on that, I believe the USA gives 50 percent of all international food aid. Isn't that correct?

Mr. BREWER. It's a high number. It sounds right.

Mr. KINGSTON. And I think——

Mr. MILLER. It's in that range, yes, sir.

Mr. KINGSTON. And I think Japan is second. And it—do you know where China is?

Mr. BREWER. I do not.

[The information follows:]

In 2008, food aid to all countries totaled more than 6 million metric tons. The United States provided 51 percent of all food aid. The European Union provided 6.4 percent, Japan provided 6.0 percent, and China supplied 0.64 percent of the total.

Mr. KINGSTON. You know, China is doing a lot of, I don't know, economic adventurism around the globe, South America and Africa. And it seems like while we're feeding the folks, they're building the structures, the roads, the bridges, and maybe that makes a louder statement, because—and I'm not certain that it is or not. But people get agitated that we don't have enough forces in the coalitions

in Iraq and Afghanistan. They ought to look at the food aid. We don't have—we really don't have enough international community support in that either. And I don't know if you want to react to that. I just want to mention that. But I think what the Chair is saying is right. I mean, you know, we keep doing the short gap food—and I've worked at the homeless shelter at our church. And you know, I always say, okay, you want to put on your halo, dust it off for the day and feel good about yourself. You know, it's a quick fix for you. But—and I just don't know if in the long run you're doing as much as you could be doing for the people who are getting the aid.

Mr. MILLER. Let me say generally——

Mr. KINGSTON. And I would certainly not hold any of you guys responsible for this direction. I'm just saying as a country we need to——

Mr. MILLER. No. I think——

Mr. KINGSTON. We need to start having these discussions.

DEVELOPMENT ASSISTANCE

Mr. MILLER. I think we would agree generally with your comments. And I think we are in the process of making what could be some very substantive changes in what we viewed both as emergency food aid in the past, versus developmental assistance, as I believe that's the point the Chairwoman was getting to. We are going to continue to provide emergency food assistance. The disaster in Haiti is a critical example of where that is sorely needed, where the United States, whether it's through USDA, USAID or other agencies, is going to respond. We need to respond. It's our global and moral obligation to respond.

But I think also looking at development assistance is something where we've been having a very substantive discussion just in recent months as part of Secretary Clinton's global food security initiative. And I think you raised a very good point, Mr. Kingston. We need to be looking at this in terms of first of all, how can we enhance productivity in many of these countries? And that's something the Secretary is very interested in accomplishing, rather than just providing them assistance year to year, and creating that kind of dependence.

I think you've also identified a key aspect of our whole of government approach, as well as what we're trying to do in terms of international cooperation, and that is just producing an additional quantity isn't adequate. We have to find a way to control post harvest losses, which are a huge problem in many developing countries, where in some cases half or more of the production is lost due to insects, due to the lack of adequate storage. We need to help those countries figure out ways to build marketing systems, to have input supply systems, to have financing if we want farmers to be able to farm and consistently raise crops. Those are issues that we're beginning to tackle on a very large scale. You know, can we do this for everyone in need around the world all at one time? No. I think we all recognize that that is impossible.

AFGHANISTAN DEVELOPMENT EFFORT

I think the activities that we have going on in Afghanistan with our provincial reconstruction teams and the effort there, again across the government effort, is a demonstration of some new thinking in that it's not just enough to provide food. It's more important that we provide them the opportunity to produce food for their own country, potentially to reestablish what had been historical markets for their commodities, and improve the economy and stability in a country, whether it's Afghanistan or somewhere else. And as I often told my friends in commercial agriculture who want to trade, the best thing we can do is improve the income levels in countries if we want good customers commercially in the future. And I think that——

Mr. KINGSTON. Have you had a chance to get to Afghanistan yourself?

Mr. MILLER. I have not, sir.

Mr. KINGSTON. You know, you have a great wheat background, and that's the most promising crop. It would be—I think it would—you know, when you can, I think you would really be valuable on the grounds there, yeah.

Ms. DELAURO. Mr. Latham.

MARKET ACCESS PROGRAM

Mr. LATHAM. Thank you very much. And actually, I want to commend the department for actually being a part of what I think will be the long term solution in a place like Afghanistan. I will never forget talking to some of my National Guard people who had come back from Iraq, and I asked them, "What's the one thing that you think we needed"—this is back when things weren't going so well, that we needed actually for the government to do that they weren't doing. And he said, "Basically, you know, the followup. Where's the rest of the government?"

Because the—there was—they would go in and fight these battles, clear out the bad guys, and there was no fill behind it at all and—with USDA. And I think that's our best opportunity in those areas. I think there's other things that are involved security wise for those families that are farmers over there, that is maybe a larger issue than what crop they plant sometimes too. But I digress. I'm sorry.

But I am concerned about the cuts in the Market Access Program. And apparently while I wasn't here you mentioned something about how—what the payback is on this. I know the wheat people—and I think it's the study that came out—came out of FAS, that said that there is a $23 return for every dollar invested as far as market promotion, in the wheat industry, anyway, according to this article. And I just don't understand. At this point in time when you would want to promote exports to promote sales—we've got pending trade agreements out there that's being stalled for various, various reasons, but—you know, which is something that we could open up some markets and maybe we wouldn't have to have quite as much market promotion, if in fact we were able to sell stuff without tariffs overseas. I don't—can you elaborate on the thinking

behind this? It just seems like the investment is certainly well worth what it costs for the return we get.

Mr. MILLER. Mr. Latham, let me respond this way. First of all, as you're aware, the budget includes significant new money for 2011 for a variety of export promotion activities. In terms of MAP, consistent with what the President proposed last year, yes, there is a modest cut proposed in the Market Access Program funding. But at the end of the day the level of funding for the MAP program is still substantially higher than its historic average over a period of time. It would be at $160 million, so that's not an insignificant amount.

I am familiar with many of the studies such as the one from U.S. Wheat Associates concerning the effectiveness of MAP. I talked with our cooperators and other MAP participants on a fairly regular basis, and yes, they clearly can provide information to show their level of success and returns in terms of utilizing that as well as our Cooperator—Foreign Market Development Cooperator Program. I think the issue with MAP is one of if we accept, and I do, that there has been a good return to the industries from the MAP dollars that have been expended, that the industries could and should probably be willing to put a little money of their money into the program still with U.S. assistance.

Secondly, we face some additional challenges in global trade that just promotion are unlikely to resolve for us, particularly in the areas of sanitary and phyto-sanitary trade barriers that are erected that are not based on science. This has a big impact on our livestock exports and a big impact on our speciality crop exports, one of the reasons for the suggested increase in the Technical Assistance for Specialty Crops program. We believe we can be more effective in resolving a number of those issues with additional funding for FAS to directly engage in those kinds of discussions, with additional funding for the TASC program and through the Cooperator program. In addition, we believe the——

PENDING TRADE AGREEMENTS

Mr. LATHAM. If I might just interrupt. I ran out—okay, thank you. We've got three trade deals sitting there that could be done tomorrow with Korea, Columbia, Panama. Is there no one at USDA yelling and screaming and saying, "Let's do these things," to push this, to open up those markets, so that we can have, you know, a fair basis? Obviously, the stuff that's being brought into this country, there's no tariff, but for us to sell into them, there's a tariff on our goods coming in. I mean, I would think someone at USDA would be just going nuts over there saying we're spending all this money on market promotion and we've got these deals here that would expand our markets dramatically. Is there anybody saying, "Let's move these things?"

Mr. MILLER. Mr. Latham, USDA has been supportive of concluding the negotiations on those three agreements and getting them passed. That was true of the previous Administration and is equally true of this Administration. But we also recognize that while we believe that there are significant benefits to U.S. agriculture that could occur under each of the three pending trade agreements, we're also cognizant that there still are some out-

standing issues related—different outstanding issues, but outstanding issues that are related to those agreements.

We also know that pushing Congress to consider those agreements when the time is not ready is not a recipe for the success that I think we would like to see regarding the final conclusion to those. But the President has indicated his interest in those agreements. My experience with USTR is that they also would like to get to the point where we could consider ratification and would, in fact, ratify those three outstanding agreements. But it does require, I think realistically, that we resolve the remaining outstanding issues with those countries. For Agriculture parochially, I think we believe that each of those agreements conveys significant benefits to U.S. producers and exporters.

Mr. LATHAM. Okay, thank you.

Madam Chairwoman.

CUBA TRADE EMBARGO

Ms. DELAURO. Just on that note, I would ask my colleague Mr. Latham and I'll ask you, Mr. Under Secretary, do you think that we ought to lift the embargo on Cuba to open up markets?

Mr. LATHAM. Well, I think as far as agricultural sales, we have that. And it's just a matter of how the credit is applied, so that's already in place.

Ms. DELAURO. Well, no. I mean, Cuba is under severe restrictions and there isn't any other country in the world that's under those restrictions with regard to the credit, and the—cash on the barrelhead as well. It's a very, very different set of circumstances. Let me ask you, Mr. Under Secretary, and I didn't get to this—do you think we ought to lift the embargo on Cuba to open up new markets?

Mr. MILLER. Madam Chairwoman, let me respond this way. First of all, in my previous life I was a farmer and actually produced crops that would be exported——

Ms. DELAURO. Right, exactly.

Mr. MILLER [continuing]. Potentially to Cuba.

Ms. DELAURO. Yes, sure.

Mr. MILLER. So I fully——

Ms. DELAURO. Connecticut, we can't send tobacco, because they—that's not, you know, so—but rice and wheat and a whole bunch of other things.

Mr. MILLER. But I do fully understand—

Ms. DELAURO. Chicken.

Mr. MILLER [continuing]. The interest of U.S. industry and exporters in the Cuban market, and appreciate their desire to see that market open more fully. Just in the last year, with the help of Congress, some strides have been made to make trade with Cuba easier. But we all recognize the situation with Cuba is complex. It is extremely sensitive. It has significant foreign policy implications that I think extend well beyond just agricultural trade with Cuba that we recognize as I believe you indicated lasted through 11 Presidents. So, you know, I'm also cognizant of that. But yes, we believe there are significant agricultural opportunities in Cuba, but we're not there yet.

Ms. DELAURO. We certainly are not, and well, that's an issue for another time. But there are those of us who are working on that aspect of it as well.

OIG RECOMMENDATIONS FOR RMA

So let me move to RMA and let me take a look at some of the OIG recommendations, Mr. Murphy. We asked the OIG to give us a list of their recommendation in the FFAS mission area that have not been implemented, so that we could review them before the hearing. There were a few open recommendations for FAS and for FSA, but there were a number with regard to RMA over the last eight years. The open recommendations about key issues such as quality control, incorrect loss determinations, improper payments, failure to act on a company's material deviation from RMA policies and practices.

Perhaps the most serious were the many recommendations following the IG's conclusion last September that—and this is the IG, this is not me, RMA lacks a comprehensive, systemic and well defined strategy for improving the integrity of the federal crop insurance program. Instead RMA's primary focus is on program delivery, providing and expanding crop insurance coverage for producers. Disturbing finding, I think you would suggest. So—and disturbing I think—you know, we have—the subcommittee has, by the way, supported giving RMA additional funds for program integrity. But the concerns that are raised by the report don't suggest that the money is being well spent. What is the problem getting to closure on the recommendations and more fundamentally, to building integrity into the crop insurance program?

Mr. MURPHY. Well, I'll address the findings first. Some of the findings go back quite a few years.

Ms. DELAURO. Right. I'm not suggesting they're your—on your watch.

Mr. MURPHY. Right. Unfortunately, I've been with the agency quite a few years, so——

Ms. DELAURO. Okay. Well, then maybe it is on your watch. Then maybe it is on your watch.

Mr. MURPHY. I think a lot of them are being implemented. One of them is the combination product that we're bringing out in 2011. Final rule is going to be published next week. I think that will address—some of those issues go back quite a way. I think integrity is a major issue with the agency. I think it's institutionalized and in all parts of the agency. Now as to whether we have a written overall comprehensive strategy, we do not. However, this is a point that the Secretary has taken his own time to discuss with me, and we are working with OIG to get a written strategy put together for them.

RMA COMPLIANCE FUNDING

Ms. DELAURO. What happened with the $1.8 million that we provided? The House did, Senate didn't. We prevailed in the conference, and I have to tell you, it wasn't an easy lift to prevail in the conference for this effort.

Mr. MURPHY. Right.

Ms. DELAURO. But no mention of any of that in any of the testimonies, et cetera. How has the—how has this helped to deal with increased compliance and oversight?

Mr. MURPHY. We are in the process of hiring 10 additional compliance investigators to assist. That will be a great help to us overall. One of the issues we have is that we're a very small agency. We have less than 500 people, and we have a huge program, a $90 billion insurance program we have to provide oversight to. So that's one of the issues. But I do thank you, Congress, for the work you did on that help. But we are in the process of hiring those right now. We do have many parts of the agency that address—and systems. One of them is data mining. This is a project that we have going on. It costs about $4 million per year. But since 2001, we've gotten about a $700 million return on it. It is a project that we work with FSA on. They are closely involved in it and they assist quite a bit. The companies are involved in it. We work with the companies on requiring quality controls. We verify those quality control programs they have. That's—the last reinsurance agreement got into that very deeply.

CROP INSURANCE OVERPAYMENTS

Ms. DELAURO. I'm going to address one more piece of this if the—let me ask my colleagues to—because this is a—I want to just finish the questions with regard to RMA. And again, this is data that is in the public domain. Federal crop insurance programs' accuracy rate is declining, and the amount of overpayments grew by 23 percent from 2008 to 2009. Let me give you a specific example. Again, an OIG report—this is from 2007, so I—but I guess you were there—reviewed 21 citrus indemnity payments, and found that erroneous loss adjustment to determinations were made on 15 of those claims. RMA has stated it has not been able to identify any trends or policy concerns surrounding its overpayments and that it may be several years before it can identify what the ongoing problems are.

You know, look, I sit in these meetings and we all do. Just—and you may—we often talk about the Supplemental Nutrition Assistance Program. It has about a 95 percent accuracy rate. It improves every year. The program is required to have continuous improvement in accuracy or it penalizes states that fail to meet the grade. And that—SNAP is the former Food Stamp Program, as you know. We keep focusing on improper payments that go to programs that assist low income populations. But FNS has strong measures in place and they are consistently improving that accuracy rate. We need to focus on programs that aren't showing this kind of an improvement.

Explain to me, if you can, why we see the rate of overpayments rising dramatically in the federal crop insurance program?

Mr. MURPHY. Well, I—Madam Chairman, any waste or abuse in a government program is a problem.

Ms. DELAURO. Any.

Mr. MURPHY. I agree a hundred percent. This is taxpayers' money. We have to be good stewards of that money. I think when you look at the work we have done improper payments at, is that

our percentages aren't that high compared to other agencies. We need improvement. I agree——

Ms. DELAURO. They appear to be growing, though. That's what—that was troubling when I read that.

Mr. MURPHY. Well, I think what OIG was doing there is looking at an area that had a known problem, and they went down—we do a lot of that ourselves, judgmental selection of policies to review when we are aware of an issue. And we do find it. We do deal with the companies when that happens. Financial penalties, a number of other penalties. We have threatened pulling companies out of the program unless they made improvements to their quality control programs. So we continue to do—but I agree, we have to do better.

Ms. DELAURO. Okay, thank you.

Mr. Kingston.

BIOMASS CROP ASSISTANCE PROGRAM

Mr. KINGSTON. Thank you, Madam Chair. Mr. Under Secretary, I wanted to ask you about the BCAP program. And I got to say, I'm really distressed on it. I think Mr. Murphy just said, you know, we need to cut out waste wherever we can. And much of the waste in government certainly is not intended to be there, but sometimes we do something on paper. It looks good, and in practicality it really isn't.

And you may remember the tax change for black liquor. I come from paper mill country, but it was a $6 billion, basically a mistake, given to paper mill companies for the black liquor, classifying it as an alternative fuel that they've been using all along.

The BCAP program is not that much different from that. You know, for years people in the wood business have always collected and gathered and transported materials to paper mills for reprocessing or transporting one way or the other. Now we're paying them $45 a ton to do it. This program started out with a projected cost of $70 million over five years and of course it's exceeded that. You're asking for $479 million now.

And I think our better bet is to just say, "We just don't need this program." We're paying people to do what they did all along. There's nothing remarkable about free money. You know, people are, you know, very excited about this program. And what I'm concerned about is if we don't kill it now, it will have its own lobbying group. It has a constituency growing, and you know how difficult it is to get out of things like this. But it could give you, you know, money for other things, so talk to me about it.

Ms. DELAURO. Would the gentleman yield for a second?

Mr. KINGSTON. Yes.

Ms. DELAURO. Because I had a question in this area as well. This is a program—there's an escalation in program cost of 30 times more expensive than the original CBO scoring for this program. I just throw that on the table. That is really astounding.

Mr. KINGSTON. And on paper it looks good, but, you know, if you come from paper mill areas, you know this is what they've always done. But now—and I kind of say now we're basically paying the mileage for kids to get the beer on spring break. It just wasn't necessary.

Mr. MILLER. Mr. Kingston, let me make a couple of comments and then I'd also like Jonathan Coppess to comment on this. This is a program that is administered by the Farm Service Agency that was a new program in the 2008 Farm Bill. Last summer we issued a Notice of Funds Availability for the first half of the BCAP program. It really is divided into two sections. One that I believe you're referring to is the Collection, Harvest, Storage and Transportation program.

Mr. KINGSTON. Correct.

Mr. MILLER. And then the second part is an incentive program that has yet to be implemented, to encourage and to help resolve kind of the chicken and egg problem we have in terms of renewable energy production utilizing advanced biofuels. The NOFA was issued. There are a number of facilities that signed up to participate in this program, and that has become the basis for the budget estimates that you're alluding to.

Just recently in early February, we did issue the proposed rule for full program implementation. At the time that that rule was published the ability to participate or to sign up to participate under the rules of the NOFA were eliminated. Now we do have some outstanding contracts. We're letting those run. Under the proposed rule, significant changes have been made in this program, recognizing, I think, a couple of points that you have made.

One, we have responded to the concern by many in the industry that products that had significant value added capacity within the industry were—that the government was now subsidizing their use for energy rather than to make particle board or some other value added product. We have addressed that in the proposed rule.

Mr. KINGSTON. And I want to point out, though, a lot of the wood pellets used for energy are not used in America. The market is generally European, and so we're actually subsidizing European fuel.

ADDITIONAL RENEWABLE ENERGY PRODUCTION

Mr. MILLER. Let me point out the other major change before I ask Jonathan to comment further, is the issue of well, are we effectively subsidizing mills for what they were going to be doing anyway. We have now put a provision in the proposed rule for which we're seeking comment that basically requires that any payments be subject to additionality. In other words, we're trying to find ways to accomplish a number of things. First and foremost, we want to get products out of the forest that are causing disease and potential forest fire problems. That was kind of the initial background of the——

Mr. KINGSTON. But now Mr. Secretary, and I'm not arguing with you, because this is a Congressional program that we started. But foresters do that. They're not dummies. They don't need the government to come in there and say, "Cull your forest."

Mr. MILLER. What we were trying to do is get the slag and slash out of the forest that they do leave behind. We recognize that they take a lot of that out. They're already utilizing it in many cases just to produce energy. We're tightening that up significantly. We still want to encourage the forest industry to participate in this program, but we want to ensure that what we're getting is addi-

tional renewable energy production and not paying for what they were doing otherwise.

Jonathan, do you want to——

Mr. COPPESS. Yeah. I think to Jim's point, to the Under Secretary's point, it's important that this was a temporary aspect and we learned quite a bit as we've gone through this NOFA. Our proposed rule attacks—it goes right at some of these issues, the additional energy production, whether or not these products can go on to higher value. You mentioned black liquor. I do want to be clear that we're not paying for black liquor, and we made certain that that's not part of that.

Mr. KINGSTON. No. It's not part of BCAP. I was just saying that's a similar program.

Mr. COPPESS. Yes.

Mr. KINGSTON. But that was a $6 billion fiasco.

BCAP POTENTIAL

Mr. COPPESS. Right. And we certainly have no interest in seeing that with this program. This program has incredible potential. What we're seeing—when you talk about pulling out diseased trees or slash, there's not much of a market. And with the economic downturn, you're watching timber industry take a big hit. There is no place to go with a lot of this. This has actually spurred some efforts. I mean, we've seen it going into schools that have switched from fuel oil to wood chips and wood pellets, so it's beginning to move some of that. There are some really good stories that come out of this. But it is a new program and we have to learn what the statute says and how some of these pieces work with each other, the renewable biomass definition with what was eligible material, and that's what we saw in this NOFA. So we were able to adjust that as we write this proposed rule, and bring that in——

Mr. KINGSTON. But in your world, which is our world of tightening budgets, you're still paying people to do what they were doing. And it might be accelerated now because they're getting paid for it, but, you know, it was happening out there. And I'm real curious about schools that are now switching to wood chips. You're telling me there are a lot of schools that have gone to wood chip heating?

Mr. COPPESS. I'm just giving another example on the good side of this. I don't have a lot of them that are doing it. I'm saying these are some of the things we've seen happen.

Mr. KINGSTON. Well, I mean—but, you know, here's where we kind of get off. We have this, "Oh, yeah, a lot of people are going to wood chips." You know, they either are or they're not. I mean, you know, this is your dollar and my dollar too at work. The projected 10-year cost of this is $2.6 billion. And I'm just saying, "Hey, gosh, if we can't cut this one, what are we going to be able to cut?"

And I don't know why you all are defending it, because it was put on you by Congress. It's not like was the Administration's baby that they said, "Oh, this is a great program." I mean, I think we can say, "Look, there were a lot of things in the Energy Bill that we did that we supported." In fact, I was one of the Republicans that supported one of the Democrat Energy bills, and I'm very interested in a lot of these things. And Mr. Latham and I have had

discussions about ethanol, which he doesn't approve of, you know, in terms of my position. But I'm just saying good gosh, this is one that we need to not just take back to the drawing board, but we need to kill it.

Mr. COPPESS. Well, again, I think we've put some very significant restrictions in the proposed rule. As we finalize that, I think that will be an important part of it. I guess I would be cautious about wanting to kill a program that we haven't even gotten implemented fully and up and running to see what it does. We're talking about one part of it.

Mr. KINGSTON. Yes, but remember—and I don't want to say—and I'm arguing with you in a good way, but here, as soon as you get this developed, you know what happens in this town, association group, lobbying group, and it's—they're never going to let it go away, never. So it's not like, well, let's give it three or four years and see what happens. The folks out on K Street don't care. They know what's happening. They're getting free money out of something that they were doing already, and these are my peeps.

Mr. MILLER. Well, in——

Mr. KINGSTON. They're not in Connecticut.

Mr. MILLER. I understand that, Mr. Kingston. But also I don't think it's our view certainly within my mission area, and I don't believe it's the view at USDA, that we were in the position to selectively determine which aspects of the 2008 Farm Bill or other legislation that we want to implement because we like it. Congress did mandate this in the 2008 Farm Bill. We did issue a NOFA. We learned a lot from it. We have proposed very substantive changes in this BCAP program.

I hope you will provide your comments during the comment period, which is still open. Those will be certainly taken under significant consideration. But it's our goal to try to meet the intent of Congress and learn as much as we can, while fulfilling I think the real goal of Congress, and that is to move us to the next step in terms of renewable energy production, and that's what we're attempting to do, sir.

Ms. DELAURO. Mr. Latham.

Mr. LATHAM. I guess I was somewhat taken aback when you said you can't pick and choose what part of the Farm Bill—you know, in our previous conversation about how you wanted to change the Farm Bill that's in place, and—but now you can't do that. I was just——

Mr. MILLER. And we are implementing the Farm Bill, we believe as it was written. But if there is legislative action, sir, we will certainly do our best to implement that, and we have proposed some changes.

PORK LOAN FIELD GUIDANCE

Mr. LATHAM. Mr. Coppess, I hate to leave you alone over there. A few questions on the pork industry concerns on this loan guidance that you've initiated, regarding your proposal to expand poultry loan guidance to include pork operations. It seems that USDA is about to regulate the pork industry the same way that you do with the poultry industry. Everything about pork is dramatically different. I'm sure you're probably aware of that, the types of con-

tracts, the length of contracts, lending requirements. And I would tell you my pork producers out in the country, and if—I don't know how much time you've spent in Iowa, but we have about six, you know, hogs for every human in Iowa, and so it's a huge industry, obviously.

In the past, you know, several years, pork producers of all kinds have voluntarily and sometimes involuntarily left the industry because of the prices and very bad economic climate as far as a pork producer and livestock producers in general. And it's impacted both producers and the growers alike. A lot of the—some of the smaller operations have in good faith built buildings and started producing for some companies that then went bankrupt and they're sitting there with buildings half paid off, and this is going to be a problem as far as them securing any kind of credit going forward if these fluctuations is out there. They really believe that it will make it more difficult for lenders to work with the farmers until they can get a contract started and start generating some income in these buildings that are empty now. Tell me, doesn't this make it more difficult for the pork producers? There is a lot of pushback, if you may not be aware, with the pork producers on this.

Mr. COPPESS. I am very aware of it, and thank you, sir. We actually met with a group of pork producers yesterday to discuss this further.

I want to be clear, and when we talk with them, explain this as well: This is not a new regulation or anything on the pork industry. What we're trying to do is with the lending programs that FSA provides—and it's a limited pool of money that we have to be able to help those producers that have generally been turned down by other credit institutions to have a chance. It's the first opportunity oftentimes to get into farming, get started, get up and running.

So we certainly are very aware of the credit situation and the concerns that are out there. What we're putting out is really guidance to our lending officers about how we evaluate these in light of the credit situation, and how we can serve with our funding pool.

So what we're saying is that, in sort of a business justification for making these loans, to make certain that when we loan to a pork operation or new pork farmer, that there's a contract in place that we then have the justification, we have the certainty that those loans can be repayed, and that that farmer is set up to be successful, and not have a problem.

So it's really just evaluating the length of time of the contracts, that they can be terminated only for cause, and that they are guaranteed sufficient opportunity when they put a barn up, that the pigs will be there, that they make money and pay back the loans.

So this is really internal guidance on how we do our lending decisions.

PORK AND POULTRY DIFFERENCES

Mr. LATHAM. The concern is the recognition that maybe a chicken is different than pigs, you know, and that the industry is entirely different. And if you're going to use the poultry model, it probably will not work in the pork side?

Mr. COPPESS. Yeah. I understand that very well. And if we mischaracterized it a little bit—we did this kind of guidance earlier

last year for the poultry industry. So while the guidance is the same, we're not trying to put the two in the same—we understand there are a lot of differences, and it's really——

Mr. LATHAM [continuing]. You release it does.

Mr. COPPESS. Understand.

Mr. LATHAM. Yeah.

Mr. COPPESS. And the goal or the point here is just helping to further guide the field as they make these decisions in a very tough credit environment, to make certain that the loans we're putting out, the loans we're making we can get them paid back, and that those growers have a chance to be successful.

And so it's really a part of that.

We also announced in that advance notice of proposed rule-making to get comments in now to help us begin to re-evaluate how we look at these across the board. Are there other things that we need to be thinking about in terms of how the situation in farm counties change over the years?

Mr. LATHAM. I would just be sensitive to the differences——

Mr. COPPESS. Absolutely——

Mr. LATHAM. Make sure that the pork producers are involved in the whole process. And if you're doing something like this, to reflect their needs, not just to try and fit them in with somebody else.

Mr. COPPESS. Absolutely.

Mr. LATHAM. Thank you.

Madam Chairwoman.

DISCRIMINATION BY USDA

Ms. DELAURO. Thank you.

Secretary Miller, it's been alluded to—I mentioned this in my opening comments—and I think you would agree, I know the Secretary has when he's been here about a kind of a long and a sorry history in USDA of discrimination against African American farmers, women, Hispanic, Native American farmers.

And there are efforts on a number of the fronts to provide some long-overdue remedies to these individuals, and efforts that I personally strongly support.

One area where discrimination has been pervasive is in the farm loan programs at USDA. I bring up this issue, because I'm looking at some of these settlement costs, which are significant. And I think we have to, you know, it's a judgment and it's a legal settlement.

So we're then faced with how do we find the resources for these very, very legitimate difficulties? Let me just ask you what actions are being taken.

As I say, this particularly has happened. It's been pervasive at the farm loan level. What actions are being taken to ensure that such discrimination doesn't happen again? What mechanisms that are being put in place for this?

Mr. MILLER. Chairwoman DeLauro, you raise a very important issue, one that the——

Ms. DELAURO. And I know it's a sensitive issue, and I know——

Mr. MILLER. One that the Secretary has spoken to a number of times.

Ms. DELAURO. Mm-hmm. Right.

Mr. MILLER. And during my confirmation hearing on the Senate, it was an issue that I addressed as well.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. I would have to say that when I went down to USDA personally, I didn't realize how big a problem and the scale of the backlog that we had.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. But the Secretary has certainly recognized the problem, both in terms of the class action or proposed class action issues, as well as individual cases.

Ms. DELAURO. Right.

REMEDIATION OF DISCRIMINATION

Mr. MILLER. We're working very hard to resolve those, as you know.

Moving forward, we are taking a number of actions, both within our national office, but more importantly out in our———

Ms. DELAURO. In the field——

Mr. MILLER [continuing]. Local offices, both through the Assistant Secretary for Civil Rights' office, as well as FSA, to first of all go out and see if we can better determine what is the root cause of these problems. And the Assistant Secretary for Civil Rights is heading up that operation that's going on right now.

We're providing training to our FSA personnel throughout the country. We are trying to instill upon them that one of the true benefits we have in this country, one of the real assets of being in the United States, is the diversity and how important that is.

I think we're seeing great progress. Many of these cases are old cases, and we just need to get them resolved and move forward.

I think we have seen the page turn at USDA, and I believe also at FSA; but it's something that we're going to monitor on a day-to-day basis, I think, for the foreseeable future.

Ms. DELAURO. If you can provide us with—I don't know if anything like this exists—but where the complaints have come from. In other words, across the country I know that this involves, you know, maybe most of the states, et cetera.

But I think it would be interesting to see visually where these problems are coming from, if you can do that, and provide us with that kind of information of where particularly things have been a problem.

Mr. MILLER. I'll be happy to work with the Assistant Secretary for Civil Rights in getting you the information.

[The information follows:]

USDA CIVIL RIGHTS COMPLAINTS FILED
FARM SERVICE AGENCY
OCTOBER 1, 2009 TO MARCH 31, 2010

State / County	Number of Complaints
AR	2
Pulaski	1
St. Francis	1
CA	1
Riverside	1
FL	1
Hillsborough	1
KS	1
Leavenworth	1
KY	1
Meade	1
MN	1
Itasca	1
MS	1
Tippah	1
MT	1
Roosevelt	1
ND	1
Bottineau	1
NJ	1
Cumberland	1
NY	1
Allegany	1
OH	1
Erie	1
PR	1
Las Marias	1
TX	1
Hopkins	1
VA	1
Northumberland	1
Other *	13
Grand Total	29

* Other: State and County data is not available in Program Complaints Management System.

Ms. DELAURO. Sure, thank you.

Mr. KINGSTON. Also, I think what would be of interest is the lessons learned in the litigation. Can we save that step through a legislative solution, rather than court solution, for the next round, for the women and the Native Americans?

Ms. DELAURO. Well, yeah. And there is legislation, as I said in my opening comments. There is legislation that would address a process, and there is a dollar amount affixed to that with regard to the women.

Okay. Thank you.

FOOD AND AGRICULTURE ORGANIZATION OVERSIGHT

Let me—and I guess this is, Mr. Brewer, or Mr. Secretary, let me just, I'm going to try to take this as a whole.

The Chicago Council on Global Affairs, they've been a major contributor on key global policy issues. And they were kind enough to prepare a memo for me that raised some possible areas for work, for our subcommittee, and that we could do with programs that were under our jurisdiction.

They had several suggestions. And let me just get your reaction to them.

First, they suggested there should be more oversight of the Food and Agricultural Organization of the UN. The Council believes that the effectiveness of FAO has been limited in recent years and that USDA should engage more actively in reviewing its capacity, management strategy, and policy-making and program evaluation.

In your view, should USDA do more oversight of FAO? And can you tell us what oversight you currently do with FAO, and what other work you do with them?

Mr. BREWER. Sure. Thank you, Madam Chairwoman.

We believe that the reform process is underway at FAO, and provides a unique opportunity to transform the organization into a more relevant, focused, and effective organization to tackle global food security issues.

We at USDA take it very seriously and have made it a main priority to see that FAO carries out its reforms and its——

Ms. DELAURO. What kind? Can you lay out for us what kinds of things have been done to get to that point?

Mr. BREWER. Sure. A couple of things is the agreement that is already underway to recraft FAO's Committee on Food Security as a forum for sharing best practices and developing metrics of agricultural development success. That's one of the main ones we're working on right now.

The other is also to provide vigorous oversight to make sure that FAO fulfills the number of functions that overlap with USDA's strategic objectives. That includes in the international regulators the Codex, the IPPC, to make sure that FAO establishes the SPS phyto——

Ms. DELAURO. Phytosanitary——

Mr. BREWER. Phytosanitary, thank you, related standards, and to support the capacity building in developing countries.

Ms. DELAURO. Who will handle that for you? I mean, who is going to do that?

Mr. BREWER. Within USDA?

Ms. DELAURO. Within USDA. Who will do the oversight?

Mr. BREWER. Well, we have an office——

[Discussion was held off the record.]

Mr. BREWER. Our mission area, Under Secretary? Is it FFAS? I believe we'll handle that.

So that would be under us. We have an office for Codex, as well as within our agency. So let me make sure of that.

Ms. DELAURO. Okay. But if you can't—just if you can——

Mr. BREWER. I can get you the exact——

[The information follows:]

The U.S. Codex Office within USDA's Office of the Undersecretary for Food Safety serves as the U.S. Codex contact point and works closely with the U.S. delegates to various Codex committees, as well as government agencies, Members of Congress, non-governmental agencies and members of the public, to represent U.S. interests in the Codex Alimentarius. The United States also currently chairs the Codex Alimentarius Commission.

The responsibility for ensuring that FAO reform occurs is a joint effort by USDA and the Department of State. Within USDA, the Office of Negotiations and Agreements of the Foreign Agricultural Service has the lead on managing relations with FAO. Specifically the FAS participates in all meetings of the governing bodies of FAO, as well as in the meetings of FAO's various technical committees. Together with the Department of State we remain fully engaged in supporting the structural reform of the organization.

An Independent External Evaluation of the FAO was concluded in 2007 which led to the adoption of an Immediate Plan of Action (IPA) to bring about major structural reforms within the organization. The overarching objective of FAO reform, as outlined in the IPA, is to transform the organization into one that manages for results. Those reforms commenced in 2009 and will be implemented over 3 years. We believe the reform process underway provides an opportunity to transform the FAO into a more relevant, focused, and effective organization to tackle global food security issues and agricultural development. USDA and the Department of State are actively involved in seeing that the FAO faithfully implements the reform plan.

Progress was made in 2009 in completing a relatively large number of IPA reforms, including the establishment of results-based management, decentralization, delegation of responsibility, and organizational restructuring and streamlining. Greater attention is being given to improved human resource management and more effective governance as well.

FAO management, along with member countries, has formulated a new "results-based" framework that was used in developing the organization's Medium Term Plan and its Plan of Work and Budget.

A new performance evaluation and management system was piloted involving over 500 FAO staff.

Organizational structures and responsibilities of headquarters and field staff have been adjusted.

Flexible working arrangements for staff were introduced and plans developed for further recruitment and development of young professional (Internship and Junior Professionals Program.)

One third of the organizations director-level positions were abolished, delivering substantial savings that were redirected towards FAO's technical programs, providing a flatter and less hierarchical management structure.

Ms. DELAURO. Right.

Mr. Kingston, do you mind if I ask just a couple related questions in this area? And then I will turn it over to you?

Yeah, that would be helpful, because that came out in there. And I think that, you know, I think you would concur with the first view that we need to have a better oversight of what is happening at FAO, and then what are the measures and the steps that we're going to try to take to get there?

Mr. BREWER. Absolutely.

Ms. DELAURO. So.

Mr. BREWER. The Secretary, the Deputy Secretary are often at the FAO conferences. We have a USDA representative, the Secretary has a representative there, so we're taking that very seriously and working hard to do that.

LOCAL AND REGIONAL FOOD PURCHASES

Ms. DELAURO. Okay.

The Chicago Council as well talked about McGovern-Dole. And as a matter of fact if I can just have some quick reaction to the suggestions that they made with regard to that program.

One, buy some food for the program locally and regionally. Let me just get a quick reaction from you on that?

Mr. BREWER. Madam Chairwoman, we have started, and last year we started a local and regional pilot procurement program that involved three countries in Africa.

Ms. DELAURO. But that's not from McGovern-Dole, that was for—I mean, you're in Tanzania, Mali, and——

Mr. BREWER. Malawi.

Ms. DELAURO. Malawi. Right. But I think that that's for the P.L. 480 program. Or maybe, you know, you tell me. I think that's P.L. 480.

Mr. BREWER. I apologize, ma'am.

Ms. DELAURO. Is that right? Yeah, it's P.L. 480, so now I'm looking at McGovern-Dole to look at, you know.

Mr. BREWER. Is this coming out of a GAO report, you're referring to?

Ms. DELAURO. Oh, no, no. You know, the Chicago Council on Global Food Security did a report, and I thought it had some good suggestions in some areas. I just want to run them by you, to see if, you know, if you have a quick reaction, you know, we can do it for further reaction, if you want.

Mr. MILLER. Well, let me react to that.

Ms. DELAURO. Sure. Mm-hmm.

Mr. MILLER. First of all, in the 2008 Farm Bill, Congress did express an interest in looking at local and regional purchases and establish some authorities to do that.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. We're happy to—and the Secretary is very interested in looking at local markets, as well. We also, I think, would agree that this is consistent with our long-term food security goals for these countries.

So I think it's something that we would be happy to explore.

MCGOVERN-DOLE PROGRAM

Ms. DELAURO. Right. Please. That's all. I know I'm just looking for ways in which we can better target our funds, or how we can expand our—you know, I'm a strong supporter of McGovern-Dole and these efforts. And I think that they succeed.

They further suggested that maybe we'd require some of the program funds to be used to support maternal and child health work. This is McGovern-Dole.

Mr. MILLER. I'd be open to exploring that as well.

Ms. DELAURO. Okay. Provide funds specifically for technical assistance on school feeding and maternal child health programs in developing countries.

Mr. MILLER. Under McGovern-Dole, we can look at——

Ms. DELAURO. Okay. Can we get this information to you, and then have you take a look at that? That would be helpful.

FOOD AID PROGRAMS

Let me just get to the last piece here, which is—I'm really pleased, Mr. Brewer, where you talked about in your testimony, the leading role that the U.S. does play in addressing hunger, malnutrition, global food security. I think it's one of the most important priorities in the bill. And we have provided significant increases for these programs in recent years.

I am concerned that while your budget proposes a $78 million increase for FAS, and it would appear that it is largely for trade-related work, that it does not request any increases in P.L. 480, the Food for Peace Program, or McGovern-Dole.

I am all for creating jobs through fair trade. I want to protect U.S. workers, public health. But you say in your testimony that we may see the second-highest-ever level of U.S. ag exports this year. And that would be without the increases that you're requesting for 2011.

And yet hunger is not going away, and it is not diminishing.

I just think we need to think about, and you need to think about, rebalancing the priorities in the request. And I don't understand why you don't request—that the request doesn't include increases for the P.L. 480 program or for the McGovern-Dole program.

We've got, and I'm apprised by staff, that the—P.L. 480—Administration has just asked for an increase in the supplemental of $150 million for P.L. 480. And that's for Haiti, I understand what it's for. But we're asking for an emergency designation for Haiti, as we should do, as we should do, in my view.

But this budget request is zero. I mean, flat. I view that as zero in terms of where we're going. It's flat-funded.

So I ask you, why doesn't it include increases in these areas?

Mr. MILLER. Madam Chairwoman, I appreciate your comments, and I know you look at those programs very passionately, and I equally appreciate your passion for them.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. But when we look at what this Administration has proposed for the two programs, McGovern-Dole and P.L. 480, that we're discussing, compared to the 2009 level, I believe the McGovern-Dole program was increased slightly over 100 percent, going

into 2010. And we certainly thank Congress for agreeing with the Administration's proposal and providing that funding.

For P.L. 480, again, compared to the 2009 levels that were agreed upon, the P.L. 480 Title II program was increased 38 percent. So I don't think in any way this suggests a lack of interest or commitment to those programs by the Obama Administration. Because we have supported significant increases in both of those programs, compared to where we were in 2009.

Ms. DELAURO. My only point on this—and I want to yield to my colleague—is that I think when the request was made in 2010, there was the sense that we weren't then going to have to ask for anything more from supplementals.

Well, here we are, we have a supplemental. And it's not unlike what happens in terms of that disaster relief side, where we've got this over here to avoid this over here, and now that this is inadequate and we're moving here—which is what's happening.

Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chairwoman.

I think these are my last questions. But it is interesting that I was reading the Gospel of John the other day. I've always been curious about this line that after the Resurrection, He saw his disciples fishing, and instructed them to throw out the net in a certain area, and they caught 153 fish. And you're giving food aid to 154 countries. And my friend always keeps saying that this is a moral obligation. And I wonder if it's not a Biblical context there.

But I've always been curious about that line, why they named this specific number of fish.

TRADE SANCTIONS

Now my question though, is just kind of an interesting question. Do you think we should continue the sanctions against Zimbabwe? And the reason why I say that, you know, we have sanctions against Cuba that we've discussed, and that one is a little bit tougher politically, because we're really doing it on behalf of Great Britain, because of the confiscation of a lot of their farmers.

But any thoughts on that?

And Mr. Brewer, I always keep calling on your resume from the private sector.

Mr. BREWER. Congressman, thank you. You're kind of pulling me into the yard of the State Department. Although I worked there early in my career, I would never presume to speak for Foggy Bottom.

You know, our activity in Zimbabwe is what we've alluded to several times earlier in this, is we are looking at,—our food aid responsibility there is to look at the needs of the native population. There is a need there for food assistance.

Mr. KINGSTON. Mm-hmm.

Mr. BREWER. And so believe that it is appropriate for us to provide that assistance to Zimbabwe.

The larger political implications of sanctions are just simply something that is—I would feel more comfortable if that comment——

Mr. KINGSTON. You know what? The question really I'm just asking you, because you have some knowledge of it.

Mr. BREWER. Yeah.

Mr. KINGSTON. But you know what? Maybe if you feel like it, call me some time.

Mr. BREWER. Why don't we talk about——

Mr. KINGSTON. Because I'd like to—I've been there twice, we've met with Mugabe on it. I don't know if it helps or not to work with someone like that. And you know, I'm just thinking about our situation in Cuba.

We deal with a lot of very tough countries that have governments that do all kinds of things. But you know, sometimes if the money's right, we still deal with them.

Mr. BREWER. I'd really enjoy talking to you off line about that.

TRADE ISSUES

Mr. KINGSTON. Well, that would be great.

And then my question also is on China. We've worked real hard to open up the poultry. Ms. DeLauro and I have worked hard on making sure that the poultry is sanitary. And now they've slapped a 64 percent import tariff on American poultry going there. At the same time Russia has decided there's an issue with the way we process poultry and chlorine in the water and things like that.

Are you guys working with your Russian and Chinese counterparts to try to figure this out?

Mr. MILLER. Mr. Kingston, let me respond to that. Last week I was in China. We were there talking about some market opening opportunities for U.S. commodities. But quite frankly, every conversation I've had with the Chinese over the last year has been one that sooner or later they do raise the chicken and poultry issue.

And so we are working on that with China. I indicated to the Chairwoman before the hearing started that we had been having conversations, we've impressed upon the Chinese their need to be fully compliant with the U.S. requirements, if they expect us to open that market.

But I think we also recognize, while no one may wish to say it, whether it's the Chinese, whether it's the Russians, or whether it's the United States, there is always a certain amount of linkage between each of these trade problems that we face with other problems that are out there.

We, I believe we've announced the agreement on pork access to China. We are also at the point where I believe we can have substantive discussions on beef. And I also think that if—and this is still a big if—but if we can find a way to resolve the Chinese desire to export poultry to the United States, assuming they become compliant with U.S. standards—and we have that equivalency—then I expect that we may see some Chinese reaction to the poultry situation there.

Three weeks ago I was in Moscow. We've had an ongoing discussion with our Russian counterparts on the situation of U.S. poultry exports to Russia. We are negotiating what we believe can be a successful agreement to re-establish that market.

But I can also tell you, these are very difficult negotiations with the Russians. But we are continuing to have conversations, and I'm hopeful that we will get this issue resolved very quickly, so that we do re-establish our market access into the Russian market.

Mr. KINGSTON. Well, thanks. Thank you.

AGRICULTURAL CREDIT INSURANCE FUND

Ms. DELAURO. Let me ask, Mr. Coppess, this is about ACIF, the Agricultural Credit Insurance Fund.

Let me just tell you where my concern is. I'll try to be concise. The 2011 budget proposes to decrease the level of funding available in the ACIF programs. Budget documents assume a decline in the demand for the loans and for financial and economic conditions to improve.

We're already beginning to hear that the level provided in 2010 may not be sufficient to meet the needs of farmers who are struggling and looking for assistance through this program.

Let me put a couple of questions forward here.

What is the status of the program for fiscal year 2010? And do you have enough funding to meet the demand now?

Mr. COPPESS. Thank you, Chairwoman. We have a report coming soon to the committee, in fact hopefully within days, on the status of 2010 funding and our estimates for that year, or for this fiscal year.

Ms. DELAURO. Right.

Mr. COPPESS. So I will refer to that report as soon as we can get that out and to you guys.

[The information follows:]

The Agricultural Credit Insurance Fund quarterly report is going through the USDA clearance process. As soon as that process is completed, the report will be transmitted to the House and Senate Subcommittees.

Ms. DELAURO. Okay. Sure. But again, just because 2009 we had problems in getting information about ACIF running out of funds. And that presented a problem.

So you talked about the quarterly report, and I'm going to presume that the Department will let us know if we are going to run out of funds by the end of the year.

And again, I don't know if you're going to answer this question in there as well, is do you still maintain that the program level of $4.7 billion will be sufficient to meet the program needs in Fiscal Year 2011?

Mr. COPPESS. That is our estimate.

Ms. DELAURO. That's, and it's part of this?

Mr. COPPESS. The fiscal 2011 budget, yes. We estimate that $4.7 billion to $4.8 billion should meet the need. That would put us even above 2009 level. I think we spent $4.5 billion in 2009.

Ms. DELAURO. Okay. So you know, we'll get the report and take a look at it and see where we are.

Mr. COPPESS. Yes.

TRADE ADJUSTMENT ASSISTANCE FOR FARMERS PROGRAM

Ms. DELAURO. Let me ask this first. And this is to Administrator Brewer. This is on Trade Adjustment Assistance for Farmers.

Mr. BREWER. Yes, ma'am.

Ms. DELAURO. It looks as if over the five-year period, this program has been authorized at $459 million, but had an outlay of only $47 million; $9.5 million of that was for administrative costs.

And in the same time period, only 30 commodity petitions were certified as eligible for assistance and payments benefited a mere about 8,400 producers.

Congress made changes to the program in ARRA. Do you believe the changes in the March 10th interim rule will result in more technical and financial assistance to the producers that need it the most? Will they improve the program? And finally, do you believe that these changes will enable a variety of commodities to take advantage of this potentially useful program? Or will a couple of commodities continue to receive the vast majority of the funds that are distributed?

Mr. BREWER. Madam Chairwoman——

Ms. DELAURO. If you can't answer the question now, if you can please get that to us. My experience with trade adjustment has been to, you know, workers who found themselves in difficult predicaments because of being displaced by trade or by overseas developments, et cetera.

And quite frankly, I've found that Trade Adjustment Assistance Program vis-a-vis workers to be woefully inadequate, and not meeting their needs. And I don't know if that's the case with this Trade Adjustment Assistance, but it seems that it's not something that we've focused on very much at all. And I would like to see what the program is about, how it's running, how it's functioning, and who's benefitting, and why haven't—we've used—as I said, $47 million out of $459 million over a five-year period.

Mr. BREWER. So we'll get that answer to you.

[The information follows:]

The new Trade Adjustment Assistance (TAA) for Farmers program has been implemented. USDA conducted extensive outreach to provide opportunities for producers most in need to access the program. Key changes were instituted including broadening of the eligibility criteria and providing more benefits to eligible producers. In addition, the program now provides more technical assistance with the objective of keeping producers and fishermen in either farming or fishing. Benefits provided under the 2002 Farm Bill program focused on retaining opportunities outside of agriculture.

While the broader eligibility criteria provide more opportunities for producers and fishermen to qualify for benefits, petitioners still must demonstrate that increased imports during the most recent marketing year compared to the previous 3-year average contributed importantly to their hardship.

USDA received a total of 17 petitions under the 2010 TAA for Farmers program announcement, which ended on April 14, 2010. Several of the petitions received were from similar producer groups that benefited under the 2002 Farm Bill program, including shrimp and other aquaculture sectors in the Gulf States and Atlantic seaboard. While this segment of the agricultural industry continues to show considerable interest, other more traditional commodity groups that submitted petitions include prunes, asparagus, cut flowers (lillies), apples, cranberries, lamb meat, wool, and pelts.

The TAA statute requires that applicants complete all phases of training within 36 months after a petition has been certified. It will take as long as 5 years from the date that a petition is certified to determine whether the benefits of the program have achieved their goal of making U.S. producers more competitive vis-à-vis imports. To track the results of the program and its effectiveness over time, USDA has procedures in place through the National Institute of Food and Agriculture (NIFA) and the University of Minnesota.

Ms. DELAURO. And again, I know we have talked about this. My colleague, Mr. Kingston, has talked about it, and it does include the Market Access Program as well.

But let me just catalogue. We have Foreign Market Development Program, Market Access Program, Technical Assistance for Specialty Crops Program, Quality Samples Program, Emerging Markets Program. These are all programs that we are engaged in. They appear to all have the purpose of promoting exports, and the programs appear to be similar. And I may be wrong about that.

You know, my questions are, why do we need so many different programs for a similar function? Are some of these programs essentially doing the same thing? And can you describe the process you use to coordinate the activities of these programs? And what steps do you take to avoid a duplication with this effort?

And how do we coordinate some of these efforts? Well, I'll get to that in a second.

This is a Market Access Program. And I'm sorry Mr. Kingston isn't here. But there is a cut in that program. But $166 million I think over five years.

The reasons cited in the budget for the cut were that MAP is duplicative of other FAS programs, and "MAP's economic impact is unclear, and it does not serve a clear need." That's end quote.

There again, I would like to know why you believe it is duplicative and why the economic impact is unclear, and why it does not serve a clear need, and why we continue to support this proposal?

Mr. Miller, let me ask you that question.

Mr. MILLER. First of all, with any of these programs, as you're aware, there are a number of various metrics that can be used to measure the success of the program.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. And not only does USDA engage in a process to try to measure the impact of these programs, but a variety of our cooperators, those who participate in the programs, do the same thing. And Congressman Kingston provided some information on that.

So there is a lot of information out there.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. We do believe that in some instances and for some of the commodities that participate in both the Foreign Market Development Program, as well as the MAP program, that there may, in fact, have been some duplicative efforts that we're trying to avoid.

Ms. DELAURO. Mm-hmm.

Mr. MILLER. We also believe that the Foreign Market Development Cooperator Program provides a greater opportunity in the future, particularly as we seek new cooperators as well as small and medium sized businesses that may want to get into the export business, as a way to help expand our exports, create new jobs, and gain more economic activity out in the country.

In terms of the variety of export programs that you identified——

Ms. DELAURO. It's about $5.9 billion for trade promotion——

Mr. MILLER. Several of those are very specific in order to address concerns that have been raised by specific sectors within the agriculture community, and Congress has seen fit to delineate the program. Such as TASC.

We believe that program is completely separate from what might occur under for-market development, or MAP.

Ms. DELAURO. Right. But I'm just saying to you—and I've asked the question in a way—look, we're going to do trade promotion——

Mr. MILLER. Yes, we are——

Ms. DELAURO. That is for sure. I understand that. But you have suggested in this program a cut for the various reasons that you have laid out.

We have a series of these programs. I would very, very much like the analysis of the programs. And are they duplicative?

COORDINATION OF EXPORT PROGRAMS

You'll get a whole variety of programs that come from this side of the table, that, you know, tell you that we need to do this and we need to do that. All of that is fairly subjective, in many instances, as to, you know, what our particular interests are.

You have a responsibility and a mission to see how these programs play out. And that's why I asked: How are these programs coordinated? Are the activities of the programs coordinated? What steps are taken to avoid duplication?

I think they're reasonable questions. You know?

Mr. MILLER. No, I would agree. And we're happy to provide you additional information on both the process as well as the analysis we've done on these.

Let me point out generally, several of the programs that you pointed out, such as TASC and the Quality Samples Program and the Emerging Markets——

Ms. DELAURO. Emerging Markets, right——

Mr. MILLER [continuing]. Do have some very unique characteristics to them in terms of the way they're administered, in terms of what would be viewed, I believe, as the two large cooperator programs——

Ms. DELAURO. Probably the Foreign Market Development——

NATIONAL EXPORT INITIATIVE

Mr. MILLER. The Foreign Market Development Program, and the MAP Program. That is a case where we have made a determination, and it's reflected in the President's budget proposal that there may, in fact, be some duplication there, that the benefits—while we believe that to a number of commodities the benefits under MAP, for instance, are still significant—it may be a program that could be reduced to ensure that we can use limited dollars more effectively in other areas.

And we do believe that the Foreign Market Development Program can be used to serve not only our traditional cooperators, but can also be used to stimulate additional export activity among small- and medium-sized enterprises. New exporters.

And if we're going to meet our National Export Initiative objectives, we need to encourage new exporters, or those that may be exporting to one country and to small markets to expand.

Ms. DELAURO. But this is where, you know, I think there's a request for what, somewhere around $34.5 million. And that's on top of the mandatory.

Mr. MILLER. Correct.

Ms. DELAURO. You know, and I've got the sheet here of who are the beneficiaries of those programs. And I think basically, what I would like to know is: Who and what organizations, who's getting these dollars?

And you know, repeatedly, who is—the unique characteristics of some of these other programs and how that translates? You know.

And we go back to where Mr. Kingston and I share this view, is what has been the result of this? What are the results? We're looking for a new result of doubling; but are we on a solid ground with what we have done, that says that adding $34.5 million on top of the mandatory money, and that that's going to get us where we want to go—when you all may very well have the data and the information, this committee doesn't have the data and the information that says "proven track record, this is how we have expanded our exports. These are the areas in which it's been done." And now we come to you and say, "If you give us $34½ million more to the Foreign Market Development Program we are going to get you to our agriculture responsibility for doubling those exports."

At the moment, we have zero information as to how we can go from A to B.

So that would be helpful.

Mr. MILLER. We'll be glad to—organizations have been recipients of Foreign Market Development, and MAP money in the past. We're also happy to provide you our view of how the additional funds could be used to achieve the objective of the National Export Initiative——

Ms. DELAURO. I want to know on what are the bases for—what is the success rate? Where is the—you know, I deal in a world, and when I can't get something quantified, I get very nervous.

I apply that to myself. When I go to my staff and I think about my election campaign and what they are doing, and I say, "How many people have you talked to?, and they say to me, "Don't worry, we're talking to them." I'm worried about who I'm reaching and how they view what I am doing vis-a-vis, you know, their comfort level with me. I want to see how we have used the money that we have provided, and what is that doing? What is its success rate? And I would like to see that. I think this entire committee would like to see that.

Mr. MILLER. Well, we'll be happy to provide that to you along with the performance metrics that we've used historically to judge the programs.

Ms. DELAURO. Right, that's great.

Mr. MILLER. And the new performance metrics that we're developing.

[The information follows:]

The Market Access Program (MAP) and Foreign Market Development Program (FMD) are USDA's two largest market development programs. The two programs are complementary. They differ in: 1) the types and duration of market development activities supported; 2) the types and number of participating organizations; and 3) the types of costs eligible for reimbursement.

MAP funded activities focus on promoting near-term sales through consumer and retail promotions. FMD activities are designed to remove trade impediments and have a longer-term results time horizon. Common FMD projects are technical assistance, trade servicing, and market research. A larger proportion of MAP funding is allocated to support market promotion activities for high value, consumer-ready products, including specialty crops and branded products being marketed by small businesses. In contrast, FMD funds only generic promotions, which tend to be for bulk/intermediate commodities. The FMD program funds neither direct consumer promotions nor branded promotions, while MAP can fund both. In 2010, MAP participants include 68 non-profit trade organizations, State-Regional Trade Groups (SRTG), and cooperatives, and approximately 700 small businesses participate under the branded program. Twenty-two organizations received FMD funding in fiscal 2010. Private companies are not eligible to receive funding under FMD. MAP funding for participants' administrative costs, including any costs for overseas offices and operations, represents a fairly small portion of annual program funding. In contrast, a significant portion of FMD funding is used to support the overseas offices and operations of participating organizations. To a large degree, the organizations that receive both FMD and MAP funding use FMD to maintain their overseas presence and MAP to implement their promotions.

The Technical Assistance for Specialty Crops (TASC) Program addresses sanitary, phytosanitary, and related technical trade barriers to U.S. specialty crops. TASC projects may augment, but do not duplicate, MAP or FMD activities. Specialty crop sector MAP participants can use the gains made from TASC market access activities to increase their market development opportunities.

The Quality Samples Program (QSP) helps U.S. agricultural trade organizations introduce products to potential importers. Neither MAP nor FMD allows for the purchase of samples. However, both FMD and MAP can provide the technical support to appropriately utilize the sample once it is in the market.

The Emerging Markets Program (EMP) is unique and distinct from USDA's other market development programs. While the underlying objective is to promote exports of U.S. agricultural commodities and products, projects are approved only for emerging markets and the range of acceptable activities has a different focus. Examples of eligible activities include feasibility studies, market research, sectoral assessments, orientation visits, specialized training, and business workshops. Typical MAP and FMD funded promotion activities (such as in-store promotions, branded product promotions, trade shows, advertising, and maintaining an overseas presence) are not eligible for EMP funding. Successes under an EMP activity often complement efforts under one of the other USDA market development programs. For example, fresh produce retail training done under EMP can help a MAP participant conduct an activity with an importer in a market that was just opened as a result of a successful TASC activity.

The Unified Export Strategy (UES) Internet tool is designed to coordinate and manage complementary programs. Program applicants submit a UES document which can serve as the application for any or all five programs, as well as the organization's activity plan. This allows applicants to identify market constraints (or opportunities), strategies to mitigate (or exploit) them and request program resources to implement the strategies. The UES allows FAS to see all programming requests at the same time and how they relate to one another. This system ensures coordination of resources. Each UES is reviewed by FAS Office of Trade Programs as well as by FAS Field Offices.

Each recipient of program funding is required to annually report results against the performance measures established in their UES. FAS staff evaluate reported results. Reviewing all UES results in 2003, participants met about 30 percent of their stated goals. By 2008, participants met about 58 percent of their performance measure goals. Reaching about 60 percent on this measure reflects both sufficiently challenging goals and a meaningful level of results.

Since 2005, FAS has tracked a number of different types of program metrics: UES performance measure results, ratio of industry vs. government contributions to promotion activities, total exports to countries in product lines where MAP or FMD funds are expended, various measures related to small company participants (i.e. number of companies making their first sale).

Market development programs contribute to FAS' agency goal to help "U.S. farmers, ranchers, and agricultural industry maintain and expand exports." FAS commissioned a cost-benefit analysis in 2007 with an independent economic analysis firm, Global Insight Inc., and recently received the results of an update of that study. The study analyzed the impact of the increase in foreign market development investment that took place under the 2002 Farm Bill through 2009. It concluded that every dollar of increased investment in the MAP and FMD resulted in $35 in exports. It also reported that U.S. agricultural exports were up $6.1 billion in 2009, compared to what they would have been without the increased investment in market development.

Additional commodity specific studies highlight the beneficial economic impact of market development programs. The U.S. Grains Council annually assesses their market development program's trade impact; this study is conducted by Informa Economics LLC. In July 2009, the study concluded that the Council's market development program accounts for $395 million in U.S. exports of the targeted commodities on an annual basis. These exports increased U.S. producer incomes annually by $915 million. This is a return of $50 for each dollar of industry and U.S. government funds invested in market development. The U.S. Wheat Associates' market development program cost-benefit study concluded that …"U.S. wheat export promotion had a large and beneficial impact for producers and the economy that far exceeded its cost." The overall average net producer revenue, derived from the combined producer and FAS market development expenditures, was estimated to be about $117 for each dollar spent.

The proposed $34.5 million increase in the FMD budget, which has remained relatively constant since the early 1980s, will augment ongoing efforts to address long-term barriers to export growth and

allow organizations to conduct new activities in existing markets and to target new markets. Increased funding will also provide new opportunities for participation and innovative activities, such as promoting broader international acceptance of agricultural biotechnology and combating persistent sanitary and barriers to U.S. red meat and poultry. Addressing these long-term barriers will maintain market share in developed markets and allow for expansion in others.

The $9 million increase proposed for TASC will be used to bolster efforts to address unique barriers that prohibit or threaten exports of U.S. specialty crops. The proposed increase in TASC reflects the growing importance of specialty crops for U.S. agricultural export growth and the contribution the program has made in resolving trade barriers.

The additional $10 million provided to the FAS will enable an expansion of export assistance efforts, in-country promotions and trade enforcement activities to remove non-tariff trade barriers. These funds would facilitate the participation of a greater number of small- and medium-sized enterprises (SMEs) at foreign and domestic trade shows, increase the number of trade missions, and increase the number of foreign buyers at U.S. trade shows.

Foreign Market Development Program Cooperator	FY 2010 Funding
American Forest & Paper Association	$3,286,753
American Peanut Council	$693,985
American Seed Trade Association	$214,329
American Sheep Industry Association	$172,932
American Soybean Association	$6,825,849
Cotton Council International	$4,753,847
Leather Industries of America	$152,789
Mohair Council of America	$14,556
National Hay Association	$72,844
National Renderers Association	$888,947
National Sunflower Association	$242,286
North American Millers Association	$57,139
U.S. Dairy Export Council	$704,974
U.S. Dry Bean Council	$129,550
U.S. Grains Council	$4,033,859
U.S. Hide, Skin and Leather Association	$146,322
U.S. Livestock Genetics Export, Inc.	$719,867
U.S. Meat Export Federation	$1,731,705
U.S. Wheat Associates	$3,845,230
USA Dry Pea and Lentil Council	$173,750
USA Poultry and Egg Export Council	$1,516,601
USA Rice Federation	$1,543,614
Reserved for Contingencies	$1,048,272
Reserved for Administration	$1,530,000
TOTAL	$34,500,000

Market Access Program Participant	FY 2010 Allocation
Alaska Seafood Marketing Institute	$4,560,897
American Forest & Paper Association	$8,091,683
American Peanut Council	$2,136,001
American Seed Trade Association	$28,178
American Sheep Industry Association	$402,156
American Soybean Association	$5,171,415
Blue Diamond Growers/Almond Board of California	$1,543,836
Brewers Association Inc.	$365,655
California Agricultural Export Council	$481,569
California Asparagus Commission	$137,700
California Cherry Advisory Board	$490,509
California Cling Peach Board	$477,568
California Fresh Tomato Growers/Florida Tomato	$900,612
California Kiwifruit Commission	$297,558
California Pear Advisory Board	$266,507
California Pistachio Export Council/Cal-Pure Pistachios	$914,804
California Prune Board	$2,964,589
California Strawberry Commission	$784,741
California Table Grape Commission	$3,495,424
California Tree Fruit Agreement	$2,439,629
California Walnut Commission	$4,550,808
Cherry Marketing Institute	$262,799
Cotton Council International	$20,332,612
Cranberry Marketing Committee	$1,632,105
Distilled Spirits Council	$187,732
Florida Department of Citrus	$5,204,718
Food Export Association of the Midwest USA	$10,514,977
Food Export USA Northeast	$7,756,283
Ginseng Board of Wisconsin	$159,710
Hawaii Papaya Industry Association	$134,434
Hop Growers of America	$187,399
Intertribal Agriculture Council	$812,643
Mohair Council of America	$116,462
National Association of State Departments of Agriculture	$2,336,105
National Confectioners Association	$1,385,073
National Hay Association	$36,000
National Potato Promotion Board	$5,152,444
National Renderers Association	$811,588
National Sunflower Association	$1,148,294
National Watermelon Promotion Board	$231,688
New York Wine and Grape Foundation	$355,981
Northwest Wine Promotion Coalition	$876,220
Organic Trade Association	$371,235
Pear Bureau Northwest	$2,872,385

Market Access Program	FY 2010
Participant	**Allocation**
Pet Food Institute	$1,436,875
Raisin Administrative Committee	$3,225,033
Southern United States Trade Association	$6,419,114
Sunkist Growers, Inc.	$4,011,195
Texas Produce Export Association	$103,746
The Catfish Institute	$285,002
The Popcorn Board	$245,322
U.S. Apple Export Council	$871,905
U.S. Dairy Export Council	$4,284,326
U.S. Dry Bean Council	$1,062,025
U.S. Grains Council	$7,389,253
U.S. Hide, Skin & Leather Association	$106,281
U.S. Livestock Genetics Exports, Inc.	$928,851
U.S. Meat Export Federation	$15,679,189
U.S. Wheat Associates	$5,487,119
USA Dry Pea and Lentil Council	$907,975
USA Poultry and Egg Export Council	$5,134,174
USA Rice Federation/U.S. Rice Producers Association	$3,771,169
Wash. State Fruit Commission	$1,110,955
Washington Apple Commission	$4,763,569
Welch Foods, Inc.	$893,415
Western United States Agricultural Trade Association	$9,454,075
Wine Institute	$7,043,762
TOTAL	$187,995,056
Reserve and Program Administrative Expenses	$12,004,944
GRAND TOTAL	$200,000,000

Ms. DELAURO. Terrific. That would be great.

I think—is not the only one here, my good colleague, Mr. Kingston, trusts me not to go crazy.

But so the hearing is concluded, and I thank you very, very, very much for your candor and for the good work that you do, and we look forward to working with you.

Thanks much.

Mr. MILLER. Thank you, Madam Chairwoman.

FARM AND FOREIGN AGRICULTURAL SERVICES

Questions from Congressman Kingston

Mr. Kingston: How much would U.S. agriculture benefit from the completion of the pending free trade agreements with South Korea, Colombia, and Panama? When is the administration expected to send Congress these free trade accords?

Response: According to the American Farm Bureau Federation, U.S. agricultural exports would increase by $3 billion per year at full implementation of all three outstanding free trade agreements. The Administration is working with Congress and stakeholders to resolve outstanding issues in these pending trade agreements, to move them forward for Congressional consideration and ultimately, ratification.

Mr. Kingston: What percentage of total agricultural exports facilitated by USDA's export programs are a result of the Market Access Program (MAP)? What types of metrics are used to evaluate the success of the MAP program?

Response: An update of a study by Global Insight Inc. analyzed the impact of the increase in foreign market development investment that took place under the 2002 Farm Bill through 2009. The study reported that U.S. agricultural exports were $6.1 billion higher in 2009 which is approximately 6.3%, compared to what they would have been without the increased investment in market development. MAP represents about 85 percent of total market development investment.

Each recipient of program funding is obligated to annually report results against established performance measures. Since 2005, FAS has tracked a number of program metrics such as Unified Export Strategy performance measure results, industry contribution, total exports in countries and product lines where MAP or FMD funds are expended, various measures related to small company participants (i.e. number of companies making their first sale)and more recently, program cost-benefit analysis.

Mr. Kingston: What percentage of U.S. agricultural exports do specialty crops currently make up?

Response: Just over 10 percent of total U.S. agricultural exports are comprised of specialty crops.

Mr. Kingston: Which, if any, crops are proving to be popular economic alternatives to the cultivation of poppies in Afghanistan? Could the USDA provide quarterly updates to the committee on the Department's strategy in Afghanistan?

Response: Alternatives to poppy would be perennial crops such as fruit and tree nuts. For centuries southern Afghanistan has been well-known for production of high value products such as pomegranates, grapes, and raisins. Other crops such as almonds, pistachios, apples, and apricots offer potential returns that could exceed those of poppy and are traditionally produced in poppy-growing areas.

Critical factors in ensuring that licit products are consistently more profitable than poppy include improving post-harvest handling and market accessibility for perishable products. The U.S. mission in Afghanistan is working to improve these components of the Afghan agricultural sector.

Yes, the Department will be glad to provide quarterly updates to the committee highlighting activities in support of the U.S. Government's agricultural assistance strategy in Afghanistan.

Mr. Kingston: In which countries have U.S. efforts to alleviate food insecurity been the most effective? What distinguishes these countries from countries where U.S. efforts have been less successful?

Response: Based on USDA's Economic Research Service indicator of food gaps (or the gap between average per capita food availability and nutritional requirements of roughly 2,100 calories per capita per day) Egypt, Bangladesh, Nicaragua, Rwanda, Mozambique, and Malawi have shown steady improvement in their food security since 1992. While the food security situation in each country changes each year, the overall trend line for these countries has been positive.

In each of these countries, the U.S. Government has taken a comprehensive approach to food security, providing a wide array of development assistance and food aid. All of these countries, with the exception of Egypt, have been identified as "priority" countries under the U.S. Government "Feed the Future Initiative."

Countries in which the food security situation did not improve much or deteriorated over the same period of time are those that faced political instability, such as Kenya, Ethiopia and Eritrea.

Mr. Kingston: Which non-government organizations (NGOs) are the best at providing assistance to foreign countries? How does the USDA determine which NGO's to partner when they need assistance on specific projects?

Response: USDA works with many NGO's that implement effective programs, but USDA does not maintain a ranking of NGOs. In deciding upon its allocations of grants, USDA assesses an organization's capability to provide the most effective assistance to foreign countries. USDA also reviews all NGOs based on a number of criteria depending on the program- and country-specific needs. This includes experience implementing food assistance programs in a specific country and compliance with program regulations and reporting requirements. In determining the general capacity of an NGO to carry out a project, USDA reviews several factors, including the organization's most recent audit pursuant to Circular A-133, Audits of State, Local Governments and Nonprofit Organizations and any unresolved findings in that audit.

Mr. Kingston: Does the federal government plan to take over crop insurance in the future?

Response: Current law generally requires the delivery of crop insurance through private sector insurance companies. Changing that public/private partnership would require Congressional action. The public/private partnership that has evolved since the early 1980's has succeeded in providing US farmers and ranchers with their most valuable risk management tools. The new SRA will serve as a solid foundation for the continued private delivery of Federal crop insurance in a prudent, cost effective and sustainable manner.

Mr. Kingston: What is the status of the FSA IT modernization project and when will it be completed?

Response: A major component of the FSA IT transformation is delivered through the Modernize and Innovate the Delivery of Agricultural Systems (MIDAS) program. The objective of MIDAS is to streamline FSA

business processes and to develop an effective long-term IT system and enterprise architecture for Commodity Credit Corporation (CCC) farm program delivery.

Thanks to the availability of Recovery Act funds in FY 2009, significant progress has been made with the MIDAS project. More specifically, FSA used Recovery Act funding to release a major acquisition solicitation that was essential to start system implementation work, continue program management and governance support, and continue business process streamlining activities that leverage industry "best practices" to reduce process errors and ongoing costs. Recently, FSA awarded the major acquisition implementation contract as well as a critical technical oversight contract.

The FY 2011 budget proposal includes the necessary resources to move ahead on schedule with IT modernization for FSA. It will support the continuation of the MIDAS project as planned along with necessary conversion of software for supporting activities to facilitate transition of FSA IT from the obsolete legacy system.

With adequate funding in FY 2010 and beyond, along with continued two year funding availability for IT expenses, MIDAS should remain on track for completion in FY 2014. The project's initial estimate of $304.7 million for the costs of implementation has not changed.

Mr. Kingston: What was the originally estimated 5-year cost of BCAP?

Response: In June 2008, when the Farm Bill was enacted, the Congressional Budget Office (CBO) estimated the 5-year costs (2008-2012) of BCAP to be $70 million.

Mr. Kingston: What is the current estimate of BCAP's 5-year cost?

Response: OMB's 2011 President's Budget baseline estimates the 5-year cost of BCAP to be $1.45 billion. CBO's March 2010 baseline also estimates BCAP's 5-year cost to be about $1.4 billion.

Mr. Kingston: What goals will be used to evaluate the timing of the termination of the BCAP program?

Response: BCAP was authorized through FY 2012 by the Food, Conservation, and Energy Act of 2008, and as such, the timing of the termination of the program is not an administrative decision.

Mr. Kingston: Does USDA believe that a Cap and Trade system is the correct approach to combating global climate change?

Response: The Administration's goal is an efficient, cost-effective and comprehensive approach to mitigating climate change that leverages the Nation's capacity for innovation, creates jobs, reduces dependence on foreign oil and leads global action to avoid the adverse consequences of climate change. A properly designed comprehensive market-based climate change policy can meet these objectives. The Statement of Administration Policy on H.R. 2454, the American Clean Energy and Security Act of 2009, notes that the legislation creates an appropriate framework.

Mr. Kingston: Given the recent Pigford settlement, in moving forward with similar settlements for women, Hispanics, and Native Americans, would legislation prove the outcome less costly? Or does the USDA believe this should all be settled in court?

Response: USDA is working with the Department of Justice to prepare a response and will provide it to the Committee when available.

Mr. Kingston: What is the current status of the "Chinese chicken" issue addressed in the FY 2010 Agriculture Appropriations bill?

Response: In order to conduct equivalence reviews of China's slaughter and processed poultry inspection system as called for under the FY 2010 Agriculture Appropriations bill, the government of China must first provide updated information regarding its food safety laws. USDA expects to receive a response to its request to China for information regarding China's new food safety laws. USDA technical experts will review this information and determine next steps accordingly.

[Subcommittee Note:

On May 14, 2010, USDA received a response to its request to China for information regarding China's new food safety laws. USDA technical experts are currently reviewing this information and will determine next steps accordingly.]

FARM AND FOREIGN AGRICULTURAL SERVICES

Questions from Congressman Sam Farr

Beginning Farmer and Rancher - Individual Development Account

Mr. Farr: The Individual Development Account concept has proven an important and successful tool to create asset-based development. The existing HHS program has helped lower-income Americans to save and purchase key assets to better their lives. The 2008 Farm Bill created an important parallel program at USDA to assist lower-income beginning farmers to save in order to be able to purchase land, livestock or other production assets. One of the only beginning farmer IDA programs in the country is happening right now in California, helping new farmers gain a toe hold in agriculture.

The USDA budget request for FY 2010 included $5 million in funding to establish IDA demonstration programs with qualified entities in 15 states but failed to include a request for FY 2011.

Unfortunately, we were not able to fund the program last year, but I hope will try again in the FY 2011 bill. Please provide the subcommittee with a progress report on the status of proposed rules for the program and any information concerning agency discussion of the process for selection of pilot states.

Response: We are currently working on regulations for the Beginning Farmer and Rancher Individual Development Accounts (BFRIDA). We envision the program being run similarly to the Department of Housing and Urban Development's (HUD) Individual Development Account (IDA) programs.

These questions are focused on USDA Secretary Vilsack's Strategic Goal of promoting biotech in foreign markets.

Mr. Farr: A recent report entitled, Out of Hand: Farmers Face the Consequences of a Consolidated Seed Industry, concludes that biotech seed patenting and intellectual property rights have been a major contributing factor in the concentration of the seed industry resulting in fewer seed choices to farmers, higher seed costs, loss of independent seed companies and an inability for seed researchers/breeders to access the genetic material necessary for seed development - in short innovation has been stifled and farmers have paid the price. Given this scenario, why is the promotion of biotech to foreign markets a priority strategic goal for USDA?

Response: USDA believes that biotechnology can and should be part of a comprehensive strategy for sustainable agricultural development and improved food security, and to address climate change. USDA also supports trade in products derived from biotech because U.S. exports of genetically engineered (GE) crops such as corn, soybeans and cotton, as well as foods produced or processed from these crops, are safe and form the majority of U.S. agricultural exports in 2009.

Mr. Farr: Does USDA contemplate using taxpayer dollars to subsidize biotech crop research in foreign countries?

Response: Section 7505 of the 2002 Farm Bill (reauthorized as Section 7310 of the 2008 Farm Bill) requires that USDA establish and administer a program to make competitive grants to eligible entities to develop biotechnology for developing countries. To date, no funds have been requested or provided for such a program.

Mr. Farr: If so, who will ultimately hold the patents for innovations in seed development achieved through publicly funded research?

Response: It is premature to speculate on the exact disposition of any intellectual property generated in the course of such a program, but at the very least, U.S. scientists and institutions involved in the research would be co-holders of the intellectual property generated.

FAS outreach and capacity building programs support countries, including developing countries, in the creation of their own biotechnology regulatory systems, encouraging the establishment of regulations and systems that are transparent, science-based, and in accordance with international standards and World Trade Organization obligations.

Mr. Farr: To-date, the only commercially available, genetically engineered crops are herbicide tolerant or insecticide resistant. Genetically engineered crops conferring drought tolerance or improved nutritional benefits do not exist. In 2008 a global collaboration of scientists concluded that biotech crops would not significantly assist in fighting global hunger and recommended the promotion of agro-ecological farming practices (International Assessment of Agricultural Knowledge, Science and Technology for Development - IAASTD). Given this scenario, why is the promotion of biotech a priority for USDA?

Response: USDA supports the use of all appropriate technologies, including biotechnology, to address critical needs in terms of food and energy security and as tools to help address the challenges of climate change. When managed correctly, USDA believes that biotech is, in fact, one solution to fighting global hunger, improving sustainable agriculture and mitigating climate change.

Several other types of traits in GE crops are currently commercially available beyond herbicide tolerance and insect resistance. There are virus-resistant crops (squash and papaya) and crops with modified oil profiles (e.g., high-oleic acid soybean). In addition, a petition for deregulation of the first GE drought-tolerant corn variety is currently under review by the Animal and Plant Health Inspection Service (APHIS) and a number of varieties with improved nutritional profiles are in various stages of development around the world.

The United States participated in the IAASTD, but was unable to provide unqualified endorsement of the reports, because of problems in the analyses it presented and how the process was undertaken. The United States had specific and substantive concerns in each of the reports of the IAASTD. Concerns included a lack of comprehensiveness, objectivity, and balance in examining certain critical areas, including the natural sciences, current and emerging technologies, agricultural trade, and policy options.

The World Bank, one of the main sponsors of the exercise, commissioned a critical independent study of the report. The Consultative Group for International Agricultural Research, the major international organization devoted to the agricultural needs of developing countries, has also criticized the report's conclusions.

Additionally, farmers around the world support the use of biotechnology through their adoption of seeds produced by using the technology on their farms. According to the non-profit International Service for the Acquisition of Agri-Biotech Applications, there has been an unprecedented 80-fold increase in hectares planted with biotech crops over the past 13 years, making biotech crops the fastest adopted crop technology in the history of agriculture.

Mr. Farr: More than 40 countries have enacted GE market restrictions or labeling requirements that have cost U.S. farmers millions of dollars in lost export sales. That figure will sky-rocket should the USDA deregulate other heavily exported food grains such as wheat and rice. Yet the USDA adamantly refuses to consider the economic impacts to farmers in its GE deregulation decision-making processes. Why doesn't the USDA consider economic impacts to farmers? Why is promotion of biotech into non-existent markets a priority for USDA when U.S. farmers are facing a severe and immediate financial/credit crisis at home?

Response: The United States maintains a robust, predictable, efficient, science-based approach to regulation of agricultural biotechnology products. APHIS' authority derives from the Federal Plant Pest Act and the Plant Quarantine Act, which were later subsumed in the Plant Protection Act of 2000 (PPA). As regulated under the PPA, GE organisms are evaluated by APHIS for their potential to be plant pests, i.e. organisms that harm plants or plant products.

APHIS is committed to an open and transparent regulatory process that takes all public feedback and comments into consideration, while continuing to protect America's agricultural and natural resources. APHIS continually evaluates its policies and regulations and makes changes as necessary to reflect the latest science and technology. These changes have strengthened our already rigorous requirements for the field testing of biotechnology-derived crops.

WEDNESDAY, MARCH 10, 2010.

FOOD AND DRUG ADMINISTRATION

WITNESSES

MARGARET A. HAMBURG, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION

PATRICK McGAREY, DIRECTOR, OFFICE OF BUDGET, FOOD AND DRUG ADMINISTRATION

NORRIS COCHRAN, DEPUTY ASSISTANT SECRETARY FOR BUDGET, HEALTH AND HUMAN SERVICES

MS. DELAURO OPENING REMARKS

Ms. DELAURO. The hearing is called to order. Let me welcome Dr. Margaret Hamburg, who is the Commissioner of the Food and Drug Administration in her first appearance before the subcommittee. She is joined by Patrick McGarey, Director of the FDA's Office of Budget and Norris Cochran, Deputy Assistant Secretary for Budget at HHS. As I've said many times over the years, and I'm sure you agree that funding the FDA sufficiently is one of the most important responsibilities under this subcommittee's purview. The American people expect the FDA to ensure the safety of the food they eat, the drugs they take and the medical devices that they rely on. They expect us to provide the resources that the agency needs to fulfill this fundamental mission on behalf of our nation's families.

With that in mind, I am proud that since taking the chair of this subcommittee, we have continued to address our responsibilities in this arena, and starting in 2007, this committee and Congress have worked in a bipartisan fashion to increase the FDA's total budget by more than $878 million. And last year, our final conference report funded the FDA at $2.3 billion, $306 million above 2009.

We do this because food and medical product safety is crucially important to our national welfare. It is in short a national security issue. I'm very proud that the agency has been able to hire thousands of new employees, scientists, inspectors and analysts doing critical work as a direct result of those increased resources. And I'm glad to see the newly proposed initiatives like the FDA Transparency Task Force that will help to improve in my view the functioning and the credibility of the agency, and I think that under Commissioner Hamburg's direction, the FDA will invest resources smartly, improve its efficiency and streamline its organization and that the agency's original emphasis on protecting the public health will be restored.

Looking ahead to 2011, I am encouraged by the administration's $2.5 billion request for discretionary resources provided by this committee, an increase of 6 percent over last year. I am also glad to see that many of the agency's most important consumer safety

initiatives are seeing positive funding increases in this budget. The Center for Food Safety and Applied Nutrition is slated to receive an additional 9.2 percent. The Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research both see their funding up by 4.2 percent. Other centers are slated for smaller increases.

We will look at the requests for all the centers to make sure the budgets proposed are well founded and sufficient to enable it to do their critical work. Taken as a whole, this budget represents a strong commitment to building on the historic levels of investment this committee has made over the last four years. Coupled with $1.5 billion in estimated user fees, this would give the FDA over $4 billion to meet its responsibilities to the American people. And they will need every penny.

In just the past month, we have seen new revelations suggesting that the diabetes drug Avanti is unsafe and should not have been approved. We have new research from the Yale Medical School that even brief exposure to Bisphenol A, a common ingredient found in plastics and aluminum cans, causes increased risks of breast cancer and uterine cancer for those exposed to it before birth. We learned that the radiation treatments that cancer and other patients rely on for help are in some disturbing cases causing harm. We have witnessed a salmonella Montevideo outbreak in crushed pepper that has already sickened 245 people. And just yesterday we found out that a processed foods company in Las Vegas, Basic Food Flavors, knew their plant was contaminated with salmonella and decided to proceed with business as usual.

These recent situations demonstrate again the sheer variety of responsibilities that the FDA must continually live up to, and the need for resources to ensure the safety of these products.

I also have some concerns about the contingency of budget increases for food inspections on the authorizations of user fees. As you know, these fees are authorized in the House Food Safety bill, but not at the same level in the Senate version. So it's an open question how the agency intends to meet these fundamental inspection obligations if user fees at the level in the budget are not authorized in the final legislation.

So as we move forward with the budget process this year and continue the process of revamping, of innovating at the FDA in order to have it meet its mission in the 21st Century, I hope, Dr. Hamburg, that you will continue to keep in mind the four guiding principles that we have laid down last year. First, we must continue to increase funding to support the FDA's mission. Second, we must improve the management of the agency and hold it accountable. Third, we must push back against potential industry influence over the agency. And finally and perhaps most importantly, we must let the scientists do their work, guided by science and not political interference.

I should say that the Commissioner's budgeted initiatives to improve the regulatory science capabilities of the FDA are a good step in this final direction. These are the four guideposts that I have used and I will continue to use in judging our progress and in evaluating this 2011 budget request.

Dr. Hamburg, I look forward to hearing how you believe the FDA plans to move toward these broad guidelines in the year to come. I look forward to hearing about new initiatives such as the recently established Center for Tobacco Products will fit into this vision. And thank you very, very much once again for joining us. I would like to recognize my colleague, Mr. Kingston, but he is not here at the moment. Mr. Latham—he's on his way?

Mr. LATHAM. I just want to welcome the Commissioner and thank you for coming by yesterday. I appreciate that very much. I yield back.

Ms. DELAURO. Okay. I think what I would like to do if Mr. Kingston is on his way, then I would, if you wouldn't mind, I would like to wait for him to make an opening statement and then we can proceed to your testimony, Commissioner. And with regard to the testimony, the entire testimony will be made part of the record. Feel free to, you know, summarize or paraphrase it, what you would like to do.

Dr. HAMBURG. Thank you.

[Recess.]

Ms. DELAURO. I made my opening remarks, Mr. Kingston. The floor is yours.

MR. KINGSTON OPENING REMARKS

Mr. KINGSTON. Well, I had an opportunity to meet Dr. Hamburg and talk to her in the past. I think she's got a great record of not just public service but service to individuals with medical needs and have a great respect for what you've done.

I have expressed to you my concern with FDA as that in the last several years you've gotten a large amount of money and I'm very concerned any time the government grows so rapidly as it has, and expressed those concerns, and that will probably be one of the things that I keep talking to you about.

The other thing is, I do support user fees and believe that you can objectively do research on medical devices and drugs and not be tainted by user fees. I think that your firewall of integrity alone is going to be high enough, but I also think that there will be structural firewalls to make sure that your scientists in the back room are not influenced by people who are trying to get rapid approval. However, I think that those who are benefitting from these products should pay more of a fee to get them approved as a way of just easing some of the burden on taxpayers and the general treasury.

So with that, Madam Chair, I'll yield the floor.

Ms. DELAURO. Commissioner Hamburg, we can proceed with your testimony and then we'll proceed to questions.

DR. HAMBURG OPENING STATEMENT

Dr. HAMBURG. Okay. Thank you very much, Chairwoman DeLauro, Representative Kingston and members of the subcommittee. I am very pleased to be here to present the President's Fiscal Year 2011 budget for the FDA. And with me is Patrick McGarey, as you noted, from FDA's Budget Office, and Norris Cochran, the Deputy Assistant Secretary for Budget at HHS.

My testimony outlines FDA's 2011 budget request. It also includes a summary of recent developments related to our new responsibilities to regulate tobacco products and some other important FDA initiatives. As you noted, this is my first time before this subcommittee and I look forward to working with all of you. I deeply appreciate the support that you've given to FDA, and I know that you share my determination to make sure that our nation can count on a strong, fully functional FDA.

FDA is an essential and unique agency, a science-based regulatory agency with a public health mission to promote and protect the health of the public. We're responsible for programs and activities that affect every American every day in very, very fundamental ways. The 2010 appropriation reflects your commitment to FDA and the health of the American people. Those funds will allow FDA to make real progress across a wide range of public health initiatives and priorities which are essential to health, quality of life, safety and security for all of us. So thank you again.

The proposed Fiscal Year 2011 budget includes $4 billion for FDA programs, which represents an increase of $755 million, with $601 million in user fees and $154 million in budget authority. We're proposing three major initiatives in areas vital to our mission: transforming food security and safety, protecting patients, and advancing regulatory science. These initiatives are crucial for the modernization of our agency in response to the challenges of the 21st Century.

The Transforming Food Safety initiative reflects President Obama's vision of a new food safety system to protect the American people and is based on the principles of the President's Food Safety Working Group: Prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. FDA proposes an increase of $326 million for Transforming Food Safety, with $88 million in budget authority and $238 million for new user fees, including $200 million for food registration and inspection.

The Fiscal Year 2011 resources would allow FDA to establish a foundation for an integrated national food safety system focused on prevention. Key elements include setting standards for safety, expanding laboratory capacity, piloting track and trace technology, strengthening import safety, improving data collection and risk analysis for foods, and increasing inspections.

This initiative will allow FDA to make the kinds of changes needed to deliver the promise of improved food safety and reduce illnesses caused by contamination of the food supply in the years to come.

The Protecting Patients initiative reflects FDA's pressing need to modernize our approach to the safety of medical products. This is a time when science and technology offers new promises for disease prevention, diagnosis and treatment, as well as new protections for safety. This is also a time when an increasing number of drugs, devices and biologics are being manufactured abroad. FDA must act as a strong and smart regulator, addressing medical product safety challenges in the years ahead.

The budget proposes an increase of $101 million for this initiative, including $49 million in budget authority. The balance is for two new user fees, generic drug fees and fees for reinspecting med-

ical product facilities. The Protecting Patients initiative focuses on four vital areas: Import safety, high-risk products, partnerships for patient safety, and generic drug review. These activities will have a significant impact on public health across the nation. This science-based strategy will build new and greater safety capabilities. They will result in fewer import safety emergencies and fewer serious adverse events associated with drugs, devices and biologics.

As the Chairwoman noted, FDA is proposing a new focus on Advancing Regulatory Science with an increase of $25 million for this much needed initiative. Regulatory science represents the knowledge and tools we need to assess and evaluate a product's safety, efficacy, potency, quality and performance. It is fundamental to all of our work at FDA, from supporting the development of new food and medical technologies to bringing new treatments to patients. In many ways, it represents the gateway between discovery, innovation and opportunity and actual products that people need and can count on. Building a strong, robust regulatory science capacity is vital to the health of our nation, the health of people, the health of our health care system, the health of our economic and our global competitiveness.

During the past two decades, research has dramatically expanded our understanding of biology and disease, yet the development of new therapies has been in decline, and the cost of bringing them to market has soared. New approaches and partnerships in the emerging field of regulatory science are urgently needed to bridge the gap between drug discovery and patient care.

Investing in regulatory science will yield better tools, standards and pathways to evaluate products that offer promising opportunities to diagnose, treat, prevent and hopefully cure disease. It will also improve product safety, quality and manufacturing more broadly, including new opportunities to better protect the food supply and support the development of healthy foods and healthy food choices.

I'd like to update you quickly also on our progress implementing the Family Smoking Prevention and Tobacco Control Act law, which gave FDA important new authority to regulate the manufacture, marketing and distribution of tobacco products. I'm pleased to report that so far we have met or exceeded the statutory deadlines in the Tobacco Control Act. During Fiscal Year 2011, we will continue to implement the Act, including overseeing and enforcing the reissuance of the 1996 rule to prevent smoking and smokeless tobacco use among young people and proposing graphic health warning labels for cigarette packages and advertising.

Finally, I'd like to take this opportunity to mention briefly some of our accomplishments in response to the recent H1N1 influenza pandemic. During the past year, FDA was able to license five different H1N1 vaccines in record time, and now more than 80 million Americans have been safely immunized. FDA also authorized the emergency use of antiviral drugs in circumstances for which they hadn't been licensed but where they might save lives. These decisions were based on careful review of the scientific data available for these products. We also conducted an aggressive proactive strategy to combat fraudulent H1N1 products.

So to conclude, FDA's Fiscal Year 2011 budget contains important funding for vital public health priorities, including Transforming Food Safety, Protecting Patients, and Advancing Regulatory Science, as well as to implement the Tobacco Reform Act and other key activities. Achieving these priorities and critical needs is possible because of your support for the Food and Drug Administration, and I thank you.

[The information follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

MARGARET A. HAMBURG, M.D.

COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE
SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT,
FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES
U. S. HOUSE OF REPRESENTATIVES

March 10, 2010

FOR RELEASE ONLY UPON DELIVERY

I. INTRODUCTION

Chairwoman DeLauro, Ranking Member Kingston, and members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of Food and Drugs. I am pleased to present the President's fiscal year 2011 budget request for the Food and Drug Administration (FDA or agency). Joining me at today's hearing is Patrick McGarey, FDA's Director of the FDA Office of Budget and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

My testimony outlines FDA's FY 2011 budget request and the policy initiatives that we are advancing in our budget. I will also summarize recent developments related to FDA actions to implement the Family Smoking Prevention and Tobacco Control Act, FDA's response to the 2009 H1N1 influenza pandemic, and other initiatives at FDA.

II. FY 2010 BUDGET

The funding that you appropriated for FY 2010 shows the depth of your commitment to FDA's public health mission and the health of the American public. On behalf of all Americans who benefit from the work of the FDA, thank you for your support.

This funding allowed FDA to make progress in a wide range of areas.

For example, in the Foods Program, we are hiring and training new inspectors, improving our scientific and technical capacity, initiating a wide range of new State and international partnerships and – working with industry, consumer advocates, and others – laying the foundation for a shift to a food safety approach focused on prevention. We also started critical work on front of package labeling, an effort that will help American families better understand the nutritional content of foods.

FY 2010 funding allowed FDA to aggressively engage with our HHS partners and industry in the public health response to the 2009 H1N1 influenza pandemic. We supported the effort to rapidly develop and deploy safe vaccines, antiviral medicines, and diagnostic tests that were so vital in the public health response.

For drugs and biologics, we began the first phase of the Sentinel system, a distributed network of electronic health data that can track the safety of medical products once they reach the market and quickly investigate potential safety signals. For medical devices, we released key guidance defining a path for more efficient and effective clinical trials.

In the Tobacco Program, we established the new Center for Tobacco Products, implemented a ban on cigarettes with characterizing fruit and candy flavors, and established a program of registration and listing.

We also began a process that will make FDA much more transparent to the American public and to the industries that we regulate. The FDA Transparency Initiative responds to President Obama's Executive Order on open government and the transparency priorities that Secretary Sebelius is advancing.

As part of our Transparency Initiative, FDA held two public meetings, launched a transparency blog, and opened a docket – efforts that received more than 900 suggestions from the public.

In January, FDA launched "FDA Basics," the first phase of the Transparency Initiative. As one observer of the agency commented, "[t]he initiative can go a long way toward educating the public about what FDA does – and how – and also provide industry with real-time answers to their daily challenges, ultimately improving product quality and patient safety." Another said, "[i]t is really well put together, clear and works quite well. . . . The site is not only supportive of transparency, but is highly instructive and educational."

The next two phases of our transparency efforts are well underway, and our goal is to provide communication with the public and industry about FDA actions and the basis for FDA decisions.

We are also developing a major performance management initiative, which will provide additional access to Congress and the public about the activities and progress on more than 50 FDA offices.

III. FDA 2011 BUDGET REQUEST

Overview

The President's FY 2011 budget includes $4.0 billion for FDA programs to protect and promote public health. This represents an increase of $756 million for FDA programs, which includes $601 million for statutory increases for user fee programs in current law and four new user fees to support public health priorities.

IV. DETAILS OF THE FY 2011 BUDGET

Transforming Food Safety Initiative

For FY 2011, FDA proposes an increase of $326.3 million for Transforming Food Safety. This increase includes $87.8 million in budget authority and $238.5 million for three new user fees related to food safety: Food Inspection and Registration User Fees, Reinspection User

Fees for food facilities and Export Certification User Fees for food and feed products. The funding for Transforming Food Safety includes the budget amendment of $8 million that the Administration recommended on February 12, 2010.

The Transforming Food Safety Initiative reflects President Obama's vision of a new food safety system to protect the American public. The initiative is based on three core principles announced in July 2009 by the President's Food Safety Working Group: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

The FY 2011 resources for Transforming Food Safety demonstrate that food safety is a national priority. It reflects the consensus among consumers, industry and experts that our food safety system needs fundamental change to prevent illness and restore public confidence.

With the FY 2011 increases, FDA will set standards for safety, expand laboratory capacity and pilot track and trace technology. FDA will also strengthen import safety and improve data collection and food risk analysis. Most importantly, the FY 2011 resources allow FDA to establish a foundation for an integrated national food safety system focused on prevention.

During FY 2011, FDA will hire 718 additional full-time equivalent (FTE) staff to expand programs that protect America's food supply. The hiring by FDA food safety programs includes more than 425 new FTE in our field operations, of which 132 FTE will be new food inspectors in the field operations of our Office of Regulatory Affairs. Among those 132 FTE, three are funded by budget authority, 99 are funded by food registration and inspection user fees, and 30 are funded by reinspection fees.

When fully trained and deployed, the 132 new inspectors will annually conduct the following additional field activities, based on budget authority and user fee funding proposed for Transforming Food Safety:

- 1,900 domestic food safety inspections
- 150 foreign food inspections
- 1,000 domestic food and animal feed program reinspections
- 200 domestic tissue residue inspections -- for illegal drug residues in meat and poultry
- 3,000 samples for analysis in FDA laboratories.

The Transforming Food Safety Initiative will also allow FDA to fund the cost of living pay adjustment for FDA professionals that conduct food safety activities and pay higher rent and related facility costs.

In addition to the priorities listed above, FY 2011 resources for Transforming Food Safety support the following domestic and foreign activities that implement Food Safety Working Group priorities.

Prioritizing Prevention –

- **FDA will issue guidances and establish new, binding standards to help prevent foodborne illness and reduce food risks.** The standards include new controls to prevent food safety risks associated with fresh produce and other commodities, standards for food inspections, and standards for collecting and analyzing food samples.

- **FDA will conduct audits of its regulatory and public health partners.** FDA audits will evaluate inspection, investigation, sample collection and analysis, enforcement, response, recovery, and outreach activities. The audits will measure performance against FDA food safety standards. FDA will also strengthen collaboration with foreign regulatory bodies to evaluate and leverage inspection data. FDA will begin to develop an updated inventory of foreign facilities to support more foreign inspections.

- **FDA will begin to establish a modern import safety program.** FDA will develop standards to evaluate food safety systems in foreign countries. FDA will also continue third-party certification efforts and develop a registry of all importers. When fully implemented, FDA's import safety program will result in greater oversight of imported foods and provide greater assurance they meet safety standards comparable to those required for domestically produced foods.

Strengthening Surveillance and Enforcement –

- **FDA state liaisons will communicate essential information on food safety standards and priorities throughout the integrated food safety system.** FDA will also develop and implement a national food inspection and sampling work plan. Working with the states, FDA will increase surveillance and sampling of feed and feed ingredients. FDA will improve its analysis of inspection results by establishing a system to electronically exchange inspection data.

- **FDA will improve risk analysis and research for food and feed safety.** FDA will expand its ability to identify products at highest risk for contamination. FDA will use this information to better target and prioritize food and feed safety sampling and inspection. As one tool for food risk analysis, FDA will enhance the food registry used to report problems with foods.

- **FDA will expand the National Antimicrobial Resistance Monitoring System (NARMS).** Expanding NARMS means more surveillance and monitoring of commodities such as seafood and animal feed. Working with CDC and USDA, FDA will also adapt NARMS to monitor emerging pathogens in food animals and retail foods of animal origin.

- **FDA will increase its laboratory capacity.** FDA will establish a new forensic microbiological laboratory and conduct more food safety sampling and surveillance.

Improving Response and Recovery –

- **FDA will conduct pilot studies with industry of track and trace technology.**

- **FDA will improve response and recovery with expanded lab capacity.** FDA will develop technology to reduce the time needed to screen for pathogens. We will focus our energies on priority pathogens and work to reduce screening time to one to two days, compared to the current five to ten days.

- **FDA will invest in enterprise information technology (IT) systems to transform food safety.** Funding for IT systems will also allow FDA to establish, collect and support the proposed new Food Registration and Inspection User Fees Program.

- **FDA will provide essential support to food program offices.** This support will allow food safety programs to achieve priority public health objectives.

Results for Transforming Food Safety –

FY 2011 funding for the Transforming Food Safety initiative will allow FDA to deliver the promise of improved food safety. With this FY 2011 investment, FDA will steadily reduce illnesses caused by contamination of the food supply in the years to come. In summary, Transforming safety will allow FDA to:

- Reduce the number of foodborne illnesses by heightening the focus on preventing harmful contamination
- Identify sources of risk in the food safety system through expanded data collection and analysis and collaboration with partners in other federal agencies and with, States, international agencies, and industry
- Improve industry compliance with food safety standards through more frequent inspection and expanded use of microbial testing and other modern tools
- Reduce time to detect and respond to outbreaks through improved staffing and procedures and collaboration with the Centers for Disease Control and Prevention and state, local, and international colleagues
- Establish stronger links between performance outcomes and resource investments by developing and tracking appropriate measures of progress on food safety
- Better integrate Federal, State, local, and foreign food safety efforts by removing barriers to full collaboration, leveraging of information, and expanding current partnership efforts.

Protecting Patients Initiative

For FY 2011, FDA proposes an increase of $100.8 million for Protecting Patients. This increase includes $49.4 million in budget authority and $51.4 million for two new user fees: Generic Drug User Fees and Reinspection User Fees for medical product facilities.

The Protecting Patients Initiative advances Obama Administration priorities for safe, quality health care for all Americans. The resources in this initiative support new tools and partnerships to enhance the safety of increasingly complex drugs, devices, vaccines, human tissues and America's blood supply.

This initiative will modernize FDA's approach to the safety of medical products at a time when the number of drugs, devices and biologics manufactured abroad is increasing dramatically. With these resources, FDA can act as a strong and smart regulator and address medical product safety challenges in the years ahead.

The Protecting Patients Initiative focuses on four vital areas: import safety, high-risk products, partnerships for patient safety, and generic drug review.

During FY 2011, FDA will hire 215 FTE staff for programs that protect patients and support the safety and effectiveness of medical devices, human and animal drugs, and vaccines, blood and other biologics. This includes hiring 85 FTE in FDA field operations, of which 40 will be new ORA medical product inspectors. Among those 40 FTE, 13 are funded by budget authority, 21 are funded by reinspection fees, and six are funded by generic drug user fees.

When fully trained and deployed, the 40 FTE will annually conduct more than 600 foreign and domestic risk-based inspections. This includes more than 225 inspections funded by budget authority and more than 380 inspections funded by reinspections and generic drug user fees. These include inspections of foreign and domestic drug, device, radiological health, and biologic manufacturers, as well as bioresearch monitoring inspections to protect patients and ensure data integrity in clinical trials. The Protecting Patients Initiative funds the cost of living pay adjustment for FDA professionals that conduct food safety activities. The Initiative also funds higher rent and related facility costs and provides essential support to allow medical product programs to achieve their public health priorities.

In addition to the activities listed above, FY 2011 resources for Protecting Patients support the following priorities.

Import Safety –

Thousands of critical medical products are manufactured outside of the United States. Increased funding for import safety will allow FDA to better understand and respond to the growing challenge of foreign manufacturing and globalization, including counterfeit products.

- **FDA will launch an electronic drug registration and listing system to stop imports of illegal drug.** FDA will also work more closely with trusted foreign regulators to monitor drug manufacturing facilities.

- **FDA will increase foreign inspections.** FDA will identify and inspect the highest risk foreign facilities. FDA will also protect patients through increased inspections of human subject trials.

- **FDA will review and use third party International Organization for Standardization (ISO) audits of foreign device manufacturers.** As a result, FDA will leverage device inspections conducted for foreign governments.

Safety of High-Risk Products –

Drugs, devices and biologics are becoming increasingly complex. To protect the American public, FDA will develop additional capacity to assess the safety of these medical products.

- **FDA will improve the safety of the blood supply, vaccines, human tissues, and cord blood.** To counter threats to the blood supply, FDA will improve the ability to prevent, detect and monitor for infectious agents. FDA will also improve its ability to analyze and respond to manufacturing deviations. FDA will also build additional capacity to identify and respond to adverse events and adverse reactions associated with biological products. FDA will improve vaccine safety through guidance for industry and better understanding mechanisms of adverse events.

- **FDA will begin to build a National Medical Device Registry.** FDA will begin a pilot project to link unique identifiers for medical devices with electronic health data. The result will be improved patient safety by creating a National Medical Device Registry.

Partnerships for Patient Safety –

To meet its public health responsibilities, FDA must interact and collaborate with many public and private entities in a medical system that is committed to safety.

- **FDA will expand postmarketing surveillance systems for medical product safety.** This investment includes support for the next stage in FDA's Sentinel Initiative. The goal of the Sentinel Initiative is to use large databases to fairly and quickly assess the safety of medical products.

- **FDA will partner with public and private organizations to reduce unnecessary adverse events, with emphasis on special populations.** FDA will also work with the private sector to reduce unnecessary medical radiation exposure.

- **FDA will improve pediatric drug and device safety.** Working with international and domestic partners, FDA will identify medical products that are safe for children and those that pose special risks.

- **FDA will improve the safety of animal drugs.** FDA will hire and train scientific staff to review adverse experience reports and require prompt corrective action.

Generic Drug Review –

- **FDA will Increase its Capacity to Review Generic Drugs Applications:** FDA will hire additional staff to support generic drug review.

Results for Protecting Patients –

FDA's Protecting Patients Initiative will have a significant impact on public health in the United States. This science-based strategy will build new and greater safety capabilities, resulting in:

- Reduced number of import safety emergencies
- Fewer serious adverse events linked to medical products
- Early identification of major safety problems with drugs, devices and biologics.

This initiative will permit FDA to rise to the challenge of protecting patients in the 21st century. The initiative supports critical international efforts, upgrades to FDA capacity, and essential partnerships with the private sector. With the FY 2011 resources, the Protecting Patients Initiative will lead to:

- Improved import safety program for medical products
- Increased capacity to conduct inspections
- Improved safety of blood, tissue, and vaccines
- Improved data collection and risk analysis for medical products
- Enhanced assessments of postmarket safety.

Advancing Regulatory Science for Public Health Initiative

For FY 2011, FDA proposes an increase of $25 million in budget authority for Advancing Regulatory Science. The Advancing Regulatory Science initiative is the backbone that supports all other FDA activities, including transforming food safety and protecting patients. At FDA, science is at the heart of everything we do - from keeping the blood supply safe, protecting Americans from global and emerging infectious diseases, supporting the development of new food and medical technologies, to bringing new treatments to patients.

Advancing Regulatory Science for Public Health reflects President Obama's commitment to harness the power of science to benefit America. In his April 2009 address to the National Academy of Sciences, the President declared, "science is more essential for our prosperity, our security, our health, our environment, and our quality of life than it has ever been before."

During the past two decades, U.S. research investments have dramatically expanded our understanding of biology and disease. Yet the development of new therapies has been in decline, and the costs of bringing them to market have soared. As a result, we have experienced lost opportunities to improve the effectiveness of U.S. medicine and the success of the biotechnology industry.

Today, FDA is relying on 20th century regulatory science to evaluate 21st medical products. Regulatory science is needed to provide better tools, standards, and pathways to evaluate products under development. It also serves to create efficiencies in the development process, and improve product safety, quality, and manufacturing. The Advancing Regulatory Science initiative represents the first comprehensive effort to modernize regulatory science at FDA.

Stem cells and personalized medicine are two examples of areas that could change the way we treat many diseases. Stem cells offer hope for treating patients with neurodegenerative diseases, such as Parkinson's and Alzheimer's disease. For the promise of stem cells to come to fruition, FDA must develop standards for stem cell therapies so that they can be produced reliably and safely. In the area of personalized medicine, FDA must work collaboratively to identify markers that can predict whether a patient will respond to certain cancer therapies. FDA must use cutting-edge science to validate these tests for use in clinical practice.

In addition to helping patients benefit from biomedical advances, improvements in regulatory science will also support better assessment of drug and device safety, better tools for food safety, and better understanding of how to reduce the enormous public health harm of tobacco products.

The Advancing Regulatory Science for Public Health initiative focuses on three broad themes: science leadership and coordination, core capacity, and modern standards for evaluating products.

Science Leadership and Coordination –

- **FDA will strengthen scientific leadership.** The Office of the Chief Scientist (OCS) will support FDA and its centers with dedicated and expert scientific leadership. OCS will work with the centers to prioritize, oversee, support and coordinate key scientific investments at FDA.

Core Capacities: Infrastructure, Workforce, Collaboration –

- **FDA will build core scientific capacity in the field of nanotechnology.** Nanotechnology holds great promise in many areas. Examples include targeting drugs to where they can do the most good and least harm and making improved material for medical devices. Yet, nanoscale materials may interact very differently with biological systems and require special methods to assess safety and effectiveness. FDA will support science focused on the sound evaluation of nanotechnology-based products. The goal is to realize their promise while protecting patients and consumers.

- **FDA will support the development and evaluation of products from stem cell innovation.** The FDA investment will support the transfer of stem cell discoveries from the bench to the bedside.

- **FDA will recruit next generation scientific staff.** FDA will begin targeted recruitment in essential areas of emerging science where FDA has an expertise gap.

- **FDA will address science issues that support a National Medical Device Registry.** FDA will begin a pilot project to link unique device identifiers with health-related electronic data to create a National Medical Device Registry. The Registry will improve our understanding of the risk-benefit profile of higher risk devices.

- **FDA will promote scientific collaboration through the Critical Path Initiative.** FY 2011 investments in FDA's Critical Path Initiative will allow FDA to foster partnerships that transform product development and evaluation sciences, advance personalized medicine, support meeting unmet public health needs, and better predict and prevent safety risks early in development.

Medical product regulatory standards –

- **FDA will update review standards and provide regulatory pathways for biosimilars.** FDA will establish regulatory guidance to provide a scientifically sound and safe pathway to characterize and develop biosimilars.

- **FDA will increase its ability to regulate animal biotechnology products.** FDA will hire and train staff to strengthen our knowledge base and thereby support the review and potential approval of animal biotechnology products.

- **FDA will promote development of healthy foods and encourage healthy food choices.** FDA will use data from well-designed studies to support a modernized food label to encourage Americans to eat healthier diets.

The Initiative also funds rent and related facility costs to conduct initiative activities and provides essential support to allow medical product programs to achieve their public health priorities.

Tobacco Control Act

On June 22, 2009, the President signed H.R. 1256, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), into law. The Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products.

FDA's goals for the tobacco program include:

- preventing youth from using tobacco and helping adults who use tobacco to quit
- promoting public understanding of the harmful and potentially harmful constituents of tobacco products
- developing a science base for tobacco regulation
- beginning meaningful tobacco product regulation to reduce the toll of tobacco-related disease, disability, and death.

In September 2009, after a national search, I selected Lawrence Deyton, M.S.P.H, M.D., as Director of the Center for Tobacco Products. Dr. Deyton is an expert on veterans' health issues, public health, and tobacco control and prevention. He also is a clinical professor of medicine and health policy at George Washington University School of Medicine and Health Sciences.

During FY 2010, FDA made substantial progress in establishing the tobacco program and implementing initial steps under the Act.

To date, FDA has met or exceeded the statutory requirements of the Tobacco Control Act, including:

- establishing the tobacco products user fee program to support FDA's tobacco program
- issuing and enforcing a ban on cigarettes with certain characterizing flavors, including fruit and spice flavors
- publishing a guidance document related to tobacco product establishment registration and product listing and began tobacco industry registration with FDA
- publishing a guidance document describing the requirements for providing listings of all ingredients used in making cigarettes, smokeless tobacco, and certain other tobacco products and began accepting tobacco product ingredient and constituent listings
- establishing an FDA program to assist small tobacco product manufacturers
- creating the Tobacco Product Scientific Advisory Committee.

FDA is in the midst of an aggressive recruitment and hiring program, with a goal of hiring 370 FTEs in the tobacco program by FY 2011. I am pleased to report that FDA has met or exceeded the statutory deadlines in the Tobacco Control Act. During FY 2011, FDA will continue to make progress in tobacco product regulation. We will learn from the successes of our international counterparts that also regulate tobacco. We expect to implement a number of key steps in the next year. These steps will include reissuing and enforcing the 1996 rule to prevent smoking and smokeless tobacco use among young people and proposing graphic health warning labels for cigarette packages and advertising.

New User Fees

The new user fees proposed in FDA's FY 2011 Budget will facilitate the review of generic drugs and enhance FDA's ability to register and inspect food and feed manufacturing and processing facilities. New user fees will also allow FDA to reinspect facilities that fail to meet good manufacturing practices and other safety requirements and allow FDA to collect fees when it issues export certifications for food and feed.

V. FDA RESPONSE TO THE 2009 H1N1 INFLUENZA PANDEMIC

I would also like to take this opportunity to report to the committee on FDA's response to the 2009 H1N1 influenza pandemic. As we reported to you last year, FDA established an incident command approach that allowed us to work across government, internationally and with the private sector to rapidly mobilize emergency response.

Key accomplishments include:

Licensing Safe and Effective Influenza Vaccines. FDA worked to facilitate development, production, and availability of vaccines. FDA licensed pandemic influenza vaccines from all five U.S.-licensed influenza vaccine manufacturers. These pandemic vaccines were subject to the same stringent manufacturing and quality oversight processes in place for seasonal influenza vaccines. More than 70 million Americans have been immunized with these vaccines, based on CDC's coverage survey estimates. Extensive safety review involving active surveillance systems that have captured information from approximately 4 million patients has found the vaccine to have the same excellent safety profile as the seasonal influenza vaccines.

Authorizing Emergency Measures. Our physicians and scientists worked tirelessly to facilitate the availability of antiviral medications to patients. FDA authorized 13 laboratory tests, 3 drugs, and certain types or models of respirators, known as N95 respirators, to provide tools to doctors across the country to fight the novel H1N1 influenza. For example, FDA authorized the emergency of use of an unapproved intravenous antiviral drug, Peramivir, to treat certain hospitalized patients. FDA's work on dosing of Tamiflu in children under the age of one year was adopted by countries around the world. In addition, FDA authorized the use of antiviral medications that otherwise might have been thrown away because they were beyond their labeled expiration dates. Our efforts on expiring drugs helped prevent shortages of essential medicines for patients.

Cracking Down on H1N1 Fraud. FDA established the 2009 H1N1 Consumer Protection Team that conducted an aggressive, proactive strategy to combat fraudulent 2009 H1N1 products. To date, the team has sent more than 80 Warning Letters to more than 85 web sites, covering about 150 different products purporting to be dietary supplements, medical devices, drugs or biologics. These Warning Letters have resulted in a compliance rate of about 80 percent.

FDA is pleased to have worked so closely with its sister agencies under the leadership of the Department of Health and Human Services in the pandemic response. We will continue our work to pave the way for manufacturers to develop faster and more reliable vaccines, antiviral medications, and diagnostic test.

VI. CONCLUSION

The FDA FY 2011 budget of $4 billion contains important funding increases for important public health priorities: Transforming Food Safety, Protecting Patients, Advancing Regulatory Sciences and implementing the Tobacco Reform Act. Achieving these priorities is possible because of your support for the work of the Food and Drug Administration.

Thank you for the opportunity to testify. I am happy to answer your questions.

ENFORCEMENT ACTIVITIES

Ms. DELAURO. Thank you very much, Commissioner. Let me make one comment and then move to a question. This is on the enforcement activities within the agency. And very quickly, during the last Administration, it often seemed that a warning letter or a confiscation of tainted goods or decisive action to protect the public was a last resort. I want to tell you that I am personally just reassured about the contrast, very honestly, and a different approach. On February 3rd, 2010, seizure of a product from a company following inspections in November-December 2009, of January 2010, again a seizure December 2009, FDA issues the first ever debarment of a food importer, stopping the individual from importing food into the United States for 20 years. August 1st, 2009, FDA seizes contaminated product after a company refused to destroy them following a June 2009 inspection.

So there seems to me to be a priority on enforcement, which is I say, very reassuring. I will get back to that because I want to ask a budget question, get back to you with your vision for improved enforcement, and I know you've spoke to this issue as well. Let me—but I think that that reflects truly a new environment and for me personally, nothing could give me again more assurance that we're on the right track.

This is a complicated budget, Dr. Hamburg, and there are lots of moving parts. We've got cross-cutting initiatives, multiple pieces, multiple centers, current law user fees, increased proposed new fees. In the foods area, the budget depends heavily on getting, as I said, $220 million in user fees that would be provided in the House bill. This is really in two parts. What I'd like to do is if you can, briefly walk us through the bullet points in the foods area to give us a sense of what is funded by budget authority, what is funded by fees. There is the assumption of the fees, as I said in my opening remarks, the Senate bill doesn't include the registration fee that makes up most of the total amount that's in the budget. That bill raises only $65 million. I want to also walk through this piece but also ask you to talk about your commitment in terms of fighting for the House level when this bill goes to conference.

2011 BUDGET

Dr. HAMBURG. Well, thank you for the question. It's a very, very important issue, and, you know, we certainly have appreciated the support given by this committee to our food safety activities and also the passage of the food safety bill by the House, and we are hoping to see it go forward on the Senate side swiftly. And it will be very important in terms of giving us additional resources and authorities.

It is a complicated budget, and as you note, there are elements of our proposed budget that rely on new user fees that don't yet exist. In thinking about how we structured the 2011 budget, we felt that we needed to be prepared for the possibility that we would have to go forward without the passage of the bill and without those additional dollars and resources. The budget authority component is more limited, $88 million, as you know.

We have targeted it in certain key ways, and perhaps a couple of examples, you know, are important, and we can certainly sit down with you and go through, you know, the entire food program. That would probably take up our whole session. But let me just make a few comments. The budget authority in the 2011 budget is really being targeted to building essential infrastructure to support program expansion and the shift to a preventive approach from a reactionary approach, recognizing that you've already made some critical investments that have helped us to start the process of staffing up, which is very, very key. Now we want to make sure that there's a sort of core infrastructure for that staff to do their important work and that as we go forward, there's an integrated, comprehensive program.

INSPECTIONS

So in one key area that I know is important to you, the area of inspection, in terms of use of budget authority, there is going to be less emphasis on inspection. We would be targeting our—we would have three FDAs—three FTEs that would be hired with budget authority, and they would really be targeting on tissue residue inspections, which is a gap. In terms of domestic food inspections and foreign food inspections, we have, you know, a pretty significant number of new investigators in the pipeline. We've hired about 700 new investigators, thanks to your recent investment. So it takes some time for training to get them up and running in the field. So we anticipate that in 2011, they will be moving into the field and able to meet some of the demands of inspection. We would love to be able to enhance them with additional user fee-based hires in the inspection area, but we do believe that in terms of the program needs, they're in the pipeline, and so we're going to be focusing the budget authority in other areas to support those activities and also the transformation of the food program and our activities. For example, it's very, very important that we strengthen the integration of our food safety program in terms of relationships with states and localities. And so we would be targeting a big chunk of the budget authority dollars, $15.2 million, to our work with states on food inspections and regulatory activities, and that's very, very important. We hope to be able to supplement that with user fee dollars as well. But they need money straight away to help them partner with us in these important activities.

FOOD SAFETY ACTIVITIES

We also do need additional money right away to help with our expansion of some of our food safety activities in terms of import safety and our work to harmonize standards and approaches, our work with other regulatory agencies and our work to strengthen our international presence as we're dealing with an increasingly globalized world and food imports coming in from over 150 countries and, you know, literally several hundred thousand facilities and producers.

So, you know, we recognize that this is a challenging science with uncertainty. We're going to work very, very hard. I have meetings later today on the Senate side to discuss the food safety legislation and try to encourage that it moves forward. It will be vital

in terms of both the additional resources and also, as you know, new authorities for FDA to be able to do its job better.

Ms. DELAURO. My time has expired, but I would just say this. I want to sit down with you or with your staff and go through the food safety piece and what is budget authority and what is user fees because I think unless we have the Senate move in the direction that the House did that we are going to see difficulties. And we should not proceed to a major legislation and reform of the system and then doom it to failure from the start. That in my view would be a serious, serious error. I think my colleagues, you know, on this committee believe that. And if we have that information, I don't know what the timetable is, though I hope it is soon on the Senate side, that what we would want to do is to sit down over there as well and try to talk about this issue so that we can not find ourselves moving backward instead of forward in this area.

Dr. HAMBURG. I so appreciate your support on this issue.

Ms. DELAURO. Sure. Mr. Kingston.

Mr. KINGSTON. Thank you, Rosa. I want to yield to Mr. Latham, who's got another committee meeting that he needs to get to.

Mr. LATHAM. Thank you, Jack. And again, welcome.

Dr. HAMBURG. Thank you.

ANTIBIOTICS AND LIVESTOCK

Mr. LATHAM. I do appreciate the fact you came by yesterday. As we talked about yesterday, farmers supplying consumers with probably the most safest, most consistent source of protein anywhere in the world, and our producers know that confidence in their products is critically important. And again, yesterday, we talked a little bit about this, but one thing that concerns me a lot is the fact that as we go through some these issues, antibiotics and livestock, that there is an element, at least the farmers would be involved in the process, and I actually would invite you to come out to my district. We have the National Animal Disease Center, the Veterinary Biologics Center. It's all in my district. We have one of the largest animal antibiotic producers, Fort Dodge Labs, has two large facilities in my district, and you'll come to Iowa and find out that there's 3 million people, but we have about 17, 18 million hogs in Iowa. That's about three to one, or excuse me, about six to one actually of hogs to people. So it is obviously a major issue for us and all the livestock production, largest as far as egg production in the country also.

But let me just ask you straight out. Is it FDA's intention, and I've got, you know, the testimony here or a story from the New York Times back last July 14th, Dr. Sharfstein saying that he wants to ban antibiotics in livestock. Is the FDA's intention?

Dr. HAMBURG. I don't believe he actually said he wanted to ban antibiotics in livestock. But I think that the issue you raise is a very, very important one. It's a major public health concern and we must work together to preserve the effectiveness of important antibiotics for both human health and animal health. And I think that, you know, what we need to do as an agency is work closely with all of the stakeholders and develop a science-based approach so that we can in fact ensure that we have the antibiotics needed to treat important diseases. And I think you've probably read the sto-

ries or know from even personal experience that this is a real world problem in terms of antibiotic resistance in hospitals, you know, having patients with disease that can't be treated because——

Mr. LATHAM. Right.

Dr. HAMBURG [continuing]. All of the traditional therapies have developed resistance. I grappled with this as New York City's health commissioner with a devastating problem of TB resurgence and drug resistance.

So we are moving forward on a path——

Mr. LATHAM. Is there any science that says there's a connection?

Dr. HAMBURG. Yes there is, there is.

Mr. LATHAM. Where? Can you——

Dr. HAMBURG. And we know that there are certain antibiotics that have been very much associated with the development of resistance in terms of their use in animal populations. But we want to ensure judicious use——

Mr. LATHAM. Can you get me that information?

ANTIBIOTIC RESISTANCE

Dr. HAMBURG. Okay. One example is the fluroquinolone drug class, which is very, very important for human health and animal health. But it actually had to be withdrawn from use because of the seriousness of the resistance concerns. We'd be happy to provide you with more information.

[The information follows:]

There are a number of medically important antimicrobial drugs that are used in food-producing animals. Some examples include the fluoroquinolones, third generation cepahalosporins, and macrolides.

These classes of drugs are critically important therapies for treating foodborne bacterial infections in humans. Therefore, if foodborne bacteria become less susceptible or become resistant to such drugs, the effectiveness of these drugs for treating foodborne bacterial infections in humans would be impaired or lost.

The fluoroquinolone and third generation cephalosporin drugs currently approved for use in food-producing animals are limited to uses that involve administration to individual animals for therapeutic purposes and require the supervision of a veterinarian.

But let me just reassure you that, you know, we are committed to a science-based approach to do what's necessary to support judicious use of antibiotics. That does not mean an across-the-board ban. It does mean that the use of antibiotics for growth promotion alone really needs to be scrutinized very, very carefully. But for the treatment of infectious disease in animal populations and for the prevention of certain disease conditions in animal populations, antibiotics have an appropriate and necessary use.

We need to engage the veterinary community and the animal agriculture community completely in our efforts, and we've been reaching out to stakeholders, meeting. I should come out and visit. I have engaged in some visits, as has Dr. Sharfstein. But it's a very, very important area for public health, and the position FDA is taking is consistent with the World Health Organization, with the CDC, with the American Public Health Association, with the American Medical Association, and the list goes on. You know, this is one of the foremost public health concerns in the nation.

Mr. LATHAM. Are you waiting for congress to address the issue or are you going to be proactive? I just have grave concerns about

the link supposedly between keeping healthy animals, and you're talking about promoting growth. Basically, a healthy animal does grow better, yes; but, there's no growth hormones or anything being involved, you know. And I honestly think that the American people would rather eat products coming from healthy animals than maybe animals that are sick.

Dr. HAMBURG. Well, we definitely want to prevent illness in animals. We want to prevent illness in people, but we do need to do this in a thoughtful way, science-based, that preserves essential antibiotics for health and disease prevention. We are working closely with industry, listening to their concerns.

We are not going to move forward and institute a policy that we have not been able to base on sound science and evidence, and explain to industry and work with them towards solutions. There also are regulatory pathways that we're looking at in terms of how we would move forward, potentially. And, of course, there is a legislative pathway that could be pursued as well.

And, as you probably know, there is one bill that is under consideration at the present time, which the administration doesn't have a formal policy on. We take a somewhat different approach than that legislation in terms of how we think about the problem of judicious use of antibiotics, whether for treatment prevention or growth promotion, but this is a very important issue. I'm very happy to continue this discussion.

Mr. LATHAM. Our time.

Dr. HAMBURG. Our time. I apologize for giving a lengthy answer, but it's important and I know it's of great concern to you and your constituents.

Mr. LATHAM. Thank you.

Ms. DELAURO. Thank you. Mr. Hinchey.

FRONT OF PACKAGE LABELING

Mr. HINCHEY. Thank you, Rosa. Commissioner Hamburg, I want to thank you very much, because all the things that you're doing are improving the FDA and making it more responsible, and making it better and stronger for the people of this country. But there are a number of other things that I think really still need to be done, if you haven't been there all that long. But I wanted to ask you about a couple of them.

Taking the initial step, for example, to rein in the food manufacturer and the misleading claims about the nutritional value of those products, and the fact that they can under the existing set of circumstances be 20 percent wrong, be 20 percent mistaken. That's something that really needs to be addressed. The FDA developed this margin of error after the bill was passed back in 1990, but it made no provision whatsoever that there could be that deep margin of error. So I'm wondering why that happened, and, even more important, the fact that that should be changed.

So I just wanted to ask you. Do you think the margin of error, 20 percent, is much too high? Or, do you agree with most of us, along with what Dr. Susan Roberts of Tufts University said recently, that a 20 percent permissible margin of error was too high and should be lowered to a maximum 10 percent.

Dr. HAMBURG: Well, I appreciate your question, and we are putting a lot of new attention and focus on front of package labeling and various kinds of nutritional and health claims on food products. The 20 percent margin of error question, I think, relates to the issue of calorie counts; and I think there are some technical issues in terms of, you know, calorie counts vary, and also the technology. But I think this is an area where we want to be as precise as possible, because it really matters to people as they try to make healthy choices for their diets. I think it's an area where we can bring new technology and advances in how we make these assessments to bear, and that's part of our Advancing Regulatory Science initiative.

NUTRITIONAL INFORMATION

I think that along with addressing those kinds of questions and how can we sort of tighten up and make more accurate our presentation of information, we are looking at other important components such as serving size, because that can be quite misleading. I think very few people eat six tortilla chips, but that's what's, you know, sort of given as, you know, a serving size in some instances. I don't know if that's an exact example, so we are looking at those issues very seriously now trying to update our nutritional guidance on standards, and also looking to how we can better present nutritional information on the front of packages and also talking with industry about concerns of inappropriate or inaccurate or misleading claims that may be made on food packaging. And, you know, we just recently, I think it was just last week sent out some 20 warning letters concerning inappropriate——

Mr. HINCHEY. So you're determined to improve this situation?

Dr. HAMBURG. We are determined to improve it. We have a team working very actively on it. We're working with industry so they understand our concerns.

Mr. HINCHEY. What about the 10 percent? Do you think that that 10 percent is achievable quickly?

Dr. HAMBURG. You know, I would have to get back to you on the specific details. You know, perhaps even look at the paper that you're referencing, but it's something that our team would certainly be eager to look at and get back to you on.

[The information follows:]

The 20 percent figure is not a margin of error. FDA's compliance criteria, including the 20 percent allowance for variation in naturally occurring nutrients, were developed as part of the 1973 final rules for nutrition labeling. In the January 19, 1973 *Federal Register*, FDA published a regulation which established a statistical approach to determine compliance with nutrition labeling requirements. The natural variation in the nutrient content of food products was well recognized, and the need to set practical limits of variation in nutrient levels for compliance purposes was the subject of extensive discussions. In developing the nutrition labeling system, it was important to provide a sufficient tolerance so that manufacturers could provide useful nutrition information on the label while meeting consumers' expectations that nutrition labeling would honestly represent the composition of the products that they purchased. The objective of the regulation was to secure compliance with requirements for average nutrient levels for units in a lot with only as much variability among units as is inherent in the naturally occurring nutrients when foods are processed under current good manufacturing practice. FDA is currently working on updating the nutrition facts label, and this is one item that we may consider reevaluating based on more recent science. However, additional research on the varia-

bility of nutrients within foods may be needed to determine if the 20 percent figure could be modified.

PHARMACEUTICAL INDUSTRY

Mr. HINCHEY. Okay. Well, I appreciate it if you would and I would appreciate all the things that you are doing. And if you would continue to focus on this kind of situation, and additionally among a variety of others the relationship between the pharmaceutical industry and FDA.

Over a course of time there has become a very sort of close relationship between these two operations: the pharmaceutical industry and the Food and Drug Administration who is supposed to oversee the pharmaceutical industry. A lot of the funding for FDA comes out of the pharmaceutical industry, which brings about a relationship which is inappropriate and really shouldn't be allowed to be there. The close relationship between the pharmaceutical industry and the FDA is something that is not being helpful to the people of this country. And I think it is hurting the FDA's ability to be objective and careful, and overseeing and engage in the right kind of oversight that is going to make the pharmaceutical industry's products safe and secure.

POSTMARKET DRUG SAFETY

Now, we have seen a number of examples of that just recently and we continue to see them over time as to the kinds of dangers that can occur if the operation is not as effective as it should be. So there should be an improvement in the agency's post-market drug safety operations, and I am sure that you agree with that. And I am just wondering what kind of activities may be intended to be engaged in to bring about the very effective separation between oversight and the pharmaceutical industry and the fees on drug company advertising to better monitor some of the ads that are put out. And when these ads are not accurate and not nearly as accurate as they should be, and, in effect, provide false information to people who makes them make decisions that may not be in their interest. So I know it's a complex set of circumstances, but I would appreciate it if you could give us some idea as to what the FDA might intend to do now to overcome this cozy, close relationship, instead of the oversight between FDA and the pharmaceutical industry.

Dr. HAMBURG. Well, thank you for the question, and I do understand and appreciate your concerns. I think you actually asked about six questions there, so I'll try to see if I can capture all of them.

CONFLICTS OF INTEREST

Mr. HINCHEY. Well, we have a few minutes. So, you know.

Dr. HAMBURG. But your opening component focused on how can we assure that we have appropriate firewalls and that we have a decisionmaking system that is based on the best possible evidence and sound science, and not undue, external influence from industry or other sources. That is very, very important to me, and, you know, I feel very strongly that our agency must have the resources

that we need to fulfill our important mission, but that we have to be grounded in science.

You know, examining the integrity of our decisionmaking and assuring that it is free from conflict of interest and other concerns is one of the most essential elements of FDA being able to do its work, being able to have the trust and confidence of policymakers and the public, and certainly one of my highest priorities. So we take it very seriously.

We have established firewalls in terms of the use of user fees. We are committed to a science-driven decision-making process, and it's a dynamic concern. We can't just sit back and say our systems are in place. Move on to the next issue. It's something we have to continually be monitoring, continually responsive to concerns as they're raised and ensuring that we have the right checks and double-checks.

ADVERTISING

With respect to your question about advertising and the volume of advertisements to be monitored is huge, and some of the investments that this committee has helped to support to expand resources in that key area and others has been very, very important. We are not able to review everything in as timely a way as we would like, but we are strengthening our staffing in that area and expanding our capabilities.

I think we also are trying to work with companies around how they can be more responsible in terms of their advertising strategies and messages, and hopefully bringing in some public health education about disease conditions as well as advertising their product and strengthening our capabilities around risk communication in terms of these issues as well. But in a world where we now have the internet as another advertising arena, it only is getting more complex and more challenging.

Mr. HINCHEY. That's another example of why it really needs to be overseen. So I am introducing some legislation, which deals with the subjects that we've just been talking about and some other things that really need to be addressed in the context of ensuring the safety and security of the people of this country.

I would appreciate it deeply if you wouldn't mind taking a look at it and giving me your impression and how you might follow through on the recommendations contained in this legislation. And thank you very much.

[The information follows:]

FDA will be happy to review your draft legislation and provide you with FDA's views.

USER FEES

Ms. DELAURO. Let me just make a point that this committee—is it two years ago—actually appropriated funds and quite frankly refused to deal with user fees in this area by the companies overseeing their ads, which I would continue to oppose. I am glad to see it is not in the budget, but we were willing to provide resources in order to address this issue and would continue to do that. And I won't get into it. Maybe Ms. Emerson does, but in fact we do have

legislation with regard to directive consumer advertising and moratorium. With that, Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chair. I wanted to touch base a little bit more on Mr. Hinchey's questions, because one of the concerns that we have and, I think, you just need to always be mindful of that firewall.

I am actually okay with the user fees, but I agree with everyone on the firewall issue. And one of the things that blurs is the revolving door of FDA employees leaving and going to work with a pharmaceutical company, or whatever. And, you know, we certainly are always accused of that in congress.

So what do you do to prevent that? Do you have as members of congress have a one-year ban on lobbying if they assume another job? Do you have anything like that?

Dr. HAMBURG. No.

FDA EMPLOYEES

Mr. KINGSTON. And is it a common practice for FDA employees to go to work for somebody that they had been regulating?

Dr. HAMBURG. You know, I am sure that we have some numbers on that. I don't know. One of the things I've been struck by is how many employees come to FDA and stay at FDA throughout their professional careers, despite the fact that they could in fact be making much more money on the private sector side. But, certainly, there are people who leave FDA and go to work for industry. But, you know, we can go back and try to get you some numbers.

[The information follows:]

There is no data that can be extracted from the FDA Central Personnel Data File to identify FDA employees who have left the organization to work for private industry.

It is only possible to identify FDA employees who have left FDA to work for another government agency. Such employees can be identified if the FDA agency code is maintained by the Office of Personnel Management and is listed in the employee's Central Personnel Data File.

Former employees are subject to certain restrictions once they leave Federal service. The post-employment restrictions are contained in Title 18, U.S.C., Section 207, a criminal conflict of interest statute.

18 U.S.C. 207(a)(1) prohibits a former employee from making any communication or appearance on behalf of another, with the intent to influence, before any employee of the United States in connection with a particular matter involving specific parties in which the former employee had personally and substantially participated as an employee. This is a lifetime prohibition.

18 U.S.C. 207(a)(2) prohibits a former employee from making any communication or appearance on behalf of another, with the intent to influence, before any employee of the United States in connection with a particular matter involving specific parties that was pending under the former employee's official responsibility during the former employee's final year of government service. This prohibition lasts for two years from the time the employee teminates government service.

18 U.S.C. 207(c) prohibits a former "senior employee" from making any communication or appearance on behalf of another, with the intent to influence, before an employee of his or her former agency for one year after terminating the senior position. This restriction applies to any matter pending in the agency on which the former senior employee seeks official action on behalf of another and is not limited to particular matters involving specific parties.

All of the above restrictions apply only to communications or appearances made on behalf of another with the intent to influence official action. The statute contains less common prohitions, such as prohibitions involving trade or treaty negotiations and former senior employees aiding or advising certain foreign entities. The statute

also contains a number of exceptions, such as exceptions for actions taken as an elected official of a state or local government.

Under a separate statute, 41 U.S.C. 423(d), there is also a one-year ban on contractor compensation for certain employees who had worked on a contract in excess of $10 million.

But I think your point about appropriate firewalls is absolutely key in terms of the use of the user fees and in terms of the relationships with the industry. It is important, obviously, that we work with industry, since we're reviewing products produced by industry and products that have huge benefits for public health.

TRANSPARENCY INITIATIVE

I believe that an area where FDA can do better and we are starting down that road is in terms of transparency, being much more clear and explicit about what we are doing, how we are doing it, what decisions we have made, how we've come to those decisions. We have a whole transparency initiative, which is moving forward, and the first stage of it is in place in terms of just a sort of a FDA, ABC, or FDA 101, were on the web.

NUTRITIONAL CLAIMS

Mr. KINGSTON. Well, let me ask you this. I think that it is. The system has been working a lot better than it was 10 years ago, so I think a lot of progress has been made.

Mr. Hinchey also talked about advertising, and, you know, I love seeing these: "Buy the little purple pill and then you too can dunk the basketball like LeBron James," even though you're 80 years old, and you're dancing and riding bicycles, and doing extreme sports. But, you know, it's not just pharmaceutical companies driving that.

A lot of times you look at the food packaging, and something's called light or low fat or healthy choices. And I read a nutrition action newsletter, and it always will look at a label of a specific product and say why it is misleading. And I'm not one for bigger government and more lawsuits in this world, but where is the line, and do you have oversight over packaging like in terms of the promises?

Dr. HAMBURG. Well, we do have a responsibility to look at health and nutritional claims, and we do work with companies to try to assure the accuracy of those claims, and we also do take certain, more aggressive actions, when they are not in compliance with the requirements around appropriate claims. And we recently, as I said, sent out warning letters about nutritional claims, health claims that we thought were inaccurate, misleading or fraudulent.

HEALTHY CHOICES PROGRAM

You mentioned the healthy choices program. You know, when that first came out, we looked at it and we were very concerned about some of the products that were getting a healthy choice check. And we wrote to industry and expressed our concerns, met with industry representatives, and they actually did withdraw that program because there were concerns that it wasn't providing consumers with the accurate information that they needed. And we're

now working towards a more science-based and more easily understood program for front of package labeling.

Mr. KINGSTON. And I don't think that there's necessarily any sort of deviousness on the part of the food industry. It's just that we live in a culture where if somebody eats two donuts instead of three, they feel like they're ahead of the game. It would never occur to us to eat an apple. So, you know, I think if somebody said, "yeah, look. This is lower calories—lower calories than what you've been eating, fatso."

Dr. HAMBURG. Right.

Mr. KINGSTON. And it's a step in the right direction, so I don't know that it is really disingenuous. It's just that it is culturally, we don't.

Dr. HAMBURG. No, I think that's right. And I think, you know, I also have to underscore that what we do with respect to nutrition is just one component of a comprehensive program that will really make a difference in terms of education and access to healthy foods and other things.

Mr. KINGSTON. Okay. Well, thank you, ma'am.

Ms. DELAURO. Mr. Jackson.

BPA

Mr. JACKSON. Thank you, Madam Chair.

Dr. Hamburg, I would like to applaud the FDA as you have reversed the agency's position on the safety of BPA to express concern about possible health risks and provide information to consumers on how they can reduce their exposure to this chemical, which is commonly found in plastics and canned goods.

The "Journal of American Medical Association" reported last year that humans with higher levels of BPA in their blood have, and I quote, "an increased prevalence of cardiovascular disease, diabetes and liver enzyme abnormalities." As a father of younger children I know I share the concerns of parents and other individuals on the safety of BPA. I understand that the FDA has planned a targeted, two-year study to determine what actions are necessary to protect public health. Could you please elaborate on the plans of the $30 million study of BPA?

Dr. HAMBURG. You are very correct that FDA has recently reviewed the scientific literature. And we have, I think, enhanced our level of concern about BPA based on emerging, scientific studies, also identified some critical gaps in our knowledge about BPA and the need to address them, and working with colleagues in government, the NIH and the CDC undertaking research activities. It's a $30 million research undertaking, as you know.

And it's to try to better understand how data that's emerged from low level exposure studies in animals actually relates to the effect of BPA and those exposures and human beings. The animal models are not exactly equivalent to humans. The animals metabolize BPA differently. It recirculates more in the animals than in humans that excrete it more quickly. So we need to understand, you know, how to compare the animal models with the human models.

And there are some additional studies that need to be done as well; and, of course, there is ongoing research beyond what we are

doing and funding that needs to be reviewed. And we are going to be looking at the totality of the data going forward. In the meantime, we do recommend that consumers that are as concerned as you are, understand how they can reduce their exposure to BPA, especially mothers of newborns who are very concerned about baby bottles. We've been encouraging industry and working with industry to eliminate BPA from baby bottles and sippy cups. And most American bottle manufacturers have done so. Also, recommendations, you can find them on our website about other ways to reduce exposure to BPA, but it's very, very important that they will have that information.

Ms. DELAURO. Would the gentleman yield for a second and then I'll provide you additional time?

Mr. JACKSON. I appreciate that. I would be happy to.

Ms. DELAURO. On this issue, because I have a question as well, and I mentioned this in my opening statement. How long is this study going to take, Dr. Hamburg?

Dr. HAMBURG. Well, we expect to have results in 18 to 24 months.

YALE BPA STUDY

Ms. DELAURO. So it's up to two years. Now, I will tell you. I started to read the report. I am not a scientist, so I will get it translated for me into lay person's language. But it is just a group of scientists at Yale University School of Medicine, Department of Obstetrics/Gynecology/Reproductive Sciences. It was recently published, "Journal of the Federation of American Societies of Experimental Biology." It found that exposing a fetus to BPA can cause serious damage.

One of the researchers likened BPA exposure to DES, which is deeply disturbing. This is on the front page of the "New Haven Register" just this week: "Yale study details how and why of BPA's danger." They specifically talk about women and infertility and uterine cancer. Again, what I don't understand about this, and I would just add to what my colleague, Mr. Jackson, has said here is that in the interim while we move at this we proceed very cautiously.

I am not against proceeding cautiously, but two years to deal with this issues, and we take as our guidepost, it would appear, the science that is developed by the industry. Instead of taking the science that is developed by academics, et cetera, who have serious concerns about this and say, okay, industry, we're going to stop this while we examine the academic science that is telling us that we've got some serious problems here. That is very, very troubling with this issue, and we've been going round and round on BPA now for a while. So you'll get your time, Mr. Jackson, but I thought it would be appropriate to, you know, add that question at this juncture with regard to your concerns about this mission.

RADIATION EXPOSURE

Mr. JACKSON. It is more than appropriate, Madam Chair. Recently, the Chicago City Council voted to ban BPA in bottles and sippy cups in May of 2009. I have a final question regarding this.

I recently met and the chair recently met with the CEO of Green Planet Bottling Company, an Illinois-based company, which produces petroleum-, chemical- and BPA-free bottles that are completely biodegradable. I am wondering what more the FDA can do to direct concerned parents and their families to options that are BPA and chemical free. Does this committee and/or this congress need to statutorily require the elimination of BPA in these bottles? And let me ask one final question given my time constraints.

Dr. Hamburg, last month the FDA announced that it would be implementing steps to more stringently regulate medical regulation, specifically forms of ionizing, radiation, including CT scans, nuclear medicine studies, and fluoroscopies, which increases a person's lifetime cancer risk. The average American's total radiation exposure has doubled in the last three decades, according to the FDA. Last month many of the manufacturers of CT scanners announced that they will begin installing safety controls, which would alert machine operators when the settings exceed recommended levels.

REGULATION OF MEDICAL RADIATION

Commissioner, what steps will the FDA take to better regulate medical regulation, and what protections are currently in place to ensure that patients received the smallest dose of radiation necessary for these tests? Also, Homeland Security and TSA recently announced the addition of full body scanners at many of the nation's airports. What role, if any, will the FDA play or has played in ensuring that these devices will be safe once they're installed?

Thank you, Madam Chair.

Dr. HAMBURG. Well, a very important question. FDA cares very deeply about this radiation safety concern and in fact has been quite proactive in responding in terms of recognizing when some adverse event reports came in about evidence of inappropriate, excessive exposure to radiation from CAT scans that there might be a broader issue here and really started to look at it in more depth.

We are working with companies that make these machines to try to move towards having systems that are less prone to error. You know, it is human error in terms of the dosage delivered; but, there are ways, you know, sort of systems engineering, to help reduce the likelihood of such errors occurring. So working to improve the quality of these devices and the safety of these devices is very, very important.

Putting out information for healthcare providers and those that are operating these machines is also very, very key, and we have been moving forward in that arena, continuing to monitor for problems as they occur, and, of course, educating consumers and providing information. We would like to move towards a system where actually individuals could keep track on a personal level of their dosage exposures over time, because I think that's important information, you know, for their own safety, and also to be able to provide their medical providers since people often move from one physician to another.

TSA SCANNERS

So that's another area where we think we can help be a catalyst to activities that will improve patient safety. With respect to the role of the scanners used in airports, the level of exposure is much, much less. We are talking on the medical side, equipment that has to penetrate the skin to visualize organs. The TSA scanners are really looking just very superficially. They're not penetrating in the same way, so the level of exposure is markedly lower. So the risk is really minuscule.

Mr. JACKSON. Does the FDA have a role in that? Given that the number of people who travel through the airports, and will be exposed to the machines?

Dr. HAMBURG. You know, even with multiple—I know many of you travel frequently.

Mr. JACKSON. It is a concern.

Dr. HAMBURG. It is a concern that I would understand, but in terms of the level of exposure, it is minuscule, because it is not penetrating in the same way. But we would be involved in terms of any indications of medical complications or adverse reactions to that scanning technology.

[The information follows:]

There is no indicator of excessive exposure on Transportation Security Administration passenger screening scanners. The Transportation Security Administration's Rapiscan Secure 1000 Single Pose backscatter x-ray systems, used in passenger screening, have engineered safety systems to prevent a dose above the manufacturer's specification.

Mr. JACKSON. Well, that's an important question. I don't honestly know the answer, but I will go back and ask that question and I hope we can address it.

Ms. DELAURO. Thank you very much, Mr. Jackson. Mrs. Emerson.

ANIMAL ANTIBIOTICS

Mrs. EMERSON. Thanks, Madam Chair, and Dr. Hamburg. Thanks for being here today and thank you again for coming to my office yesterday. It was good to visit with you there.

Let me just ask a very, very brief, or mention a very brief follow up on the issue of animal antibiotics. I've got a very, very, very rural district and so I will have counties that might have a hundred thousand, a hundred fifty thousand head of cattle or what have you and maybe one large animal veterinarian. And so, it puts us into a real dilemma as you all develop new policies with regard to the use of antibiotics. And I just would like to have you, as you proceed, you know, keep that in mind that it's, that it is an issue in many circumstances for, and I would imagine that our colleagues who live out in Montana and Nevada and New Mexico, you know, they've got much farther areas with which to deal and probably have the same issues with regard to lack of large animal vets. So, let me make that comment.

COUNTERFEIT PRESCRIPTION DRUGS

Let me go onto my question, which deals with the existence of counterfeit prescription drugs within our borders. And I do remain

very concerned about the fact that we still have big problems with this. And you know, it's obvious that the high prices of many name brand drugs make counterfeiting well worthwhile and this is an extremely important safety issue for millions of American consumers.

I'm also told that counterfeit drugs are produced and enter our system from both outside and within our borders and I'm also told that the counterfeiters have gotten so good and are so adept now at not only replicating the look of the pills they are trying to impersonate but as well as the packaging and even the bar codes on the boxes can scan at the pharmacy checkout without sending up any kind of red flags.

So, I have three questions with regard to this issue. Number one, how prevalent is the problem in your opinion? Can you talk a little bit about the efforts undertaken and planned by you all at the FDA to locate counterfeit drugs and get them out of the U.S. supply chain and tell me what kind of measures are needed to continue to reduce the opportunities for counterfeits to get into the hands of American patients. And then I guess at the very end, how do you all share this responsibility with the state boards of pharmacies? Thank you.

Dr. HAMBURG. Thank you for the question. This is a huge and growing concern and it's a problem within our borders. It's also a problem around the world and, in fact, in some parts of the developing world some studies suggest that between 30 and 50 percent of some of the drugs available actually are counterfeits, so this is really a huge concern that affects the health of us all.

We take it very seriously and we do undertake investigations to try to identify counterfeit products and their manufacturers. We welcome input from all sources when concerns are raised. When we do find problems, of course, we work with the appropriate enforcement agencies to take serious, swift, and decisive action and also to provide information to consumers about the risks. You are absolutely right that both the volume and the quality of counterfeits is increasing and it adds new challenges and I think FDA has a special role to play there and has made contributions already but some of the investments in science can help us to do a better job.

We have developed new technologies so that we actually, and we've put out guidance around, substances that can be put into pills that aren't harmful or affect the use of the product but can enable validation of the authenticity of a product.

We've also developed technologies, I was recently at JFK where a lot of important drugs come in, and they had me put on some funny glasses and use, you know, special light where you can actually scan products to determine if they're counterfeit or not. Because often the pills themselves look exactly right. Some of the counterfeits you see coming in are laughable and you wonder why anyone would possibly take this product if, in fact, they ordered it and it was presented to them.

But it's really a very, very serious problem. It's one that I think the answer has to be undertaken on an international basis because it's their products that are produced domestically but a large part of the flow is coming in from imported drugs. And the World Health Organization is actually taking this up at its World Health Assembly this spring and of course, we'll be participating, but

working with other regulatory authorities and law enforcement worldwide, as well.

RESOURCES TO PREVENT COUNTERFEIT DRUGS

Mrs. EMERSON. Do you have any suggestions? Well, first of all, any suggestions about what type of technology might be helpful in abating the problem of the counterfeiting, number one, and number two, do you have within your budget the means, let's say hypothetically, that you've come up with this idea, whatever it might be, you know, using those funny glasses or what have you. Do you have enough money in your budget to really monitor every kind of drug coming into this country? And that obviously is what is produced here.

Dr. HAMBURG. Yes. We do not have enough resources or the complete authorities that we need to really address this problem worldwide and I hope that over time I'll be able to work with all of you to address this important issue. It's a huge concern.

I should have mentioned also that unique identifiers and the ability to really have a pedigree to assure authenticity is very, very important. And that's, you know, something that we are trying to move forward on, but it's also an arena where some additional authorities would be necessary.

But this is so key and it's only a growing problem and it's a tragedy that, you know, people are counting on drugs to treat serious medical problems or to prevent important conditions and unknowingly, you know, are taking something that at best will do no harm, but may actually make their condition worse or make them sick.

Mrs. EMERSON. So what kind, what specific authority might you need from us?

Dr. HAMBURG. Well, I think, you know, number one, we need to continue to be able to expand our global presence in terms of being able to monitor products and how they're made and to be able to assure the supply chain in ways that are critically important to prevent counterfeits, but also to prevent economic adulteration and other forms of contamination of products. We need also to have the ability to really track and assure authenticity of products through a pedigree approach.

We need to be able to continue to strengthen our, you know, inspectional capabilities at the border, but recognizing that, you know, the volume of stuff coming in, you know, will always make that a challenge, but we are now developing ways to target in a more risk-based approach and including strengthening our intelligence networks, so it means working with other partners to have a better sense of manufacturers and importers that have had problems in the past and to share information with other regulatory authorities when problems emerge.

Mrs. EMERSON. Well, we certainly, I know, Madam Chair, it would be helpful for us to be able to work with you to try to come up some good solutions to this and we'll look forward to working with you. And thanks for letting me go a little bit over.

Ms. DELAURO. Sure, no, thank you, and it's an important area and we'll work with you on what kinds of authorities are needed. Mr. Bishop.

SALMONELLA

Mr. BISHOP. Thank you very much. Welcome, Dr. Hamburg. As a result of recent FDA investigation into a case of salmonella in Tennessee, it was found that hydrolyzed vegetable protein was a source of the salmonella, which was found to be a commonly-used ingredient and a flavor enhancer for many processed foods including soups, sauces, chili, stews, hot dogs, gravies, seasoned snack foods, dips and dressings.

My first question is, how would the administration's new standards of food safety have prevented this latest case of salmonella and in particular, its potentially far-reaching penetration in the food chain?

FOOD INSPECTION METHODOLOGY

Secondly, I wanted to ask, with regard to the possibility of creating a new federal food inspection methodology, that based on the fact that many people are of the opinion that the FDA is not able to exert the needed leadership accountability on food safety issues because it has no single official whose full time job it is, and who has a line authority over all the elements of FDA's food safety program?

So, my second question would be, given that view, don't you think that it's time, and it would be appropriate, for Congress to change the way that we currently manage the food safety program?

And my third question has to do with reaction versus prevention with regard to food safety. The newly adopted inspection regime, which is basically an audit program, and you've got an additional $396,000 in one new employee to try to address that through audit with the prevention. And my question there is, how will this new prevention program with just one employee and just $396,000 actually work to accomplish our food safety, your food safety, mission?

Dr. HAMBURG. Okay. First question, I'm happy to be——

REPORTABLE FOOD REGISTRY

Mr. BISHOP. One additional, I should mention.

Dr. HAMBURG. Right. I'm happy to be able to tell you that with the recent salmonella contamination of the hydrolyzed vegetable protein product, there was actually a new program that had been put in place, our reportable food registry, that enabled us to quickly identify the contamination with this product and actually to act before there were any human documented cases of disease associated with it.

So, I think it's a good example of being more preventive than reactive. We also, I think, can learn from this case about how important the——

Mr. BISHOP. You reacted soon enough to prevent further damage.

Dr. HAMBURG. Prevent human cases, which is—. There has been no disease associated with it. There has been a significant cost to industry in terms of product that can't be used, but we were able to get out a bit in front. Our goal is to get out even further in front in terms of preventing these problems in the first place. And with the passage of the new food safety legislation and with some of the activities that we're doing to transform our food safety program, we

will be working with companies in order to put in place preventive controls so that we can identify where are the points in the life cycle of a product that are most vulnerable to contamination and how can we shore those vulnerabilities up and prevent the contamination from happening in the first place.

So, it is our hope that we will be able to make sure and steady progress moving forward, especially with additional new resources and hopefully with some additional new authorities to really have a preventive program in place.

DEPUTY COMMISSIONER OF FOODS

With respect to your concerns about the organization of food safety activities within FDA and accountability and there being no single person at a high level in charge, I'm happy to say that one of my first actions as the new Commissioner was to address that problem. And the individual is sitting right here, Mike Taylor, who is Deputy Commissioner for Foods. He has my ear 24 hours a day. He is responsible for aligning all of the different components for food safety and nutrition within FDA. He is responsible and accountable.

It also, by having this higher level individual, gives us, I think, a higher level of coordination with other critical partners inside government and outside government. So, I think that the establishment of that position and his recruitment, and now the operationalization of a much more coordinated program has benefits and will continue to accrue benefits.

Mr. BISHOP. Was his assumption of those duties just by designation, by regulation, or by statute?

Dr. HAMBURG. It was a formal reorganization, which came up to the Hill for approval or sign off——

Mr. MCGAREY. Notice. Notice.

Dr. HAMBURG. Or notice.

Mr. BISHOP. So it was regulatory? It was through——

Dr. HAMBURG. It was bureaucratic is all I can say. I mean, I couldn't just come in and do it, I had to, through the department, and then with notice to Congress, undertake a formal, official reorganization.

Mr. BISHOP. APA, the Administrative Procedures Act, is what you used?

Dr. HAMBURG. You know, I turn to——

Mr. MCGAREY. I'll comment and say that we did, subsequent to sending the notice to Congress, submit the full details in the *Federal Register*. So, they were published under that document.

Mr. BISHOP. All right. Okay.

Dr. HAMBURG. And your last question, I sort of answered in my earlier answer about the importance of moving towards a preventive rather than a reactive approach, which saves lives and saves money.

FOOD SAFETY

Ms. DELAURO. Thank you. I know Mr. Kingston is coming back but we'll proceed on. I do think in some ways Mr. Bishop endorsed, if you will pardon me, a single food agency hearing his comments. So, thank you, Mr. Bishop.

I want to ask some questions about food safety. We get lots of references from the administration to the membership of the food safety working group and they talk about major departments, agencies, several offices of the White House participate. My understanding, and I want to put on the record that, in fact, one of those offices is the Office of the U.S. Trade Representative. And I personally find it troubling that the USTR has said, and I've got his citation here.

USTR

"The USTR is the lead agency for matters relating to international trade and therefore plays a significant role in food safety issues as the United States both imports and exports significant quantities of food. As such, USTR is an active member of the President's food safety working group."

What expertise does USTR have on food safety?

Dr. HAMBURG. You know, I can speak to the FDA role in food safety far better than I can speak to the USTR. What I can say is that clearly, issues of food and food safety are important trade issues but that my first priority, and I think, you know, what the American people, you know, really care about is that they can have confidence in a safe and wholesome food supply.

FOOD SAFETY WORKING GROUP

Ms. DELAURO. What role does it play in the working group?

Dr. HAMBURG. To date, the issues that have been taken up in the working group, you know, have really focused on the framework for the program defining the pillars of the program in terms of strengthening prevention, inspection and enforcement and response and recovery. I don't believe, but I haven't been at all the meetings of the working group, that specific trade discussions have been undertaken at the working group. I'd be happy to find out and get back to you.

[The information follows:]

The President created the Food Safety Working Group on March 14, 2009, to promote a public health-focused approach to food safety based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. Consistent with these principles, the Food Safety Working Group seeks to promote better coordination in Federal efforts to improve food safety and to develop short and long term strategies to make food safer. The FSWG is chaired by Secretaries Sebelius and Vilsack, and participating agencies include the Food and Drug Administration, Food Safety and Inspection Service, the Centers for Disease Control and Department of State, the Environmental Protection Agency, and several offices in the Executive Office of the President, including OMB, OSTP, and USTR. Each of these agencies is called upon by the Food Safety Working Group to offer input to their areas of competence in furtherance of the overarching goal of ensuring that the nation's food supply is safe.

CODEX

But, you know, I think there has been, you know, a continuing dynamic, both domestically within the government and internationally through CODEX and other entities, about these issues of the relationship between public health and trade concerns and my feeling is that at the end of the day, the public health voice must be

very clear and very strong because, you know, protecting the health of the public is the first priority.

TRADE VS. PUBLIC HEALTH

Ms. DELAURO. Well, I think you know, and Mr. Taylor knows, as well, my concerns in this area. What we've seen over the years is that, in fact, trade has trumped public health. And I will go back, just in some recent history about a working group under prior Administrations, in the Clinton Administration, and I just don't want to speak off the top of my head to see if the trade representative, you know, participated in those. I don't think so, but I'm not sure, so I don't want to talk about what I'm not of. But I think that immediately sends off, and I'm not asking you to comment, this light bulb's in my mind, in terms of what, where our priorities are. Clearly, our priorities need to be about the public health.

With regard to the working group, is that just going to continue on or is it going to make a series of recommendations and then that will get implemented or this just an ongoing group?

COORDINATION AND COMMUNICATION

Dr. HAMBURG. My sense is that it will be ongoing. It offers an important forum for coordination and communication of activities. As you well know, there're many components of government that are involved in food safety issues. I think fifteen different components of government are part of the working group. It's chaired by HHS and USDA and, of course, FDA and USDA represent, you know, the bulk of the food safety-related activities.

But, there're other important components and I think it does give an important venue for coordination and communication that otherwise probably wouldn't happen even with the best of intentions.

EQUIVALENCY PROCESS

Ms. DELAURO. Let me, and I'm just going to make a comment on this because I think it's an item for another time. I don't know where you're going on the equivalency system, like USDA has for imported meat and poultry. I remain very concerned that, in fact, this approach compromises public health for the sake of trade. I've just seen so much of it over the years.

Last year, this subcommittee held a hearing about the equivalency process and trade at USDA. This is an issue that I'm going to continue to follow very closely and intend to have future hearings which address the influence of trade on our food safety and our public health. And I think, quite frankly, I think our trade agreements, and some of those that have already been passed, and when we have not taken due consideration of public health in a formidable way and we find ourselves in a position where, if we want to correct those things after the fact and knowing about what the adverse conditions are, that then we find ourselves in a position of subject to litigation. So, my view is that we ought to anticipate these issues, be very stringent with regard to our food safety, as it applies to our trade agreements and have a hearing that is solely focused in that area so that we can look at it and make some recommendations.

My time has elapsed, but I do have three or four other questions with regard to food safety but we'll come around again.

Ms. Emerson. Why don't we go to you?

FOREIGN FOOD INSPECTIONS

Mrs. EMERSON. Let me go back, if I could, Madam Chair. We were talking a little bit about the food safety bill. Yesterday we talked about the number of foreign, the additional 1,900 domestic food inspectors and 150, well, maybe it's 1,900 additional domestic food inspections, and 150 additional food inspections done internationally.

And I guess I'm a little bit concerned about the low number for the international inspections, particularly given the 20 percent or so of the food consumed in the United States is imported.

Do you think that we're dedicating enough resources to inspecting foreign food?

Dr. HAMBURG. Well, I think we need, you know, more resources and more activities to address the overall import safety concerns. I think it is important to recognize that what we're asking for in fiscal year 2011 is part of a comprehensive strategy to use the additional resources that you have given us over time and that it's not that we think that domestic inspections are more important than foreign inspections, but it's that we have teed up in our hiring pipeline and new FTEs, individuals that will be enhancing our international inspections.

So, our overall number of inspections that will be accomplished in fiscal year 2011 will be more than——

Mrs. EMERSON. The number of inspections?

Dr. HAMBURG. The number of inspections that are mentioned there in terms of additional new dollars. In addition, you know, we have created a cadre of experts in foreign inspection. They're not the only ones that will be doing foreign inspections, but they have expertise around an important set of issues that have to do with food safety and foreign inspections. So, those resources will augment what we're doing.

IMPORT SAFETY

And I think, realistically in terms of dealing with the import safety question, we have to recognize that we have to have strategies that extend much beyond simply doing inspections. We really need to work with other regulatory authorities to try to ensure that the standards of production are equivalent to what we're undertaking. We need to work with international bodies to try to put in place, you know, harmonized standards and approaches. It's going to have to be a multi-layered strategy because the challenge of import safety is just so huge and growing. So, we're bringing a range of different tools to bear, expanding our foreign presence, also expanding our inspectional capability.

INSPECTIONS AND USER FEES

Mrs. EMERSON. Will the addition of more inspectors and/or inspections be contingent on new users fees, for example?

Dr. HAMBURG. Some of our inspectional capability, in terms of the fiscal year 2011, is very much linked to, I mean, almost all of it is very much linked to the new user fees. And, of course, the new legislation is quite prescriptive in terms of inspectional responsibilities, particularly on the domestic side. So, you know, if we are to meet those goals, as outlined in that legislation, we're going to need resources to do so.

Mrs. EMERSON. So, is it, I mean, in your opinion, do you think it's too prescriptive with regard to, for example, a southeast Missouri vegetable farmer as compared to a Chinese food processor?

RISK-BASED APPROACH

Dr. HAMBURG. You know, I think that the number of inspections, as laid out in that bill, you know, clearly put, you know, a more rigorous focus on domestic inspections, but I think that how we target inspections should really be using a risk-based approach. And that one of the opportunities that we now have as we move towards transforming our food safety system and really trying to have a preventive approach and a more risk-based approach, is to use what will always be limited resources in terms of the contrasts between, you know, the need and what we might like to do in the best of all possible worlds and what we can do, you know, we want to be wise about how we do it. And we want to apply the best possible science and technology so that we can make inspections more efficient, as well.

Mrs. EMERSON. I just got a little bit worried perhaps that we could've been a wee bit overly prescriptive just because I keep remembering in my head, watching that 60 Minutes report on some of the fish that is farmed over in southeast Asia and, you know, I'm always now very label conscious when I buy any kind of seafood. And so those things make me nervous. And I think, you know, that is generally more of a problem than the guy in my district who does actually grow vegetables or cantaloupes, or watermelons, or the like, and so I just want to make sure we're doing enough with the increased importation of food.

Dr. HAMBURG. It's a huge area of interest and concern to me and I look forward to working with you as over time, you know, we shape this program.

Mrs. EMERSON. Thank you. Thanks, Madam Chair.

RISK-BASED AT USDA

Ms. DELAURO. Before I yield to Mr. Kingston for a special introduction, let me just say, and we can't go into it now, but this is by way of, by testimony because the Commissioner just started to talk about risk-based inspection and that's in the budget. Risk-based does not currently have, FDA does not have current, currently have adequate data-gathering tools and systems comparative risk evaluation models, or the internal structure needed to apply risk-based approach to recognizing response to the emerging evolving food safety issues and problems.

We can't talk about it now, but we need to talk about that. I've watched risk-based at USDA and it was, they had to stop what they were doing because, in fact, there wasn't the adequate data

and the research, et cetera, on which to be able to make that kind of risk-based determination.

You're a student of this. We cannot move forward without data and analysis before we deal with risk-based. And I believe you agree, and so we will continue to talk about that. And with that, Mr. Kingston, let me just yield to you. This is very exciting. Mr. Kingston, go ahead.

Mr. KINGSTON. Thank you, I don't know why I said that.

Ms. DELAURO. Well, we were talking about food. So——

[Laughter.]

Mr. KINGSTON. But it's a great pleasure for me to introduce one of the greatest athletes in the United States' history. And that is Hershell Walker, Heisman Trophy winner, and national championship—Hershell from the University of Georgia.

[Applause.]

Mr. KINGSTON. And Hershell, the reason why he's so relevant is we spent so much time in this committee talking about childhood obesity, childhood hunger, nutrition, physical fitness, and getting these kids away from the Nintendo game.

He's also with Larry Franklin of the Franklin Glove Company and Bill Sales of the Sporting Goods Manufacturer's Association. And they've been all over this, trying to get kids healthy and active.

And I want to let Hershell say "Hello." But one thing I want to say that he will not tell you. At the age of 47, he decided to take up the mild pansy sport of mixed martial arts. And he defeated in two minutes and 17 seconds most recently a 26-year-old professional boxer.

So he doesn't sit down. And Hershell, do you want to say hi to everybody?

Mr. WALKER. I didn't know I was going to get put on the spot. So first, you know, I'm glad you guys are here, because, you know, what I'm here doing is talking about obesity.

You know, as a kid growing up, I was a little bit overweight, chubby, fat, or whatever you want to call me. And I also had a speech impediment. But I was very fortunate to have two parents, and also to have a PE coach that talked to me about being physically fit.

And because this PE coach gave me a program to do, I became valedictorian of my class. Because it gave me confidence, and because I had the right parents. They gave me the right things to eat and the right things to keep me healthy.

And so that's what I'm here to do, is to talk about that we got to continue to get all the kids healthy, continue to keep them healthy. Because I think a fit kid is a fit adult. And I think that's going to help a lot out in the long run.

My mother always say, "Why don't we take care of these small problems first? And it won't grow into a big problem?"

Because no matter what everyone thinks, that baby is the prettiest, no matter how ugly the child may be.

[Laughter.]

Mr. WALKER. But that's one thing we have to do.

I want to just thank all of you for giving me this opportunity, because you guys got a lot more important things to do than to listen to me talk about this here.

But I want to thank you. And you know, Mr. Kingston, we've known each other for a long time. He's helped me out in so many things. And I want to just say thank you, God bless you.

Thank you, guys, for giving me this chance.

Ms. DELAURO. Thank you.

[Applause.]

Ms. DELAURO. Mr. Hinchey.

NUTRITIONAL CONTENT

Mr. HINCHEY. Thank you very much, Madam Chairman.

I just want to return briefly to this 20 percent issue. And first of all, I just want to thank you once again for all the work that you're doing.

This Food & Drug Administration is so critically important to the safety and security of the people of this country. That 20 percent margin of error is on the nutritional content of the products, the overall nutritional content of the products.

So it's very, very important. And that 20 percent margin was initiated by the FDA. I wonder if you know why the FDA did that long before you got there?

Dr. HAMBURG. Right.

TWENTY PERCENT MARGIN OF ERROR

Mr. HINCHEY. Why they did it? What was, you know, the origin of that? And do you think it would be reasonable to require food manufacturers to add a disclaimer on a nutritional content label, that would just let the people who are buying the product know that the FDA allows a 20 percent margin of error in determining the accuracy of the nutritional content of the material that they're buying and eating?

Dr. HAMBURG. Well, I think that the best answer to your question is for me to actually go back and get you the real information to your specific and rather technical question. I mean, I can imagine that it was established, based on the technical capacities of laboratory tests to determine. I mean, there's always a margin of error.

But I don't know. And so we will get back to you on that.

[The information follows:]

The 20 percent figure is not a margin of error. FDA's compliance criteria, including the 20 percent allowance for variation in naturally occurring nutrients, were developed as part of the 1973 final rules for nutrition labeling. In the January 19, 1973 *Federal Register*, FDA published a regulation which established a statistical approach to determine compliance with nutrition labeling requirements. The natural variation in the nutrient content of food products was well recognized, and the need to set practical limits of variation in nutrient levels for compliance purposes was the subject of extensive discussions. In developing the nutrition labeling system, it was important to provide a sufficient tolerance so that manufacturers could provide useful nutrition information on the label while meeting consumers' expectations that nutrition labeling would honestly represent the composition of the products that they purchased. The objective of the regulation was to secure compliance with requirements for average nutrient levels for units in a lot with only as much variability among units as is inherent in the naturally occurring nutrients when foods are processed under current good manufacturing practice. FDA is currently working

on updating the nutrition facts label, and this is one item that we may consider re-evaluating based on more recent science. However, additional research on the variability of nutrients within foods may be needed to determine if the 20 percent figure could be modified.

But I agree with your underlying concern that it's very important that consumers get accurate information, established when making choices for health. And I think that we have an important role to play in making sure that the information that's provided is as accurate as possible.

And then I think we have to work with others, including people like we just heard from, in terms of educating the public about making healthy choices. And so I think, you know, it's an important question, and we'll get back to you.

Mr. HINCHEY. Okay. And if you wouldn't mind, take a look at that situation, to make a determination as to whether or not that would require them to put a disclaimer on the product that they're manufacturing. So people just know what they're getting. And maybe reduce that 20 percent to at least 10 percent as soon as possible. And that would be a very positive thing to do.

Dr. HAMBURG. Okay.

FOSAMAX

Mr. HINCHEY. If I could just ask you one other question. As we know what happened with ABC News, and how they ran a story on Monday, which talked about Fosamax, a drug used by women to prevent broken hips and, you know, how all of that process got so complicated and people got seriously ill as a result of—cause of—broken legs in a number of women.

The story also said that Merck, the manufacturer, did not change the labeling on the drug for 16 months, to reflect the side effect after the FDA raised the issue. So the FDA raised the issue with them, told them what they saw was going on and their concern about it, and that it was 16 months before Merck did any change in the labeling to inform people.

So I'm wondering why it took so long for Merck to take the appropriate action, and why the FDA didn't require Merck to act sooner? And what are we doing now? What do you think the FDA should be doing, or is doing now to really address this issue?

Dr. HAMBURG. Well, this is obviously a situation of enormous concern. Many woman take this product in order to protect their bones. And we want to ensure that there are not complications, such as you were just describing.

It is also one of those situations, where it's very, very important to look at the science and take a thoughtful approach, and whether it is very clear that a large number of women taking this medication did have fractures. I think what's less clear is whether the medicine was the cause of the fractures. And that's the question that has to be critically examined and answered. And there is a team at FDA looking at the data we need, I think to move as swiftly as we can, looking at all of the available data, to make determinations.

I know that in an earlier point in discussions with Merck around labeling, I think, you know, actually that Merck was prepared to

go forward with the label, but that the group at the FDA did not feel that the data actually demonstrated this enhanced risk.

But it's an area that we will be working on very intensively. I think it is very, very important that we ensure within FDA that we have a strong approach to assuring drug safety.

DRUG SAFETY

I'm moving forward with some strategies to enhance how we address drug safety, because especially as we strengthen our activities in the post-marketing surveillance area following the 2007 enactment of the FDAAA, we got additional authorities to strengthen our ability to follow a drug, beyond the time of approval, to really understand its use in people in the real world, you know, that we're seeing an increasing number of safety signals. We need to be able to respond as quickly as possible and as authoritatively as possible to emerging safety concerns, always, always, always bringing the best signs to bear on those critical decisions.

Mr. HINCHEY. Well, I appreciate that very much, and I thank you for everything that you're doing. But I just think that these things need an awful lot of attention. And I know that, you know, you haven't been here very long, I mean, on this particular job. And the things that you're doing are exemplary, as far as I know. And that's something that really, really needs to take place.

But why it would take somebody, you know, like Merck to take a year and four months to make the kind of correction that could be critically important for the safety and even the life of some people, is a mystery to me. And I think it's something that really needs to be overcome. And there needs to be a very more effective, perhaps relationship between the Food and Drug Administration and the agencies that are being overseen.

And I know that over time, there has become a very close sort of relationship, including the funding that comes out of those agencies to Food and Drug Administration.

And all of things, I think, really need to be looked at more carefully, and hopefully improved, so that the safety and security of people in this country can be improved, as well.

And I thank you very much, for everything you're doing.

Ms. DELAURO. Mr. Kingston.

TOBACCO OUTREACH AND EDUCATION

Mr. KINGSTON. Thank you, Madam Chair.

Dr. Hamburg, on the tobacco outreach and education money, it would appear that with the decline in tobacco use and all the other efforts that are out there through the Master Settlement Agreement, that that would not be the best use of FDA's funds. Since you are going to have the regulatory burden already, it would appear to me that the education issue is somewhere being handled.

I know a government agency would never turn down an opportunity to expand its budget. But it just seems that that's not necessarily the best expenditure of the dollar.

Dr. HAMBURG. Well, I appreciate your question. You know, a couple things. One is that, you know, we are not seeing the continuing declines in tobacco use that we would like to see in this country, and it has huge implications for public health.

So I think we need to continue our overall tobacco use prevention and cessation activities. In terms of the FDA role that the Tobacco Act actually requires us to address a couple of key areas that are not specifically education, but in fact it's on marketing, labeling, and the manufacture and composition of tobacco products.

So I think we will actually be, through this activity, making a unique contribution in some key areas. For the first time, for example, we will actually have information about the ingredients in tobacco products and be able to really assess scientifically the health implications of these products.

We also will have authorities to address some of the labeling issues, which are very, very important in terms of getting information to consumers about products and——

Mr. KINGSTON. Well, I understand that aspect of it. But it would appear whether you could coordinate the education and outreach through some other recipient of MSA money, rather than you need to do it yourself.

Dr. HAMBURG. And we're not actually undertaking through this set of activities education and outreach activities, per se. We are working in coordination with other parts of government and also, you know, with state authorities and others, in terms of some key aspects of the law, the education and outreach being one. And also you know, some of the enforcement activities will be undertaken at the state level, as well.

But your point is well taken about assuring good use of resources. But we actually, you know, talk about prescriptive pieces of legislation. There's a very clear set of activities that we are required to undertake, under the law. We are very pleased to have this new responsibility, and believe that we will make a real difference in public health, reducing preventable disease, disability, and death.

But we are really targeted in a couple of key areas, some of which really are novel in terms of government regulatory activity.

Mr. KINGSTON. Also, I wanted to give you some numbers that I had from your budget from 2007; that in 2007 there was a 6 percent increase, 2008 14 percent, 2009 23 percent, and in 2010 17 percent, and the proposed I think 23 percent for the request.

And that's just so out of whack with the household budgets and the recession that, you know, that is where my concern about money in the big picture comes from, is just there have been some healthy increases, which I wish I had that in my retirement account. I wish I had that in my own salary. I wish I had that in my own household budget. As do most American people at this point.

But you know, that's not keyed into the economy.

Dr. HAMBURG. Well, what I can tell you is that in all honesty, I think that the budget increases that FDA has received in the last couple of years and the request in 2011, is vitally necessary and appropriate in terms of the essential and unique mission of FDA and what has, in fact, been a history of chronic underfunding in many, many vital areas to protect the health of the public.

I think when you——

Mr. HINCHEY. Now let me kind of, having said that, and I know my time's up, but these numbers come from the CDC: 76 million

food-borne illnesses are reported a year, 76 million, a big number. Three hundred thousand hospitalizations, 5,000 deaths. Although the deaths aren't always attributable to food-borne illnesses.

Dr. HAMBURG. Mm-hmm.

Mr. KINGSTON. But 5,000 associated deaths. Big numbers. CDC numbers. Three hundred million Americans, though, eating approximately three meals a day, never snacking.

Dr. HAMBURG. Unlikely.

Mr. KINGSTON. That would be 900 million meals a day, or 328 billion a year. So if we divide 76 million by the 328 billion, we'd have a food-borne illness rate of 0.0002 percent, or 99.98 percent success rate, in terms of what we're consuming.

CDC numbers standard math, no editorial in there. Now I'll begin the editorial comment, which we all share a great goal of food safety here. But if funding is always inadequate, something's going on beyond the government. And thank goodness that funding, that concerned is the private sector, that even if they didn't care, that want your repeat business, and they're not going to get if they're poisoning you.

So there's a lot going on in terms of food safety well beyond Washington, D.C. Otherwise, we wouldn't have such a remarkable success rate.

And so often, when we talk about increasing budgets, because of, you know, some processing plant having salmonella, we sort of overexploit that, overdramatize it, in order to beef up budgets here.

And it's good politics for everybody, and it actually certainly comes a lot more from us than it does from you. But I always like to inject those numbers in the record. And I know I'm out of time.

Dr. HAMBURG. Can I comment? You know, I think these are very difficult economic times. We have to be very responsible stewards of our resources.

But I really think, you know, that this is a major public health concern. We're talking, numbers are, you know, not completely accurate. They vary. But, you know, using your numbers, 5,000——

Mr. KINGSTON. No, not my numbers, CDC numbers.

Dr. HAMBURG. CDC's, okay. I'm sorry. But, you know, we're talking about, you know, preventable deaths and a lot of preventable illness. We're talking about additional costs to the health care system. We're talking about lost productivity in the work place, because of these illnesses. We're talking about very significant costs to industry, because of food-borne outbreaks, when there was the Georgia peanut contamination problem with the Peanut Corporation of America. And it costs the peanut industry a billion dollars.

Mr. KINGSTON. But that actually was a criminal activity.

Dr. HAMBURG. Well, you know, sadly some of what we see in terms of food safety does have to do with intentional, you know, contamination. And we've seen that internationally, and we've seen that there is irresponsible-becoming-criminal-activity, that has allowed contamination situations to develop and persist.

But I think that, you know, this is really a very, very important problem that has to be looked at and measured in many different ways.

And you know, I've been very frankly surprised and encouraged by how much the food industry actually supports the idea of a

strong, fully functional FDA, because they see it as in their best interests. I think we all recognize that the problem is large, that the responsibility is shared. But the benefits in terms of improving health and strengthening the economy is real.

PEANUT CORPORATION OF AMERICA

Ms. DELAURO. Just—and you can get back to us on this, Dr. Hamburg—what's the status of any criminal prosecution of those involved with the Peanut Corporation of America? So that if somebody could get back to us on that? Because as my colleague pointed out, it was a criminal activity.

[The information follows:]

In accordance with DOJ policy, the U.S. Attorney's office for the Middle District of Georgia is responsible for answering any questions about any open investigations about this matter.

I would just say that in Iraq after 9–11, where we were surprised with the deaths of, you know, 3,000 people or more, we went to war in Iraq, and we spent trillions of dollars to do that. We know that 5,000 deaths are preventable. That we did not know was happening. We know 5,000 people die or roughly that number every year.

I believe we ought to go war, and that responds to this effort as well, because we know that these deaths are preventable.

Ms. Kaptur.

ACCOUNTABILITY

Ms. KAPTUR. Thank you, Madam Chair. Welcome very much. Really glad to have you here, doctor. And wish you well in your work on behalf of our country.

I wanted to just compare something that's happening with invasive species and the cost to the American taxpayer of trade agreements that are terribly flawed and do not account for environmental health, and an analogy to your agency.

If we look down the list of what USDA in its role has in trying to control invasive species, everything from Emerald Ashborers, which are destroying 20 million trees in our area, due to their import, on landscape material, it is staggering. We're losing ten percent of our tree cover. And all the costs of that remediation are being born by the U.S. taxpayer.

Asian longhorn beetle, destroying our hardwoods. Same thing.

We don't deal very effectively with holding those responsible accountable. We put the cost on the taxpayer. It's a great deal if you can get it. That means the importer's not responsible, the foreign company's not responsible. All the people that made money, not responsible.

There's no international tort system that actually would place the blame where it belongs, and rigorously, then, control that behavior, because they would actually be made to pay for the harm that they've done.

As I look at your responsibilities, I look at things like heparin being imported, or recently now this hydrolyzed vegetable protein recall. And I'm asking myself the question—I'm looking at your budget, and you're asking for a lot more money—$747 million,

nearly a billion dollars, three-quarters of a billion dollar's increase—and I'm saying to myself, so we're going to put inspectors in China, we're going to put inspectors in Mexico.

Who's going to pay for all this?

We've got more imports, bad stuff. Melamine in pet food, heparin killing people.

And my big question to you is, how do we hold them accountable? What's the system to hold them accountable? Rather than our taxpayer money going into paying for their wrongdoing and never holding them accountable? Because that's a great deal.

They'll just keep doing it; they'll do more of it, because they don't get caught that much.

So my first question is that.

CHINA

And my second one is related to China, since a lot of what's been happening relates to countries that don't have really good environmental standards. How can FDA assure, in working with undemocratic countries like China, that don't have transparent legal systems, they don't have environmental standards—who would want to live in all that pollution, anyway—how do we hold those who are profiting off that very clever system of non-responsibility? How do we get at them?

Dr. HAMBURG. Well, I think, you know, we need enhanced accountability in both cases that you describe and very important challenges.

In terms of our ability to hold people accountable, with respect to food and medical products, you know, there are varying ways that we can do it, and varying strengths of legal leverage that we have. And it varies by product.

HEPARIN

Ms. KAPTUR. Well, let's take heparin. Let's take heparin. How do we hold responsible—maybe describe the process to me, and I'll ask additional questions for the record. How much of heparin's ingredients are imported versus manufactured domestically? Who does it? And what would your guess be, would most of the ingredients for heparin be manufactured in the United States now?

Dr. HAMBURG. Well, with heparin, you know, an important precursor product was being manufactured in China, and still is largely manufactured in China, from what I understand.

An American company was responsible for the ultimate product; but they, with the heparin contamination case, had the problem that the supply chain had this contamination upstream. Now there are much more rigorous systems in place, recognizing that type of problem in terms of trying to assure the safety of the supply chain, which industry has the responsibility for, and we have a responsibility for——

Ms. KAPTUR. I'm going to interrupt you, Commissioner, because I've only got 26 seconds here. You know how you diagram a sentence—Maybe you're too young—back when we were taught in school we learned how to diagram a sentence.

Dr. HAMBURG. Right.

Ms. KAPTUR. How can you diagram for me what happened with heparin? From the American integrator, U.S.-based integrator, I guess, and all the component parts that went into heparin—let's just take that one——

Dr. HAMBURG. Yeah.

ADDITIONAL AUTHORITIES

Ms. KAPTUR. I'd ask you for the same on melamine, if you can do that in the pet food disaster. How do we figure out who's the subject of the sentence? Who are the dangling participles? Can you do that at FDA?

Dr. HAMBURG. You know, I think one of the reasons why we are so eager to get the additional authorities that would come with that food safety bill—and we talked about earlier the need for some additional authorities as well as resources on the import safety, is that securing the whole supply chain is a complex issue, and it's getting more complicated in our globalized world.

Ms. KAPTUR. Well, could I ask you, then—you say wait for this food safety bill. Well, right now I don't want to wait for that bill. I support it, I support Congresswoman's DeLauro's leadership on this so much.

But can you provide, just with one product, can you diagram for us what happened? Does FDA today have that capability?

Dr. HAMBURG. You know, I don't know whether going through heparin is the best way to get at what I think you're asking for, which is accountability in terms of when there are problems, what actions can be taken——

PRECURSOR PRODUCTS

Ms. KAPTUR. I want to know just what happened in this situation. Which companies are responsible? Which subcontractors are responsible?

Dr. HAMBURG. Yeah. The problem was that the precursor product—and you know, I wasn't at the agency at the time, so I don't know all the details—but the precursor product was coming from many different sites, with very little regulatory——

Ms. KAPTUR. More than 100 sites, would you guess? More than 100?

Dr. HAMBURG. You know, I just don't know. I'd be happy to have someone brief you on the whole heparin situation——

Ms. DELAURO. Great.

Dr. HAMBURG. But it's coming in. There was adulteration that was quite deliberate, and actually, you know, fairly sophisticated in terms of the compound that was used to sort of extend the volume of material, and reduce the cost of production.

So there was a contaminant that was introduced. There was not an appreciation that that had happened. It was able to go undetected by the existing screening methodologies. And we learned of it when people started getting sick.

The additive that was used caused allergic reactions in people.

PRIVATE INTERESTS

Ms. KAPTUR. You know, Madam Chair, what I would really appreciate—because this is complicated—but if we could take a product, like heparin, and track it back and see what happened, then we can better understand where your systems break down, and where you are not able to guarantee public health and safety.

And we can look at the private interests that are doing this to us. Right now, we're all talking generally. But if we could have a couple examples—I'm thinking of heparin and melamine as the two that are really important to us here—if you can help us unwind that, I think it would greatly illustrate what we're trying to get to here.

Mrs. EMERSON. Will you yield just for a second?

Ms. KAPTUR. I yield to the gentlelady.

Mrs. EMERSON. Because before you got here, Marcy, we actually talked about, you know, what authorities would the Commissioner need in order for us to better track, if you will, all of the different ingredients, et cetera, that go into the chemical makeup, if you will, or the parts of a pill or however the medicine is delivered.

And so we're going to work real closely on that, because that hopefully would then solve the problem that is very prevalent in some cases, that you're talking about today.

So——

Ms. KAPTUR. Thank you.

Mrs. EMERSON. So maybe you would help us do that too?

Ms. KAPTUR. Yes, I'd be glad to work with the gentlelady on this, obviously. Thank you very much.

Mrs. EMERSON. And I would welcome the opportunity to work with you on this, because it is, you know, such an important issue. And I think, you know, whether you're looking at heparin or melamine, it's emblematic of a much larger set of concerns, where we really need, you know, a new paradigm for our approach, and we need to make sure that we have the tools and resources to do the job.

Ms. DELAURO. Thank you. Mrs. Emerson.

And then——

LABELS

Mrs. EMERSON. Thank you. I just have one more question, Dr. Hamburg.

And it's something that I brought up with you yesterday, but I'd like to go back into it a little bit more. And it has to do with a potential rule published in the unified agenda of FDA that the law that defines a label as written, printed—I have to read this—or graphic upon immediate container, for prescription drugs. And I know that you all at FDA have announced a safe use initiative to reduce preventable harm by identifying the specific preventable medication risks and developing implementing—this is in your written description—"implementing and evaluating cross-sector interventions with partners."

However, the unified agenda announces FDA's intention to make professional prescription inserts electronic only, without any backup system. And I mean, we all remember with great sadness

what happened during Hurricane Katrina. And we just really need to think about that to illustrate, in my opinion, the inadvisability of having no printed information backup system in place.

ELECTRONIC INTERESTS

Because we have cable malfunctions, you have electric outages, minor storms. I mean, I couldn't get my Internet to work in my house this morning at 7:00 a.m.

So anyway, these things happen. And the fact that we have in my district a very heavy senior population that these folks don't use computers.

And so going to simply electronic inserts to describe side effects of medicines and the like, to me, well, it scares me, number one. Because I think that it could cause huge problems.

But can you explain why you all want to change a step as important as that labeling in the patient professional prescription process, at least before you even do a risk analysis?

Dr. HAMBURG. Well, yeah, I think and talk to people. You know, obviously, our goal is to try to meet the information needs of people and to help support people in the safe and appropriate use of medications that they need. I don't think the intention is to not make that information available to people through other means, but their important benefits from having a system that is electronically based, the benefits are that number one, it's more easily accessible.

You can't lose it. And it can be rapidly pulled up by physicians at the time they might be prescribing a drug and very significantly it can be updated in a way that paper inserts cannot be. So if new safety information on a product or new recommendations for appropriate use emerge, it can be rapidly modified on an electronic label. But we also want to have what is referred to as a single patient leaflet, which is an informational that can be given to a patient at the time that they are prescribed a drug that contains the up-to-date information on the use of that drug.

But, you know, it's important enough that I raised the question after our conversation yesterday, but I will be getting more information on it to make sure that I fully understand the issues at hand, and I certainly take your concern about the older Americans that may not be computer savvy and have no interest in ever becoming computer savvy. And, of course, those are among the people that are using the most drugs. And under the most complicated circumstances in terms of appropriate use, so we have to be sure that we are reaching those senior populations with the best, most accurate, and understandable information about appropriating this.

Mrs. EMERSON. Well, I mean I am assuming that. So what you're basically saying is that people will not go without getting some kind of extra little piece of paper in their little bag with their prescription outlining the side effects, et cetera. But if you need more up-to-date information, you would be able to then electronically get it.

Is that what you're saying? Because I would think that the pharmacist would go ahead and print out for you, if that person, the pharmacist, is asked to do so, which I think has got to be mandatory here, because, you know, when you're taking six different drugs, you just don't know necessarily they react with one another.

Dr. HAMBURG. What's going to be electronic, the in-package insert, is actually, I think, viewed by most people as not what the patients use, but many do. But there's other guidance, of course, about appropriate use of medications that come with the drug, the prescription, and can be made available to patients. But the information is very important to have access for providers and that's where having it electronic, it also can link it in to other databases that are important for full use of the information. So having it electronically is clearly a benefit, especially in terms of this ability to update as new guidance emerges and all of that.

Mrs. EMERSON. Sure. I have no problem with that whatsoever.

Dr. HAMBURG. But it's absolutely key that patients that are actually using these medications have ready access in whatever form they are likely to use to the material and that's what I will, as I said, go back and ask additional questions. But on my first foray into understanding the issue that you raised with me, I was told that the intention was not to prevent people from getting access to paper information about the appropriate use of the medications, the contraindications to use.

Mrs. EMERSON. Right.

Dr. HAMBURG. And other, really important and risk-related information.

Mrs. EMERSON. No. I appreciate that and I look forward to working with you. I just want to make sure.

Dr. HAMBURG. Yeah. No. We aren't going to make assumptions that people will know to ask for something.

Ms. DELAURO. Sorry. Mr. Farr.

Mr. FARR. Thank you very much, Madam Chair. Thank you very much for being selected, an honor to have you here as the "drug czar," I guess.

Dr. HAMBURG. The drug and food czar, and cosmetics and tobacco.

FDA AND USDA

Mr. FARR. Yeah, everything. Well, I got elected to Congress and learned after going through local government and state government that Washington as the Federal Government is what we do here is silos. And when you think of silos you think of agriculture. Right? So, this committee, and, in fact, this committee does a lot of silos itself, but it's the only committee in the House or the Senate that has jurisdiction over both USDA appropriations and FDA appropriations. So this is really the only chance to have one stop for what I think frankly is very awkward. And I doubt that my wife could tell me the difference between what the Department of Food Safety and Inspection does and what FDA does.

I don't know how many people in this room know the difference, you know, and you think when you see the Department of Agriculture, it relates to food. And you see the agency that says the Department of Food Safety that it has to do with food, everything in food, but indeed it doesn't and it's only meat, poultry and eggs. A lot of the discussion here, frankly, is because the issues of drugs and drug safety is so keen, and we are dealing with food safety. And I apologize for not being here during that dialogue. I was actually at Homeland Security.

We were talking about FEMA and about One Stop. And it seems to me that ideally we'd have one stop for food. We wouldn't have two different departments administering these things, because it just becomes awkward. But on the other hand, the majority of the food safety aspects, other than what USDA does is in your department. And the emphasis in the department has been probably more on drugs than on food, in reality, and frankly your incredibly distinguished background. And the experiences you have have been more of the urban side of medicine and the delivery of medicine. And I was thinking that, you know, in FEMA I mentioned this morning what we try to do for responding to this kind of thing is to prevent it from happening in the first place, and there's a lot of emphasis in the FEMA budget to do prevention.

In essence, I mean, if you're doing your job, which is to prevent these wrongs getting into the process of allowing illnesses to develop, it is in the prevention business. So, in medicine, you don't have a national emergency room response. Emergency rooms are on the local level. So what I am trying to get at is that I think you have an incredible role. We discussed this in my office, a little bit of trying to bring together. And, frankly, Madam Chair, perhaps in the future we ought to have the hearing on the USDA food safety at the same time we're having the hearing, so we can really get into the entire range of food safety, because you have now the responsibility, as we do this new food safety bill, of building credibility.

I represent a really incredible amount of productive agriculture and it's really fresh. I mean there isn't a kill step when you go to lettuce. You know. You don't cook lettuce and eat it. You can wash it with chlorine, but so the emphasis is now on growing practice. It's the prevention. And I would really love to see you be that crossover director that can bring both USDA and FDA together on food safety, because I don't think it's ever been done. And whenever there's an outbreak, you know, it's a crisis between who's supposed to respond.

CRISIS COMMUNICATION

And, frankly, as I've said, I think there's a whole need to do crisis dialogue, crisis communication. Because when the spinach, which most of the spinach in the United States is grown in my district, 70 percent of all the spinach, and there are certain seasons and months when spinach can come in from other states and other countries, but year round. So we got hit, probably lost $200 million in private investment. A lot of people went out of work.

A lot of farmers and poor people were out of work. Farm workers couldn't get jobs. And the problem is we just did a voluntary recall, so the companies didn't collect on insurance, because it was voluntary. You didn't have a disaster. If this had been declared a natural disaster they would have had disaster insurance. If it had been declared that we have to condemn it, we would have had a takings payment, but voluntary. And so all these people voluntarily took all the spinach off the shelves and buried all the spinach in the fields and dumped all the spinach in the trucks, and did all that stuff, and then found out nobody would help them.

So then it got into, you know, maybe the call. The message didn't come out very well, the disaster message, and perhaps we should have thought it through before we just said—because frankly to this day we've never recovered the consumption of spinach and a lot of other leafy greens were affected, so I'm not going to ask any questions right now other than because I've submitted some to you and we've talked some in our office.

FARMERS AND FDA

My point here is I think you have a remarkable role and this committee is the place to really bring this crossover between USDA, because the farmers don't trust FDA. They have never worked with FDA and you've only been there as the bad cop in a sense, and so I think we have to win. How do we make the FDA the support group for food safety and agriculture, because we're going into ways that we've never done before. And what I'd like you to do is use the ability to have a level playing field across this country for agriculture, if indeed the best management practices and food safety practices are being done in some states, then require all the states to do that.

That will make for equal competition and equal reliability in food safety. Thank you.

Dr. HAMBURG. Thank you.

FOOD SAFETY—GAO

Ms. DELAURO. Thank you, Mr. Farr.

Let me try to just run through a series of questions, if I can, because I've got a lot of questions. And again with regard to food safety, August 2009, GAO called for changes by both USDA and FDA, and how they act when calls involving school food take place.

Recommendations: FNS, FDA, should complete an MOU on how they are communicating during investigations and recalls that might involve school food. Have FDA revise its recall audit checks to make sure schools are adequately represented. Where do you stand in terms of implementing these recommendations?

Dr. HAMBURG. You know, we are working I think really quite closely with USDA. My sense is, you know, it's a more coordinated effort than in many past years. We have the luxury of having high level people on our staff that used to work at USDA and they have high level people that used to work at FDA, so there is already an openness and understanding of culture. It's very, very important.

Ms. DELAURO. Are we going to implement those recommendations at FDA that we mentioned with regard to the GAO report?

Dr. HAMBURG. You mentioned a memorandum of understanding. I don't know precisely what that is. We can get back to you.

[The information follows:]

In its report, the GAO Report stated: "We recommend the Secretary of Agriculture direct FNS and that the Secretary of HHS direct FDA to jointly establish a time frame for completing a memorandum of understanding on how FNS and FDSA will communicate during FDA investigations and recalls that may involve USDA commodities for the school meal programs, which should specifically address how FDA will include FNS in its prerecall deliberations."

FDA and FNS have collaborated to develop a Memorandum of Agreement, or MOA, that will address the GAO's recommendation. Specifically, the MOA is between the Department of Health and Human Services, Food and Drug Administra-

tion and the following agencies within the United States Department of Agriculture: the Agricultural Marketing Service, the Food and Nutrition Service, and the Farm Service Agency. The MOA is intended to strengthen and facilitate the exchange of information among the participating agencies during investigations and recalls that may involve USDA commodities such as those offered through the National School Lunch Program, and the Woman, Infants, and Children Program.

The basic framework of the MOA is complete and is under review by the agencies. Final clearance will follow, with a targeted completion date of the summer 2010.

Ms. DELAURO. Okay. If you can get back to us on the implementation of those recommendations that came out of the GAO report in August 2009.

Dr. HAMBURG. Yeah. Yeah, but we take those kind of recommendations very seriously and, you know, see that that partnership is key. And, especially as Mr. Farr was saying, you know, get more involved in terms of activities dealing with farms and agriculture.

Ms. DELAURO. Okay.

Dr. HAMBURG. It's essential.

BINDING STANDARDS

Ms. DELAURO. You talked in your testimony about binding food safety standards and funded by $4.5 million, and budget authority $21.5 million in user fees. I am delighted to see reference to binding standards. Would these only be possible if new FDA food safety regulation is passed or are you contemplating some way to do them under the authorities you have now?

Dr. HAMBURG. I think we want to move forward under authorities that we have now. There may be some elements that would be greatly enhanced by additional authorities, but I think that there are avenues for us to pursue. You know, I'm not exactly sure what all you're looking at there in terms of——

Ms. DELAURO. Well, we've always dealt with guidance, and I tell you. If I see the word, I want to scream when I see the word "guidance." We have dealt with that for so long. You now started to talk about binding standards, binding food safety standards. So if you can let us know there again with regard to that what your reference is in terms of its binding and the use of current authority to do some of this versus having to wait.

[The information follows:]

FDA is planning to propose regulations setting clear, enforceable standards for fresh produce safety at the farm and packing house. FDA intends to propose a rule with the purpose of reducing the risk of illness associated with contaminated fresh produce. FDA intends to base the proposed rule on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, known as the GAPs Guide.

Dr. HAMBURG. Okay. I hear you on guidance. I have to also in the spirit of full disclosure say that as I've been in this role, I can see the real utility of guidance in terms of being able to move much more swiftly than in other domains, so that we're going to have to have a balance.

Ms. DELAURO. You're going to have to redefine guidance for us and happy to be open to that. But I'm up to here in guidance for the last several years.

Dr. HAMBURG. Okay.

GENERIC DRUG USER FEES

Ms. DELAURO. So, as you know of not getting us anywhere, you know, and I appreciate the new translation of guidance.

So generic drug user fees are $38 million. 2011 proposed a number of times. Predecessors have been optimistic about it. It has gone nowhere. So I know about the backlog and what we need to do to move forward and I believe in trying to move this process forward. I would like to see a generic user fee enacted, but without the kinds of strings attached that we have with PDUFA.

It is my view that the performance standards have imposed unreasonable deadlines on FDA drug reviewers and it is bad morale, bad for public health. We recently had an executive of one of the major generic manufacturers who is quoted as saying: "We support user fees. The only thing we ask is performance metrics." Referring to the brand name companies he said, and I quote: "They pay their $1.2 million and they get their files acted upon. I would like assurances that we would not go down that path with a generic user fee."

Dr. HAMBURG. I would only underscore "acted upon" doesn't necessarily mean approved.

Ms. DELAURO. There is so much pressure on the reviewer, and we have seen some of the adverse reactions to that recently and have talked about them. And so I would really like the assurance that we are not going to go that same road.

Dr. HAMBURG. Well, you know, we're just beginning those conversations. I am guardedly optimistic. I hope I won't fall into the category of my predecessors of hitting a brick wall. You know, I think we clearly have a situation at the present time that's not sustainable. It is not acceptable to have backlogs, especially when these generic drugs represent very, very important drugs for people at affordable prices. So we are about to begin those discussions and we will be mindful of your concerns and the concerns expressed by others on this committee.

Ms. DELAURO. Exactly, because we have gone down not a good road.

Dr. HAMBURG. Right.

Ms. DELAURO. And the other direction should be visited.

Dr. HAMBURG. And I think, you know, the other aspect of this is that we want to have accountability in everything we do, but we also don't want cumbersome metrics that actually end up slowing the process and distracting us from the ability to actually address the review process and the backlogs, and make the decisions that need to be made. So I think, you know, those are going to be certainly issues for me going into these discussions.

BLOOD COLLECTION AND THE RED CROSS

Ms. DELAURO. A quick question. First of all, I applaud the work of the Red Cross, and I think they do just wonderful, wonderful humanitarian work. On the other hand, we have for a quarter of century the FDA has really grappled with issues related to blood collection by the Red Cross.

FDA has two consent decrees, assessed the Red Cross at least $20 million in fines. The problem still seems to be unresolved. How do we fix this?

Dr. HAMBURG. You know, this has been a saga that has persisted for much too long. We have been in intensive discussions. We see measurable progress and that's encouraging, but we haven't gotten far enough. We are trying to really sit down and figure out a systematic oversight mechanism so that we can be extremely explicit about what we expect and how we are going to measure their progress towards those goals. And, you know, we are going to use the other tools, regulatory tools we have in terms of fines as we also work with them.

Ms. DELAURO. Red Cross deals with 40 percent of the nation's blood supply. Look. This is an October 30, 2009 letter to the Red Cross. FDA said about 231 significant violations at 12 Red Cross facilities across the country. As I say, you know, they're the first on the scene. There's all kinds of humanitarian great work that they do, but this smacks of a very serious problem that they have. They oversee 40 percent of our blood supply.

Dr. HAMBURG. Right.

Ms. DELAURO. So, you know, this is not one where I think—you know, we've got to get it done. It's got to get done fast.

Dr. HAMBURG. You know, I hope that very soon I can report back to you that we have made the kind of measurable progress that you're looking for. You know, we have asked them to do some very rigorous changes in their program management and oversight. They have modified, you know, their systems and their governance. We are still, you know, watching and working with them very carefully because they are not where they need to be. And, you know, it has been surprising to me to look at the record and how long this has persisted. And I share your concern that this cannot go on as it has been going on.

Ms. DELAURO. Well, and continue to let us know how we can be helpful in this regard. I mean, this is outrageous that this has gone on for so long.

Ms. Kaptur.

ECONOMIC COSTS OF VIOLATIONS

Ms. KAPTUR. Yes. Thank you, Madam Chair.

Commissioner, how does one quantify the true economic cost to our country of the food and safety violations that your agency regulates? Has GAO ever done a study on that?

Dr. HAMBURG. You know, I don't believe that there's been that kind of comprehensive analysis. You know, we have talked a little bit about how that kind of analysis would be helpful to us in terms of I think talking about, you know, the funding of FDA and the resource base, and our ability to fulfill our mission, I think if people really understood the broad, economic consequences and inability of FDA to fulfill its important roles and fulfill them well, you know, I think perhaps it would be more understandable why the kind of investments that have been made in the last couple of years are appropriate and necessary, and are moving us towards getting us to where we need to be.

Ms. KAPTUR. Thank you. I think, Madam Chair, this is an area we ought to think about encouraging to take a look at the full, weighted cost of this, and the budget that the FDA has, because we have the costs of obviously illness, people not being able to go back into the workplace. There are all kinds. There's a quantification that one could be of what the true costs really are, and perhaps we can ask the GAO by letter to do that as a part of our work.

Ms. DELAURO. With regard to that, I understand that there was a peer study that has done some work in that area, and why don't we take a look at that and see how comprehensive it is and see what else we might be able to do.

Ms. KAPTUR. Then I have a series of questions. You may not be able to respond to all of them, but you'll get the trend of the thinking, and perhaps the agency can respond.

Dr. HAMBURG. Okay.

HEPARIN

Ms. KAPTUR. Okay. Describe to us what Heparin is medically used for. What is its cost to the average patient who is billed under Medicare for that product? How many pharmaceutical companies supply the final product in our marketplace? Would it be more or less than 10 companies? And give the names of those companies. How large is that market in this country, the dollars annually expended for the procurement of that product?

How many companies do the separate ingredients come from? That goes back to my sentence diagramming I referenced in the prior questioning period. And what percent of Heparin's ingredients are domestically produced versus foreign produced? Do you have a feel for any of that at this point, any one of those questions or how you could obtain that information?

Dr. HAMBURG. Well, I can tell you what it's medically used for.

Ms. KAPTUR. Okay.

Dr. HAMBURG. I can't answer your questions about cost or number of producers.

Ms. KAPTUR. Is FDA able to get inside information?

Dr. HAMBURG. We can certainly give you a much more comprehensive and informed response than if I tried to answer now. I mean it's an important drug in terms of its medical use for thinning of blood and preventing clot formation that can cause stroke and pulmonary embolism and other complications. It is a product that has a supply chain that involves international sources for the precursor products. It has, I think in terms of the production. I think there's one U.S. manufacturer at the present time, but, you know, I think we should get back to you.

Ms. KAPTUR. Yes. Would anyone on your staff know that and be able to state it for the record at this point? And that so-called provider would actually be an integrator of components that come from somewhere else. Am I hearing this correctly?

Dr. HAMBURG. Yeah. I mean many of the drugs that are used in this country are composed with components that come from other places. Actually, about 80 percent of the active pharmaceutical ingredients in drugs that we use in this country come from overseas, so Heparin is not unique in that way.

Ms. KAPTUR. I am hearing you.

Dr. HAMBURG. But I think we'd be happy to provide you with a detailed response.

PHARMACEUTICAL COMPANIES

Ms. KAPTUR. If you could give us straight what's going on, and I'm very interested in looking at the Medicare payouts and the Medicaid payouts for the use of these pharmaceuticals, and who is benefiting in this marketplace. When I find the name of the company, companies, then I'm going to go to the stock exchange and see if they're there, and what their profits were last year.

I am very interested in this marketplace and who actually controls it. If it's only one supplier, wow. That's pretty amazing. I thought, I mean, there obviously aren't a hundred suppliers of Heparin is what you're saying to me from your knowledge.

Dr. HAMBURG. You know, I am reluctant to be specific because I don't actually know the details. That information exists. I'd much rather go back and get you accurate information, and I think we can supply that.

Ms. KAPTUR. As a physician, do you know if I am in the hospital and I am a patient, how many bags or how does this get injected into the patient? Do you need it forever?

Dr. HAMBURG. No, you need it in an acute setting.

Ms. KAPTUR. An acute setting?

Dr. HAMBURG. It is intravenous medication.

Ms. KAPTUR. And what would be the cost of that? As a physician do you happen to know in New York City if you have to have Heparin how much are you charged in the hospital?

Dr. HAMBURG. It's been more than a decade since I've administered or prescribed Heparin, so, you know. Let me get back to you with, you know, the concrete data that you are asking for, because that information exists.

Ms. KAPTUR. Okay.

Dr. HAMBURG. But I would be fishing if I tried to provide that to you now.

[The information follows:]

FDA emphasizes swift, aggressive enforcement action to increase security over the drug supply chain and to identify risks to the public health. Once a flaw is detected in the supply chain, FDA moves quickly to take regulatory action to ensure that any risk to the public health is contained or eliminated. FDA recently unveiled initial steps designed to hone the effectiveness and timeliness of our regulatory and enforcement system. These steps include setting post-inspection deadlines for regulated industry to respond to significant FDA inspection findings; working more closely with FDA's regulatory partners; prioritizing follow-up on warning letters and other enforcement action; being prepared to take immediate action in response to public health risks; and developing and implementing a formal warning letter close-out process where a firm that has fully corrected violations will be issued a close-out notice that is posted on our website which we hope will motivate companies to take corrective actions.

The Office of Criminal Investigations, or OCI, engages in a wide-variety of law enforcement activities that protect public health and American consumers, including investigating counterfeit products, tampering, fraud, and economically motivated adulteration involving FDA-regulated products. OCI maintains ongoing contact with other international, federal, state, and local law enforcement agencies. OCI also is FDA's lead point of contact with the U.S. intelligence community. In addition, OCI is a charter member of the Permanent Forum on International Pharmaceutical Crime and has a representative assigned to the Washington, D.C. U.S. National Central Bureau of the International Police Organization, commonly known as INTERPOL.

Heparin sodium is derived from porcine intestinal mucosa. Intestines are extracted through a machine to produce a pulp. The pulp is then heated in the presence of protease enzymes to separate proteins form heparin. Resin is added to complex and bind the heparin material. Salt water separates the resin from heparin, and the resin is filtered away. Alcohol separates heparin from salt water. The heparin is then removed and dried. The crude heparin product is then purified and refined under specific processes set by the manufacturer to produce the heparin Active Pharmaceutical Ingredient, or API used in the final product.

Heparin is used to prevent and treat blood clots in the veins, arteries and lungs. Heparin is commonly used before certain types of surgery, including coronary artery bypass graft surgery, and in kidney patients before they undergo dialysis.

The four Pharmaceutical companies with FDA approved applications to market heparin are APP Pharmaceuticals, LLC, Baxter Healthcare Corporation, B. Braun Medical, Inc. and Hospira, Inc.

The major American companies that market heparin are APP Pharmaceuticals, LLC, Baxter Healthcare Corporation, and Hospira, Inc.

The corporate headquarters for APP Pharmaceuticals, Inc is located in Schaumberg, Illinois. The corporate headquarters for Baxter Healthcare is located in

Deerfield, Illinois. The corporate headquarters for Hospira is located in Lake Forest, Illinois.

It is difficult to pinpoint an annual sales amount for heparin as the product is primarily distributed in hospitals and dialysis centers, not through prescription. However, a February 20, 2008 article in the Chicago Tribune, entitled "Baxter Rival Gains Sales Amid Heparin Uproar" cited analysts who estimated that the annual sales for heparin in America were between $50 and $60 million dollars. Also, an article entitled, "The Heparin Story" in the February 23, 2009 edition of the Bernstein Report on BioBusiness stated that more than 10 million Americans receive heparin every year; more than 70 million vials are sold for cardiac surgery, dialysis and a wide variety of other uses. Another 50 million units of heparin flush are used annually.

The exact quantities of heparin active pharmaceutical ingredient that are being imported and then combined to produce heparin are not standard amounts. Each manufacturer has their own methods to produce heparin, based on specifications in their drug applications, and each may receive raw or crude heparin from different suppliers.

The active pharmaceutical ingredient, or API, in heparin is biologically derived heparin. Heparin is a large-molecular weight compound that is obtained from mucosal tissues of pig intestine. The crude material is purified into the API before being constituted into the finished dosage form. Manufacturers of the finished dosage form may each receive raw and crude heparin from different suppliers. Each manufacturer may also have different methods to produce their final product.

FDA has taken steps to improve its inspection program, especially in foreign facilities in the wake of the heparin contamination crisis. FDA has created and staffed a dedicated foreign drug cadre and has increased the number of foreign drug surveillance inspections. FDA also has investigators permanently stationed in China and India as members of the FDA posts in those countries. These investigators conduct inspections independently and are working with local regulatory partners to build capacity for inspections. CDER and ORA continue to increase the number and use of translators on foreign inspections, particularly those occurring in China. FDA is also increasing its Pharmaceutical Inspectorate, a group of the highest certified drug inspectors within FDA, who focus on performing foreign and domestic inspections of complex pharmaceutical manufacturing technology. FDA's inspection program involves manufacturers of both active pharmaceutical ingredients and finished dosage forms.

FDA has also developed and maintained a comprehensive import sampling plan designed to help ensure the quality of heparin drug products, including but not limited to crude, API, and finished dosage form drugs, entering into the U.S. The heparin sampling assignment assures FDA reviews all entry documents and labeling submitted for heparin products offered for importation into the U.S. and performs a reconciliation examination for each shipment. Shipments imported by, or consigned to, firms identified on the attachment for the assignment can be released without sampling once compliance with all regulatory requirements is verified. FDA has also increased monitoring of imported drug

products and screenings of products that FDA believes are of heightened susceptibility to economically motivated adulteration.

Your question highlights the fact that FDA increasingly faces challenges due to globalization of drug development and manufacturing. Not long ago, most drugs sold in the United States were developed, studied, and manufactured in the United States. Today, we routinely review and monitor drugs that are studied or manufactured, at least in part, outside the United States. The supply chain for finished drugs and active pharmaceutical ingredients now frequently links to manufacturing sites in China and India. With the globalization of the supply chain, FDA faces an ever-growing number of brokers, traders, distributors, re-packagers, and other players involved in the import of pharmaceuticals. To ensure drug quality, FDA has to devise and evaluate more complex risk scenarios and to apply more sophisticated technologies for screen and evaluate drugs entering the United States.

The heparin contamination crisis was one of the driving forces behind establishing FDA foreign offices. In November 2008, FDA officially opened its office in China with locations in Beijing, Shanghai, and Guangzhou. FDA has also opened offices in India, Latin America and Europe. Specific to China, in December 2007, the Department of Health and Human Services announced a Memorandum of Agreement with China to improve the safety of drugs and medical devices.

FDA has 22 confidentiality agreements with counterpart drug regulatory authorities under which we can share information related to reviews and inspections supporting our efforts to manage the challenges presented by global production of drugs and biologics. An example of the enhanced collaboration between FDA and foreign regulatory authorities is the API Pilot Program with the European Medicines Agency and Australia's Therapeutic Goods Administration in which participants share information about API inspections. The term API refers to active pharmaceutical ingredients used in the drug manufacturing process. FDA has also been and continues to be actively involved with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. This conference has issued guidance to industry on effective pharmaceutical quality systems.

FDA has not conducted an economic analysis of the impact of heparin contamination in terms of lost sales, deaths, or other societal costs.

There is no system in the United States that completely and accurately captures injuries and deaths due to heparin or any other pharmaceutical product. However, a review of the reports to FDA's Adverse Event Reporting System, known as AERS, received from January 1, 2008 to March 31, 2008 revealed 94 fatal cases reported after heparin therapy with at least one AE term from the list used to identify an allergic-type event.

FDA assessed three deaths as having a probable or likely association with heparin therapy, and six deaths as having a possible association. In the three probable or likely cases, FDA could not make a link between a death and possible contamination because FDA did not have lot numbers for the heparin administered to the patients. FDA's assessment found that the strength of association between heparin treatment and the patient's death was unlikely in 41 cases. FDA could not assess a possible link in 44 cases.

In a passive surveillance system such as AERS, there are many limitations such as potential underreporting and lack of complete case information. The increase in reports of allergic-type events after heparin administration, including deaths, noted in late 2007 to early 2008 returned to baseline in the Spring of 2008.

FDA has not been able to recover any damages to date.

FDA does not have the statutory authority to make those liable pay for the costs FDA must expend after such a recall has occurred.

FDA has not performed a cost estimate on staff time and resources that were expended on the Heparin recall and associated deaths and injuries. However, FDA staff expended countless hours of time and resources managing this crisis.

Once Baxter notified FDA of allergic reactions associated with heparin that Baxter manufactured, FDA began its investigation. FDA developed analytical methods to test heparin samples, and then collected and tested samples. FDA conducted an investigation into the supply chain to identify the unknown contaminant. FDA staff worked around the clock to investigate and find the problem, monitor the recall, and keep the public informed about the status of the safety of the heparin supply. FDA also worked with international partners in defining the scope and nature of the problem and make sure that an adequate supply of heparin was available to patients who needed it.

FDA does not maintain information about patient billing under Medicaid for heparin or any other drugs.

The percent of heparin components produced domestically versus abroad is determined by each manufacturer according to their own specifications. In their applications, manufacturers of the finished heparin to be marketed in the United States disclose the source of the active pharmaceutical ingredient. In general, the source that a manufacturer uses to supply ingredients is information that is trade secret, commercial confidential or other otherwise protected from disclosure to the public under the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and FDA regulations implementing these laws.

Ms. KAPTUR. Thank you very much. Thank you, Madam Chair.
Ms. DELAURO. Mrs. Emerson.

DIRECT CONSUMER ADVERTISING

Mrs. EMERSON. Dr. Hamburg, let me follow. The Chair had started the discussion about direct consumer advertising, and let me just discuss it a little bit more in detail and ask you a couple of questions. There's a "New York Times" article of March 5th that talks about the amount of money that drug makers spent in advertising in 2009. It says that the drugmakers spent a combined $4.51 billion on directed consumer ads for prescription medicines. Two-thirds of that or $3 billion went for TB. Another 1.9 billion was spent on magazine ads, with both levels nearly the same as they had been the year before.

Newspaper ads increased by 11 percent to 162.6 million. Radio ads jumped by 112 percent to 46.3 million. Spending on Internet ads, which has doubled over the last five years, hit 117.4 million, up 31 percent, while 7.6 million was spent on outdoor ads such as billboards. Now, I do know on the Internet, I mean I have more spammed drug ads coming to my BlackBerry than I know what to do with. But, anyhow, be all that as it may, the Chairwoman and I are sponsoring legislation that would ban direct consumer advertising for new drug and device products in the first three years after approval of the product.

And certainly now, just by looking at these ad numbers, it is probably not something that is particularly popular among the drug industry and our broadcasting and media friends. But we are only one of two countries in the world, with the other being New Zealand, that do allow DTC.

So my question is: What are you all doing about these ads to make sure that they are accurate and properly warn consumers about the side effects? What are you doing to make sure that FDA's increased resources are protecting the public from misleading ads? Has the FDA used its increased resources to hire more people to review the direct-to-consumer ads for devices and for prescription drugs?

Dr. HAMBURG. A very, very important set of questions. And I have to say I was startled when I learned that we were one of two countries in the world that had direct-to-consumer advertising.

And I think that we have expanded our activities in terms of review in the direct-to-consumer arena thanks to additional resources. But it has been an area of FDA activity that has been very minimal in terms of staffing vis-a-vis, you know, the volume of products.

I think you raise another important question about the timing of when ads go up. And we certainly do know that most of the advertising is focused on new products, and that is early when we know less about potential safety issues that may emerge. You know, so that is something that I have been thinking about and worrying about.

We do review the ads and can take action when we think that, you know, there are misrepresentations or inadequate presentation of risks, et cetera. But the volume makes this very, very difficult,

the fact that, you know, we don't review them, sign off, and then they go up, so we are sort of always running to keep up.

I think it is an area that requires more scrutiny. Obviously, there are important First Amendment issues here and other things. But from a public health perspective, you know, we want to make sure that people get information to help them make the right choices to protect their health.

ADVERTISING AND THE PUBLIC HEALTH

Advertising certainly is a very effective way of communicating messages. I would like to see advertisements contain more fundamental public health information, even if they are advertising a product; it is an opportunity to potentially provide some basic information about the underlying medical condition to help consumers know more and make better choices.

But, you know, it is a very important area. I think it is an area where we are strengthening our activities. But I cannot say that I think that we have reached the appropriate, necessary system in terms of our oversight ability. And also, I think further discussions with many partners—you know, the public policymakers and industry about how we can address this issue in a way that, you know, really makes sense for the most important people, which are——

Mrs. EMERSON. Well, half the time—no, I shouldn't say half the time; that is an exaggeration. In some instances, you know, it seems that I, at least personally, have learned about new diseases that I never knew existed simply because now there is a drug being marketed to tell us about like restless leg syndrome.

For example, I mean, seriously, if I got a crazy horse in my leg at night, I got a crazy horse in my leg, got up, walked around, and it was gone. I mean, it is just—I just—I feel real strongly that it needs to be—I mean, the oversight probably needs to be much tighter.

But I also am a little bit concerned, too, about the proliferation or the possible proliferation of these ads on social networking—Twitter accounts, Facebook, I mean, all sorts of things where there is really no ability to provide any kind of—what do you have, 40 characters or 40 words? There is no way to say, you know, this side effect has blah blah blah, like all the TV ads do.

So, I mean, it is very worrisome to me.

Dr. HAMBURG. No. There are real issues.

Mrs. EMERSON. And I think we need to have some special attention focused.

Thank you, Madam Chair.

BPA

Ms. DELAURO. Thank you. Let me again try to run through a whole bunch of questions.

As a quick followup on the BPA discussion, Commissioner, are you aware of the study that was done by the Yale scientists?

Dr. HAMBURG. You know, I have not looked at it directly. I understand that it was a study that was done in mice, and using much higher doses than humans would normally be exposed to. But, you know, I think——

Ms. DELAURO. I know you will read it. Let me just—or have your folks take a look at it. I would love to be able, you know, to review the findings and see what we have there. I think that would be helpful.

Dr. HAMBURG. It is very important, you know. You and I share a commitment to having our decisionmaking be driven by data and evidence. And we need to look at everything that is out there, assess it, engage in a robust discussion of the science, and then hopefully make the best possible decisions.

SALMONELLA MONTEVIDEO

Ms. DELAURO. Great. This *Salmonella* Montevideo recall, this is an interesting one because we are dealing with, I think, salami and black or crushed red pepper. And excuse me for saying this again. This is, you know, being reviewed by two different agencies, USDA and the FDA.

But there is a likelihood that the pepper was imported. Can you tell us where the pepper—what country or countries the products in question came from?

Dr. HAMBURG. I believe that there were a couple of sources for the pepper, and that they were international sources. I hate to start pointing fingers when I don't know. Vietnam was one of the sources—and Mike Taylor has disappeared. But, you know, we can get you the specifics.

[The information follows:]

The FDA, working with the Centers for Disease Control and Prevention, the USDA Food Safety and Inspection Service, the State of Rhode Island, and other states, are investigating the recent *Salmonella* Montevideo outbreak associated with salami products. During the investigation, FDA collected 238 samples of black pepper, red pepper, environmental samples and other spices. Of the samples collected, 211 were negative for *Salmonella*, 6 were positive for *Salmonella* Montevideo matching the outbreak strain and 6 were positive for *Salmonella* Montevideo which did not match the outbreak strain. FDA is still processing fourteen samples.

All positive *Salmonella* samples were collected at the manufacturer of the salami products, Daniele International. The positive samples traced back through different supply chains to Vietnam, India, and possibly China.

Based on the evidence it currently has, FDA has not been able to conclude where in the supply chain the contamination may have occurred. as part of the investigation and as a precaution, FDA established additional import controls on spices from firms or countries associated with these supply chains. As a result of these import controls, FDA has found one positive sample involving a strain that is not association with the outbreak.

Ms. DELAURO. That is fine.

Dr. HAMBURG. But there were international sources, and there were, you know, multiple sources in terms of the companies involved.

Ms. DELAURO. Okay. Now, I also understand that FDA started a risk profile on spices last spring. When do you expect that to be completed?

Dr. HAMBURG. Again, I need to get back with you on that. But spices do represent, you know, a special concern because once they get into the food supply, they are everywhere.

[The information follows:]

FDA is in the process of taking a closer look at the handling of spices from farm to table. In the spring of 2009, FDA began work on a spice risk profile. A risk profile is designed to capture the current state of knowledge related to an issue under FDA's jurisdiction and identify any knowledge gaps.

This particular risk profile focuses on microbiological contaminants and filth issues related to spices. Some members of the spice industry have already agreed to provide data to FDA for the risk profile. The risk profile will provide vital information to FDA officials who make risk management decisions. The information will also help FDA determine the best way to mitigate foodborne illness issues associated with spices. Specifically it can help FDA determine how to allocate resources, whether guidance for industry or for FDA inspectors is appropriate and whether there is a need for new rulemaking.

CLINICAL TRIALS

Ms. DELAURO. Right. A quick question on the oversight of clinical trials and your acknowledgment that FDA currently inspects less than 1 percent of clinical trial sites. And, you know, the issue is that without inspecting these sites, it is a matter of time before we have bad data that might lead to bad decisions.

There is also, as I understand it—we have got, you know, the outsourcing of clinical trials, which is posing—and offshoring the trials, which has been—at least, newspaper accounts talked about some concerns about the lack of safeguards for the participants.

I was pleased to see that in the budget, you are looking at the problem. The request is for $500,000 in one FTE for bioequivalence in generics. Let me just ask you: Don't we need more to deal with this?

Dr. HAMBURG. You know, this is why I gave Congressman Kingston my response about, you know, I don't see our budget increases as being excessive. I think that, you know, we have such a depth and breadth of responsibilities, and responsibilities that are so essential in so many different ways.

And, you know, in many instances—in most instances—we are undertaking activities that nobody else is prepared to do if we don't do them. And so, you know, yes, there is more work to be done. You know, we are building on a foundation that has been strengthened thanks to the investments that this committee has helped to spearhead for us in recent years.

We have to be realistic about how much we can absorb each year in terms of really putting those dollars into practice in a responsible, accountable way. But, you know, I cannot come before you and say that we don't need to keep continuing to expand in some essential areas that are a priority for health.

GRAS

Ms. DELAURO. Yes. Well, it would seem to me that that would be one of them.

Let me ask a question about GRAS substances. A GAO study again, how FDA handles what are referred to as generally recognized as safe. I have real concerns about some of the substances that are allowed in the foods through the GRAS process.

I have looked at the diacetyl issue, you know, for the last several years, diacetyl in popcorn and lung disease. The system is voluntary. Companies can make these decisions without informing the FDA. To me, that is unacceptable.

What is your position on reforming the GRAS system?

Dr. HAMBURG. Well, you know, I think it is one very important area of, actually, a number of arenas of activities where I think we have a responsibility to sort of systemically look at how, in the

modern era, we need to upgrade, modernize, or modify our regulatory frameworks.

And some of that, of course, will require ongoing work with Congress. Our new general counsel, Ralph Tyler—who was here, I think—and I have had the discussion about how important it is that we look at some of this because, you know, FDA has a wonderful history. But many of our authorities and our procedures and our legal framework was put into place in a very different era. And we need to address that.

NANOTECHNOLOGY

Ms. DELAURO. Because, I mean, I think we are also looking at the regulation of nanotechnology materials in foods under that GRAS determination. You know, if this is all voluntary, we have no way of knowing what foods contain nanotechnology.

I am going to maybe answer the question I asked you. I have to imagine that it is an affirmative. Do you think this is a safe way to regulate materials that we know little about? I mean, the answer to that—how can it be, you know, a safe way to do that?

Dr. HAMBURG. You know, I think it may be useful in certain categories, but for other categories, it is not. And I think we have to look at that, you know, and ask just the questions that you are asking. I share your concerns.

Ms. DELAURO. But let me ask this: Has FDA decided to allow these materials in food with no warnings or labelings before we have had adequate research on these? Are we allowing nanotechnology?

Dr. HAMBURG. With respect to nanotechnology? Well, you know, nanotechnology is present in a whole range of products. We take very seriously our responsibility to look at the emerging technology in terms of safety concerns, short-term and long-term safety concerns. But it is an issue that we need to address with respect to foods, with respect to cosmetics, with respect to drugs and devices as well.

And we are—you know, this budget has requests for additional dollars to strengthen our nanotechnology activities. And, you know, we have a program that was put in place. We are also working with some external experts to help us look at the data and ask these questions, too.

DIETARY SUPPLEMENTS

Ms. DELAURO. I would just say this. I think that if we are looking at funding to check into this and doing the research, I don't think we can do two things at the same time. We need to get the research in order to do it, in order to say they are safe, and so you can say that without equivocation.

And so that is what I would just, you know, offer, to say this: You can't do both things at the same time. Let's get the research and then make the determination as to whether or not they are safe. And it seems to me that we don't have the research now that allows for them to be designated as safe, which again calls into question this area, which I take you at your word that you are investigating.

Let me move to dietary supplements, a GAO report on FDA's work on dietary supplements, January 2009. This has all kinds of statistics on how rapidly growing the industry is. I found interesting that there was no reference in the budget for additional funding for dietary supplement work by the FDA. You know, is that correct? And if so, why?

But also, I wanted to get your view on the bipartisan view in the Senate, Dorgan and McCain, that would require supplement manufacturers to register with FDA, to disclose all the ingredients in their products. It would also give FDA mandatory recall authority to remove dangerous products from the market.

This is a recommendation of that 2009 GAO report. Do you think you should have these powers?

Dr. HAMBURG. I haven't had a chance to review that bill. But, you know, I share your concern about assuring that these dietary supplements that people take, assuming that they are safe and will actually promote good health, we need to make sure that they are in fact what they purport to be and that they will not do harm.

DSHEA

You know, we got new authorities through DSHEA, and we are still moving towards full implementation on the good manufacturing practices side. For example, we expect that all of the businesses, including the small businesses, will be on board by 2010. But that is very important.

Ms. DELAURO. The safety issues are critical.

Dr. HAMBURG. The adverse event reporting has been very, very important. You know, I think it was in 2007 you gave us that additional authority. And based on that, we have taken enforcement actions. You raised that in the beginning, you know, removing some dangerous products from the shelves and providing consumer information as well.

I think that we do have money in the 2011 budget, and we had additional new money in the 2010 budget. So we are continuing to expand activities in that area. And of course, the inspectional activities are part of that.

But, you know, I will look with interest at this bill in terms of what additional authorities are——

FOOD LABELING

Ms. DELAURO. I will tell you what I think I would like to do in this area. And I think that in the course of our hearing process is to—I mentioned earlier we will do one on trade and food safety. I think we need to do a hearing on dietary supplements. I think we need to look at this area.

When you have got 50,000 safety violations or incidents a year and issues, I think that merits us taking a look at what is happening here. And this is not—I just think it is a very, very big issue that hasn't been discussed at all, you know. And so we need to really move in that direction.

Affirmative labeling. Front-of-package nutrition labeling. And I guess a couple of my colleagues have mentioned that. You know what a strong advocate I am of your role in regulating the packaging and the issue of confusing and misleading labels. And I com-

mend you for the actions that you have taken. And we went through this issue with the Smart Choices piece.

But there is a guidance letter, I guess, in 2009 regarding food labeling. You say that the FDA will proceed with enforcement actions against products that have false or misleading labeling. The guidance document, can you update us on the activities of that?

Dr. HAMBURG. Last week, we in fact sent out 20 warning label letters, I think, on that topic.

Ms. DELAURO. That is right. You said that.

Dr. HAMBURG. So we are, you know, taking it very seriously.

Ms. DELAURO. One of the concerns—you have got the Journal of the American Medical Association carried an article suggesting that the problem of front-of-package labels has become so serious that we should consider banning claims from the front of packaging. What do you think about that idea?

Dr. HAMBURG. Well, there certainly are a lot of claims on the front of packaging.

Ms. DELAURO. Right.

Dr. HAMBURG. You know, every available space is used for something. You know, I think——

Ms. DELAURO. I know you are looking at developing criteria in this area, and part of the budget document is——

Dr. HAMBURG. Yes. I think that the front-of-package information is mixed in its value. I mean, I think there is a very positive, proactive value to providing accurate, science-based nutritional information on the front of the package. I think, you know, the concern is about the sort of cacophony of other messages, you know, that are on the front of package.

Ms. DELAURO. Right.

Dr. HAMBURG. And I think, you know, the question about a ban obviously extends far beyond, you know, the responsibilities of FDA and get you into other domains.

But I think, you know, it is very, very important that we have the opportunity to provide important nutritional notification that people want. I think it is very, very important that that not be clouded by claims that are misleading, inaccurate, or fraudulent.

Ms. DELAURO. Are you going to put together a regulation in this area? Is that what you are going to do? And what is the timing on that?

Dr. HAMBURG. Well, we currently are undertaking some consumer research about how people respond to information. We are working on, you know, and looking at sort of different models for presenting information.

We are working on standards for nutritional information that would be used in whatever presentation format was decided upon, where we are trying to work with industry, with manufacturers and retailers, to find a presentation approach that they are comfortable with. Actually meeting with the Grocery Manufacturers of America later today to talk about some of these issues.

We are trying to learn from the experience of other countries that have moved, either voluntarily or mandatorily, to different types of front-of-package nutritional labeling. So we are moving forward. I mean, I hope by the end of the year we will have a strategy well established and even beginning to implement.

SMART CHOICES

Ms. DELAURO. As part of this discussion, when I—and this was on the issue of the Smart Choices debate that we had—when I talked to the folks from Smart Choices, you know, several months ago—and obviously you moved in a very aggressive direction here, which was laudable—one of the things they said that they were dealing with was nutrients to limit—total fat, saturated fat, trans fat, cholesterol, added sugar, sodium, in some cases calories. And they were following that guide.

And the point I want to make here is that they said, in particular, the limitations set for saturated fat, cholesterol, and sodium are equal to or lower than FDA's healthy regulations, and the level set for trans fat is consistent with FDA policies, where no governmental level has been set.

Regarding added sugars, it is important to note that FDA does not restrict added sugar levels in any of its applicable nutrition-related regulations. So by addressing added sugars, the Smart Choices criteria go farther than FDA regulations in this regard.

Are you looking at that?

Dr. HAMBURG. We are looking at the issue of added sugar, and we, I think, plan to have that as part of our updated standards.

INDOOR TANNING

Ms. DELAURO. Great. Thank you. Thank you.

A couple more areas here. Indoor tanning devices, which we have talked to. And there again, I believe you have an advisory committee meeting coming up some time this month?

Dr. HAMBURG. Yes. Yes. Yes. Yes.

Ms. DELAURO. Assuming the advisory committee confirms the new data and finds that there is an increased risk of using these devices, what are the next steps the agency intends to take, and what would be the timetable for those next steps?

Dr. HAMBURG. Well, you know, of course, I am not going to jump in front of the advisory committee. But we will take very seriously their recommendations, and I think we will move towards action steps quickly. This issue, as you know, has been out there for a while, and I think we do need to take definitive action.

And I think, you know, as you have pointed out, there are issues around the adequacy of the warning, and there are issues around the safety of the procedure.

Ms. DELAURO. Right. In addition to examining the possibility of reclassifying the devices, you are going to look at the current labeling requirements for indoor tanning devices. Is that right?

Dr. HAMBURG. Yes.

Ms. DELAURO. Okay. Let me—really, I truly only have a couple more questions, I promise you. So——

Dr. HAMBURG. No one can accuse you of being disinterested.

ANIMAL BIOTECHNOLOGY PRODUCTS

Ms. DELAURO. Animal biotechnology products. Whoa. I can start by saying that this is—your budget requests $1.9 million to build expertise for the regulation of these animal biotechnology products.

It is not a large amount of money. It is large in comparison to some of the other increases in the budget.

Understanding the value of these products, I hesitate when I read that: "This investment will create a regulatory pathway for animal biotechnology." I think—I mean, I know FDA over a year ago approved the first biological product produced by genetically engineered animals three weeks after issuing guidance on the regulation of such animals.

So I have a question there: Shouldn't the pathway already exist and have been used for the February 2009 approval? How will this pathway differ from the regulatory pathway for other drugs to treat human disease? And how many applications are already in the queue at the FDA? Can you talk about which stakeholders the FDA plans to work with on this initiative, and how you hope to increase public confidence in the FDA's ability to regulate this technology.

Dr. HAMBURG. Well, you are right. There was, you know, the action that you cited taken at an earlier time. But there are different—we are talking about sort of different products and uses here so that there isn't one common pathway because there is the possibility of products that are produced by animals using these recombinant technologies, and there is also the possibility of these technologies being used for food production.

Ms. DELAURO. Right.

ADVANCING REGULATORY SCIENCE

Dr. HAMBURG. You know, these are areas of emerging science. And this is why, you know, those investments that we talked about before in Advancing Regulatory Science are so important because, you know, these are areas where we need to have the in-house scientific capability to assess fully these emerging technologies.

We also have to have the access to appropriate outside experts. They do raise, you know, complicated issues that go beyond simply the science of safety as well. You know, you appropriately addressed the issues of confidence of the public and openness of information to consumers.

So it is a complicated area. And I think, you know, we are moving forward in a stepwise, thoughtful, and science-based way. But, you know, there definitely is a need to address this in a way that isn't a cookie cutter approach or just, you know, a stamp it kind of bureaucratic approach.

And it is an area where, while there is a limited number of products that have come before us, you know, I think we can only sort of anticipate that as science advances, that we will be asked to look at more products and different types of products.

Ms. DELAURO. I think I just want to say on this, and maybe it would be a more informal gathering because, really, I mean, there are, you know, new dimensions. And for the entire committee, both side sort of the aisle, maybe we could do something in an informal way that talks about—an informal meeting where you can lay out for us some of these new areas.

You know, I am not a scientist, so mysteries to me. And I look at, you know, a chart like that and I say, whoa, you know. Where are we going?

Dr. HAMBURG. Yes. Yes.

Ms. DELAURO. But, you know, I mean, I think that there are new areas. And we need to stretch the edge of the envelope in terms of that research. But I also think it would be enormously helpful for those members of the committee, again, on both sides of the aisle that would like to get the benefit of understanding what those new areas are where we can ask questions about it and have everybody be able to ask questions about it.

Dr. HAMBURG. Okay. I think that would be useful for everyone.

FOOD SAFETY REGULATION

Ms. DELAURO. I essentially have one more question. I actually have two. But the food safety legislation, I just want to ask you, because the Senate is going to act, what are the critical pieces of what has happened in the House that you believe we have to come out with in the Senate?

Dr. HAMBURG. Well, you know, I do think that the user fee issue is absolutely essential in order to give us the resources that we need to undertake the job. I think mandatory recall authority is essential in order to have the kind of swift action and accountability that we all know is important.

I think routine access to records is critically important so that we can really assure a preventive approach in compliance with these activities. I would say those are probably the most essential.

TRACEABILITY

Ms. DELAURO. For my purposes, the performance standards and the, you know, traceability process——

Dr. HAMBURG. Yes. Yes. Absolutely.

Ms. DELAURO [continuing]. I think are absolutely critical to getting us where we need to go, and recall authority, obviously; we have been talking about that for a long time. So obviously, we are going to—you will. We are going to keep a close watch on what is happening in the Senate.

OFF-LABEL ADVERTISING

A final question is the off-label marketing guidance that was issued at the end of the last Administration, six days before it ended. This is about guidance to facilitate off-label promotion of drugs and medical devices by drug and medical device companies.

I don't know what your views are on that policy. And will you move to withdraw it or to revise it?

Dr. HAMBURG. You know, I am not prepared to speak specifically to the question that you posed, but to say that I take the issues of off-label advertising and promotion very seriously because, you know, I think it is moving health care providers and consumers to understand that a use of a medication is proven when, you know, it hasn't been approved by the FDA for that indication.

In the practice of medicine, you know, there has always been the flexibility to provide medications based on your best clinical knowledge and experience. But I think to mount, you know, campaigns to encourage use and provide what is often limited scientific studies to support a perspective that isn't fully vetted and hasn't had

the benefit of formal review, I think is not good for patients. And I think the legal system has also demonstrated that it goes beyond the boundaries of what is appropriate practice and legally sanctioned.

Ms. DELAURO. Well, I hope you will give it some thought and see what you will do either to revise or to withdraw the guidance. And we can talk further about that.

Dr. HAMBURG. Okay.

Ms. DELAURO. With that, I want to say thank you to you for your candor, for your clarity, and for elucidating a number of issues. And I appreciate it. Look forward to working with all of you.

I applaud all the initiatives so far, and the aggressiveness with which you are approaching, if you will, a restructuring of the FDA and bringing it to what both sides of this committee have talked about for a long time, is restoring that gold standard to the Food and Drug Administration.

Thank you very, very much. Appreciate it.

Dr. HAMBURG. Thank you.

Ms. DELAURO. The hearing is concluded.

QUESTIONS SUBMITTED BY REPRESENTATIVE FARR

FOOD SAFETY

Mr. Farr: Fresh fruits and vegetables are perishable and the quality depends on how quickly the produce gets to consumers. I am getting reports that FDA's testing for food safety, at the border and elsewhere, is taking a long time to get results. Until the results are back, the produce is held so delays have a devastating impact. What can be done to speed the test results? For the record, can you provide information on the number of tests and the time it takes before the held produce is released.

Response: Because bacterial cultures require time to grow, preliminary results for standard microbiological testing take on average up to four days. After we receive a presumptive positive result, primary pathogen identification takes on average up to 10 additional days, and more complex analyses can take up to 21 days. Standard pesticide preliminary results take on average one day, and final results for samples where results are presumed to violate safety standards take on average two days.

In FY 2009, FDA analyzed 2,241 imported fresh fruit and vegetable samples for either microbiological or pesticide contamination. 2,078 of those samples were found to be in compliance and were released. FDA's average time from entry to final action was just over seven calendar days. The average elapsed time between recording of analytical results and release was approximately one and one half days for microbiological analyses and two days for pesticide analyses.

FDA uses a mobile laboratory with microbiological and chemical capabilities for rapid and large-scale screening of imported and domestic produce near the sample collection point. The laboratory uses rapid screening technologies that provide preliminary microbiological results on an average of two days. In FY 2009, FDA deployed the mobile laboratory to California and Arizona. In FY 2010, we have six mobile laboratory deployments scheduled.

FDA has taken significant steps to increase our laboratory capacity and capabilities, including the development of a Science Strategic Plan. Our Analytical Tools Initiative promotes field-wide use of new or previously unused rapid screening technologies in the laboratory and at the point of sample collection. These rapid analytical tools will provide on-site screening information that may help expedite final disposition of imported foods. FDA has also established three high-throughput food microbiology laboratories and one high-throughput food chemistry laboratory. These fixed-site laboratories have the capacity to screen a high volume of samples in a reduced amount of time.

Mr. Farr: Small growers in my district often sell to larger processors. Household names depend on small growers. If food safety rules exempt small growers, won't these small growers lose out on selling to these marketing outlets?

Response: FDA is committed to developing a produce safety proposed regulation that is scalable for firms of different sizes. While certain basic aspects of food safety may be considered appropriate for all growers, FDA will be evaluating possible exemptions from all or part of the regulation that may apply to certain firms. FDA will also be evaluating the potential economic impact of the regulation on all produce growers, including small growers.

Mr. Farr: The FDA has identified "recovery" as a key element of its response to a food safety crisis. Leafy green growers in my district suffered enormous losses when FDA told consumers to stop eating spinach and those losses continued long after the incident ended. Please tell us of FDA's plans to limit the collateral damage to innocent growers of safe products and how the agency may assist growers recover from the shocks that come with a food safety scare?

Response: FDA has a responsibility to inform the public when potentially contaminated products are being removed from the marketplace and concurrently to help consumers distinguish products that are not associated with a recall or emergency. FDA is working with other federal, state and local regulatory agencies to respond more rapidly to foodborne illness emergencies, identifying the specific affected food products more quickly, and therefore minimizing or eliminating the need to provide broad based consumer warnings during an investigation. One example is the launching of the reportable food registry, which allows FDA to obtain product distribution information more quickly, thereby helping to quickly target the affected product.

In order to communicate complex messages more effectively, FDA has begun a series of consumer social science research projects, which will provide information on how consumers perceive FDA's messages and how best to proceed. FDA is also working to develop effective preventive controls to minimize the chance of these events happening and to develop strategies that will allow consumers and retailers to distinguish recalled products from products that are not implicated in a recall.

FDA is also working toward improvements in the traceability of all foods, including produce, that would also minimize the economic damage to growers. This combination of more rapid response and identification of the specific lots of affected product, improved consumer messaging about the products in the marketplace that are not associated with the emergency, improved traceability, and improved ability to distinguish re-introduced products should help limit the collateral damage to firms whose products are not implicated in a foodborne illness emergency.

Mr. Farr: Has FDA identified its research needs to fill gaps in our knowledge about food safety risks with produce? This subcommittee has provided money to the Center for Produce Safety to add to funds the industry has put up to fund rigorous, applied research on food safety. Does FDA work with the Center?

Response: FDA's Center for Food Safety and Applied Nutrition has developed a strong working relationship with the Center for Produce Safety - CPS - located at the

University of California, Davis. FDA personnel are currently engaged and actively participate on the CPS Advisory Board and Technical Committee. The CPS Advisory Board provides guidance regarding CPS' overall strategic direction while the CPS Technical Committee provides input into CPS' research priorities, writes and reviews requests for proposals and reviews and ranks incoming proposals for technical merit and potential funding. On June 24, 2010, CPS, the FDA Western Center for Food Safety and the Joint Institute for Food Safety and Applied Nutrition are sponsoring a Produce Safety Research Priorities Workshop on the UC Davis campus. This workshop coincides with the CPS Inaugural Produce Research Symposium, which is scheduled for June 23, 2010. These meetings will provide an opportunity to understand currently funded on-going produce safety research efforts in government, industry and academia, review produce research priorities, facilitate cross pollination of research ideas and techniques, and minimize duplication of efforts.

PALLETS

Mr. Farr: As you may be aware, there is quite a lot of concern about the use of toxic chemical deca-bromine in the plastic pallets used in the food industry. There have recently been laws passed in Maine, Oregon and Vermont that ban the use of deca-bromine as a fire retardant. To what extent does the FDA dedicate resources to train its field inspectors to look for contamination of food from hydro-cooling and wet room cooling of fresh fruit and vegetables from plastic pallets containing deca-bromine?

Response: FDA's Office of Regulatory Affairs - ORA delivers a one week training course that covers 21 Code of Federal Regulations Part 110, Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food. This course targets FDA investigators and state inspectors and addresses the proper use of equipment and utensils, related to design, construction, preclusion of contaminants, and cleaning. The course also addresses the fact that food contact surfaces should be made of non-toxic materials and maintained to protect food from contamination and unlawful indirect food additives. The course covers a variety of examples of compliance and noncompliance with equipment surfaces across the board in the manufactured food industry. Currently the course's content does provide a multitude of unapproved and approved food contact surfaces and materials. As a result of concerns raised last year pertaining to deca-bromine in hydro-cooling and wet room cooling of fresh fruit and vegetables, FDA has modified the course to specifically address this issue.

Mr. Farr: For example, plastic pallets that are used in these cooling operations are often dripping wet and may be leaching deca-bromine. I would also like FDA to provide this committee with the guidance you provide inspectors that enables them to spot this unapproved use of plastic pallets in food contact?

Response: Plastic pallets containing deca-bromine are not authorized for use in contact with food. If an inspector were to observe a dripping-wet plastic pallet holding food, it could trigger a question about the regulatory status of the plastic and any adjuvant chemicals. FDA investigators are trained to look for and document during inspections

evidence of practices in the manufacturing area that could lead to the adulteration of finished products. We would consider evidence of a dripping wet plastic pallet, that came in contact with food or a food contact surface, to be a Current Good Manufacturing Practice deficiency that our investigators are trained to document for further Agency consideration.

Mr. Farr: Will you assure this committee that America's fruit and vegetables do not come into contact with deca-bromine from the use of plastic pallets that transport and store fresh produce?

Response: Although there is no way to offer 100 percent assurance that unauthorized uses of food contact substances would not result in contamination of fruits or vegetables with deca-bromine or other substances, FDA has maintained its position that deca-bromine is not authorized for use as a food contact substance and has communicated that position to manufacturers and users of plastic pallets. We will continue those efforts within the constraints of Agency resources and priorities.

NATIONAL ANTIMICROBIAL RESISTANCE MONITORING SYSTEM (NARMS)

Mr. Farr: How has funding for surveillance of antimicrobial resistance through NARMS changed over the last 5 years?

Response: FDA recognizes the public health value of the National Antimicrobial Resistance Monitoring System, known as NARMS. The funding level for NARMS has remained consistent for the last five fiscal years. The following table displays FDA appropriation amounts for NARMS for the last five fiscal years, including the amount that FDA has allocated to the United State Department of Agriculture - USDA - and the Centers for Disease Control and Prevention - CDC.

NARMS Funding FY 2006 – 2010

	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
USDA	$1.4M	$1.4M	$1.4M	$1.4M	$1.4M
CDC	$1.8M	$1.8M	$1.8M	$1.8M	$1.8M
FDA*	$3.5M	$3.5M	$3.5M	$3.5M	$3.5M
Total	$6.7M	$6.7M	$6.7M	$6.7M	$6.7M

* Included in this figure are lab supplies FDA purchases for USDA and CDC

Mr. Farr: In 2007, the FDA's Science Board made specific recommendations on steps to strengthen the NARMS surveillance system. What progress has FDA made in implementing these recommendations?

Response: In response to the 2007 FDA Science Board subcommittee evaluation of the National Antimicrobial Resistance Monitoring System or NARMS, FDA has

conducted a pilot study with the University of Maryland testing retail meat samples for Methicillin resistant *Staphylococcus aureus,* also known as MRSA. FDA will use the results of the study to determine the correlation, if any, of the presence of MRSA in retail meat samples to clinical cases of infection in humans. NARMS has also provided funding and training for state FoodNet partners to test retail meats for MRSA. NARMS scientists are evaluating new methods to improve recovery of foodborne pathogens from meat and animal samples and are examining various cuts of meat for any differences in pathogen prevalence in order to increase the number of bacterial isolates for testing.

FDA and the United States Department of Agriculture - USDA - are investigating options to overcome limitations of the current sampling scheme. NARMS leadership has held discussions with the USDA's Food Safety and Inspection Service, also known as FSIS, as well as with commodity groups, to seek potential alternatives to overcome biases in samples collected at the slaughterhouses from food animals.

FDA has expanded support for international capacity building in surveillance of antimicrobial resistance in foodborne pathogens through the World Health Organization. FDA has significantly improved reporting timelines from 3.5 years to 14 months and has launched a user friendly data query tool on the web.

FDA and the Centers for Disease Control and Prevention are working to establish an integrated NARMS database. A development environment is currently evaluating system architecture and test designs have been implemented. The business and tactical plans and harmonized data dictionary have been completed. FDA is developing data intensive testing methods, also known as microarray technologies, to more rapidly and comprehensively characterize strains of foodborne bacteria.

An FDA strategic planning meeting in August 2009 focused on progress implementing the FDA Science Board recommendations, as well as addressing new priorities and additional strategic plan development. FDA is tentatively planning to hold another strategic planning meeting in 2010 with a similar focus. Additionally, FDA has scheduled a public NARMS meeting for July 15 and 16, 2010 to seek input from international partners and stakeholders. The FDA Center for Veterinary Medicine is determining how NARMS can support the specific regulatory responsibilities of other FDA Centers.

Mr. Farr: What would FDA need in support from Congress to fully implement the recommendations of the FDA Science Board on NARMS?

Response: FDA appreciates the support Congress has given to maintain the mission-critical National Antimicrobial Resistance Monitoring System - NARMS program. FDA continues to address and implement many of the FDA Science Board recommendations with its annual appropriations in an effort to maximize the leveraging of resources between FDA, USDA and CDC.

Mr. Farr: Does NARMS have adequate resources to respond to emerging threats such as livestock associated MRSA and imports of food and feed?

Response: Current funding for the National Antimicrobial Resistance Monitoring System - NARMS - has permitted FDA to leverage its resources and scientific staff with partners at the University of Maryland to conduct a pilot study testing retail meat samples for Methicillin resistant *Staphylococcus aureus*, or - MRSA. FDA will use the results of the study to determine the correlation, if any, of the presence of MRSA in retail meat samples to clinical cases of infection in humans. NARMS has also initiated surveillance in 2010, in collaboration with the Centers for Disease Control and Prevention and select FoodNet laboratories, for the presence of MRSA, as well as other pathogens of public health interest, such as vancomycin-resistant enterococci and Clostridium difficile, from in retail meats in collaboration with CDC and select FoodNet laboratories.

NON-THERAPEUTIC USE OF ANTIBIOTICS

Mr. Farr: Did drug sponsors respond to FDA's concerns raised about their products?

Response: FDA requested information from the sponsors of penicillin-containing new animal drugs approved for use in the feed of food-producing animals. FDA received limited information from one sponsor, but the information did not address FDA's concerns.

Mr. Farr: What were the results of the FDA's safety reviews of penicillin?

Response: FDA has reviewed all available scientific information relevant to assessing the safety of using the penicillin class of antimicrobial drugs in the feed of food-producing animals. Since FDA is broadly concerned about the use of all medically important antimicrobial drugs that are important for therapeutic use in humans as a non-therapeutic use for production purposes in food-producing animals, FDA's concerns extend beyond the penicillin class of drugs. Therefore, FDA is completing a broader review of the issue.

Mr. Farr: What action has FDA taken or is taking to respond to the safety concerns regarding non-therapeutic use of antimicrobial drugs?

Response: FDA continues to be concerned about the use of medically important antimicrobial drugs that are important for therapeutic use in humans in food-producing animals for production, non-therapeutic purposes. FDA does not believe that it is judicious to use these important drugs for such purposes in animals. Therefore, FDA is developing a strategy to assess all relevant information related to the production, non-therapeutic use of such drugs, to engage in outreach to stakeholders to discuss the public health concerns associated with such use and possible strategies for addressing these concerns, and to evaluate all options with regard to appropriate actions. Moving forward with this strategy to address this important public health issue is a priority for FDA.

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA)

Mr. Farr: What actions has or is FDA taking to ensure that antimicrobial use in food animals does not lead to the spread of MRSA in food animals and their handlers?

Response: FDA is reviewing all available information relevant to the use of medically-important antimicrobial drugs, such as drugs that are important for therapeutic use in humans, for non-therapeutic, production purposes in food-producing animals to identify any development of antimicrobial resistance in human bacterial pathogens, including Methicillin resistant *Staphylococcus aureus,* also know as MRSA. FDA has engaged in wide public outreach to discuss the public health concerns associated with the use of antimicrobial new animal drugs in animal agriculture. These outreach activities provide an effective means for stakeholders and other members of the public to directly engage FDA in dialogue about strategies for addressing emerging antimicrobial resistant pathogens, including MRSA.

Mr. Farr: Has FDA taken any steps to determine the extent to which MRSA is present in food animals in the US?

Response: FDA is reviewing all available information relevant to the use of medically-important antimicrobial drugs, such as drugs that important for therapeutic use in humans, for non-therapeutic, production purposes in food-producing animals to identify any development of antimicrobial resistance in human bacterial pathogens, including Methicillin resistant *Staphylococcus aureus,* or MRSA. FDA has conducted a pilot study with the University of Maryland testing retail meat samples for MRSA. FDA will use the results of this study to determine the correlation, if any, of the presence of MRSA in retail meat samples to clinical cases of infection in humans. The National Antimicrobial Resistance Monitoring System has also initiated surveillance in 2010, in collaboration with the Centers for Disease Control and Prevention and select FoodNet laboratories, for the presence of MRSA, as well as other pathogens of public health interest such as vancomycin-resistant enterococci and Clostridium difficile, in retail meat.

Mr. Farr: Does FDA consider MRSA when making decisions about the safety of animal drugs?

Response: FDA recognizes that foodborne human exposure to antimicrobial resistant bacteria is complex and often involves contributions from other sources of exposure, for example, direct contact between animals and humans or introduction of resistant bacteria into the environment. However, FDA believes evaluating antimicrobial new animal drug safety relative to the most significant exposure pathway, the foodborne pathway, is the best way to assess the risk of antimicrobial new animal drug use in food-producing animals. Nonetheless, as FDA stated in Guidance for Industry number 152, Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their

Microbiological Effects on Bacteria of Human Health Concern, while FDA's primary focus is on foodborne pathogens, other non-traditional foodborne pathogens, such as Methicillin resistant *Staphylococcus aureus*, may be considered when deemed necessary.

QUESTIONS SUBMITTED BY REPRESENTATIVE BOYD

OYSTERS

Mr. Boyd: Last fall, the FDA decided out of the blue to create a ban on Gulf Oysters harvested during the summer months. After years of working with the Inter-State Shellfish Commission (ISSC) and others, the FDA decided unilaterally to impose this new rule. Thanks to the work of many in Congress, we were successful in getting the FDA to back away from this. Nobody disagrees that we need to do all we can to provide a safe product, and this especially includes those in the oyster industry. But now, the FDA plans to study alternative methods to preventing Vibrio Vulnificus. Can I get any assurance that the FDA won't try to impose a sudden ban on oysters again and will FDA work with the industry and Congress before making a move such as this?

Response: FDA will conduct an independent study to assess how post-harvest processing or other equivalent controls can be feasibly implemented in the Gulf Coast in the fastest, safest and most economical way. While this study is ongoing, FDA will reach out to state and federal authorities and the Gulf Coast oyster industry to discuss their concerns about FDA's policy and measures the industry is pursuing to make oysters safer. FDA is committed to assisting local farmers implement post-harvest processing.

Some actions that FDA will undertake include continuing to collaborate with the Interstate Shellfish Sanitation Conference to address *Vibrio vulnificus* in the Gulf Coast region, including discussing the scope and results of studies, and meeting with the Board. FDA will also continue working with the National Marine Fisheries Service to offer technical assistance to facilitate implementation of post-harvest processing or equally effective alternatives, including process validation and alternative technologies like off-shore relaying, and Hazard Analysis and Critical Control Points plan development

FDA-STATE RELATIONS

Mr. Boyd: You mention in your testimony that the FDA "state liaisons will communicate essential information on food safety" to the states. That's great, but my main concern is whether the FDA is listening to the states. During the FDA created tomato disaster in 2008, FDA and CDC immediately seized upon tomatoes as the problem, rather than listen to Florida officials who knew they weren't. Worse, FDA created a scare for the consumers of tomatoes and essentially destroyed an entire harvest of the product, and gave no compensation the innocent farmers or others involved. Will the FDA start working closer with our states during food illness issues and actually listen, or is this going to be a top-down relationship?

Response: FDA is working with federal, state, and local partners to develop and implement an integrated national food safety system to ensure uniform and consistent coverage and inspection quality from farm to table. The integrated food safety system will build on a strong base of working collaboratively with regulatory and public heath

partners to move towards a prevention based food safety system. A critical component of the system is enhanced communications among all regulatory and public health partners.

In August 2008, FDA hosted a national meeting, Gateway to Food Protection, which focused on efforts to work together toward an integrated approach to address the challenges of the growing global food supply. Outcomes of the meeting included the creation of an FDA Federal-State Partnership for Food Protection Coordinating Committee consisting of federal partners and a variety of representatives from our state, territorial, tribal and local regulatory and public health partners. The committee serves a strategic and technical role, advising FDA on necessary infrastructure and food safety implementation strategies essential to building a national food safety system.

Enhancing FDA's information sharing authority is also a critical element of an integrated federal-state system and is essential during a foodborne illness outbreak to speed the investigation to help protect consumers and help industry recover faster. FDA supports including language in the pending food safety legislation to enable FDA to share certain protected information with our state and other partners.

The Partnership for Food Protection work groups were also formed to focus on specific topics and achieve specific objectives by fall of 2010. The work groups are focusing on improving interactive information technology, training, response, and risk-based work planning. The lessons learned and other results from these groups will be incorporated into the plan for an integrated national food safety system. The system will encompass inspections, laboratory testing, and response and will place priority on preventing foodborne illness, in both food for humans and animals.

QUESTIONS SUBMITTED BY REPRESENTATIVE KAPTUR

HYDROLYZED VEGTABLE PROTEIN RECALL

Ms. Kaptur: For a number of years, I have always questioned the ability of FDA to recover products after inspection activities. While the voluntary recall of the Hydrolyzed Vegetable Protein has just begun, does FDA have any estimates of your ability to recover this product?

Response: The recall of Hydrolyzed Vegetable Protein, or HVP, was a voluntary recall performed by the responsible firm. As such, the firm will be recovering the product. FDA is monitoring the firm's recall and recovery effort, which is currently underway. FDA does not currently have any estimates on the amount of HVP that will be returned to the firm. Much of the recalled HVP was already incorporated into other products by the firm's customers, and so would not be recoverable by the firm. We are monitoring the firm's efforts to determine the disposition of the affected HVP and will be performing checks to determine the effectiveness of the firm's notification to its customers.

Because of the scope of use of the HVP product, FDA took several steps to instruct industry and protect consumers from potential *Salmonella* infection. FDA advised industry that the recalled bulk HVP product should be destroyed or reconditioned according to procedures validated to inactivate *Salmonella*. Additionally, it is appropriate to use an ingredient or product that contains the recalled HVP if the ingredient or product will receive a validated kill step for *Salmonella* or assurance from customers that the kill step will be applied further in the supply chain. FDA also recommended recalls of products that consumers might eat without any processing or cooking steps to address the potential risk, and advised consumers to review the FDA website for a list of recalled products. The nature of this recall does not require a physical return of the product but can include such options as return, destruction, or reconditioning of the product in order to make it more suitable for use. Using all these methods we concluded that the public will be adequately protected against this *Salmonella* contamination.

Ms. Kaptur: Unlike a recall where the product and recovery is simple, the product involved in this recall is a basic ingredient used in many types of products. This type of recall is complicated and may require an extremely detailed investigation by FDA. Does FDA have the ability to recover the costs associated with this recall from the company if they knew about the causes of this recall?

Response: FDA does not currently have statutory authority which would allow recovery of costs associated with a firm's voluntary recall.

Ms. Kaptur: What type of legal recourse do the consumers or other companies have because of a possibly tainted product?

Response: To the extent that a consumer or a corporation is seeking legal recourse for personal or corporate injury due to tainted food, FDA does not provide legal advice. Typically, consumers or companies with questions regarding legal recourse following injury from a tainted food consult with an attorney with knowledge of this area of law.

Ms. Kaptur: While the recall has just started, what volume of product has already been recovered?

Response: The Southern Nevada Health District has agreed to inventory and place a hold on Basic Food Flavors Hydrolyzed Vegetable Protein, or HVP, product produced on or after September 17, 2009. They will also place a hold on all product returned back to Basic Food Flavors from their HVP customers. The holds will remain in place until a reconditioning procedure is approved.

Thirty-two firms that used HVP in their products have recalled products and issued press as of March 10, 2010. However, the nature of this recall does not require a physical return of the product but can include such options as return, destruction, or reconditioning of the product in order to make it more suitable for use. Using all of these methods we feel that the public will be adequately protected against this *Salmonella* contamination.

Ms. Kaptur: The Hydrolyzed Vegetable Protein (HVP) recall has now involved many other companies which use this product as a base for other materials. Just today Nestle in Ohio has announced a recall of 6,000 pounds of a ready-to-eat (RTE) bacon base product that may be contaminated with *Salmonella,* a recall being overseen by USDA's FSIS. Significant differences exist in FDA and USDA's authority;, however, the consumer doesn't know the difference and wants to know that the agencies are working together to product their product through a seamless supply chain. Please describe the types of coordination that FDA is conducting to ensure that meat based recalls are using the most up to date information in the HVP recall.

Response: FDA's Office of Enforcement within the Office of Regulatory Affairs routinely contacts the United States Department of Agriculture, or USDA, when products and ingredients under recall affect USDA regulated products.

FOOD SAFETY REAUTHORIZATION

Ms. Kaptur: One of the basic assumptions you make in this budget request is a user inspection fees for food inspections. However, based on discussions from the United States Senate, it doesn't seem likely an inspection fee will be authorized. If this is the case, then it will be this committee's responsibility to make up the difference in dollars. Could you please comment on this situation?

Response: For FY 2011, FDA proposes an increase of $220.2 million for Food Registration and Inspection User Fees. FDA also proposes an increase of $87.8 million

in budget authority to support Transforming Food Safety priorities. If Congress does not enact legislation for FY 2011 that contains Food Registration and Inspection User Fees, FDA will have to rely on the $87.8 million budget authority increase to begin to Transform Food Safety. Without the proposed fees, FDA will have a greatly reduced ability to implement the priorities announced by the President's Food Safety Working Group.

The affect on FDA will be a significantly reduced ability to implement President Obama's vision of a new food safety system to protect the American public. For example, FDA will not be able to hire 479 FTE to conduct important food safety priorities, including 99 consumer safety officers to perform food safety inspections. The result will be a reduction of the following food inspection activities compared to the level supported with proposed user fees: 1,900 domestic food safety inspections, 150 foreign food inspections, 200 domestic tissue residue inspections – for illegal drug residues in meat and poultry and 3,000 samples for analysis in FDA laboratories.

Not receiving these fees will significantly undermine FDA's ability to implement the major activities to Transform Food Safety, beginning in FY 2011. FDA will have a greatly reduced ability to set new standards for safety, expand laboratory capacity, pilot track and trace technology, strengthen import safety, improve safety data collection, conduct food risk analysis and most importantly establish a foundation for an integrated national food safety system focused on prevention.

Ms. Kaptur: As FDA's authorities increase FDA regulators will find themselves increasing associated with activities that USDA has traditionally been involved. Historically, FDA has been opposed to a sliding scale fee which charges large processors differently than smaller individuals. Philosophically, why should small producers subsidize the complicated inspections at large processing facilities?

Response: To clarify, the legislation makes it clear that the new provisions do not alter USDA's jurisdiction and, in many places, explicitly requires consultation with USDA. With regard to new requirements, such as the produce safety standards, FDA is already working closely with USDA as we develop those standards. USDA also will be involved in the implementation of such standards, including an extensive outreach program to help the affected industry comply with the new standards. FDA recognizes the importance of working with USDA, with its expertise in agricultural production and its significant workforce, to help inform and implement the standards. FDA and USDA also are working together to ensure that our produce safety and quality activities are complementary and consistent and take into account the diversity of farming operations.

Regarding a sliding scale for fees, the Administration has not taken a position on a sliding scale for fees. FDA's primary concern is that the required fees provide sufficient resources for FDA to fulfill its new responsibilities. FDA also believes that all registered facilities should be required to pay a fee.

Ms. Kaptur: FDA needs new authorities and dollars to engage in the inspection activities required. However, will FDA consider implementing fees that are based on the

risk and quantity that processors include, not simply just a uniform fee implemented across the entire market?

Response: As you noted, FDA needs fees to provide sufficient resources to meet the inspection frequencies and other responsibilities. FDA believes that all registered facilities should be required to pay a registration fee, and we note that FDA's activities do not vary substantially from facility to facility. The President's budget includes a fee for registered food facilities. The fee will help cover the cost of inspections and other food safety activities that will benefit the food industry as well as consumers. FDA will implement any new fees in accordance with the statutory authority.

CHINA AND OVERSEAS

Ms. Kaptur: FDA is increasingly engaging in activities overseas, negotiating with foreign food inspection systems and opening more offices overseas. How can we be assured that these offices are not simply conducting their activities according to directives from our trade office?

Response: FDA's mission is to protect and promote the public health in the United States. While we recognize that our work can, indeed, impact trade in a number of ways, FDA is not a trade promotion agency and does not have a trade mission. In doing our job, we do not consider whether a product is made in by a domestic or foreign manufacturer. We do care whether a product on the market in the U.S. complies with our public health standards, laws, and regulations. In performing our statutory public health work, we strive to assure that trade in the products for which FDA is responsible in the U.S. is trade in products that benefit, rather than threaten, the public health of the American people.

Ms. Kaptur: What types of firewalls has FDA put in place to assure that the Chinese offices are focused on food safety?

Response: FDA's posts in China are staffed with senior FDA experts whose role is to support the decision-making process for FDA-regulated products. Several people in our China posts' full-time focus is on food safety issues: the two foods inspectors in the Guangzhou post and the senior foods expert in Beijing. Their work is focused on continuing to build and improve FDA's working relationships with its counterpart food safety agencies at national, provincial and municipal levels in China. These individuals also engage with firms in China that wish to export food products to the U.S. to help assure that these firms are aware of the food safety standards their products must meet in order to be admitted to the U.S. These individuals also work with other U.S. agencies, such as USDA and the Department of Homeland Security, that are also stationed in China to leverage the information these agencies have on food safety issues and to coordinate approaches to addressing common food safety problems and helping assure that unsafe products do not reach U.S. shores.

In addition, our foreign offices have well-defined goals pertaining to facilitating our mission to protect and promote the public health in the U.S. by ensuring that the products for which we are responsible meet our statutory and regulatory requirements and are safe, effective and properly labeled, as appropriate.

Ms. Kaptur: FDA has been conducting more work with Chinese officials and is operating under a memorandum of understanding with their government. How can FDA assure that in an undemocratic country without transparent requirements and open laws can work effectively with our country?

Response: FDA works with counterpart agencies from around the world on common issues of food and medical product safety. These agencies are parts of many different types of governments, and the individual agencies each have different authorities, jurisdictions and cultures. However, we believe that, despite the differences in government organization, agency authorities and cultures, we benefit significantly from proactive engagement with these counterpart agencies, because we regulate global commodities which, at any given time, may be under the oversight of several different agencies as they progress through the international supply chain to the United States.

Around the world, FDA's foreign government counterpart agencies differ from FDA, and from each other, in terms of the confidentiality and other laws to which they are subject, the history and maturity levels of the agencies, and the magnitude of impact on the U.S. of their regulated products. FDA has different levels of engagement with each of its counterpart agencies, and does not use a one size fits all approach.

One of the benefits of having FDA senior staff located permanently in China, in particular, is that they are able to understand more fully the nuances of working with our counterparts and the subtleties of the actions that they take, and are able to build stronger and more robust relationships with them that allow us to better decide what information we can usefully leverage to help assure the safety of the supply chains for food and medical products used in the U.S. The government in China is responsible for the safety of these products within their jurisdiction, and they have a great number of people engaged in this activity. We believe that, by engaging proactively and constructively with the food and medical product safety authorities there, we can obtain better information with which to inform the decision-making process at FDA regarding products from China that are being presented for admission into the U.S. and that are being developed or grown for export to the U.S.

Ms. Kaptur: Especially after cases like those associated with the heparin scare have killed American citizens, what steps have you taken to mitigate criminal activities to confuse American consumers?

Response: FDA emphasizes swift, aggressive enforcement action to increase security over the drug supply chain and to identify risks to the public health. Once a flaw is detected in the supply chain, FDA moves quickly to take any and all applicable regulatory action to ensure that any risk to the public health is contained and ideally,

eliminated. FDA recently unveiled initial steps designed to hone the effectiveness and timeliness of our regulatory and enforcement system. These steps include: setting post-inspection deadlines for regulated industry to respond to significant FDA inspection findings, working more closely with FDA's regulatory partners, prioritizing follow-up on warning letters and other enforcement action, being prepared to take immediate action in response to public health risks, and developing and implementing a formal warning letter close-out process where a firm that has fully corrected violations will be issued a close-out notice that is posted on our website which we hope will motivate companies to take corrective actions.

The Office of Criminal Investigations engages in a wide-variety of law enforcement activities that protect public health and American consumers, including investigating counterfeit products, tampering, fraud, and economically motivated adulteration involving FDA-regulated products. OCI maintains ongoing contact with other international, federal, state, and local law enforcement agencies and is also FDA's lead point of contact with the U.S. intelligence community. In addition, OCI is a charter member of the Permanent Forum on International Pharmaceutical Crime and has a representative assigned to the International Police Organization's Washington, D.C. U.S. National Central Bureau.

HEPARIN

Ms. Kaptur: I am very interested in the supply chain of heparin and would like for you to describe in greater detail the companies involved in producing this product. For the record, please outline for me the ingredient steps for producing heparin.

Response: Heparin sodium is derived from porcine intestinal mucosa. Intestines are extracted through a machine to produce a pulp. The pulp is then heated in the presence of protease enzymes to separate proteins from heparin. Resin is added to complex and bind the heparin material. Salt water separates the resin from heparin and the resin is filtered away. Alcohol separates heparin from salt water. The heparin is then removed and dried. The crude heparin product is then purified and refined under specific processes set by the manufacturer to produce the heparin active pharmaceutical ingredient used in the final product.

Ms. Kaptur: What is the medial need that heparin serves?

Response: Heparin is used to prevent and treat blood clots in the veins, arteries and lungs. Heparin is commonly used before certain types of surgery, including coronary artery bypass graft surgery, and in kidney patients before they undergo dialysis.

Ms. Kaptur: How Many pharmaceutical companies produce heparin?

Response: There are currently four pharmaceutical companies with FDA approved applications to market heparin.

Ms. Kaptur: What are the major American companies that produce Heparin?

Response: The major American companies that market heparin include APP Pharmaceuticals, LLC, Baxter Healthcare Corporation, and Hospira, Inc.

Ms. Kaptur: Where are these companies located?

Response: The corporate headquarters for APP Pharmaceuticals, Inc is located in Schaumberg, Illinois. The corporate headquarters for Baxter Healthcare is located in Deerfield, Illinois. The corporate headquarters for Hospira is located in Lake Forest, Illinois.

Ms. Kaptur: What are the annual sales of heparin in the American market?

Response: It is difficult to pinpoint an annual sales amount for heparin as the product is primarily distributed in hospitals and dialysis centers, not through prescription. However, a 2008 article cited analysts who estimated that the annual sales for heparin in America were between $50 and $60 million dollars. This information is the article titled "APP Pharmaceuticals Gains Sales Amid Heparin Uproar," printed in the February 20, 2008, edition of the Chicago Tribune. A 2009 report stated that more than 10 million Americans receive heparin every year, more than 70 million vials are sold for cardiac surgery, dialysis and a wide variety of other uses. Another 50 million units of heparin flush are used annually. The source of this article titled "The Heparin Story," is the February. 23, 2009, edition of BioCentury: The Bernstein Report on BioBusiness.

Ms. Kaptur: In terms of principal parts of heparin, what are the quantities of heparin that are imported which are then combined to produce heparin?

Response: The exact quantities of heparin active pharmaceutical ingredient that are being imported and then combined to produce heparin are not standard amounts. Each manufacturer has their own methods to produce heparin, based on specifications in their drug applications, and each may receive raw or crude heparin from different suppliers.

Ms. Kaptur: Where are the principal inputs produced for heparin, please describe the companies.

Response: The active pharmaceutical ingredient in heparin is biologically derived heparin. Heparin is a large-molecular weight compound that is obtained from mucosal tissues of slaughtered animals such as pig intestine. The crude material is purified into the API before being constituted into the finished dosage form. Manufacturers of the finished dosage form may each receive raw and crude heparin from different suppliers. Each manufacturer may also have different methods to produce their final product.

Ms. Kaptur: In terms of the FDA inspection process for the entire supply chain, how can FDA ensure that all the principal parts for heparin are safe?

Response: FDA has taken steps to improve its inspection program, especially in foreign facilities in the wake of the heparin contamination crisis. FDA has created and staffed a dedicated foreign drug cadre and has increased the number of foreign drug surveillance inspections. FDA also has investigators permanently stationed in China and India as members of the FDA posts in those countries. These investigators conduct inspections independently and are working with local regulatory partners to build capacity for inspections. CDER and ORA continue to increase the number and use of translators on foreign inspections, particularly those occurring in China. FDA is also increasing its Pharmaceutical Inspectorate, a group of the highest certified drug inspectors within the Agency, who focus on performing foreign and domestic inspections of complex pharmaceutical manufacturing technology. FDA's inspection program involves manufacturers of both active pharmaceutical ingredients and finished dosage forms.

FDA has also developed and maintained a comprehensive import sampling plan designed to help ensure the quality of heparin drug products, including but not limited to crude, API, and finished dosage form drugs, entering into the U.S. The heparin sampling assignment assures FDA reviews all entry documents and labeling submitted for heparin products offered for importation into the U.S. and performs a reconciliation examination for each shipment. Shipments imported by or consigned to firms identified on the attachment for the assignment can be released without sampling once compliance with all regulatory requirements is verified. FDA has also increased monitoring of imported drug products and screenings of products which FDA believes are of heightened susceptibility to economically motivated adulteration.

Ms. Kaptur: Since the principal parts for heparin are produced in so many places, how can FDA's ensure that its interaction with the various companies and countries are sufficient to protect the integrity of heparin in the supply chain?

Response: FDA increasingly faces challenges due to globalization of drug development and manufacturing. Not long ago, most drugs were developed, studied, and manufactured in the United States. Today we routinely review and monitor drugs that are studied or manufactured, at least in part, outside the United States. The supply chain for finished drugs and active pharmaceutical ingredients now frequently links to manufacturing sites in China and India. With the globalization of the supply chain, FDA faces an ever-growing number of brokers, traders, distributors, repackagers, and other players involved in the import of pharmaceuticals. FDA has to devise and evaluate more complex risk scenarios and apply more sophisticated technologies to screen and evaluate drugs entering the United States to ensure their quality.

The heparin contamination crisis was a driving force behind the establishment of posts abroad. In November 2008, FDA officially opened its office in China with locations in Beijing, Shanghai, and Guangzhou. FDA has also opened offices in India, Latin America and Europe. Specific to China, in December 2007, the Department of Health and Human Services announced a Memorandum of Agreement with China to

improve the safety of drugs and medical devices. FDA has 22 confidentiality agreements with counterpart drug regulatory authorities under which we can share information related to reviews and inspections supporting our efforts to manage the challenges presented by global production of drugs and biologics. An example of the enhanced collaboration between FDA and foreign regulatory authorities is the API Pilot Program with the European Medicines Agency and Australia's Therapeutic Goods Administration in which participants share information about API inspections. FDA has also been and continues to be actively involved with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, which has issued guidance to industry on effective Pharmaceutical Quality Systems.

Ms. Kaptur: Has FDA conducted an economic analysis of impact of the Heparin scare in terms of lost sales, deaths or other societal costs of this dramatic scare?

Response: No, FDA has not conducted this type of economic analysis.

Ms. Kaptur: How many Americans were killed or injured from the failure of the heparin scare?

Response: No system in the United States exists that completely and accurately captures injuries and deaths due to heparin or any other pharmaceutical product. Thus we cannot give you a single, precise number. A review of the reports to FDA's Adverse Event Reporting System received from January 1, 2008 to March 31, 2008 revealed 94 fatal cases reported after heparin therapy with at least one adverse event term from the list used to identify an allergic-type event. We assessed three deaths as having a probable or likely association with heparin therapy, and six deaths as having a possible association. In the three probable or likely cases, an assessment of the link between the death and possible OverSulfated Chondroitin Sulfate, or OSCS, contamination could not be made since lot numbers were not provided. The strength of association between heparin treatment and the patient's death was assessed as unlikely in 41 cases and found not assessable in 44 cases. In a passive surveillance system such as AERS, there are many limitations such as potential underreporting and lack of complete case information. Of note, the increase in reporting of allergic-type events after heparin administration, including deaths, noted in late 2007 to early 2008 returned to baseline in the Spring of 2008.

Ms. Kaptur: What damages either criminal or civil has FDA been able to recover from those liable for the heparin scare?

Response: To date, liability has not been established.

Ms. Kaptur: Does FDA even have the authority to make those liable for these types of recalls pay for the costs FDA must expend after such a recall has occurred?

Response: No, the FDA does not have the statutory authority to make those liable pay for the costs FDA must expend after such a recall has occurred.

Ms. Kaptur: Is there a cost estimate from FDA on staff time and resources were expended on the Heparin recall and associated deaths and injuries?

Response: FDA has not performed a cost estimate on staff time and resources that were expended on the Heparin recall and associated deaths and injuries. But I can say that FDA staff expended many hours of time and resources into managing this crisis. Once FDA was notified of allergic-type reactions associated with heparin manufactured by Baxter, FDA began its investigation starting with the development of analytical methods and the collection and testing of heparin samples and then progressed with an investigation into the supply chain and identifying an unknown contaminant. FDA staff worked around the clock to investigate and find the problem, monitor the recall, keep the public informed about the status of the safety of the heparin supply, worked with international partners in defining the scope and nature of the problem and made sure that an adequate supply of heparin was available to patients who needed it.

Ms. Kaptur: What is its cost to the average patient who is billed under Medicare for this product?

Response: FDA does not maintain information on patient billing costs under Medicare.

Ms. Kaptur: What percent of Heparin's ingredients are domestically produced versus foreign produced?

Response: The percent of heparin components produced domestically versus abroad is determined by each manufacturer according to their own specifications. In their applications, manufacturers of the finished heparin to be marketed in the United States do disclose the source of the active pharmaceutical ingredient. We would need to review each application to determine the percentage of foreign made components in each finished heparin product available on the U.S. market. Please note that in general, the drug applications contain information that is trade secret, commercial confidential or other otherwise protected from disclosure to the public under the Freedom of Information Act, the Trade Secrets Act, the Privacy Act, and FDA regulations.

QUESTIONS SUBMITTED BY REPRESENTATIVE HINCHEY

IMPLEMENTATION ON REMS REQUIREMENT

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA). With direction from Congress, the FDA developed the Risk Evaluation and Mitigation Strategies (REMS) program to protect patients by requiring additional safety measures for drugs that may result in significant side effects when taken incorrectly.

One category of drugs that Congress wanted REMS to cover is called "fast-acting fentanyls," or "rapid onset opioids," which includes the drugs Actiq, Fentora and Onsolis. These extremely powerful drugs are taken to treat pain in adult cancer patients.

Each of these opioid drugs have common safety risks, including the risk of death when used by patients who are not opioid-tolerant. Further, the three drugs are only distinguished by their delivery mechanism: one is a lozenge, one is an effervescent tablet and one is a fast-dissolving film.

In March 2008, the FDA decided that Actiq should be placed under the REMS program to ensure that the benefits of the drug outweigh its risks. In September 2008, the FDA made the same determination for Fentora, another opioid.

Despite this action, only Onsolis, the third opioid, is currently subject to a working REMS. This is because the manufacturers of both Actiq and Fentora have so far failed to comply with the FDA's order to subjecting them to REMS. Remarkably, the FDA has allowed this to happen even after the improper use of Fentora resulted in 5 deaths, and required a "Dear Doctor" letter to physicians nationwide detailing the safety concerns with these products if used improperly.

Actiq and Fentora currently account for 99% of the opioid market. The FDA's lack of action has had the perverse effect of making these drugs easier to obtain then the only opioid which is actually being reviewed under the REMS program. In my opinion, the FDA's failure to enforce its order is validating bad behavior and unnecessarily increasing the risk to cancer patients.

Mr. Hinchey: Why hasn't FDA done anything in the past two years to ensure that the manufacturers of Actiq and Fentora implement the REMS requirement, especially in light of the fact that one has been approved for Onsolis?

Response: Under section 909 of the Food and Drug Administration Amendments Act, also known as FDAAA, a drug approved before the enactment of FDAAA is deemed to have in effect an approved REMS under section 505-1 of the Food, Drug, and Cosmetic Act, if, on the effective date of FDAAA there were elements in effect to assure safe use. Sponsors who were deemed to have approved REMS were required to submit proposed REMS by September 21, 2008 to FDA for review and approval. Actiq had elements to assure safe use in effect before FDAAA and, therefore, has a deemed REMS

in effect. Fentora had a risk management plan that was not considered to have elements to assure safe use and does not have a REMS that was deemed approved. However, both Fentora and Actiq are marketed under the risk management plans agreed to before FDAAA, and both will be required to have a new, approved REMS. Development of new REMS for marketed products under the FDAAA provisions is a complex undertaking, and FDA is working actively with the sponsors of these and other products deemed to have REMS to convert the pre-FDAAA risk management programs to REMS.

Mr. Hinchey: Do you believe that this lack of enforcement is putting cancer patients at risk?

Response: FDA does not believe that cancer patients are being placed at risk by the lack of a final REMS for these products. Actiq and Fentora are drugs approved with risk management plans currently in place that FDA found to be adequate to ensure safe use of the drugs. New REMS, when approved, may reflect enhancements to these programs to further ensure safe use of the drugs.

FOLLOW-UP QUESTION ON FDA'S MARGIN OF ERROR GUIDELINES

Mr. Hinchey: Commissioner Hamburg, can you tell me why the FDA decided that a 20 percent permissible margin of error was acceptable for the nutritional content found on food product labeling?

Response: It is important to understand that the 20 percent allowance is not a margin of error. FDA's compliance criteria, including the 20 percent allowance for variation in naturally occurring nutrients, were developed as part of the 1973 final rules for nutrition labeling. In the January 19, 1973 Federal Register, FDA published a regulation which established a statistical approach to determine compliance with nutrition labeling requirements. The natural variation in the nutrient content of food products was well recognized, and the need to set practical limits of variation in nutrient levels for compliance purposes was the subject of extensive discussions. In developing the nutrition labeling system, it was important to provide a sufficient tolerance so that manufacturers could provide useful nutrition information on the label while meeting consumers' expectations that nutrition labeling would honestly represent the composition of the products that they purchased. The objective of the regulation was to secure compliance with requirements for average nutrient levels for units in a lot with only as much variability among units as is inherent in the naturally occurring nutrients when foods are processed under current good manufacturing practice.

Mr. Hinchey: What scientific process, if any, did the FDA use to settle upon this 20 percent figure?

Response: The compliance procedures outlined in the 1973 final rule, which was established by notice-and-comment rulemaking, were statistically evaluated and judged adequate. The setting of practical limits of variation in nutrient levels for compliance purposes was the subject of extensive comments from trade associations, manufacturers, consumer groups, and nutrition professionals.

There is natural variation in the nutrient content of food products. In developing a nutrition labeling system, it is important that the manufacturers be permitted a sufficient allowance so that they may provide useful nutrition information on the label – information that consumers rightly expect to honestly represent the products they buy. This regulation is intended to secure compliance with requirements for average nutrient levels for units representative of a lot, with only as much variability as is inherent in the naturally occurring nutrients when foods are processed under current good manufacturing practice.

Mr. Hinchey: Do you believe that a 20 percent margin of error is too high?

Response: As I explained earlier, the 20 percent value is not a margin of error but rather an allowance for naturally occurring variation in the nutrient content of foods. FDA may re-evaluate this allowance during our update of the nutrition facts label and additional research may be needed to modify this allowance.

Mr. Hinchey: If your answer to the question is yes, I would like to know what the FDA plans to do to decrease the margin of error and when this action will take place.

If your answer to that question is no, what evidence can you provide to me to prove to me that this is very high margin is reasonable?

Response: As stated in the responses to the previous questions, the 20 percent value is not a margin of error but rather an allowance for naturally occurring variation in the nutrient content of foods. Reducing naturally occurring variation in the nutrient content of foods is beyond FDA's control. However, when the 1973 rule was published, FDA encouraged industry and the United States Department of Agriculture to develop comprehensive nutrient composition data on an industry-wide, regional, and manufacturer basis. Comprehensive data obtained regularly over an extended period of time for an individual product would undoubtedly yield better information on nutrient variability. FDA is in the midst of a nutrition initiative which includes evaluation of current nutrition labeling regulations as well as an enforcement component.

For all nutrients, regardless of regulatory class, FDA's compliance procedures are based on analysis of a composite of 12 consumer units, one taken from each of 12 different randomly chosen shipping cases, to be representative of a lot of product. Thus, identification of a representative sample according to a statistically determined sampling plan followed by its analysis is fundamental to FDA's compliance procedures. Convenience samples, for example, a single item selected from a grocery store shelf or a single item picked from a restaurant menu, are not used because they fail to meet FDA's compliance criteria.

Mr. Hinchey: Do you support requiring food manufacturers to add a disclaimer on a nutritional content label letting consumers know that the FDA allows a 20 percent margin of error in determining the accuracy of nutritional content?

Response: As explained earlier, the 20 percent value is not a margin of error but rather an allowance for naturally occurring variation in the nutrient content of foods. For the reasons that we explained in responses to your questions, FDA believes that such a disclaimer would be inappropriate.

QUESTIONS SUBMITTED BY REPRESENTATIVE JACKSON

GENERIC DRUGS

Mr. Jackson: Currently generic drugs save patients substantial health care costs, an estimated $750 billion within the last decade and account for 70% of the total of the 2.9 billion prescriptions filled in the United States. With the growing number of generic applications and limited staff resources, the FDA currently has a significant applicant backlog which has prevented the timely review and approval of new generic drugs.

Dr. Hamburg, I know you share my concern for the backlog. In the budget justification, the FDA estimates that within five years of the proposed user fees, 80% of the applications will be reviewed within 12 months. What is the current FDA response rate for applications? Is the proposed $36 million industry user fee and the hiring of additional staff, enough to bring down the backlog and quicken the FDA's response rate to new applications?

Response: The current median time to approval is approximately 26.7 months. However, the time to first response - after an initial review - is significantly less, usually within about 12 - 14 months. The approval time has increased due to several factors including the receipt of over 800 new generic drug applications, the increasing complexity of the applications being reviewed which require more time for review and approval, and the fact that many of these applications cannot be approved until related patents or exclusivities held by innovators or the first-to-file generic manufacturer expire. In terms of the benefit to consumers, it should be noted that only a small portion of applications in the backlog are for first generics, or for the second, third, fourth or fifth new application that will compete with the first generic and result in a lower price for consumers. FDA already places a priority on the review of first generics. FDA believes that the collection of a to-be-determined amount of user fees and the hiring of additional staff will bring down the backlog and quicken the response rate for other new applications. FDA estimates that the hiring of additional staff will enable FDA to process 60 to 70 applications per month.

NEUROBLASTOMA

Mr. Jackson: Dr. Hamburg, both the House and Senate Committees have encouraged FDA to prioritize the review of new treatments and clinical trials for a particularly devastating pediatric cancer called Neuroblastoma.

Young patients face a dismal 20% survival rate--a survival rate which, unlike other pediatric cancers, has not improved in decades. I hope we can work together to support families as they pursue all promising treatment options.

Response: We share your concern regarding neuroblastoma. Several medical officers in the Office of Oncology Drug Products are pediatric oncologists by training, and have had first hand experience caring for children with this devastating disease.

FDA would likely grant a priority review for any drug or biologics application that was submitted for the treatment of neuroblastoma, thereby ensuring a six month review, rather than the standard ten month review. Children's Oncology Group's recent analysis of a trial evaluating a monoclonal antibody in children with poor risk neuroblastoma demonstrated a significant improvement in progression free survival. In response to the results of this trial, FDA has been working with the National Cancer Institute's Cancer Therapy Evaluation Program, also known as CTEP, to facilitate development of this new treatment. We have worked with CTEP to facilitate a path forward for the submission of an appropriate application that can lead to approval for this agent.

FDA's work related to cancer and bringing new treatments to patients is untiring. For example, CDER regularly meets with sponsors to advise them on drug development, including study design, safety, and other factors toward the goal of submitting an application for marketing approval. We meet regularly across our own product centers to be sure that we are collaborating and coordinating our work in specific clinical areas.

We try to find ways to incentivize drug development for pediatric treatments, especially pediatric cancers. For example, the Best Pharmaceuticals for Children Act that Congress renewed under the Food and Drug Administration Amendments Act of 2007 allows for six months of pediatric exclusivity for drug products in return for voluntarily conducting FDA-requested pediatric studies. FDA also has encouraged development of agents for the treatment of neuroblastoma by including development programs for these agents in the Orphan Drug Program.

BPA AND CHEMICAL FREE BOTTLES

Mr. Jackson: Dr. Hamburg, I would like to follow up on the question I asked about BPA during the Hearing. What more can the FDA do to direct concerned parents and families to chemical and BPA free products? Would you be willing to meet with companies like Green Planet Bottling, the Illinois company I spoke about during your Hearing?

Response: Studies employing standardized toxicity tests have thus far supported the safety of current low levels of human exposure to bisphenol A, also known as BPA. However, on the basis of results from recent studies using novel approaches to test for subtle effects, both the National Toxicology Program at the National Institutes of Health and FDA have some concern about the potential effects of BPA on the brain, behavior, and prostate gland in fetuses, infants, and young children. In cooperation with the National Toxicology Program, FDA's National Center for Toxicological Research is carrying out in-depth studies to answer key questions and clarify uncertainties about the risks of BPA as a residual manufacturing impurity in certain food-contact articles. While FDA learns more about the possible effects of very low exposures to BPA, we are supporting industry's efforts to move away from the use of BPA, particularly in those applications involving infant formula and infant feeding articles.

FDA provided substantial information to assist consumers in reducing BPA exposure in our January 15, 2010 update on BPA. As our current efforts to support industry's move away from BPA-containing materials produce additional information that may be useful to consumers, we will update our advice.

Finally, as part of our efforts to help consumers reduce their exposure to BPA, we have committed to assisting companies in bringing safe alternative food contact materials to the market. Therefore, we are pleased to meet with any company to assist it in complying with the applicable statute or regulations.

QUESTIONS SUBMITTED BY REPRESENTATIVE LATHAM

ANIMAL ANTI-BIOTICS

Mr. Latham: Do you think the agency's veterinary medicine approval process for antibiotics, at this point in time, sufficiently protects public and animal health?

Response: Yes. FDA's new animal drug approval process provides for a rigorous and science-based evaluation of the safety and effectiveness of new animal drugs. In 2003, FDA set forth a process for evaluating the potential effect of antimicrobial new animal drugs on non-target bacteria as part of the new animal drug application process through the issuance of Guidance for Industry, Number 152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern." This guidance was the product of a deliberative process involving broad input from the public and animal health communities. Guidance for Industry 152 describes a risk-based assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs in food-producing animals and also describes examples of possible risk management steps or conditions that may be appropriate to mitigate potential risks.

Mr. Latham: When Congress reauthorized the Animal Drug User Fee Act in 2008 it required FDA to collect data on sales of antibiotics used in veterinary medicine. Will you provide the committee a report its progress in collecting this data and if is has gained any insight from it?

Response: Section 105 of the Animal Drug User Fee Amendments of 2008 established additional requirements regarding the submission of sales and distribution data for antimicrobial active ingredients in new animal drugs approved for use in food-producing animals. The statute requires the sponsors of such products to submit the first report including this additional information by March 31, 2010. The FDA has developed a designated FDA Form to facilitate the submission of the required data by the drug sponsors. However, since the reports are not required to be submitted to FDA until March 31, 2010, FDA has not yet had a full opportunity to review this data.

PRESCRIPTION DRUGS

Mr. Latham: Some critics of the FDA charge that the user fee program encourages FDA to deemphasize drug safety. Can you describe how the FDA is implementing the authorities outlined in the most recent PDUFA reauthorization and whether or not the user fees are improving pre- and post-marketing review of drug products?

Response: PDUFA is a program that has brought accountability to the process of drug review, both for industry and FDA. Under the program, FDA is provided funding through user fees to assure that appropriate resources are brought to the task of review. For our part, FDA has committed under PDUFA to work to meet agreed upon goals for

timely completion of reviews and other activities, such as scheduling meetings with industry over the course of drug development. The user fee program has improved the pre- and post-marketing review of drug products by providing for increased staff to perform the reviews. With better staffing levels we have been able to more thoroughly address the full life cycle of drug development, both pre- and post-marketing. With the relief provided by increased resources, our staff is better able to keep abreast of and integrate cutting-edge science into their work, ultimately leading to higher quality assessments of safety and efficacy. This applies to pre-market review, post-market review and their seamless integration. One example of this integration is the Safety First Initiative launched by our Center for Drug Evaluation and Research, or CDER. The Safety First Initiative seeks to assure drug safety throughout all drug products' lifecycle by giving pre-marketing drug review and post-marketing safety equal focus. Under this initiative, CDER has developed a fulltime cadre of drug safety experts who are Deputy Directors for Safety and Regulatory Project Managers in every one of our drug therapeutic divisions. These experts establish teams to tackle post-marketing safety issues in a timely manner, establish work plans to address them in a timely way, and track all activities related to assure monitoring and closure.

Mr. Latham: Congress specifically designed the 2007 user fee program so that FDA could add more reviewers and support staff and upgrade its information technology systems to ensure more thorough reviews of new drugs and biological products that adhere to FDA's traditionally high standards for approval. Is there anything in the user fee program that compels FDA to approve a drug product that is not supported by appropriate evidence of safety and effectiveness?

Response: Nothing in the user fee program compels FDA to approve a drug product that is not supported by appropriate evidence of safety and effectiveness. Since 1938, every new drug has been required to be the subject of an approved new drug application, or NDA, before it could be sold in the United States. An NDA or a Biologics License Application includes all animal and human data and analyses of that data, as well as information about how the drug behaves in the body and how it is manufactured. The NDA submission must provide enough information to permit FDA reviewers to make a determination of whether the drug has been shown to be effective for its proposed use or uses, whether safety has been assessed by all reasonably applicable methods to evaluate safety, whether the drug is safe for its intended use, that is, the benefits of the drug outweigh the risks for the doses being proposed for approval, whether the drug's proposed labeling provides adequate directions for use, whether postmarket studies are required, whether a REMS is required to ensure that the benefits outweigh the risk and whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity. FDA conducts a thorough review of the data and considers how the benefits compare to the risks when making a decision of whether or not to approve a drug. The user fee program includes FDA's commitment to communicate the results of this complete regulatory review, back to the application sponsor, within a more predictable timeframe.

Mr. Latham: Are there instances where FDA has relied on user fees to review a product but nevertheless failed to approve an application to market a drug?

Response: User fees are a significant funding source for review of new drug applications. However, the Prescription Drug User Fee Act, or PDUFA, does not establish drug approval as a goal in and of itself. PDUFA establishes goals for completing reviews of drug applications once they are submitted. When a new drug application is submitted FDA conducts a thorough review of the safety and effectiveness data, including conducting manufacturing inspections and considers how the benefits compared to the risks to decide whether or not to approve a drug. Some applications are approved, while others are not.

Mr. Latham: Some have criticized the FDA for being too lax in its safety reviews and for approving drugs that are unsafe. Can you briefly describe the FDA's process for reviewing the safety of a drug product – the types of studies and information that are reviewed, the levels of review within FDA, the time required to review this information – so that this Committee can get a better sense of the scope and depth of the FDA review process?

Response: The pre-market process for approving drug products begins with the drug companies who must first test their products. FDA monitors the company's clinical research to ensure that people who volunteer for studies are protected and that the quality and integrity of scientific data are maintained. When FDA receives a new drug application, the Center for Drug Evaluation and Research, or, CDER, assembles a team of physicians, statisticians, chemists, pharmacologists, and other scientists to review the company's data and their proposed use for the drug. Only if the drug meets FDA statutory standards for safety and effectiveness is it approved for sale. CDER does not actually test the drug when we review the company's data. By setting clear standards for the evidence FDA must receive to approve a drug, including evidence for demonstrating the safety of the drug, FDA helps medical researchers bring new drugs to American consumers more rapidly.

Once a drug is approved for sale in the United States, FDA monitors the use of marketed drugs for unexpected health risks. FDA relies on voluntary reports of drug side effects from patients, doctors, and other health care professionals through its MedWatch system. Data from MedWatch voluntary reports are combined with required data from drug manufacturers are entered into our powerful drug safety tool called the Adverse Event Reporting System. FDA also has a system called the Vaccine Adverse Event Reporting System, or VAERS, to track adverse events in vaccines.

Our safety reviewers monitor the data in the reporting systems looking for indications of potential serious, unrecognized drug and vaccine associated reactions. If unanticipated risks are detected after approval, we take steps to inform the public and change how a drug is used or even remove a drug from the market. When a safety issue arises, we decide what type of data and analyses are needed. In some cases, FDA may require the sponsor to conduct an observational epidemiology study or a clinical trial. In

other cases, FDA itself, or in collaboration with outside groups, analyzes data. We may also seek advice from advisory committees, comprised of external experts who provide independent opinions and recommendations about the safety issue.

Mr. Latham: Do you believe there is a difference in the risk presented between different types of products regulated by FDA, such as OTC drugs or food versus medical devices? Given FDA's limited resources, do you support a risk-based approach to conducting Good Manufacturing Practice inspections, whether the inspections are conducted domestically or in foreign countries?

Response: Yes. Each product area such as foods, drugs, and medical devices has its own risk to public health. Relative risk is assessed based on the likelihood that the occurrence of a specific hazard in a product that is consumed or used will cause an adverse health effect and the severity of that health effect. The goal is to use risk-based approaches to focus resources to maximize public health impact by adjusting the level of regulatory scrutiny or intensity commensurate with the risk to public health.

Applying a risk-based approach to selecting and conducting Good Manufacturing Practice inspections, domestic and foreign, ensures that FDA resources are used most effectively and efficiently to address the most significant public health risks. Success of a risk-based approach depends on our ability to systematically tap into existing internal and external knowledge and understanding about what can go wrong with food, drug and medical device manufacturing and what impact it would have.

A risk-based approach to conducting Good Manufacturing Practice inspections is the most efficient and effective inspection method available. A risk-based approach provides a continuous, consistent, science-based process that provides transparency and rigor to the decision-making process. With an ever increasing number of domestic and foreign regulated firms, a risk-based approach provides a public-health based framework for our activity, allows for an efficient use and allocation of our resources that provide the appropriate amount of focus to each firm and to the greatest area of risk at each firm, and provides greater protection of public health.

Mr. Latham: In your view, can the safety, quality and authenticity of imported products be assured by inspection or testing programs alone? Is it important to strictly control and monitor the conditions under which products are manufactured and distributed? What role do the Good Manufacturing Practice requirements play in helping to assure that safety and quality are built in to all products?

Response: Assuring the safety, quality, and authenticity of imported products requires a multi-faceted approach, so FDA addresses product safety throughout the global supply chain, preventing or identifying problems at the point where they could occur. There are three key elements to the new approach: seek better controls at the points of production or processing, hold importing companies responsible for their supply chain, and deploy our resources strategically to optimize impact on public health. Steps have already been taken to incorporate these three elements into our current strategy.

Through collaboration with foreign regulatory partners, or when FDA conducts inspections of foreign firms, FDA reviews and evaluates inspection results. If FDA identifies problems with a product, FDA can establish import controls to prevent such products from entering U.S. commerce unless and until the problems are rectified.

FDA believes that firms importing products into the U.S. must establish systems to assure the safety, quality and authenticity of such products. If FDA identifies products of foreign origin that violate safety or other standards from information obtained at the source or through surveillance programs, FDA believes the importer must be made aware of it and implement corrective actions to correct the problem and it from recurring. FDA can subject importers with a history of problems to additional import controls.

FDA is optimizing resource targeting by selecting firms for foreign inspection through risk models based on the inherent risk of the product, as well as other risks like volume of product and inspection history. Completing the fiscal year 2010 of PREDICT, FDA's new risk-based import entry review system, will greatly enhance our targeting of examination and sampling resources.

Mr. Latham: Can you describe the current system for drug review and how innovator's manufacturing practices play a role in the system? Specifically what happens at each inspection point? How can we ensure that the FDA's system adequately meets the needs of getting new products safely to market while appropriately balancing risks and ensuring the integrity of marketed products?

Response: Preapproval inspections play an important role in determining that an innovator has the capability to manufacture a product according to the specifications it describes in its application. FDA targets critical or complex steps or processes in the described manufacturing process for inspection prior to an approval decision.

In accordance with cGMPs, manufacturers should have adequate monitoring and testing procedures in place to ensure the manufacture of products with adequate strength, quality, identity and purity. It is the manufacturers' responsibility to ensure these procedures are followed and that the manufacturer documents compliance during the actual manufacturing process. FDA inspections, while sometimes involving an inspection of ongoing manufacturing, generally focus on the documentation of process by the firm in ensuring it has produced consistent product of appropriate strength, quality, identity and purity, as well as corrective and preventive actions when product does not meet these standards.

The system of getting new products safely to market is fundamentally a system based on risk-benefit analysis. FDA's science-based approach to the drug approval process recognizes that even with the safest and most effective treatments there are people who will respond adversely to medications. Ensuring that FDA's system adequately meets the needs of getting new products safely to market means deploying resources to safely evaluate the large number of new applications that FDA reviews. As

part of this review, FDA identifies drugs with the greatest adverse risk potential before they reach the general population, where they can potentially creating a public health crisis.

Increasingly, FDA efforts include inspecting manufacturing sites abroad that are cited as manufacturing facilities in drug applications. FDA resources also support greater emphasis on post-marketing surveillance to maintain the integrity of marketed products through inspections and enforcement of current good manufacturing practices.

Mr. Latham: You have rightly identified the need to develop unified interoperable early warning systems to detect emerging pathogens found in food as well as the incorporation of technology that will deliver more accurate testing results in a much shorter period of time. Are other federal agencies with responsibility for food safety, such as CDC, developing systems that are interoperable with yours? Do you think they should be utilizing the same technology upgrades that FDA is pursuing?

Response: There is a shared interest among the Centers for Disease Control and Prevention - CDC - , the United States Department of Agriculture's Food Safety and Inspection Service – USDA's FSIS -, and our state regulatory and public health counterparts to engage with us in the developing interoperable data systems to improve signal detection and trending. Several inter-agency workgroups are investigating the possibilities and developing strategies for such data sharing. It is prudent to use compatible technologies as we work to make our own agency systems interoperable and to integrate with other data systems to achieve this goal.

Mr. Latham: In your proposed budget, you note that our domestic food supply chain is overseen by a mix of federal, state and local entities, which presents a real challenge in terms of coordination. More specifically, you note that FDA "is unable to rely on many state and local surveillance sampling results due to inconsistent methods." Is this due to the fact that many state and local public health authorities have been unable to upgrade their technology due to budget constraints? Would coordination improve if there was a single interoperable technological approach from the FDA down to the state and local level?

Response: Due to the differences between the various state systems, at this time it is difficult for FDA to accept laboratory analytical data from non-FDA laboratories, regardless of affiliation, and use this data to take FDA regulatory action. In some cases however, we have reviewed state analytical data and supported and endorsed the state's regulatory follow-up actions. State and local laboratories are not necessarily behind on technology, but rather cannot afford the burden of accreditation for their laboratories. Accreditation can be lengthy and costly, and is not a requirement to operate the laboratories at the state or local level. State and local laboratories that are accredited to International Organization for Standardization - ISO - 17025 are considered equivalent to FDA laboratories, provided they use prescribed accepted methods for sample analysis as well as providing for proper sample collection and chain of custody.

FDA has approached a group of state laboratory managers and will be hosting a meeting of state food testing laboratories at various stages of ISO accreditation. The objectives of this meeting are to evaluate the process of preparing all regulatory laboratories to use the accepted analytical methods and to ensure proper sample collection and chain of custody. The underlying goal of this effort will be developing a process and procedures manual to facilitate the accreditation of state laboratories as well as implementing accepted methods, including sample collections and chain of custody.

FDA has also worked with states and their submitted sample analysis data, including methods used and analytical packages, to clarify the data presented for FDA use, requested additional analysis to remediate the analytical package, or to set the stage for changes in the future by states for FDA data acceptance. In addition, the Electronic Laboratory Exchange Network is an operational database that FDA uses to share analytical data between FDA and the states.

Mr. Latham: How aggressive is FDA in pushing technology to decipher an outbreak once one occurs? I understand that this currently takes a very long time and the success rate of actually identifying the source is well below 50%.

Response: FDA relies on cutting edge technology and established methods to decipher foodborne disease outbreaks as early as possible. FDA uses PulseNet, a national electronic database of deoxyribonucleic acid – DNA – fingerprints of foodborne bacteria coordinated by the Centers for Disease Control and Prevention – CDC. FDA and its federal, state and local partners identify pathogens such as *Salmonella, Listeria*, or *E. coli* O157:H7 in samples of food products they collect through ongoing surveillance programs. FDA and its partners then upload the fingerprints into PulseNet to determine whether they match isolates recovered from ill patients. This process allows FDA, working in conjunction with CDC and other partners, to ascertain potential links between specific food vehicles and human illness. The intention of this endeavor is to shorten the delay between the onset of an outbreak and its recognition by public health authorities.

QUESTIONS SUBMITTED BY MR. LATHAM ON BEHALF OF MR. LATOURETTE

I wish to inquire about an FDA regulatory situation involving the Department of Defense and a company in Mentor, Ohio, called STERIS. I understand that you personally have met both with Congressman LaTourette and Senators Brown and Voinovich regarding an ongoing – and still unresolved – regulatory issue affecting this company and approximately 70 percent of the operating room facilities in the U.S. I also understand that through these meetings and various updates, you have conveyed a transition plan away from the use involving a sterilization product that STERIS patented, which the FDA initially cleared in 1988, and which is used some 30,000 times per day and is reported to have sterilized some 300 million medical devices since its initial approval by FDA, all without reports of any serious injuries, deaths, or other adverse events related to the proper use of the product.

I have here a document, Madame Chair, that I would like to submit to the record. It is a listing of military bases that have been told that under a current FDA transition plan ruling, their orders of sterilization products (S20 sterilant) for our servicemen and women cannot be shipped. Now, I'm told the reason for this is because the FDA has directed STERIS to limit purchases of S20 sterilant to an average monthly use, based on individual customer order history. That may sound reasonable enough, but we're talking about military users in foreign countries, on the battlefield, on ships, and in other remote locations, where travel time to get the product is dependent on much more than just the United States Postal Service. For this reason, many of these bases place their orders on a yearly time frame, like the 16th Medical Logistics Battalion, based at Camp Carrol in South Korea. They have an average monthly use of just one case of S20 sterilant, but the Battalion only places one purchase order, for 12 cases, one time per year – a quantity that, under your transition plan, exceeds the FDA mandated average monthly use shipment limit. As such, you are preventing our servicemen and women the continuity of the supply of a medical device sterilization consumable, which is widely used on a daily basis in the Department of Defense's fixed and mobile medical installations in the United States and internationally.

Mr. Latham: Now, I understand STERIS hasn't submitted paperwork to your approval and you have as such determined that the product is not legally marketed, and this is the basis of your reason for this action. Can you tell us why – for U.S. military customers outside of the U.S. – why these men and women cannot have guaranteed supplies and must instead be subject to ordering supplies monthly, a process that does not meet military needs in remote locations on land and at sea?

Response: STERIS made several significant changes to the device that FDA cleared in 1988 – the System 1 Processor, or SS1 – that could significantly affect its safety and effectiveness. These changes require a new FDA review. Had Steris sought clearance of the changed SS1, and had FDA cleared it, then it might still be legally marketed. Instead, after a May 2008 Warning Letter, STERIS assured FDA and its customers that it would transition them to legally-marketed alternatives to the SS1.

After an inspection and meetings with STERIS, FDA determined that STERIS was not appropriately transitioning its customers. Thus, in December 2009, FDA advised healthcare providers that FDA had neither approved or cleared the SS1 nor made any determinations regarding its safety or effectiveness. FDA recommended that providers transition to alternative reprocessing systems as soon as practicable.

FDA initially estimated a three-to-six month transition period, based on discussions with outside constituents. FDA then engaged with other healthcare providers and professional organizations and learned that a six-month period could present significant difficulties for some providers, which could adversely affect patient care. As a result, FDA extended to eighteen months the recommended transition period. In its extension notice, FDA stated its expectation that, during the transition period, STERIS would continue to support use of SS1s already on the market – including SS1 accessories such as sterilant.

FDA's view of an appropriate transition process includes the scenario described in your question – a military base's one-time-per-year sterilant order that is repeated in a subsequent year. FDA is prepared to work with individual users, including the military, to address concerns about their inventory practices. FDA's concern for patient care extends to the men and women serving our nation at home and abroad.

Mr. Latham: As you have no reports of an incident involving a patient arising from proper use of this product, and any reports you have involving health care workers are infrequent, especially in relation to the number of products in use, and may actually be the result of user error, can you tell us – in instances in which no alternative is feasible – what are you doing to ensure you are not causing a matter of national security and public health concern for our military?

Response: FDA agrees that there are infrequent reports of injury caused by the SS1. But I hope you will agree that it would be bad policy to allow medical devices to be marketed so long as there are no disproportionate reports of patient harm. This model would require patients to serve as unwitting test subjects.

FDA has received some reports of SS1 malfunctions that had the potential to cause or contribute to serious patient injuries. Further, infections that occur after a procedure using a device reprocessed in the SS1 may be difficult to attribute to the SS1 and therefore go unreported.

While healthcare facilities should replace SS1s as soon as practicable, FDA supports a transition that safeguards patient health, including patients in our military. For example, FDA's recommended transition period accounts for concerns about the supply of alternative devices and the time required to purchase and install these devices. Following its recommendation of a three-to-six month transition period, FDA engaged with healthcare providers and professional organizations to confirm that this timeline was feasible. When FDA learned that a six-month transition period could present significant

difficulties for some providers, FDA extended to eighteen months the recommended transition time.

FDA believes that all of these steps reflect a responsible approach that threatens neither national security nor public health. Indeed, FDA believes that the real public health threat is illegally-marketed medical devices with unknown safety and effectiveness.

Mr. Latham: May I have your commitment that you will provide timely, appropriate guidance that enables the Department of Defense to make purchases of a critically needed supply for military installations worldwide?

Response: We stand ready to provide all possible guidance on FDA-related matters that support the Department of Defense's crucial mission.

Mr. Latham: Can you tell us how your proposed budget will help your communications responsibilities to the American people?

Response: The proposed budget will help our communications responsibilities to the American people by providing the opportunity to continue the work we have begun as part of the Center for Devices and Radiological Health—CDRH—FY 2010 Strategic Priorities. One of the four CDRH priorities is to "Enhance Communication and Transparency," which presents significant opportunities to improve our effectiveness in fulfilling our mission. Improving communication and increasing transparency – with our external constituencies – will maximize the public health benefit of our actions and increase the trust and confidence of the American people.

CDRH communication priorities are outlined in FDA's Strategic Plan for Risk Communication. CDRH is developing processes to test medical device communications to assure that proposed recommendations are practical in the health care setting. CDRH is leading FDA's efforts to develop and conduct research to determine the most effective format and content for consistently communicating information about medical devices to users and prescribers, developing and implementing educational programs and activities to increase the understanding of the public, healthcare professionals, and the press about medical product regulation, and partnering with clinical facilities in the MedSun network to assess the impact of FDA recommendations for device safety.

Mr. Latham: Your agency is tasked with protecting the public health. It would seem to me that communications should be front and center in achieving those goals, and yet, Members have spoken to me about case after case where your agency has been less than clear, in fact, contradictory, between your compliance office, your communications office, and your legislative office. What are you doing to ensure that the information your various divisions relay is the same?

Response: To ensure that we provide consistent information to the American people, FDA is developing ways to harmonize appropriate criteria, procedures, content,

and format for public notifications regarding emerging risks of medical products. As part of CDRH's 2010 Strategic Priorities, CDRH is developing processes to ensure communications are created with participation from all relevant internal divisions, including the development of question and answer documents to be used when responding to inquiries from the American people. These documents are distributed throughout the organization to assure consistent communications.

Mr. Latham: Let me give you an example. Your compliance office wanted health care facilities to transition out of a sterilization product, made by STERIS, in 3 – 6 months. I understand a firestorm soon erupted when this news was distributed, including from the Veterans' Administration, alerting you that this timeframe was absolutely unrealistic, and your agency then had to deal with numerous conference calls from users completely confused about the actions your agency was taking and how they had to comply. After this expense of your staff hours and time at taxpayer expense, you changed course, thankfully so, to prevent the potential cancellation of surgeries in ORs across the country, which would have caused a health care crisis, the very thing your agency is called on to prevent. You then personally met with Members of Congress informing them of this new course of action. Yet, your revised transition plan didn't come out "next week" as promised, and instead, the next news these Members heard was that your agency was issuing a consent decree, which indicated that the transition period would end in 5 months, 6/30/2010, even though you told these Members it would be 18 months.

Not only is this confusion very frustrating and time consuming for all of us, I am greatly disturbed to know that this is an example of how your agency responds to public health issues.

What steps are you taking to provide clear, timely, informative, and accurate information to your various divisions, Congress, and the public?

Response: FDA has taken numerous steps to provide clear, timely, informative, and accurate information throughout FDA and to Congress and the public. The Strategic Plan for Risk Communication outlines FDA's strategy for communicating product risk in the 21st century. This document defines key areas in which strategic actions, in collaboration with domestic and international stakeholders, can improve risk communication. The plan includes over 70 actions FDA plans to take within the next few years and 14 actions we plan to accomplish in 2010.

The communications surrounding the STERIS matter reflect these objectives. For example, FDA accompanied its December 2009 notice to healthcare providers with a detailed Q and A document that addressed many of the questions the notice generated. FDA has since been supplemented this document based on stakeholder feedback. FDA has also provided an E-mail address and toll-free number. There has been extensive use of these resources.

The day after issuing its notice, FDA conducted a media call and a stakeholder call with more than 60 healthcare provider associations to explain the notice and respond to questions. This was followed by a call the next week with more than 1,700 healthcare facilities and stakeholders. Additional outreach includes meetings and teleconferences with the American Hospital Association, the Federation of American Hospitals, Health Corporation of America, the Joint Commission, the ECRI Institute, and hospital members of FDA's MedSun network.

Based on feedback from constituents, in mid-December, FDA posted online specific instructions to help healthcare facilities identify legally-marketed alternatives to the SS1. This document includes all FDA-cleared reprocessing devices.

FDA has repeatedly discussed its actions with STERIS and members of Congress, including a teleconference and in-person briefing of Congressman LaTourette.

Throughout these frequent communications, FDA has provided a clear explanation of its actions and practicable guidance for healthcare providers.

WEDNESDAY, APRIL 28, 2010.

DRUG SAFETY

WITNESSES

HON. CHUCK GRASSLEY, RANKING MEMBER, SENATE FINANCE COMMITTEE

HARLAN KRUMHOLZ, M.D., MSc, HAROLD H. HINES JR. PROFESSOR OF MEDICINE AT YALE UNIVERSITY SCHOOL OF MEDICINE

DR. SIDNEY WOLFE, DIRECTOR OF THE HEALTH RESEARCH GROUP AT PUBLIC CITIZEN

Ms. DELAURO. The hearing is called to order. First I want to welcome today's speakers. On the first panel we have the Ranking Member of the Senate Finance Committee, Senator Charles Grassley of Iowa. And on panel two, Dr. Harlan Krumholz, Harold H. Hines Jr. Professor of Medicine at Yale University School of Medicine, Dr. Sidney Wolfe, Director of the Health Research Group at Public Citizen.

I want to say a thank you to all three of you for being here today for your hard work on the issue of drug safety. And Senator, I want to say a particular thank you to you for taking the time for joining us on this side of the Hill. I'll be honest, members here who don't often see senators cross the divide and come and do hearings on this side. I want to thank you for your leadership as well in producing the staff committee report that will be discussed today. And also personally I would just say is you and I have interacted on the drug safety issue, but also on the farm bill when we sat together for all of those hours trying to do what's best for this nation with regard to its farmers and to rural America. So it's an honor and it's a pleasure to have you here with us today.

Regarding this troubling report, first—let me just say this. The report poses many questions, and as the subcommittee with jurisdiction over the FDA, it behooves us to look at it, to address it. While we did not invite representatives from Glaxo and the FDA to discuss the matter today, on account specifically of their own pending negotiations, we do have the senator with us of course. We have two independent experts to help us to sort through the information today.

Regarding the troubling report, let me first say that by bringing lifesaving drugs to the marketplace, pharmaceutical companies are applying our country's greatest resource, its innovative spirit to help people live longer, healthier, more productive lives. Most people at some point experience the direct reach and the power of these drugs to cure illness, to heal wounds or to halt disease. I am here today as someone who has felt that power when more than 20 years ago I was diagnosed with and survived ovarian cancer. And so when the FDA is weighing whether or not a particular drug is safe enough to be on the market, I understand that there are

often many competing issues in play. Sometimes people suffering from a given illness after consultation with their doctors will willingly accept some extremely severe side effects for a chance at relief or recovery. Case in point, chemotherapy, where we factor in some truly terrible consequences only because the disease of cancer is still more life threatening than the cure.

So as both the preeminent guardian of the public health and an agency whose mandate emphases innovation, part of the FDA's responsibility is to carefully weigh these sorts of pros and cons before coming to a conclusion about the safety of a given drug. But to be able to make these important, indeed life or death decisions on behalf of the public health, the FDA scientists and regulators need to have all the pertinent information about a given drug at their disposal. They need the regulatory tools and the regulatory science capacity to draw their own independent and unbiased assessments of a drug's safety. And if a drug is in fact deemed unsafe by the agency, the agency needs the structural and the political capacity to ensure its recommendations are subsequently put into action, followed and enforced.

Which brings us to the case before us today concerning the diabetes drug Avandia. As you all know, the Senate Finance Committee staff investigative report revealed that for many years the manufacturer knew much more about the risks of the drug than it revealed to the FDA. This report poses several troubling questions for this subcommittee. Most obviously if Avandia is unsafe, how did it ever get on the market in the first place? For that matter, why is it still on the market right now? What does the case of Avandia tell us about the FDA's current ability to conduct its drug safety responsibilities?

Looking at the details of the Avandia story, the major studies suggesting this drug was safe was the Record trial, R-e-c-o-r-d, sponsored by its makers GlaxoSmithKline. As we now know and as the Senate committee staff report reaffirms, serious questions have been raised about this clinical trial's scientific merit. And last month the Mayo Clinic released an analysis which found 90 percent of the scientists who published articles supporting Avandia had financial ties to Glaxo.

Astonishing to me is the fact that in June of 2007, two scientists at the FDA's Drug Safety Office, after going over all the evidence recommended that Avandia be removed from the market. But nothing came of this decision, and in fact, Avandia is on the market right now, pending the findings of the TIDE study which is expected to be published in 2015. 2015. We should not take so long to study a drug about which such serious safety issues have been raised. As the Senate report and others have noted, lives are at stake, and one has to wonder what is the purpose of a drug safety office if its recommendations are ignored at the agency.

Consider how long this process has already taken. When this drug was approved in 1999, the FDA requested that Glaxo conduct a post-market study, the ADOPT study, which finally came out in 2006. In the intervening years, Glaxo continued to praise their new drug even as scientists on their staff began to recognize and flag serious problems with Avandia. And now we are talking about waiting until 2015 before a reevaluation. Simply put, this process

should not take 16 years, and particularly not when the drugmaker in question has a record of promoting a drug even in the face of dire warnings.

We are here today to ascertain what the Avandia case tells us about drug safety at FDA, but in many ways, this is not a new story. We saw similar problems with Merck, who used ghostwriters to promote their own studies of their pain medicine Vioxx, or consider Trasylol, the heart surgery drug linked to kidney failure that the FDA failed to remove from the market in a timely fashion, resulting in an estimated 22,000 preventable deaths. Cases and controversies like these, or Ketek, that goes on. It's alarming to all of us, and with every new case they look less and less like outliers and more and more like symptoms of a dangerous and a systemic failure in our regulatory apparatus.

In testimony before the Senate Finance Committee in 2004, Dr. David Graham, an epidemiologist at FDA, testified that because of the culture at the Center for Drug Evaluation and Research, the U.S. was virtually defenseless against another drug safety disaster like Vioxx, and it would be a question of time before another disaster would strike. It may be that Avandia is that disaster. From every indication we have seen, this looks like an instant replay of what transpired with Vioxx.

So I hope that today we can work toward identifying exactly what happened with Avandia, what went wrong, when, who knew about it, and more importantly, hope we can begin to figure out ways to address the continuing drug safety problems with the agency. On one hand, we clearly need to establish more independent regulatory science capability so that the agency can make evaluations about drug safety free of industry pressure. We obviously need more disclosure, transparency from the pharmaceutical companies themselves so that we do not have another situation where the only safety assessment of a given drug is the one, as what appears to be clearly compromised as the Record trial.

In restructuring the FDA towards a more scientific bent and in mandating the industry post-summary level results of clinical trials online, the FDA amendment that we passed in 2007 has and should continue to make a difference on these fronts. But as we know, increased scientific capacity and more industry transparency are only part of the solution. We need to change that culture at the FDA, make it more proactive rather than reactive, to assure that there are clean, consistent, well defined, delineated lines of communication between the scientists examining the drugs and the regulators making decisions.

In this last regard, the evidence suggests that we should look into strengthening either the independence or the powers of the FDA's Drug Safety Office so that its recommendations no longer go unheeded.

Senator Grassley, thank you very, very much, and I thank Dr. Krumholz and Dr. Wolfe for being with us today to help us get at these continuing problems. And with that, let me ask our Ranking Member, Mr. Kingston, if he would like to make a statement.

Mr. KINGSTON. Thank you, Madam Chair. And Senator Grassley, it's great to have you here. And I am—have read your report, and I am very interested in the fact that during this period of time

since 2007 to now, FDA funding has actually gone up substantially, and yet it seems like the results—I'm a believer that funding isn't the FDA's biggest issue as much as reform is, and I think this is all part of that. So I look forward to hearing your comments and I yield back.

Ms. DELAURO. Okay. And with that, Senator, let me just say that throughout your career you have really been a champion of improving both the FDA and our drug safety in particular. We owe you a debt of gratitude for your steadfastness in this area. You've been a member of the Congress for 35 years, a senator for three decades. You've worked to cultivate an independent and transparency at this agency and to restore the preeminence of scientific inquiry on which it was founded. So I commend you on this proven record of leadership. And also let me just say thanks to you for being here today, and particularly after a 5K run this morning. Bless you. And Senator, we'd love to hear your testimony this morning.

Senator GRASSLEY. My time was nothing to brag about. Chairman DeLauro and Ranking Member Kingston, and of course all the distinguished colleagues who are here, I appreciate very much the invitation to speak and the kind words that the chairman has expressed. Far too often we read press reports about partisan warfare and a do nothing Congress, so I'm glad to see both the Senate and the House, Democrats and Republicans, coming together to work to protect the American supply of pharmaceuticals.

As Ranking Member of the Senate Finance Committee, I have made it my job to look into various aspects of the health care industry. I do this to protect the public's health and to guard the taxpayers' pocketbook. As part of this duty, I've taken a keen interest in the Food and Drug Administration and the pharmaceutical and device industries.

Back in May of 2007, Senator Bachus, who I've had the privilege of working with on ten years on this committee, four years that he's been chairman, six years that I was chairman, anyway, we opened up an inquiry into Avandia, a drug sold at GlaxoSmithKline to control glucose levels in diabetes. We started this inquiry because the New England Journal of Medicine published a study which found that Avandia may cause heart attacks. Obviously, this was bad news because one of the things diabetics are most at risk for is of course heart attacks.

The Finance Committee staff spent over two years combing through hundreds of thousands of pages of documents. So I will give you the opportunity to decide what you want to do with the staff report, but I'll leave it with you. Back in 1999 when Avandia first came on the market, executives of GSK intimidated a physician. I want to emphasize, intimidated a physician at the University of North Carolina. The physician was worried that Avandia might cause heart attacks. To suppress his comments, top officials at GSK called his superiors and had him sign a form that he would no longer criticize the drug. Senator Bachus and I released a report on this finding, and I will leave that document for the record if you wish. The 2007 study——

Ms. DELAURO. Without objection.

[The information follows:]

[The report can be found at: http://finance.senate.gov/newsroom/chairman/release/?id=bc56b552-efc5-4706-968d-f7032d5cd2e4.]

Senator GRASSLEY. Okay. Well, thank you. So this 2007 study that first caught the committee's attention was submitted to the New England Journal of Medicine by Dr. Steven Nissen, professor and cardiologist at the Cleveland Clinic. However, GSK got a copy of the manuscripts before it was published. One of the experts who was peer reviewing the study found the New England Journal of Medicine leaked it to GSK. This allowed GSK to launch a public relations campaign to undermine legitimate concerns that Avandia might cause heart attacks.

Then last February, Senator Bachus and I published a committee staff report on Avandia. This report is about 15 pages long and contains another 300 pages of attached internal documents, charts and e-mails. With this report, we wanted to let the people of America know what the company knew and when the company knew it. Here is what we found. Shortly after GSK got a copy of Dr. Nissen's study, they had their own statistician dissect it. GSK's statisticians found the study to be scientifically sound. However, GSK immediately drafted talking points to undermine Dr. Nissen's study. At times, these talking points run counter to legitimate concerns of Avandia's very own safety that was raised in e-mails by GSK's own scientists. In an internal e-mail, GSK's head of research discussed, quote/unquote, "take home messages" of the research on Avandia.

If you look through the report that the Finance Committee released, you'll find this e-mail on page 163. In that e-mail, GSK's head of research pointed out that Avandia has an increased risk of cardiovascular death. So let me emphasize the word "death," cardiovascular death. Not heart attack, not heart failure, but death. Well, the American public never knew about this risk until the committee released the Avandia report. And you still can't find any mention of quote/unquote, "cardiovascular death" in the warning section of Avandia's label.

There are other findings in this report, but I would also like to discuss some internal FDA documents that we came across during our inquiry. When concerns were first raised by the safety of Avandia, the FDA responded by requiring GSK to do a safety study. Well, some safety, drug safety experts inside FDA looked at this study that GSK was doing with patients, and wrote that it was, in their words, "unethical."

Here's the troubling thing about the study. The patients that enrolled in that safety study never learned that FDA's own safety experts thought that the trial was unethical. At least they didn't know this until the Finance Committee made the internal FDA documents public in February.

This is not the first time questions have been raised about whether or not a study sanctioned by the FDA was ethical. In 2006, I inquired about FDA's decision to allow a study of the blood substitute Polyheme to proceed without adequate prior informed consent from the potential study participants. I raised questions about the FDA's decisions, especially in light of the fact that another office within HHS, the Office of Human Research Protections, disagreed with the FDA. In particular, I was concerned that during

this study when subjects arrived at the hospital after being treated with the blood substitute and a real blood became available, the real blood was withheld from the patients as part of the study protocol.

To end, I would like to highlight that I feel that we can all learn from FDA's handling of the drug Avandia. Because I think that we all want to move forward and make this agency better. The Avandia case is another example of why I twice introduced legislation to establish independent Office of Drug Safety at the FDA, and this is something I could talk about for as long as you want to listen, but we don't have time for that. So I will concentrate on what I was trying to accomplish in this legislation.

The center, the legislation proposed a center of post-market drug evaluation and research. And it would tackle the lack of equality between the Office of New Drugs, which decides whether to approve a drug in the first place, and the Office of Surveillance and Epidemiology, and I'll refer to that as OSE. OSE is the office that monitors a drug's safety once it's on the market and being sold to the patients, and maybe it's better to say just post-marketing surveillance.

The imbalance between the Office of New Drugs and let me just say post-market surveillance, was apparent in the Vioxx controversy about six years ago, and we can see it today in instances involving Avandia. Individuals in the office responsible for post-market surveillance should be allowed to provide an independent opinion based on best available evidence. FDA employees dedicated to post-market surveillance should be able to express their opinions in writing and independently without fear of retaliation, reprimand or reprisal, and we run into that all the time. And thank God that there are really people within the agency that want the public to know, and when they don't get the attention of the people within the FDA, they have guts enough to come forward to people like me and probably like you, Madam Chairman.

Instead, the FDA physicians and scientists committed to post-marketing monitoring of drugs have sometimes, as I've just indicated, been suppressed. In the case of Avandia, it appears that they have been worse than suppressed. They've just simply been ignored.

Before I conclude my remarks, I'd like to call to your attention another matter related to drug safety. As you may have seen in press reports over the last two years, FDA has been taking action against some unapproved drugs. The problem is, FDA does not have a complete and accurate list of all of the products sold on the U.S. market, including unapproved drugs. So the agency can't take appropriate enforcement action. I hope that we can work together to ensure that the FDA has the resources and tools to ensure that the drugs in our medicine cabinets are safe and effective and approved for use by FDA.

This concludes my testimony, and once again thank you for the invitation, but also to tell you that I look forward to working with you as you continue your oversight of our country's pharmaceuticals, which remain vital to our public health. And I appreciate your leadership and the work of the committee in this area. Thank you.

[The information follows:]

Statement of Senator Charles E. Grassley
Before the United States House of Representatives
Committee on Appropriations
Agriculture Subcommittee
April 28, 2010

Avandia and Drug Safety

Chairwoman DeLauro, Ranking Member Kingston, and distinguished colleagues, thank you for inviting me to speak today at this hearing on drug safety.

Far too often, we read press reports about partisan warfare and a "do nothing" Congress. So I am glad to see both the Senate and the House, Democrats and Republicans coming together to work to protect the American supply of pharmaceuticals.

As the Ranking Member of the Senate Committee on Finance, I have made it my job to look into various aspects of the health care industry. I do this to protect the public's health and to guard their pocket book.

As part of this duty, I have taken a keen interest in the Food and Drug Administration and the pharmaceutical and device industries.

Back in May of 2007, Senator Baucus and I opened up an inquiry into Avandia, a drug sold by GlaxoSmithKline to control glucose levels in diabetics.

We started this inquiry because the New England Journal of Medicine published a study which found that Avandia may cause heart attacks.

Obviously, this was bad news, because one of the things diabetics are most at risk for is a heart attack.

The Finance Committee staff spent over two years combing through hundreds of thousands of pages of documents. Let me tell you a little of what they found:

Back in 1999 when Avandia first came on the market, executives at GSK intimidated a physician at the University of North Carolina.

The physician was worried that Avandia might cause heart attacks. To suppress his comments, top officials at GSK called his superiors and had him sign a form that he would no longer criticize the drug. Senator Baucus and I released a report on this finding, and I would like to enter that document into the record at this time.

The 2007 study that first caught the Committee's attention was submitted to the New England Journal of Medicine by Dr. Steve Nissen, a professor and cardiologist at the Cleveland Clinic.

However, GSK got a copy of the manuscript before it was published. One of the experts who was peer-reviewing the study for the New England Journal of Medicine leaked it to GSK.
This allowed GSK to launch a PR campaign to undermine legitimate concerns that Avandia might cause heart attacks.

Then, last February, Senator Baucus and I published a Committee Staff Report on Avandia. This report is about 15 pages long, and contains another 300 pages of attached internal documents, charts, and emails.

With this report, we wanted to let the people of America know what the company knew, and when they knew it.

I would now like to tell you some of what we found:

Shortly after GSK got a copy of Dr. Nissen's study, they had their own statistician dissect it. GSK's statistician found the study to be scientifically sound.

However, GSK immediately drafted talking points to undermine Dr. Nissen's study. At times, these talking points run counter to legitimate concerns of Avandia's safety that are raised in emails by GSK's own scientists.

In an internal email, GSK's head of research discussed "take home messages" of the research on Avandia. If you look through the report that the Finance Committee released, you'll find this email on page 163.

In that email, GSK's head of research pointed out that Avandia has an increased risk of cardiovascular death. Let me emphasize this—cardiovascular death. Not heart attacks. Not heart failure. Death.

Well, the American public never knew about this risk until the Committee released the Avandia report. And you still can't find any mention of "cardiovascular death" in the warning section of Avandia's label.

There are other findings in this report, but I would also like to discuss some internal FDA documents that we came across during our inquiry.

When concerns were first raised about the safety of Avandia, the FDA responded by requiring GSK to do a safety study.

Well, some drug safety experts inside FDA looked at that study that GSK was doing with patients and wrote that it was "unethical."

Here's the troubling thing about the study: the patients that enrolled in that safety study never learned that FDA's own safety experts thought that the trial was unethical.

At least, they didn't know this until the Finance Committee made that internal FDA document public in February.

This is not the first time questions have been raised about whether or not a study sanctioned by the FDA was ethical.

In 2006, I inquired about FDA's decision to allow a study on a blood substitute, PolyHeme, to proceed without adequate prior informed consent from the potential study participants, especially when another office within HHS, the Office for Human Research Protections, disagreed with the FDA's decision.

In particular, I was concerned that during this study when subjects arrived at the hospital after being treated with the blood substitute and real blood became available, the real blood was withheld from the patients as part of the study protocol.

To end, I would like to highlight what I feel we can all learn from the FDA's handling of Avandia. Because I think that we all want to move forward and make this agency better.

The Avandia case is another example of why I twice introduced legislation to establish an independent office of drug safety at the FDA.

The Center for Postmarket Drug Evaluation and Research would tackle the lack of equality between the Office of New Drugs (OND), which decides whether to approve a drug, and the Office of Surveillance and Epidemiology (OSE).

OSE is the office that monitors a drug's safety once it's on the market and being sold to patients.

The imbalance between OND and OSE was apparent in the Vioxx controversy about six years ago, and we can see it today in the incidents involving Avandia.

Individuals in the office responsible for post-market surveillance should be allowed to provide an "independent opinion" based on the best available evidence.

FDA employees dedicated to post-market surveillance should be able to express their opinions in writing and independently without fear of retaliation, reprimand, or reprisal.

Instead, the FDA physicians and scientists committed to post-market monitoring of drugs have sometimes been suppressed. In the case of Avandia, it appears that they have been ignored.

Before I conclude my remarks, I would like to call to your attention another matter related to drug safety.

As you may have seen in press reports over the last two years, FDA has been taking action against some unapproved drugs.

The problem is—FDA does not have a complete and accurate list of all of the products sold on the US market, including unapproved drugs, so the agency can't take appropriate enforcement actions.

I hope that we can work together to ensure that FDA has the resources and tools to ensure that the drugs in our medicine cabinets are safe and effective and approved for use by the FDA.

This concludes my testimony, and I once again thank you for this invitation. I look forward to working with you as you continue your oversight of our country's pharmaceuticals which remain vital to public health. I appreciate your leadership in this area.

Ms. DELAURO. Thank you, Senator, and we appreciate again your leadership. I know you are pressed for time. I know my colleague, Mr. Kingston has a, he says a very quick question here, so I'll do that because I don't want to hold you up.

Mr. KINGSTON. Thank you, Madam Chair. I'm going to yield my time to you because I think the senator covered my question with the 2006 incident, because what I wanted to know is how often does this sort of thing happen, and your testimony did mention 2006 and also Vioxx, so that was my question and I'll yield to you if the senator has time.

Ms. DELAURO. What I would love to do, Senator, if what we can do is you do have a piece of legislation that dealt with the restructuring of the agency in this regard, with regard to the Office of New Drugs and surveillance and epidemiology, and I think that the committee would be very interested in taking a look at that document to see—you make very, very valid points. The report does. There have been GAO reports, others who have intimated that that is a direction that we ought to go in.

I think there is indicative of the approval of Avandia in 1999 the particular person who signed the approval in fact is now the person who is reviewing the process. So, therefore, you inherently build in difficulty to start with, and you don't get the kind of independence that you need. So we would love to work with you on that.

Very, very quickly, with regard to the TIDE study, and I noted in your letter to Commissioner Hamburg that you expressed concern about the safety of that study. Do you have any thoughts as to whether or not that ought to continue, whether that should stop, or are you taking a look at that?

Senator GRASSLEY. Well, we're taking a look at it. I haven't drawn any conclusions yet. But I think that you—there's some evidence of the same concerns that we have throughout, whether it's Avandia or other things that we have studied and looked into, and, you know, you're trying to get at the basic culture of the organization and trying to change that culture. And one of the ways I think is the best way to change is to make sure that there's a clear separation between post-marketing surveillance and approval of the drug beforehand.

I just think it's human nature for people that approve a drug to ride herd on those that, after it's out in the public and millions of people are using it instead of tens of thousands of people in the study, that you're obviously going to have some reactions that ought to be taken into consideration, and that there shouldn't be any obstacle to that being made public and warning people about it. And then you have kind of the people that approve the drugs not wanting egg on their face if they've originally approved it. And we found that so often, and so many good people in post-marketing that are willing to come forth and tell us that they think things are wrong, and they've been right so often, you know. And there's so much intimidation, you know, on publishing papers of some of these people that I could go into a whole history and give you all sorts of intimidation that comes in that area. And maybe it's a problem throughout government, you know, but you can't look at every agency in government, but, you know, it's typical of people to want their agency to look good, and I just think that the more

that you try to cover up things, the more you end up when the truth finally comes out.

So the idea is to get people to think in terms of working for the American people and not just working for their agency, and for agencies to think in terms of well, we're all in this game together. We ought to be pulling together for the taxpayers and the American people as opposed to worrying about our—like one agency I referred to as "our institution." And it wasn't the FDA, and I won't name the agency, but "our institution." And I said, you know, that's what's wrong with you. It's not your institution. You work for the American taxpayers, and we're all in this together, and the people are our boss, you know.

Ms. DELAURO. Mm-hmm. Well said. And I would say even with regard to other agencies, and this is where you have really made a mark is the fact that this agency particularly with regard to the independent review and the science, this agency deals with life and death. Some of our other agencies do not do that. And so the consequences are severe.

Senator GRASSLEY. And if people have respect for the scientific process, the scientific process, sound science is a heck of a lot better than political science, because it's got a process that proves itself. You know, every position a scientist takes is subject to peer review. Let the process work out, see. But you find too much human intervention in the scientific process, not just in FDA and a lot in EPA, you know, in a lot of our trade issues overseas, political issues or interfering with the so-called safety of a product, you know. Let science prove itself. We got a whole bunch of scientists in pairs that say whether food is safe or not, you know, and make a scientific judgment. But you've got politicians interfering all the time. So to some degree, you've got, maybe not elected politicians, but politicians or political views intervening now. I don't mean Democrat Republican.

Ms. DELAURO. No, I understand. Right. Thank you very, very much, Senator. We're grateful for your testimony and grateful for spearheading this report which I think will help to make a difference. We look forward to working very closely with you and with your staff in this effort. Thank you.

Senator GRASSLEY. Just call me anytime and I'll come over to your office.

Ms. DELAURO. Will do. Thank you. Thank you.

Senator GRASSLEY. Not too many senators offer that.

Ms. DELAURO. Right. Not too many senators offer that effort. We will ask Dr. Wolfe and Dr. Krumholz to join us at the witness table.

Let me introduce our panelists. Dr. Sidney Wolfe, you have been a fierce and a formidable advocate for American consumers and families for decades as both a physician, as director of the Health Research Group.

I must tell you that I do office hours every weekend and I go to a library, I go to a stop and shop, and the area is notified that I'm going that be there, and I had a woman, her name is Captain Lou Morowitz, who stopped by the office hours in Woodbridge, Connecticut on Saturday. She had no idea we were doing a hearing, what we were doing. And she said to me, have you ever read the

newsletters that Dr. Wolfe sends out? And she handed me the whole sheaf of the newsletters. So, well known, well known. And this is obviously the document is Public Citizen's Drug Safety Information pamphlet, so you make a difference in people's lives, and I applaud you for your service.

And I also want to introduce Dr. Krumholz, who is the author of more than 250 journal articles as well as the book, "The Expert Guide to Beating Heart Disease," a member of numerous cardiovascular care communities, including the American Heart Association and the American College of Cardiology. You two have spent a career helping us to better understand, look after your heart, your public education efforts on heart disease and your strong advocacy of hospital reform have done credit to your university and to our state. Dr. Krumholz is affiliated with Yale University in my home town of New Haven. And I thank you for joining us today. I thank you both for looking into these issues of drug safety at the FDA and sharing your wisdom and knowledge and expertise with us today.

Dr. Wolfe, if you will proceed, and then we'll move to Dr. Krumholz. And as you know, your full statements will be part of the record, so you're free to summarize in any way that you choose. Dr. Wolfe.

Dr. WOLFE. Congresswoman DeLauro, members of the subcommittee, thanks for letting me testify on the serious dangers of the diabetes drug, Avandia. I will present arguments strengthened by new information since we originally asked FDA to ban this drug in October 2008 as to why an unethical international experiment in 14 countries involving the drug called TIDE requested by the FDA must be stopped immediately. We're in the process of writing to Commissioner Hamburg going into some of these details. I'll sketch some of them out today. And simultaneously, why rosiglitazone must be removed from the market.

Almost at the same time as our petition to ban the drug, an expert committee representing the two largest organizations of diabetes experts in the world, the American Diabetes Association and the European Association for the Study of Diabetes, issued a consensus statement based on a careful safety review that quote, "Given that other options are now recommended, the consensus group members unanimously advised against using rosiglitazone."

It's of particular interest that one of the members of this committee was Dr. John Buse, who Senator Grassley referred to as the North Carolina physician who Glaxo tried to intimidate out of being critical of the drug and resisting the intimidation he signed off on this consensus statement that basically you should not use this drug. So the leading diabetes organizations in the world say don't use it.

Since then, considerably more evidence since our petition concerning unique risks and any lack of a unique benefit of rosiglitazone have been published. But nevertheless, starting in May 2009, the manufacturer, Glaxo, as ordered by the FDA, started to recruit for a large 16,000 person randomized trial to evaluate the cardiac safety of rosiglitazone in comparison to standard treatment and in comparison to another drug in the same family, pioglitazone.

Thus in the face of recommendations not to use the drug by the leading diabetes organizations, a large human experiment to further establish the dangers of rosiglitazone under the urging of the FDA has begun. And I'd like to add a little detail to that, which is something must not be working out very well in terms of recruiting for the study.

In the last four weeks, that's from March 31st until now, a number of new places where these experiments are going on have been added. And I'd like to mention these places. India, Pakistan, Mexico, Latvia and Colombia. So we are moving into, amongst other things, some third world countries under the urging of the FDA to try and do an experiment that is completely unethical.

I just want to review a couple more recent studies that point out how dangerous this drug is. One is Glaxo's own study, referred to by you, Congresswoman, and by Senator Grassley, called Record. The FDA is reviewing the study. But in the meantime, under the gun I think of the FDA, the company is starting to publish some things that are a little less favorable for the drug than what they did before.

This is a study involving four-and-a-half thousand people. These are all people with diabetes who weren't being adequately controlled with one diabetes drug, so they split them in half. Half of them were given rosiglitazone and the other half were given another older diabetes drug. And what happened was, a significant doubling of heart failure deaths, significant increase in hospitalizations of the group given rosiglitazone, and although it doesn't appear in the summary of the study, we did a little statistical analysis, those people admitted to the hospital with heart failure, there was almost a fourfold increase in all subsequent cardiovascular deaths in the group getting rosiglitazone.

This study is extremely relevant for looking at how unethical the TIDE study is because it answers one of the very research questions of that study. How does rosiglitazone compare to standard diabetes treatment? The answer is very poorly.

Another even more recent study, or this study was done by Canadian researchers on their Canadian single payor database, all the people in Ontario over the age of 66, 40,000 people. This study showed—and this was looking at rosiglitazone versus pioglitazone—and this study showed that for every 120 people getting rosiglitazone instead of the other drug, one of them would be hospitalized for heart failure and there would be a number of deaths. The conclusion of this study published in the British Medical Journal in August was thousands of additional adverse outcomes, including deaths, from the use of rosiglitazone rather than pioglitazone.

And this study answers the other question of the TIDE study, which is how do these two drugs compare with one another. It's an observational study, not a randomized controlled trial, but the two groups were just about identical.

And finally, Johns Hopkins researchers reviewed 40 different randomized controlled trials looking at a variety of diabetes drugs, including rosiglitazone and pioglitazone. The only drug that improved cardiovascular outcomes was the old, relatively inexpensive drug, metformin. The only diabetes drug that increased cardio-

vascular risk was rosiglitazone. It was not quite statistically significant, but it was an increased risk of 1.7 times.

In addition, looking back at all of the quote, "controversy" about the increased heart attack risk, there was a study done five years ago showing that if you take rosiglitazone, you come out much worse in terms of your serum cholesterol, serum triglycerides than you would if you took pioglitazone. So there's even some plausible reason why there may be increased heart attacks.

So in summary, there are many studies showing increased cardiovascular risk of rosiglitazone compared with pioglitazone. There's not one study showing the opposite, namely an increased risk with pioglitazone compared with rosiglitazone, one of the main purposes of this TIDE study.

And I want to just close by briefly reviewing the reasons why this trial is unethical and must be stopped before additional preventable injuries and deaths occur. As was mentioned by you, Congresswoman DeLauro, this study, which started recruiting in May of 2009, is scheduled to go until 2015. So during a period of time when it is quite clear that this drug is dangerous in comparison with old diabetes drugs and dangerous in comparison with Actos or pioglitazone, they are recruiting from all over the world, including the United States and Canada but now recently Pakistan and India, which from an ethical perspective, it gives our international reputation a huge step downward to be recruiting people in countries that we are trying to have good relationships with, but the study itself is unethical.

Dr. David Juurlink, physician, pharmacologist, head of internal medicine in Canada at one of the Sunnybrook Health Sciences, one of the University of Toronto teaching, had a lot of input into this because he was the principal author of the Canadian study that showed when you look at rosiglitazone versus pioglitazone, rosiglitazone comes out much worse. And so he and I went over some of these reasons why this trial is unethical.

The primary purpose of this trial is to establish with certainty whether or not rosiglitazone is indeed more dangerous than pioglitazone. However, now there are well documented differences in the risk and I have gone over some of them between the two demonstrated in several studies in the United States, Canada and the UK. The TIDE trial defies a basic tenet of clinical trial design. The trial should be conducted to determine the balance of risk and benefit and not simply to provide absolute proof on harm, because rosiglitazone has no safety or efficacy advantage, not even a theoretical one, over pioglitazone, and because a wealth of data now suggests rosiglitazone carries greater list than pio, it is not possible to advance a cogent argument that this trial is ethical.

Another reason why the trial is unethical is absence of equipoise, which means in English that when you go into a study, there should be reasonably equal possibilities that one arm of the study is going to do as well as the other one. In other words, it refers to the fact that no subject receive an intervention known to be inferior to current standards of care. They're justified only in cases where expert scientific community is unsure about the comparative merits and interventions.

This is clearly not the case for rosiglitazone. Several guidelines and medical reviews have all demonstrated rosiglitazone has an inferior safety profile to pio and to the positions of the American Diabetes Association. And the final reason is unfavorable balance of benefits and risks, which I have gone over. The risk of harm with rosiglitazone is substantial, and it's highly unlikely and statistically improbable that patients in the rosiglitazone part of the study will derive any additional clinical benefit beyond that provided by pioglitazone.

As I mentioned before, there is now 137 places in the world involved in this study. Fifty more were added just between four weeks ago and now, and it includes a number of countries including the developing countries I mentioned. And in summary, the TIDE trial continues to recruit patients despite a lack of equipoise, exposing thousands of high risk patients, because in order to get into the trial you already have to be an increased cardiovascular risk, to a drug with an unfavorable safety profile with no clinical advantage over its comparator.

It is almost certain that prospective study subjects are deprived of the opportunity to make a fully informed decision because the consent form, at least the version we've seen, doesn't clearly present the kinds of information that we know about the drugs that I've just gone over.

It is difficult to imagine that a patient would willingly participate in a trial involving a drug that according to the American Diabetes Association has concerns—has safety concerns that leave it with no present day role in the management of Type 2 diabetes, which is what those organizations concluded. The TIDE trial can only continue with the misplaced objective of proving definitively what many studies have already suggested, that rosiglitazone is indeed more dangerous than pioglitazone. The price of such definitive proof will almost certainly be measured in the lives of study subjects who have been incompletely informed about the available evidence regarding the risks and benefits of participation.

And just one more thing, which is these are the data showing that in 2006, there were 11.3 million prescriptions for rosiglitazone, 11.3 million for pioglitazone. After the concerns started getting voiced, the last year we have complete data for, 2008, there had been a slight increase in pioglitazone, Actos, 12.5 million. Rosiglitazone had fallen to 3.1 million. So aside from being rejected by the American Diabetes Association, the drug is being rejected by most doctors in the country. Four times as many doctors are prescribing Actos than Avandia.

[The information follows:]

Testimony of Sidney M. Wolfe, M.D.
Director, Health Research Group at Public Citizen
Before House Agriculture-FDA Appropriations Subcommittee Hearing on Avandia
April 28, 2010

Congresswoman DeLauro and members of the subcommittee, thank you for the opportunity to testify on the serious dangers of the diabetes drug, rosiglitazone (Avandia). I will present arguments, strengthened by new information since we originally petitioned the FDA to ban the drug in October, 2008, as to why an unethical international experiment in 14 countries involving the drug, called TIDE, requested by the FDA, must be stopped immediately and, simultaneously, why rosiglitazone must be removed from the market.

Almost simultaneously with our petition to ban rosiglitazone, an expert committee representing the two largest organizations of diabetes experts in the world, the American Diabetes Association and the European Association for the Study of Diabetes, issued a consensus statement, based on a careful safety review, that: "given that other options are now recommended, the consensus group members unanimously advised against using rosiglitazone."[1]

Since then considerably more evidence concerning the unique risks and any lack of a unique benefit of rosiglitazone have been published, but, starting in May, 2009, the manufacturer, GlaxoSmithKline (GSK), as ordered by the FDA, started to recruit for a large, 16,000 person randomized trial to evaluate the cardiac safety of rosiglitazone in comparison to standard treatment and in comparison to another drug in the same family, pioglitazone. Thus in the face of recommendations not to use the drug by the leading diabetes organizations, a large human experiment to further establish the dangers of rosiglitazone, under the urging of the FDA, has begun.

Newer Evidence of Cardiac Risks of Rosiglitazone

1/ GSK Study, RECORD, published online January 29th, 2010

This randomized controlled trial involved 4447 people inadequately controlled on metformin or an older sulfonylurea diabetes drug. Half of them were given rosiglitazone and the other half were given, in addition to what they had previously taken, either metformin or a sulfonylurea. In addition to a significant doubling of heart failure deaths or hospitalizations in the group given rosiglitazone, among those admitted to the hospital with heart failure, there was a significant, more than four-fold increase in all subsequent cardiovascular deaths in the rosiglitazone group.[2] This study is extremely relevant for the TIDE study since it answers one of the research questions of that study: how does rosiglitazone compare to standard diabetes treatment: The answer is very poorly.

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[1] Diabetologia. 2009 Jan;52(1):17-30. Epub 2008 Oct 22
[2] European Heart Journal, publishe online January 29, 2010.

2/ Canadian Population-Based Study comparing rosiglitazone with pioglitazone

This observational study, published in August 2009, evaluated cardiovascular outcomes in 39,736 people who were started either on rosiglitazone or pioglitazone from 2002 through 2008. The authors found major differences in the risk of congestive heart failure and death from any cause in patients taking rosiglitazone as compared to those taking pioglitazone. They estimated that one additional hospitalization for heart failure would occur annually for every 120 patients prescribed rosiglitazone rather than pioglitazone, and that one additional death would occur each year for every 269 patients treated with rosiglitazone rather than pioglitazone.[3] At the population level, this translates into many thousands of additional adverse outcomes resulting from the use of rosiglitazone rather than pioglitazone. This study strongly answers the other part of the research question in TIDE: how do the cardiac risks of rosiglitazone compare to those of pioglitazone.

3/ Johns Hopkins study reviewing 40 randomized, controlled trials involving cardiac risks of older diabetes drugs

Of all the drugs evaluated, metformin hydrochloride was the only drug associated with a decreased risk of cardiovascular mortality compared with any other oral diabetes agent or placebo; The only diabetes drug with increased cardiovascular risk was rosiglitazone, for which the increased risk was 1.68, falling just short of statistical significance.Pioglitazone had neither increased nor decreased cardiovascular risk in the six randomized trials that comprised the study.[4]

Older evidence of differential risk of rosiglitazone and pioglitazone on blood lipids

One plausible biological hypothesis to explain the relatively recent findings of increased risk of heart attacks for patients using rosiglitazone in some studies is that rosiglitazone has much more deleterious effects on serum cholesterol and triglycerides than pioglitazone. Eight hundred patients were randomized to get either rosiglitazone or pioglitazone. Those who took pioglitazone had significantly greater decreases in their triglycerides, much lower increases in total cholesterol and significantly smaller increases in LDL cholesterol.[5]

Summary of relative risks of rosiglitazone and pioglitazone

Whereas there are many studies showing increased cardiovascular risk for rosiglitazone compared with pioglitazone, there are no studies showing the opposite: increased risk of pioglitazone compared with rosiglitazone. There was a 20 to 3 vote by an FDA advisory committee in July 2007 that there were data from randomized trials suggesting that rosiglitazone increased the risk of ischemic events (such as heart attacks). The FDA, later

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[3] BMJ 2009;339:b2942
[4] Arch Intern Med. 2008;168(19):2070-2080
[5] Diabetes Care, Volume 28, Number 7, July 2005.

that year, ordered a black box warning on the drug stating that one study "showed AVANDIA to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction." It pointed out that other studies had not confirmed this but such a warning about possible heart attacks has never been placed on pioglitazone.

Why the TIDE trial is unethical and must be stopped before additional preventable injuries and deaths occur from exposure to rosiglitazone

(This portion of the testimony greatly benefited from the input from David N. Juurlink MD, PhD, FRCPC, FACMT, FAACT Attending Physician, Division of General Internal Medicine, Head, Division of Clinical Pharmacology and Toxicology, Sunnybrook Health Sciences Centre Scientist, Institute for Clinical Evaluative Sciences and the principal investigator fort the Canadian study comparing rosiglitazone with pioglitazone (see reference 3 above.)

In light of the growing evidence that rosiglitazone imparts greater cardiac risk than pioglitazone yet offers no particular advantage, the Saudi Arabian drug regulatory agency has recently removed rosiglitazone from the market.

The trial is unethical for several reasons:

1. Misplaced scientific objectives

A primary purpose of the TIDE trial is to establish with certainty whether or not rosiglitazone is indeed more dangerous than pioglitazone. However, there are now well-documented differences in cardiovascular risks between rosiglitazone and pioglitazone, demonstrated in several studies conducted in the United States, Canada and the UK. The TIDE trial defies a basic tenet of clinical trial design – that trials should be conducted to determine the balance of risk and benefit and not simply to provide absolute proof on harm. Because rosiglitazone has no safety or efficacy advantage – not even a theoretical one – over pioglitazone, and because a wealth of data now suggests rosiglitazone carries greater risks than pioglitazone, it is not possible to advance a cogent argument that this trial is ethical given the present state of evidence.

2. Absence of clinical equipoise

Clinical equipoise requires that no subject receive an intervention known to be inferior to current standards of care. RCTs are justified in cases in which the expert scientific community is unsure about the comparative merits of interventions, and there should be equivalent evidence for the two interventions. This is clearly not the case in the context of rosiglitazone and pioglitazone. Several guidelines and systematic reviews (the highest level of evidence) have all demonstrated that rosiglitazone has an inferior safety profile relative to pioglitazone, and the positions of the ADA and EASD support this.

3. Unfavorable balance of risks and benefits of rosiglitazone

The balance of risks and benefits on rosiglitazone is clearly unfavorable. *A priori* the risks of harm with rosiglitazone are substantial, and it is highly unlikely and statistically improbable that patients in the rosiglitazone arm will derive any additional clinical benefit beyond that provided by pioglitazone. There are several different classes of drugs available to treat patients with type 2 diabetes that do not carry these risks.

Current Status of TIDE Clinical Trial Sites

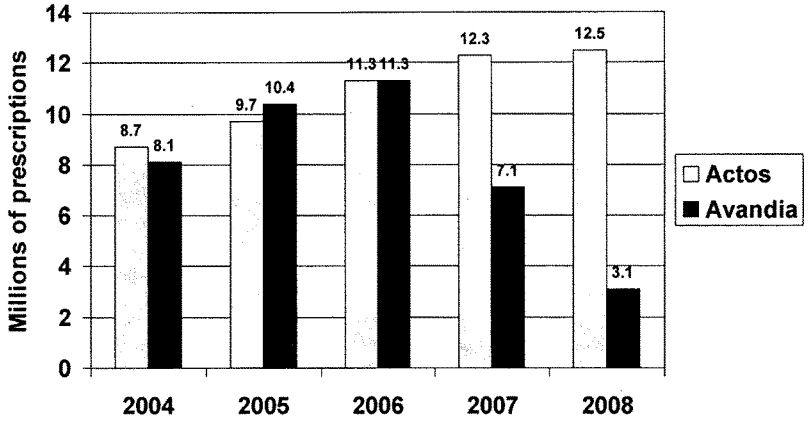
This trial now involves 137 sites in 14 countries (see below), including 19 sites in the U.S and 34 in Canada. Presently, 83 of these sites are recruiting subjects for the trial, which has an anticipated sample size of 16,000 subjects and a targeted completion date in 2015. In an apparent attempt to increase enrollment, 53 new sites were added between the previous posting on March 31, 2010 and the updated posting on April 23rd.[6]

Summary

The TIDE trial continues to recruit patients despite a lack of clinical equipoise, exposing thousands of high-risk patients with diabetes to a drug with an unfavorable safety profile and no clinical advantage over its comparator. It is almost certain that prospective study subjects are deprived of the opportunity to make a fully informed decision because the consent form does not present an accurate portrayal of existing safety concerns. It is difficult to imagine that a patient would willingly participate in a trial involving a drug that, according to the American Diabetes Association and its European equivalent, has safety concerns that leave it with no present-day role in the management of type 2 diabetes. The TIDE trial can only continue with the misplaced objective of proving definitive proof of what many studies have already suggested – that rosiglitazone is indeed more dangerous than pioglitazone. The price of such definitive proof will almost certainly be measured in the lives of study subjects who have been incompletely informed about the available evidence regarding the risks and benefits of participation.

[6] Clinicaltrials.gov, accessed 4/22/10 (3/31 posting) and 4/26/10 (4/23 posting). Other countries include Chile, Colombia, the Czech Republic, Denmark, Germany, India, Latvia, Mexico, Pakistan, Netherlands, South Africa and Sweden.

Decrease in Avandia Prescribing after Publication of Studies About Cardiac Risks



Prescription Data from Drug Topics Magazine

Ms. DELAURO. Thank you very much, Dr. Wolfe. Thank you very much.

Dr. Krumholz.

Dr. KRUMHOLZ. Thank you for allowing me this opportunity to prevent testimony about what we need to do to improve decision-making by patients, clinicians, policymakers, about pharmaceutical products. It is indeed an honor for me to be here. Thank you very much.

My name is Harlan Krumholz. I am a professor of medicine at Yale, a practicing cardiologist, and an expert in outcomes research, a field of investigation that involves practical research that's intended to guide clinical care in health care policy. I am also a member of the Institute of Medicine.

While the focus of today's subcommittee meeting is on Avandia, my focus is a bit broader. The nation's experience with Avandia makes it abundantly clear that in order to improve public health and safety, we need to ensure that information from clinical drug research is available to make sound, reasonable decisions about the drugs and devices being evaluated and to improve the communication of trial research.

I would like to touch on just a few of these opportunities very briefly. First, we need to make sure that the information from clinical trial research is available to make these sound decisions that I am talking about. When the public health is involved, patients, clinicians, policymakers must know what can be known about these drugs.

We must have access to all available, clinical trial research for comprehensive analyses to enable us to enable us to have the most complete understanding of the balance of risk and benefits of drugs. It's not happening. We too often are making inferences about drug safety based on inadequate data. Now, in part, this is because sometimes we lack the appropriate studies that we need. The studies haven't been completed; but, in part, and disturbingly, the situation occurs because not all clinical research is published. It's not put into the public domain.

Maybe half of the trials that are conducted never go through peer review, so there is knowledge out there that never comes before our eyes that we aren't even aware of. And then in addition not all the data that are collected that are relevant to questions about safety even among the published studies get out in front of us so that we can make judgments about them. These data are rarely available for analysis by independent groups; not just the FDA rarely has it. But then even beyond the FDA are independent groups having access to this?

Because science is based on the fundamental ability to reproduce findings, reanalysis of data by independent groups ensures that it reflects the truth. It gets out there. You can't hide it if many people have the data; and, it can't be done unless those data are available. And I think Representative Kingston mentioned Vioxx. Vioxx has been mentioned. It's an instructive example to us. As a result of the Vioxx litigation our research group was granted access to all of Merck's internal data. This is outside the trial. We did this as research, not funded by the litigators, anything, but we were able to get access because of the litigation.

So we were able to get all of the hard drives of raw data sent to us, stacks of it, and go through it for every trial that had been conducted on Vioxx, and actually look at what had been collected. And it turns out that when you look at that data and you analyze it carefully, despite the claims by the company that there was no evidence of harm, you could see harm emerging from the trials from their own data as early as 2001.

Remember, the drug was approved in 1999. 2001 you can see what their data—if you had been looking at it—the harm. It's 'til 2004 that it's taken off the market, because that harm becomes manifest in another trial. Now, I'm not here to say that Merck was hiding information. I'm not here to say that they knew that, but I'm saying it is what could have been known had their data been produced, had independent groups been looking at it.

I'm going to leave neutral the fact of what was known in the company. I'm just going to say that this is the kind of thing that is possible to know, and if you have the privilege of selling the drug, I think that privilege comes with the responsibility of sharing the data upon which that drug's justification is based upon which its approval is based, upon which our assumptions of safety are based.

Now, take the case of Avandia. There are unfortunately parallels here. The concerns that are being voiced about Avandia are based on analysis of data that were only in the public domain because of the Paxil litigation. If there is no litigation for Paxil, and Spitzer in his settlement is not having the company need to put in the public domain all their data, then there is no opportunity to look at the entire world experience in the trials of this.

And when Nissen, as you've heard, and his colleague were able to look at this, it's when the concerns about the heart attack risks emerged. Now, there was some question about it earlier, but this was when it began to gain force, and more people began using this in getting the study. Now, he did that though without the raw data. This is a much less definitive, much less authoritative look. I'm here to tell you I still don't think we know the full story on Avandia.

We have not been able to see the raw data files; and, even at the FDA, I'm not sure that they have all the files. I know they have Record. I'm not sure they have all of them. I'm not sure it's being systematically evaluated. I am sure there are no academic groups that are having access to this to do this independently.

Now, here's what I recommend. We need to increase transparency in the clinical trial research enterprise. As the "FDA Amendments Act of 2007" now requires that all summary level results from clinical trials be posted within 12 months of study completion, and that was a good move. That was excellent. It was a move towards transparency. You said that the results had to be available, but they're raw results. I mean they are summary results, and they are not always comprehensive and they are not always easily accessible.

I strongly recommend that raw data files from the trials that are relevant to these drugs be made available. They can be made available under data use agreements, but the independent groups in

cases where congress or the FDA or others are raising critical safety concerns.

Nissen writes his article in 2007 based on the litigation available summary data. In 2010 we still do not have the disseminated raw data files for independent analysis to tell us where we stand with this drug; and, meanwhile, I said maybe heralding the fact that four out of every five prescriptions are for actives, the drug remains a billion-dollar drug.

There are millions and millions of prescriptions being written; and, today, we still do not, I believe, know the full answer of the risks of the drugs because we haven't been able to go through the raw data files. Second, if concerns are raised by congress, the manufacturer, the FDA or by outside investigators, I believe that we should insist that there be independent replication of those results that can be done quickly by groups outside the FDA who are commissioned to do this work so we can ensure that we can be confident in the results. This is too important.

We are seeing millions of prescriptions. The chance of this drug doubles heart failure. It increases by 30 percent risk of heart attacks. Millions of Americans are taking these pills. This is, I believe, an urgent situation. It's not one where we have the luxury to wait a long time; so, quickly, the other issue for me is about the need to communicate the results. We need more effective ways of conveying information about what is known, what we can know; and, particularly, about these safety concerns.

Many patients assume that treating their diabetes will improve their outcomes, and they would be surprised to hear the conversation that we are having today that in fact it may do the opposite. Importantly, in the "Patient Protection Affordability Care Act of 2009," Section 3507, there is a requirement for the addition of quantitative summaries of benefits and risks to prescription drugs under standardized format. Bravo for that, but it's going to be the keys to the implementation.

How is it implemented? What would we improve about the communication of Avandia? Well, first of all, we might say that Avandia lowers blood sugar levels and improves the control of diabetes, but we would want to disclose to any patient taking it that we have a high level of uncertainty of whether that makes any difference in terms of their life. And, we have a fairly good certainty that it doubles the risk of heart failure. And we are pretty sure that it may increase by 30 percent the risk of a heart attack. And if you look at ads traditionally, it's in the smallest print.

I mean you've got to have a magnifying glass to read this kind of information on many of the promotional materials where it says this drug has not been shown to reduce heart attacks or improve survival, when in fact we should be saying it may increase and it should be in big print in any of these promotional things. So I believe it's our responsibility to disclose. I wonder how many of the millions of Americans taking this drug have had that disclosed.

Have they signed an informed consent, "I am willing to take this drug," in practice? But, I recognize it could have big risks, so my recommendation is we need to clearly disclose this kind of information to patients. We have to work hard to make sure we know what can be known and we make sure that people know it. And this is

going to be the devil's in the details, but it can be done. These themes about transparency and communication are resonating throughout medicine in many parts.

I am very involved in quality care work with CMS and with the public reporting of outcomes. We are moving in this direction. I believe it's had very important, positive effects on quality of care. I believe it can do the same for drug safety.

Thank you.

[The information follows:]

For Release only by the House
Committee on Appropriations

Statement of Harlan M. Krumholz MD,
Harold H. Hines, Jr., Professor of Medicine at Yale University School of Medicine
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration and Related Agencies

Thank you, Madam Chairwoman, and members of the Subcommittee for allowing me this opportunity to present testimony about what we need to do to improve decision-making by patients, clinicians and policy-makers about pharmaceutical products.

My name is Harlan Krumholz. I am the Harold H. Hines, Jr., Professor of Medicine and Epidemiology and Public Health at Yale University School of Medicine, where I am Director of the Robert Wood Johnson Clinical Scholars Program and Director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation. I am a practicing Cardiologist and an internationally-recognized expert in outcomes research, a field of investigation that involves practical research to guide clinical care and health care policy, as well as a member of the Institute of Medicine, the health arm of the National Academy of Sciences.

I am the author of the book *The Expert Guide to Beating Heart Disease: What You Absolutely Must Know* and have written or co-authored more than 500 articles, reviews, and editorials in peer-reviewed medical journals, including articles relevant to the topic today. In addition, I am currently leading initiatives under contract with the Centers for Medicare & Medicaid Services (CMS) to develop national measures for public reporting of hospital performance, promoting transparency about hospital quality through the use of rigorously developed, clinically-important outcome measures such as mortality and readmission rates for common causes of hospitalization.

While the focus of today's subcommittee meeting is on Avandia, or rosiglitazone, my focus is broader. The nation's experience with Avandia makes it abundantly clear that in order to improve public health and safety, we need to ensure that information from clinical trial research is available to make sound, reasonable decisions about the drugs and devices being evaluated and to improve communication of trial results among patients, clinicians, policy-makers, and drug manufacturers. I would like to touch on some of the opportunities I have identified that can lead towards improvement.

Background

In 2006, as a cardiologist and epidemiologist, I was asked for my expert opinion by plaintiffs in litigation against Merck related to Vioxx (rofecoxib). After extensive review of public and private documents, I spoke to the likelihood of Vioxx having caused adverse cardiovascular events among several individuals. This experience deepened my understanding of the clinical trial research process and many of the challenges facing regulators as they evaluate drugs for approval or for new indications. In particular, the challenge of making use of all available clinical trial data to better understand drug efficacy and safety.

The similarities in the stories of Vioxx and Avandia are remarkable.

This brings me to my first point: **ensuring that information from clinical trial research is available to make sound, reasonable decisions about the drugs and devices being evaluated**.

When the public's health is involved, patients, clinicians, and policy-makers must know what can be known about a drug. They must have access to all available clinical trial research for comprehensive analyses and the most complete understanding. We too often make inferences about drug safety based on inadequate data. In part, this situation occurs because we simply lack the appropriate studies.

In part, this situation occurs because not all clinical trial research is published. Moreover, not all data collected within a clinical trial is published, even when the main findings are. These data are rarely available for analysis by independent individuals or organizations. Because science is based on the fundamental ability to reproduce findings, re-analysis of data ensures that it reflects the truth, and cannot be done when the data are not available.

What is the analogy here? It is like your favorite baseball team keeping the results of some of their games out of the standings. Is the team doing well or not? If you are only seeing partial results, you will find it hard to know. If companies are not sharing all their data from the trials, we cannot know about the safety of their drugs.

As an example, Vioxx was approved for use in the United States in 1999. The following year, in 2000, a clinical trial published in the New England Journal of Medicine found that Vioxx increased the risk of heart attacks when compared with naproxen. However, the company disputed the significance of these results and the drug was not withdrawn from the market until 2004, after more clinical trial evidence had accumulated.

Was all information from clinical trial research made available to make sound, reasonable decisions about Vioxx?

The answer is no.

In the course of the litigation, our research group was granted access to all of Merck's internal clinical trial data, all of the raw data files, including many of their trials that were never published and information that never made it into public view. We conducted an analysis in which we combined the data from the studies over time, as the results became available – revealing what could have been known at various points in time. This approach is traditionally described as a cumulative pooled analysis.

We found that the increased cardiovascular risk associated with Vioxx when compared with placebo was evident very early in the accumulated evidence of clinical trial data. When data from all of the clinical trials were examined together, there was a strong suggestion of risk by the time of the New England Journal of Medicine publication, and the risk reached a high level of scientific certainty by 2001, four years before Vioxx was taken off the market.

Again, the similarities between Vioxx and Avandia persist.

Because of litigation, Avandia's manufacturer, GlaxoSmithKline, made available on a company website data it would not traditionally have published: summary information for all clinical research trials examining Avandia. Many of these trials had not been published in the peer-reviewed literature.

Without access to the raw data files, investigators from the Cleveland Clinic were still able to pool this summary information for analysis and identified an increased cardiovascular risk associated with the drug. Their analysis and those of others would have been much stronger – much more definitive – if the raw files had been available.

How can we ensure that information from clinical trial research is available to make sound, reasonable decisions about drugs and devices being evaluated or approved by the FDA?

Recommendations

First, we need to increase transparency in the clinical trial research process. As the FDA Amendments Act of 2007 (FDAAA) now requires that all summary-level results from clinical trial research be posted within 12 months of study completion, I would strongly recommend that the raw data files be made available as well. The raw data is required for the most accurate and rigorous evaluation, allowing an assessment of quality and validity and enabling standardization of the analyses across studies and direct calculation of pertinent outcomes, which will ensure the best possible understanding of the accumulated evidence.

Second, if concerns are raised by the manufacturer, or the FDA, or by outside investigators, I would strongly recommend an independent evaluation of the data and report by at least two groups of expert, non-industry-affiliated investigators so that the findings can be verified.

Finally, when concerns about drug safety are verified, I would strongly recommend that the FDA commission an independent and impartial panel of experts to review the analyses and provide a report to Congress, made available to the public, comprehensively detailing what is known about the drug's efficacy and safety.

Once the accumulated evidence is synthesized and determined, **we need to improve communication of trial results among patients, clinicians, policy-makers, and drug manufacturers**.

We need more effective ways of conveying information about what is known about the expected benefits and risks of drugs – particularly those with substantial safety concerns. Many patients assume that treating their diabetes will improve their outcomes by reducing their risk of many health problems, including heart attacks and heart failure. They would be surprised to learn that the opposite seems true.

I have published an opinion that patients deserve to know their options – as well as the clear risks and benefits associated with clinical strategies that are offered to them. I consider this to be true informed consent – and what every patient deserves. In our current system we have not achieved this type of clear communication about key information.

Importantly, as part of the recently enacted Patient Protection and Affordable Care Act of 2009, Section 3507 requires the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs. The rationale is that this information will improve health care decision-making by clinicians, patients and consumers.

What would improved communication about Avandia discuss?

First, in terms of drug effectiveness, clinical trial evidence clearly demonstrates that Avandia lowers blood glucose levels, which we would expect to improve patients' management of diabetes. However, there is no clinical trial evidence that Avandia reduces the risk of heart attacks, a common adverse event for patients with diabetes, or improves survival.

Second, in terms of drug safety, pooled clinical trial data demonstrate that Avandia is likely to increase the risk of heart attacks and certainly increases the risk of heart failure, an equally dangerous event.

How clearly is this information being provided to patients? Are all patients who are taking Avandia aware of the known and probable risks of the drug? As I recently wrote in another editorial, I do not know why any clinician would prescribe a medication that is associated with such risk when so many alternative drugs are available on the market. So why does the drug remain among the most popular for diabetes?

Recommendations

We need to avoid drugs without proven clinical benefits and with proven risks. I strongly recommend that we clearly disclose to patients when we do not know if drugs have a beneficial effect . Patients need to be in a position to make a fully informed decision about taking a drug, which requires that they know not just that a drug lowers blood glucose levels, but actually lowers the risk of heart attack or death. Where there are no studies on the impact of the drugs on patients' lives – whether they help them avert adverse events – and live longer and better – then there needs to be clear disclosure in any promotional material.

These themes about transparency and communication are resonating throughout medicine. The efforts to improve quality of care are based on assumptions that data should be shared in order to provide a common understanding that will guide practice and policy. Such an approach is paying dividends in the area of quality of care; it can do so in drug safety as well.

Ms. DELAURO. Thank you both very, very much.

Let me ask you just right off the bat, Dr. Krumholz. Would this TIDE study that we are moving toward in 2015, and I don't know the scope of the trial, would that allow for the full disclosure of the raw data that you are talking about? Do we know that so as to get at the issue in terms of coming to some view as to what?

I have of sense of where Dr. Wolfe is coming from with regard to the TIDE study, but I want to find out if what you are advocating here, and very strongly advocating, which makes enormous sense, is that part of this effort. And is that the direction we are going in?

Dr. KRUMHOLZ. Thank you very much. Here is what I am saying. Almost 50 trials have been conducted with Avandia, and as of now, I know when I say raw data. It seems like inside baseball stuff. You know, raw data, what does he really mean by that?

I am saying that when you are forced to just look at summaries in spreadsheets and then sort of take the numbers from the counts that have already been summarized by others, then you can't standardize the analysis across the studies. You can't do the kind of sophisticated statistical work that is really required to make the very best and most definitive inferences about what it actually shows. So I am saying, tomorrow.

What I don't understand is the drug is called into question earlier in 2003, a little bit, 2007 with great force. Why didn't that mean an immediate call to say you know what? Tomorrow, we want all the raw data that you have upon which we made decisions about approval available to the FDA who is going to conduct their own independent analysis and get two independent, academic groups.

Maybe we can put drug A, drug B. We don't even have to tell the groups which drug is which. Tell us what you think these data show with the very best data that are available to me. That's the minimum of what we would expect, and we would want to get a speedy analysis and determination about whether we have a problem. Now, so, Congresswoman, that's sort of what we could do with what already exists.

TIDE is just trying to prevent information to us in 2015. I don't know who would sign up for TIDEs. I mean, I'm trying to think would any of us sign-up for a trial where we say, first of all, the comparison with Actos. I mean there are other options too, so both Actos and Avandia increased the risk of heart failure by about double. So they both have some problems, but more than that, I am asking you to sign-up for a trial to say, you know, I want to make sure one of these drugs isn't harmful. Would you mind joining the trial?

And, you know, you are going to go to one arm or the other. And the best result of this study is that you are not going to be harmed if you're in the group that we're concerned about. And I don't know how the informed consent writes. It's somebody says, "Well, what do I get out of this?" Well, you may contribute to medical research and you may be in the group that doesn't get harmed; or, we may find out, actually, that the group you're in that we thought was going to harm you didn't. I mean, it doesn't. I don't quite get how it works.

Ms. DELAURO. Should we stop it?

Dr. KRUMHOLZ. I think it should stop. I don't think it will help us make a determination about the trial.

Ms. DELAURO. Where do you think in terms of the issue of raw—is this on so I'm not taking up all the time?

Court REPORTER. It's on.

Ms. DELAURO. Okay. Dr. Wolfe, do you agree with Dr. Krumholz about raw data files, publicly available, not just the summary results, and how are we going to? What arguments are the companies going to use against such a requirement?

Dr. WOLFE. We have, as Dr. Krumholz has, for a long time argued that there should be almost immediate and complete access to all the data. If you were a company and you stand to gain $5 billion, if the data shows that the drug is safe and effective, and you stand to lose a lot of money if it doesn't, you will put your spin on it. And unless people who don't have a financial spin have access to the raw data, so they can actually look at it and see what it really shows—not what it shows in the best financial life of the company—we just can't trust the process at all.

And, we also as mentioned before have a difficult time trusting the process at the FDA when the people who approved the drug and seem too often to tenaciously hang onto the drug, no matter what kind of safety concerns are raised, are the decisionmakers. Dr. Jenkins in 1999 was amongst the people approving the drug, and now he's charged with the FDA's safety review on the drug. It is not likely based on what FDA has done so far that he is going to come out in what we would call the correct posture, which is this drug is too dangerous.

The trial, which is besmirching the reputation of FDA and this country being done all over the world should be stopped, so I certainly agree with Senator Grassley and others who believe that there should be much more independence within the FDA of people looking at this. And as Dr. Krumholz says, other people, even outside the FDA in addition should have a right to look at these data and help make the decisionmaking in a way that's best for patients or patients in clinical trials that should not be going on as opposed to what's best for selling this drug.

I meant to say when I showed or talked about those data that there four times more prescriptions for Actos than for Avandia, but that still leaves three million prescriptions in 2008 and probably not that many fewer in 2009. So there are huge numbers of people being exposed in the marketplace to a drug and then more in the human experimentation place. It's got to stop.

Dr. KRUMHOLZ. I will just add. I mean I believe that there's proprietary interest prior to approval. I mean companies are trying to develop drugs that have made substantial investments. They want to try to protect certain strategies that they are undertaking.

Once it's approved, I believe the privilege of selling in the marketplace, as I said, comes with the responsibility of providing. What would you want to hide at that point? I mean the drug is approved. You're out selling it. All of the information that is available to know about the drug should be in the marketplace of ideas about, you know, what does this drug do, what does it provide. And that kind of debate can occur in an unintimidated forum. And that's

what I'm not sure. I mean, and in this digital age it's not so difficult to pull together. If you can't as a company, pull together your raw data files, it makes me wonder about the quality of your internal research.

Ms. DELAURO. Let me make two quick points, and then I want to yield to Mr. Kingston. One is that as I understand it, as a condition of approval that the company was supposed to engage in a trial—an adopt—that's the adopt. Right. That took almost seven years to, you know, get done. That in and of itself in terms of where along the continuum there had been raised serious issues about what was going on with this drug.

But, I also just want to reinforce something that Dr. Wolfe said, that this is a testimony from Dr. Jenkins before the Energy and Commerce Committee—I say this for my colleagues so that this is not just made up—Dr. Jenkins says, "I was the senior member of the review team that reviewed Avandia back in 1999. I actually signed the approval letter for Avandia in 1999." Now, again, this is the individual who was doing the review of the review, so I think the point is well taken.

Mr. Kingston.

Mr. KINGSTON. Dr. Krumholz, I was wondering. On the raw data it is proprietary, and so what you're saying is the moment that the drug is approved and on the market, then it should be revealed.

Dr. KRUMHOLZ. Thank you. So, you know, that would be I believe the best case scenario that we allow the sort of transparency upon which the drug is approved. That kind of data can be available for analysis, but at the very least, when a threshold of concern about safety emerges from congress, from the public, from the agency, from other sources, there is some support for concern as there was in Avandia.

At least at that point, I mean, if we're not going to make it available on approval and I think that might be a bridge too far, that would be wonderful; but, let's just even talk about when concern are raised like this we should spring into action and say we need to know what can be known based on what's already done.

Ms. DELAURO. We being the FDA?

Dr. KRUMHOLZ. We being the public. We being Americans. I mean this is being sold. Our mothers, our fathers, our friends, our neighbors are taking these drugs. There should be people who can independently pursue this, and there's no reason for the data not to be available. And that's my principle concern. And, again, the Vioxx episode was instructive. Had that data been available, many people looking at it, three years before it was taken off the market, I think it would have emerged that there were issues that needed to be addressed; and that's what I'm advocating.

Mr. KINGSTON. You know, on the independent groups.

Ms. DELAURO. Dr. Wolfe, congressman.

Dr. WOLFE. Well, finish congressman. Finish your question, please.

Mr. KINGSTON. Do you have something on the questions?

Dr. WOLFE. No, just finish what you're talking about with him. I just have something.

Mr. KINGSTON. Just inspired, I want to say.

Dr. WOLFE. By you.

[Laughter.]

Mr. KINGSTON. Well, I'll yield to you in a second. I guess the question that I have on the independent groups so often in Washington and Senator Grassley had talked about the politicians and not necessarily meaning the elected politicians. But, you know, everybody in this town often has a bias. And, the independent groups, who would they be that, you know, because there are a lot of groups who make a living off "the sky is falling"—and it doesn't matter what the issue is—they're on all sides of it.

How do you keep it scientifically pure?

Dr. KRUMHOLZ. Yeah. I'm glad. I don't think there is such a thing as scientific purity, and people do come at these with different points of view and different relationships as well. That's why even my suggestion was, one, if it's in the public domain, there's many people who can look at it. You may hear different views of it, but at least it's getting it out there too.

If you can get two independent groups where it's even shielded, then that can give you more confidence about it. But any group that does it, and it could be there are lots of groups with expertise, academic groups and also companies that do this kind of work, they've got to be transparent on what they do. You know, nothing they do can be like here's the black box. We did a lot of stuff. Here's the results.

Everything they do has to be able to say here are the steps we took. Here's the decisions we made. Here's the results we found, because I don't trust, you know, you can totally insulate. Everyone's got a little point of view, but that's why when it's out there, no one's point of view is saying you haven't seen the data. I have, and here's what it says.

Mr. KINGSTON. Well, you know, one of the things that's coming out with the miracle, biological drugs that are coming out is that we have certain firewalls to keep the FDA approving the drug, talking to the scientists within the drug community who's developing it. And I think, you know, that's a well-intended firewall. Yet, at the same time, some of the stuff is so specialized that it's almost saying, well, you cannot talk to Einstein about the theory of relativity, since he developed it. And so I think that sometimes, that with good intentions we may have done something that we're not quite thinking through in terms of scientists. And I just wanted to comment on that.

Dr. KRUMHOLZ. I really appreciate that, and here's what I think when it comes to safety. I mean I should be able to explain it to my mom. I mean, you know, this isn't rocket science stuff. I mean I don't need to explain to her the underlying mechanism of the drug. I don't need to explain to her the theory of how all this works and what's going on in the human body. She just needs to be able to count.

Mr. KINGSTON. Well, no. I'm talking about inside the FDA. Should the FDA be able to talk to the scientists who developed it?

Dr. KRUMHOLZ. Yeah. I don't believe we should be separating people in different corners where they can't talk. I mean there are a lot of discussions about how these kind of interactions should occur. There are low integrity and high integrity interactions at

every different level of groups, and I think in the FDA we want to try to promote high level, high integrity transparent conversations.

Sometimes, they have to occur proprietary, because they're early in the development. But you want the people, I think, to be talking to the FDA about what the path is, but the data needs then to be really clear and open.

Mr. KINGSTON. I am watching with a lot of interest the reform of derivatives; and, the more I've looked into that, the more I've realized how few people know it.

Dr. KRUMHOLZ. Understood it.

Mr. KINGSTON. And so I do think a lot of this is talking to each other and more information, and trying to keep a high firewall.

I was going to yield to Dr. Wolfe. I don't know where the time is. But, I did want to ask you how was Dr. Cruze forced to sign this paper?

Dr. KRUMHOLZ. Dr. Buse?

Mr. KINGSTON. Buse, excuse me.

Dr. KRUMHOLZ. Well——

Dr. WOLFE. Well, the company literally made threats to him that, "If you don't keep quiet, we are going to get you in trouble with your university," whatever. It was fairly intimidating. And I think that, you know, anyone in that position would be intimidated.

He fortunately, as I mentioned, signed off on this document saying unanimously, "Don't use this drug," so the intimidation didn't work very well. But it's very unseemly, it's——

Dr. KRUMHOLZ. Well, they sent somebody of a high level, who was a prior academic and then in industry, to his boss——

Dr. WOLFE. To try and get him in trouble.

Dr. KRUMHOLZ. And his boss talked to him, and I think he thought it's not worth the aggravation. I mean, what are they going to do? They're not—there is only so much they can do. But they can make it uncomfortable for him. And they—according to documents that came out of the report, they—when your boss calls you in and says, "You've got to stop this," you can either say, "I don't care what you say," or you can say, "It's not worth the aggravation."

Ms. DELAURO. Let me just—and, Congressman Kingston, I will make you a copy of this—this was the report that went before the Finance Committee, "The Intimidation of Dr. John Buce and the Diabetes Drug Avandia," and it talks very specifically about who did go to see him, and who communicated with him.

And he wrote—and they referred to his letter as a retraction letter. They used it, quite honestly, pretty politically to make a demonstration. He said, "The company's leadership contacted my chairman and ensured an ugly set of interchanges occurred over a period of about a week, ending in my having to sign some legal document, in which I agreed not to discuss this issue further in public."

He ended his—it says, "I was certainly intimidated by them. It makes me embarrassed to have caved in several years ago." But I will get you this document so that you can take a look at it. Thank you.

Mr. KINGSTON. Thank you.

Ms. DELAURO. Mr. Farr.

Mr. FARR. Thank you very much, Madam Chairwoman. We appreciate having this hearing. And the FDA is always coming out in national polls as the one entity of government that people usually trust. And I think it's got the highest ratings of anything in the Federal Government. And it's interesting, we spend very little time on drug issues, because most of it's on agriculture. But on the whole food safety issues before us, the concern here is that the FDA would over-react to put small farmers, organic growers out of business, because it would require that everything be grown in a sterile environment.

But it's interesting that we are using today's hearing to talk about, you know, erring on the side of caution on prescription drugs. As I read the Department's annual—they put before this committee the whole, you know, explanation of what they're responsible for, and it says that the Department is responsible for ensuring that prescription, generic, and over-the-counter drug products are adequately available to the public, and are safe and effective. The program is also responsible for monitoring all drugs that are marketed in the United States for unexpected health risks, and for monitoring and enforcing the quality of those drug products.

It seems like Senator Grassley's statement says that the FDA does not even have a complete or accurate list of all the products that are sold in the U.S. market, including unimproved drugs, so that the Agency has no ability to take the enforcement responsibilities that they have. And you are pointing out that they're just—they failed to, essentially, recognize, in approving the drug, just recognize its risks.

So, my question really goes, doesn't this open up a huge liability issue, if the responsibility for the Federal Government is to ensure the safety of this? And that our safety checkers are erring on the job? And what does it do for your—in your world of practicing physicians who prescribe these drugs—they still have to be prescribed—what risk does it open up to them?

It seems to me that this is—could—I mean, it's huge litigious issues here.

Dr. WOLFE. Yes. Well, I mean I—Dr. Krumholz, I'm sure, will have something to say on this also.

I am reminded about three or four years ago Congresswoman DeLauro had a hearing on drug safety. And Dr. Woodcock, who is head of drugs at the FDA, was a witness, and I was a witness. And at 8:00 the night before the hearing, the FDA suddenly announced that they had a new initiative, and it was called, "Safety First," and we all wondered what was going on before then.

I think the FDA should be leading in drug safety in this country. And, instead, it's really following in drug safety. When the American Diabetes Association says, "Don't use this drug," when most physicians are rejecting the prescribing of it, where is the FDA? They have had the information. They really haven't done anything. We warned readers of the newsletter that Congresswoman DeLauro held up years ago to stop using this drug. We warned them to stop using Vioxx many years before it came off the market.

So, when there is enough data to look at it objectively and say the benefits are clearly outweighed by the risks, why is the drug on the market?

Mr. FARR. Why would—with that information, why would doctors still prescribe it?

Dr. WOLFE. Well, the company——

Mr. FARR. Because aren't you at risk in doing that?

Dr. WOLFE. Doctors are frequently influenced by the drug industry. Some Canadian researchers estimated a couple of years ago that $52 billion a year is spent in this country advertising and promoting drugs. And one of the main sources of information for too many doctors is the drug company, as opposed to reading articles or going even further. There is a lot of information on FDA's website, which most people don't know exists, that the average practicing physician doesn't have a chance to look at.

So, the prescribing practices are not terrible, but they could be much worse if doctors got more information, if patients got more information. Just as we said——

Mr. FARR. So——

Dr. WOLFE [continuing]. No one fully informed about this TIDE study would ever participate. No patient would knowingly allow their doctor to prescribe this drug if they knew about the risks of the drug.

Mr. FARR. Well, yes, and I think that goes to Dr. Krumholz's point of transparency.

The one question I have—I mean, here we are in politics, and we—you know, everything we have to do is transparent, to being a candidate for office, and certainly transparent on everything, your whole—sources of income, everything like that.

But what you see in this field is also what you call hit pieces, where the opposition takes that information and turns it into a negative. You have a lot of competition out there, a lot of money to be made on these break-through drugs. And, boy, if you get one, your company and your stock is going to go crazy.

What would prevent an adversary company, knowing that there is about a break-through development, just doing everything they can to poison the process so that you really don't have any fair judgement about—I mean, I believe in transparency. Obviously, we live on it. But on the other hand, I think you're seeing a lot of misinformation in America right now, and people believing the misinformation.

Dr. WOLFE. Ten seconds, and then Dr. Krumholz. The point that Dr. Krumholz focused on, transparency, if things were really transparent and independent people were able to look at it, the ability of a renegade company or a company like that to be able to undermine something like that would be severely limited. It's because so much of this information is secret and not available to everyone that things like that could go on.

Dr. KRUMHOLZ. Yes, I think that's the best way to prophylax, is to have information available and have people be able to use it.

But you know, I think you're identifying a key issue here, which is that—and that's why I talked about transparency, I talked about being able to analyze the best data, and I talked about communication. If you've got three million prescriptions still going on—I can't—in our area I've talked to the diabetologists. I said, "Who is using this drug, still?" None of them are using it. But people are.

A lot of people still are. And there is a lot of promotion of the drug still, now.

And you look at azitamide, for example, a cholesterol lowering drug, I mean, everyone said this should be a drug of last resort, because we won't know if that drug is safe and effective until 2013—after the drug was introduced in 2001. I mean, this is replaying out in many different scenarios. And even though everyone says, "Look, it's okay. We don't know if it's harmful"—we don't have the information on harm like we do here—but you know, that "we won't know for a long time," it's still selling, you know, two billions of dollars of drugs.

Phenofibrate was just shown in two trials not to be effective. It's a $1.3 billion drug. I mean—and it's a lot on the promotion.

So it's, I think, our job to make sure that the data upon which we have this is out, and that the communication is clear. And you're absolutely right, there is risk for people doing things. But the truth is it's on the market. So the assumption is, if it's on the market, it must be okay. And, you know, we need to get out clear messaging, I think, and that's——

Mr. FARR. Do you think that Senator Grassley's bifurcation of the FDA's responsibilities is the right way to go?

Dr. KRUMHOLZ. Yes, that's another issue. But I do think it's very hard for the group that was invested—just cognitive psychology, you know. You made a decision, and for you to go against that decision, some of the data which still may have been even knowable back then, it's very difficult. I think an independent group that has no dog in the fight, that basically is empowered—we do have to encourage innovation.

I mean, we have a fine balance here. We don't want to create so many barriers and difficulties that we can't get new and important drugs out in the market. So I don't think—you know, it's this balance we have got to strike. And—but on the side of safety, that's why I'm pushing for the transparency. Let us know what can be known, and then let us figure out what we need to know in order to move forward.

Dr. WOLFE. In terms of the bifurcation question——

Ms. DELAURO. If I could just interrupt for a second, Doctor——

Dr. WOLFE. Yes, please.

Ms. DELAURO [continuing]. Because we will get to that.

Dr. WOLFE. Yes.

Ms. DELAURO. I want to try to get to Mr. Hinchey's questions, because Farr's time has run out. And so let me go to you, Mr. Hinchey.

Dr. WOLFE. We need to talk to more pharmacists.

Mr. HINCHEY. Well, I hate to interrupt you.

Dr. WOLFE. No, no, please go on.

Mr. HINCHEY. This is fascinating. Thank you very much, Madam Chairwoman, and thank you very much for drawing attention to this issue. This is critically important, and it's, in a perverse way, fascinating. And it's clear that the motivation of money to be made is one of the driving forces in the context of dealing with this issue, and dealing with it in ways that are harming so many people. So, Dr. Wolfe and Dr. Krumholz, thank you very, very much.

I want to also express my appreciation to Senator Grassley. And I share his views about ensuring that there is an independent office within the Food and Drug Administration that would be responsible for post-market drug safety, and that can analyze scientific data and solicit the opinion of experts without fear of reprisal or interference from the drug manufacturers.

And, coincidentally, I have introduced the FDA Improvement Act, which creates a center for post-market drug safety and effectiveness, independently, in the context of the FDA. And—which will provide an independent opinion about drugs currently on the market. And I think one of the main reasons that I have introduced the FDA Improvement Act is because I believe the relationship between drug manufacturers and the FDA has become much too close, and it has resulted in action or inaction, not in the public interest. In fact, as we have seen, very contrary to the public interest.

Dr. Wolf, I wanted to ask you, can you elaborate on the results of the clinical trial conducted by GlaxoSmithKline that was ordered by the FDA? And you talk about it, and you state in your testimony that many of the participants who took Avandia died during the trial, as I understand it. Is that correct? They died during the trial?

Dr. WOLFE. Well——

Mr. HINCHEY. Why hasn't the FDA stopped the trial?

Dr. WOLFE. Well, I was talking about the trials that were finished. In the trials that are finished, both the one that Glaxo did, the record study, and in the retrospective study done in Canada, there was an excess of people dying—being hospitalized. There is no question those studies are over now.

And what I was saying is that the study that the FDA ordered, the new one, the TIDE study that's just beginning a year ago, is continuing to do the same thing. In other words, Einstein made the most cogent definition of insanity, which is if people keep doing things and expecting different results, that's what insanity is. Once you have done enough studies to show the drug is harmful, why do more studies?

And I think it's particularly bad, because the FDA wonderfully—thanks to the congress—has this new authority in 2007 to order companies to do studies. And they should be using the authority to order them to do studies that are ethical and that are going to provide new information. And this study doesn't do any of that, and that's why the FDA needs to stop it before people in India or Pakistan or Colombia or the United States or Canada are further damaged, as the predecessors were in the studies you're referring to.

Mr. HINCHEY. Thank you very much for that. Would you—do you believe that an independent post-market drug safety office would help prevent things like Avandia-type incidents in the future? And what other changes would you have us make, or recommend for us to make within the FDA, to improve the oversight of drug safety?

Dr. WOLFE. This is now—I find it hard to believe, myself—this is the 39th year since I left NIH to start doing this kind of work. And a chronic theme that has never changed—if anything, it's getting worse lately—is the lack of independence of the people who are skilled, expert in epidemiology and drug safety, to have their views acted upon. It's always been going on.

They've changed the name of that office four or five times in response to criticisms, but the function and the dependence and the subordinate position of that office, compared to the office of new drugs, has stayed the same.

So, the legislation you've introduced, the legislation in the Senate, really needs to be passed. It needs to be in the FDA. There are some people who think that it should be outside the FDA. I think that's not a good idea. Your legislation says, "Let's have it in the FDA, but let's have them do things that can be paid attention to."

The list of drugs that the people in the office of drug safety—to simplify its name—have said are dangerous and should come off the market keeps growing and growing, and it takes way too long for this to happen. They just—the funding—you know, this year more than $700 million in drug industry money—goes directly to the drug part of the FDA. Most of it is used to pay for the review of drugs.

So, this office of new drugs that keeps putting its thumb on the safety people is getting a huge amount of money. They should be getting money to do their purpose, but they shouldn't be getting it from the drug industry. It's clearly having a negative impact. So repealing that law that funds the FDA through the drug industry is just as important as the legislation you're talking about, which is separating out, empowering for the first time, the drug safety people.

Ms. DELAURO. That law being PDUFA. Mr. Kingston.

Mr. KINGSTON. Thank you, Madam Chairwoman. I wanted to get back to the question on the malpractice, because how exposed are doctors on this? It would appear to me there would be a lot of concern in the individual practice. Even though I understand the influence that the pharmaceuticals might have on them, it still seems like they would be cautious.

Dr. WOLFE. Well——

Mr. KINGSTON. And maybe that's what is driving this, as much as anything.

Dr. WOLFE. Yes, there is a precious small amount of litigation against doctors for prescribing problems. There is a small amount of it. But not very much. It is not very big, in the scope of all litigation brought against doctors.

And, of course, if you are the company, as long as the drug is on the market and your lawyers tell you, "Put enough warnings in there so that if these doctors still prescribe the drug it will be on their ticket and not on ours," that's part of what happens with labeling. But that, of course, is not the issue with a drug that shouldn't be on the market in the first place.

I guess the only—Dr. Krumholz was just talking about before what would you put on the label of Avandia that would take care of this, and it should say, "Do not use." But "Do not use" means that the FDA screwed up and left it on the market when nobody should be using the drug.

So, I think that your point is a good one, that some doctors may not be prescribing as much, not simply because of a fear of malpractice on that issue, which isn't very good, but because they don't want to practice bad medicine. I don't think any doctor intentionally wants to harm their patient.

And they see studies showing increased heart attack, and then they see other studies with heart failure and so forth. They say, "Why not prescribe another drug that works through the same mechanism"—Actos, for example—"or why not, even better, prescribe these older drugs that are safer, we know more about them, there are fewer surprises?"

So I think that, in the sense that you're talking about, the marketplace, as in doctors' prescribing practices, are moving in a better direction—not fast enough, but they are way ahead of the FDA, which is sort of frozen on this issue.

Mr. KINGSTON. Dr. Krumholz, let me move to another question, and let you answer this and, if you want to, backfill some of this stuff.

In terms of international testing and international record-keeping, how standard is it and how practical is it to be able to take Canadian tests or European tests and shed light on a question like this?

Dr. KRUMHOLZ. You mean studies?

Mr. KINGSTON. Yes. Excuse me, yes.

Dr. KRUMHOLZ. Yes, it's not a problem at all. I mean there are standardized approaches. They are actually getting these trials together for the FDA. I mean they need to follow standard principles, in terms of studies, and——

Mr. KINGSTON. Is their data more accessible, particularly the raw data?

Dr. KRUMHOLZ. In other countries?

Mr. KINGSTON. Yes.

Dr. KRUMHOLZ. I'm not aware that the companies are making—no, because we would get access to it, too. I mean, nobody is doing this. And what I don't understand is, again, once millions of people are taking this, why that transparency doesn't exist, why we can't promote that.

I want to just quickly—just to give you some insight, because you may be puzzled, like, "Why is anyone prescribing this drug?" There are a couple of things that happen. One is, in medicine, we become enamored of making people's lab tests look good. I mean, this drug makes people's lab tests look better. We think, if we lower their blood sugar levels, it's better for them.

The truth is it may or may not be, because some drugs actually have beneficial effects, some don't. Just like cholesterol, there are some drugs that lower cholesterol that actually even can cause harm. Some drugs that lower cholesterol can have benefit. Drugs have thousands of effects. When we measure one singular effect, like what does it do to a single blood test, it doesn't often tell us what it does to the person in their life. You've got to study that in these kind of trials.

So, a doc uses it, they're used to giving it to patients, they see good lab tests come back. Some people are hedging whether there is harm. Some people have different relationships. When you have statements that say it's harmful, they are in documents that, you know, sometimes not everybody sees. Meanwhile, they are getting a lot of promotional material. And they are thinking about thousands of decisions.

And so, it's sort of easy to kind of stay with the status quo, and it takes something strong, some strong messaging, to overcome that.

Mr. KINGSTON. Well, let me ask you about the status quo, because a lot of drugs say, "Do not take if you're pregnant, or if you have a heart disease," or if you're older, or whatever. Maybe there is something else that we need to know about that people should be cautious of, and I don't know what it is.

But it is true that some drugs work for some people and they don't' work for somebody else, and we're not sure why, right?

Dr. WOLFE. Well, I don't think there is any identifiable group of people for whom this drug has benefits that outweigh the risk. I think that what you're—we are all in favor of the FDA maximally using its ability to warn, educate doctors, patients, for a drug that has some unique advantage. But, as mentioned earlier, the main thing that adult onset type II diabetics die of is cardiovascular disease. And, therefore, the test of a diabetes drug is does it decrease cardiovascular disease? When it increases cardiovascular disease, something is very, very wrong, and the drug just shouldn't be around.

So, instead of saying, "Well, if you could identify a group of people that shouldn't use it, and others who have benefit, leave the drug on the market," no such group has been identified. Of all countries—because, in other ways, they are not that progressive—Saudi Arabia banned this drug recently because they did not think that there was any evidence that there was a group for whom the benefit outweighed the risk.

Dr. KRUMHOLZ. But let me say it's a good question. I mean, are there responders and non-responders? And you always want to look for it. So far, there hasn't been a group.

The other benefits for diabetes drugs could be decreased amputations, blindness, kidney function, there is a whole range of things that we're interested in. And so far——

Dr. WOLFE. A lot of them are cardiovascular-related, though, right?

Dr. KRUMHOLZ. And so far, this drug hasn't been shown in that area, either.

Ms. DELAURO. With regard to FDA standards and the overall—there seems to be we have got systemic failure here at some level. But you look at the FDA standards. This is a Wall Street Journal article recently that said that, "Senior FDA officials have asked their staff to review how FDA makes decisions about drug safety and in particular what evidence it needs about a drug's risks to take it off the market."

Now, I commend and appreciate the drug safety decision that the agency is now making to take a look at that. You know, that is as I said commendable. But it is a little stunning to read this. It is a little bit about safety first within less than 24 hours of a hearing on safety. Shouldn't the FDA have known for years what evidence it needs to take a drug off the market? What is the systemic failure within the process now that—you know, which there is Avandia there is Vioxx—there may be, there are lots of examples of the failure here. How do we begin to look at addressing that failure so that we are not five years from now trying to figure out what the

process should be? I think that is the fundamental issue that we need to grapple with here.

Dr. KRUMHOLZ. Thank you. I think that is a very important comment, and I guess what I wonder as a citizen—I mean I don't know that I have special knowledge of what they should do, but I mean where is the emergency?

Dr. DELAURO. You do.

Dr. KRUMHOLZ. Well where is the emergency response? You know, once—where is the predictable triggering of events? It is sort of like preparedness, right? I mean, we know that even with best intentions and best data we can approve drugs that we are going to learn about as they are taken by millions of people. The companies should want to know with clear transparency what are the steps that are being taken and what are the expectations. It is not good for them either to be uncertain about this kind of thing. And there should be clear protocols processes.

It is just preparedness saying—you know, no one should be surprised and when something like Nissen's article released in 2007, we should not be in 2010 saying we still don't have all the data, we still don't have all the facts, and we are in the same place we were when this came out. After the companies own med analysis said there was a 30 percent increase in heart attacks, after four other or three or four others came out and said it, and nothing that has come that has come out since has been sufficiently reassuring to say that this isn't the truth.

Now, it may be that the FDA says well, with kind of risk and no unique benefit we think it should stay on, and they can justify that. But it has got to—so, okay. Where is the process? But that should have correlatively quickly. I just don't think three years down the line we are still wondering, what is the exact process by which this should happen? I mean we should know this is predictably occurring and how do we deal with it?

Ms. DELAURO. Well, the thing about it—let me just interrupt for a second. The fact of the matter is, is that as I understand it, the company Glaxo would not accept the fact of an independent review by Dr. Nissen, but said that their statisticians had to examine the information.

Now, what I also want to figure out—yeah, there is clearly you know, the company piece, but there is also an FDA piece here. And where we set out the parameters or the guidelines or the dictates of what needs to get done when you are looking at those results. And I will make this one point before I kneel to you Dr. Wolfe—whenever we get into the difficulty and there is a question asked to the science, the outcome, we always we always appear to act on behalf of the industry. Whether it was Vioxx and four years later this drug and now it is a number of years later. We do not act saying, okay we have a—the notion is let us leave this go on for another several years while more people die before we truly do address it and err on the side of public health.

Dr. KRUMHOLZ. Well, so I agree that it is important to be erring on the side of public health. I want—I envision a world where we are basically we are not polarizing, we are basically telling the companies this is the way business gets done. We want you to make a profit. We want you to do well by doing good. We want new

products that are going to enhance people's lives, but we also need to work together. And as representative Kingston said, "You know, there is no necessarily independence since we have to bring it out of the companies, we have to get the real data, we have to say is this all of it? And we have to decide what it says and then make decisions based on it."

But you are absolutely right. I mean the tail can't wag the dog here. I mean basically the public's interest is what should dominate and—I totally agree with you.

Ms. DELAURO. Dr. Wolfe and then Mr. Farr.

Dr. WOLFE. One place the FDA to my knowledge hasn't begun to look in this little process you described is other countries. As you know, because I sent you a copy of this letter, I wrote to the FDA a couple of months ago saying, "Here are three drugs. We have asked you to ban all three of them. None of them have any unique advantage in terms of effectiveness. Two of the three: Darvon, Darvocet and Meridia sibutramine, the diet drug, have been taken off the market in Europe. The third which is Avandia has now been taken off the market in Saudi Arabia." So, why is that other countries have a mechanism that when for drugs that don't have any unique benefit there is well documented risk that clearly outweighed whatever benefit minimal though it may be, they moved to take these off the market?

The FDA as Dr. Krumholz just alluded to sort of—the default is, well, it doesn't have any unique advantage. It has some clear risk but we just aren't quite up for taking it off the market. I mean I have had many conversations with Dr. Woodcock about this and she is just uncomfortable being a regulator. And I think that for someone who is the heads of drugs at FDA, being uncomfortable with being a regulator is incompatible with being the head of that division. And example after example after example are occurring.

We are a laughing stock of other countries for leaving these drugs on the market. We are going to be more than the laughing stock of these countries when we are doing what FDA insisted on in this trial in Pakistan, Colombia, et cetera, et cetera, et cetera. So I think that there is something wrong with the decision making but they seem to be approaching it in a theoretical kind of way and not being that interested in the individual examples. What went wrong?

I mean, when I was a resident in medicine if someone died and you didn't understand what was going on, 70 or 80 percent of the time we had an autopsy done, and you learned something. The FDA seems very reluctant, resistant to doing an autopsy on the mistake after mistake after mistake after mistake they keep making. One thing that they would conclude as just alluded to by representative Hinchey is that part of the autopsy is because they didn't listen to some of their own scientists there. I mean every one of these instances where another country is taking a drug off the market, we haven't.

There are people in the FDA who said it has no unique advantage, it has unique risks, get it off the market. No one paid any attention to them. So, the process is really filed off. It needs to be changed before more people die from these drugs. The three drugs that I wrote you about—wrote this to Commissioner Hamburg and

Deputy Chief Commissioner Sharpstein, 25 millions prescriptions a year for the three drugs. More for anything than—you know, more for Darvon. But, these are people being exposed to drugs, being injured, killed, with no hope of any significant benefit.

Ms. DELAURO. Very very quick because my time is about to run out, but are there other countries that you speak of Dr. Wolfe, have they separated out the function of new drugs and then the review process?

Dr. WOLFE. The FDA has more employees and drugs than the entire rest of the world combined. And I am not sure they even in some countries get to that level of sophistication. But they are more attuned to the public health than the FDA seems to be and are protecting the public instead of protecting companies.

Ms. DELAURO. Thank you. Mr. Farr.

Mr. FARR. I want to follow up on that question, although I don't want to beat a dead drug but——

Dr. WOLFE. Please do.

[Laughter.]

Mr. FARR. We have experienced where the Secretary of Transportation in 9/11 that day shut down every single aircraft in the air immediately over U.S. airspace. We saw the FDA demand—and it is a voluntary recall of all the spinach in the United States, whether it was in your refrigerator, whether it was in the store, whether it was on the way to the store in trucks, whether it was in the growing fields in my district because that is where most of the spinach is grown, and they did it immediately.

When it gets to drugs why can't they just stop it? I mean why don't—is it a liability issue? We got into a discussion with them on sort of the crisis communication. I mean was it a smart thing because we—what happens is that if—I think this is the case—if the government orders a destruction particularly in livestock or anything like that, then there is a taking and you have to compensate for it. They didn't really have the authority to demand a recall on spinach so it was a voluntary recall. But everybody thinking, well if the government asks for this we are going to comply because we want to be good stewards of the product; a lot of people have died from this, but we will probably get compensated. And they didn't. So that was a whole issue of how you do it.

Is that the issue? Is it they are worried that somebody will file a lawsuit because there is a taking because you have decided this drug is no longer effective, and it is dangerous, and it ought to be off the market? I mean you said something Dr. Wolfe about a number of drugs that are out there that have already been banned and are still on the market.

Dr. WOLFE. In other countries.

Mr. FARR. Oh, in other countries. But when we ban them in this country they are no longer on the shelves. I didn't know whether they——

Dr. WOLFE. Well, right. I mean they may be in people's houses and everything. I mean, it is interesting you mention this food example because the thing that precipitated my writing in March to the FDA was the FDA wisely, cautiously ordered a recall of thousands of food products that had these textured vegetable proteins because there were some bacterial contamination. No one had got-

ten sick yet, no one had died. They though correctly from a public health perspective, that is the thing to do. It is similar to——

Mr. FARR. Err on the side of caution.

Dr. WOLFE. Err on the side of caution. And yet quite the opposite in the drug area there. Erring on the side of recklessness.

Mr. FARR. What is that? Why not? Is it a liability issue? What is it?

Dr. WOLFE. It is bad judgment. Whatever it is, it is obviously affected in not a case by case basis by taking $700 million a year from the drug industry; there are a bunch of things. The drug industry has enormous power here. There are more drug lobbyists than there are total members of the House and Senate. So they have a huge amount of power in Washington, and to me it isn't surprising. It should be unacceptable that this keeps going on drug after drug after drug after drug.

Dr. KRUMHOLZ. I will just say it is a very complicated situation. And in the case of someone eating bad spinach or meats, I mean you actually can identify the person who dies. In this case, it is probabilistic. A bunch of people take the drug, there is a 30 percent increase in risk of heart attacks, so that gets kind of deluded. You give it to them, their blood sugar gets better. People are getting lulled into a sense of security. The company gets out to keep opinion leaders, and academics are giving talks who don't emphasize the problem. There are articles that are ghost written, and I am talking generically within the institute, there is marketing efforts and this information doesn't always get out.

Mr. FARR. But as you said we have a cop in charge of this. We have somebody whose responsibility and judgment, professional judgments are hired for. There has got to be an MD or I think. Don't they have to be——

Dr. KRUMHOLZ. I think it is where the thermostat is set. So on the food side it seems like the thermostat is set if there is a concern let's be safe. On the drug side I think the thermostat said—you know, and I have often said, where is the burden of proof? Isn't the burden of proof on showing it is safe not assuming it is safe until beyond of a doubt it is proven to be harmful? I mean, I think that is too stringent.

I think in efficacy when you are actually trying to show benefit and you are going to give people drugs, it should be beyond a shadow of a doubt that it is beneficial. On safety, if more likely than not this is causing harm, I think I have to say that we have to wait until we get more information, we can be reassured. I think there are two different thresholds. Benefit, you need to really be sure unless it is a disease for which there are no options, and there is you know, people are desperate for anything. But in most cases they really need to have strong evidence about benefit to get out there. Safety, it shouldn't be probably safe. It needs to be we are very confident about the safety.

Ms. DELAURO. Mr. Hinchey.

Mr. HINCHEY. Thank you again Ms. Chairman. This is very fascinating and it is something that is very very important. And one of the things that you keep pointing out I think is the relationship, well not directly, but the relationship between the FDA and the prescription drug companies. And I think that the questions that

were just asked show how the FDA can work very effectively, be very positive, do good strong things. And how at other times it can be very very bad not doing the kinds of things that really need to be done.

I was really amazed learning about that problem with Avandia. That the FDA ordered GlaxoSmithKline to conduct a safety study, and then it later labeled that safety study as unethical.

Dr. WOLFE. We labeled it as unethical. The FDA thinks it is very ethical thus far unfortunately.

Mr. HINCHEY. Yeah, right. They do. That is right. So it did not disclose the opinion of the volunteers participating in that study. That was—the whole thing just seems to be quieted down or secret now in some ways. Does the FDA have procedures that it failed to follow that would have required it to disclose its concerns to those volunteers and elsewhere?

Dr. WOLFE. Well, what you are talking about is the informed consent. We have seen the February 2009 informed consent sheet and there were some things lacking on it. It is said, and we have not been able to get a copy of it, that the informed consent sheet is better now. It is not possible that the informed consent sheet remotely reveals all of the information that should be there. If it did, it would come to the same conclusion as the American Diabetes Association which is you shouldn't use the drug. It would not be recruiting subjects for an experiment if the conclusion was don't use the drug. I mean if the American Diabetes Association information was on the sheet, the informed consent sheet was we diabetes doctors say don't use it, I don't think a lot of people would sign up for the trial.

And in fact, even with what I would bet is a less than adequate informed consent sheet, there aren't a lot of people signing up for the trial, which is why I think they are desperately going to all these other countries around the world to try and recruit more people.

Dr. KRUMHOLZ. To be fair and just so you know what others would say is they did all have to go through institutional review boards so the—ethics boards that have approved this study in order for it to go forward. What seems strange is if we wouldn't use the drug anyway, why would you randomize people to be on it just to prove that maybe it is not harmful? It seems to me, I don't understand it but, I mean just to be fair I am going to let you know that people are going to say that investigators are going to say we went through institutional review boards.

Dr. WOLFE. But I am not sure. I think that is absolutely correct, and I think that the initial decisions by some of these institutional review boards to approve the study were not informed now with the new information that keeps coming out on the newer evidence of risks.

Dr. KRUMHOLZ. And they are not expert in this area, and may have assumed if someone is bringing it forward that it is a reasonable effort equipoise.

Mr. HINCHEY. What do you feel about the post market drug safety operation? Should that be put into play? Is it going to be positive?

Dr. WOLFE. Well, 30 years ago as opposed to now, if there were safety questions about a drug it would be more likely the FDA would say, okay, well let's wait a minute, let's get the answer. Now, too often they say, well yeah, there are some safety problems. Let's approve the drug and do a post market study. And now the FDA has the authority to fine companies if they don't do these and so forth.

But the idea of waiting until after a drug is mass marketed to find out things about it particularly if it doesn't have any unique advantage, as opposed to finding it out before it is out of the barn door, just does not seem like a good thing. Clearly, the number of post marketing studies that have been recommended or asked for by the FDA has gone way up and in many cases they should have held the drug up.

Mr. HINCHEY. Dr. Krumholz, what do you think?

Dr. KRUMHOLZ. Well you know, I think these are critical studies. There are some things that you can't know until millions of people take the drug. I think that we need to have oversight about what the experience is, particularly around these new drugs with novel mechanisms for which we don't have a lot of experience and we are uncertain about what is going to happen to people. I think that information needs to be widely shared. We need to be able to follow it and there needs to be independence of that group that is doing it.

I worry about the mice guard and the cheese if you are really putting it in position where basically you got a company where they can drag their feet or—I mean again, these need to be independent efforts in which we are all working together for the common good. And again, there are many good people in these companies who want to know the answers. It is when marketing mingles with science that we get into trouble. But there are many good respectable highly admirable individuals, and we need to bring those people out. We need to work together and we need to create independence of that post marketing experience; it is very important.

Mr. KINGSTON. In NASA or space exploration, had they been in charge of Europe during the days of Columbus, we would probably still be living in Europe. I feel they have become very risk-averse.

And, as you know, I mean, that's the tendency of a bureaucrat, is to—safest way to deal with something is not to make a decision. And that's a concern that I have. Because, you know, one of the balances here is that if you're a drug company and you've got this sweetheart deal of keeping your patent on the market now for—is it 12 years? Then, you know, really, you know—no, I think it's been extended now, under the health care bill, from 5 to 12.

Ms. DELAURO. No, that's Biologic.

Mr. KINGSTON. Biologic, okay. But you know, you don't really care if—I mean, you do care, but you know, there is a monetary incentive not to have a new drug out on the market—get out there.

And so, if you have FDA, who is too risk-averse, not wanting to make decisions, and a drug company that maybe can wink and nod about the whole thing saying, "Well, you know, we've got a new drug coming down, but—can't get it done, but in the meantime we've got our 5-year"—and 12-year, if you're Biologic—"patent," that could also be a formula for disaster.

So our, you know, concerns could have an effect that we're not thinking about.

Dr. WOLFE. Yes, I—this is an issue that comes up from time to time. We are all in favor of drugs that appear to be break-through drugs, really adding an important thing to what we can prescribe for patients, getting approved as quickly as possible and as safely as possible.

It's interesting. The drugs that wind up being discussed here, none of them are really break-through drugs at all. So it's really a matter of slowing down, putting the brakes on the drugs that don't even arguably have some reasonable theoretical advantage, and letting FDA spend more time, and more quick time, on the break-through drugs.

This country is really not in any kind of problem because there are drugs that should have been approved that haven't been. It's quite the opposite. I mean, there used to be a myth about 30 years ago called the drug lag. And there was a commission which Congressman Gore and former Congressman Scheuer were on, and they could not find any example of a drug that had gotten on the market—an important drug that had gotten on the market—in any other country before the United States.

So, I think that the concern is there. But all the drugs that get in trouble, by and large, are these me-too drugs that really don't offer any advantage. And it's—if the FDA asymmetrically says, "Let's put the brakes on those, and, if anything, speed up safely the break-through drugs," I think we will all be fine, and the concerns that you and others have would just not be carried out.

Dr. KRUMHOLZ. Yes, we tolerate safety issues in drugs that provide unique benefit.

Dr. WOLFE. Cancer drugs, for instance.

Dr. KRUMHOLZ. But it's a question of the balance.

Dr. WOLFE. Right.

Mr. KINGSTON. Thank you. Yield——

Ms. DELAURO. To that end, there are a number of drugs approved for type II diabetes. So, I mean, it's the whole issue of, you know, some of the drugs may offer benefits that are less—where you're at less of a risk. And you know, but yet we move to these other efforts.

Dr. WOLFE. Well, I mean, this record study that Glaxo did pretty much showed that. Looked at—old diabetes drugs are safer, more effective——

Ms. DELAURO. Oh, my God.

Dr. WOLFE [continuing]. Than the new ones. As——

Dr. KRUMHOLZ. And, let's just say——

Dr. WOLFE [continuing]. In Rosiglitazone.

Dr. KRUMHOLZ. And less expensive. I mean, as the health care system is looking for value, it's actually the——

Dr. WOLFE. Yes.

Dr. KRUMHOLZ. Anyway, those are——

Ms. DELAURO. Let me—a couple of pieces—well, one of the things that is coming up, can you ever have these post-market surveys run by the company that—are you going to have some independence? I mean, there is—you think we can——

Dr. KRUMHOLZ. The companies shouldn't be running the post-marketing surveillance.

Ms. DELAURO. That's—yes, okay.

Dr. KRUMHOLZ. Yes, right.

Ms. DELAURO. Again, my—you know, one of the—we're talking about, you know, independent review and looking at the data and in the public domain. And yet, what's the function of the FDA? What is the function? And who at the FDA ought to be reviewing these, and what about the expertise at the FDA that is independent?

So shouldn't it be housed at the FDA, rather than having a company conducting a study? Or either another—or another independent body looking at it? Isn't that what the FDA——

Dr. KRUMHOLZ. Well, this is happening with devices, I think——

Ms. DELAURO [continuing]. Is all about?

Dr. KRUMHOLZ. It's happening with devices more often, but yes. It should be housed within the FDA, who is finding contracts and others who can do this under jurisdiction of high—and with high standards about what that information is going to be.

Dr. WOLFE. Yes, I mean I—I think, as you—I'm on FDA's drug safety advisory committee. So, aside from the FDA staff, FDA has the ability to get people from academia, from wherever——

Ms. DELAURO. Right.

Dr. WOLFE [continuing]. To augment what they may not know in certain areas. There are certain specialists in cardiovascular disease who are brought in by FDA to look at a drug, to hear an advisory committee.

But I think that the focus needs to be on the FDA, its own staff, free of conflict of interest, the advisory committees much more——

Ms. DELAURO. Free of conflict.

Dr. WOLFE. And more than they used to be, freer of conflict of interest, as opposed to out there with the company, who is sort of putting their spin on it, and saying, "Well, I think this," and they don't give you the full raw data, and therefore their conclusion is difficult to challenge.

Ms. DELAURO. Or they have financial interests.

Dr. WOLFE. Always.

Ms. DELAURO. So let me just—PDUFA, PDUFA. I'm not going to go through it all. But your views, should we move away from the reliance on user fees and binding performance that the FDA has to negotiate with the drug companies in exchange for the fees?

Dr. WOLFE. Well, the law has been in effect for 18 years now. And it came into being at a time when the budgets were tight, as they always are, and Congress essentially said, de facto, "Hey"——

Ms. DELAURO. Can't afford this.

Dr. WOLFE [continuing]. "The drug companies are going to have to pay this money, because otherwise they won't be able to put in new drug applications," so they're sort of like ducks in a barrel, or something like that.

And whereas the idea of getting more FDA staff to review drugs and so forth is a good idea, it's too important to leave to the financing of the drug industry. I mean, the amount of money, compared even with the NIH budget—and the NIH budget, which is—I come from NIH, so I like the idea that NIH is getting adequately fund-

ed—but their budget is over $30 billion. Why is it that Congress can't allocate the $700 million, as opposed to $30 billion, that would take away the industry's financial input into the FDA?

So, I think the law should be repealed. It keeps getting worse and worse. And originally it was just drugs, then devices, then biologics——

Ms. DELAURO. Now they're looking at generics.

Dr. WOLFE [continuing]. Veterinary drugs——

Ms. DELAURO. Generics.

Dr. WOLFE [continuing]. And it will—and it's moving in the direction of generics. I think it's had a lot of negative influence.

The whole attitude at the FDA is—we surveyed doctors at the FDA in 1998 to see what impact it was having, and they said the standards they believe are lower, they are being told to be more quiet at FDA advisory committee hearings. So I think the whole culture there is not good, they have lost a huge number of people who felt that the atmosphere was changed significantly, once that law was passed in 1992.

Dr. KRUMHOLZ. Yes. I mean, here is my quick view. I think, on the performance side, we need the performance. I mean, we need the accountability. I mean, we need to be able to move things through in an efficient——

Dr. WOLFE. Absolutely.

Dr. KRUMHOLZ [continuing]. And high-quality way. So that should be an expectation of government, about how that agency works.

Dr. WOLFE. Without industry funding.

Dr. KRUMHOLZ. The industry funding, I think, is just—is misplaced. I mean, it's not fair to the companies, it's not fair to the public. It creates bad psychology, in terms of relationships. There should be independence.

And, you know, I don't see how that—I see it was a convenient thing to do. Certainly, though, the companies should expect, when they're working with the FDA, that they're going to get timely responses, good guidance, it's going to be clarity, transparent. They should get—sure, every—that should happen.

But to think they have to pay for it, and then—it creates, I think, a dynamic that ends up changing the thermostat even in ways that are maybe unintended.

Mr. KINGSTON. Madam Chairwoman, would you yield a minute?

Ms. DELAURO. Sure.

Mr. KINGSTON. I have asked this question of the FDA many, many times. And I get assured over and over again there is a big firewall. And so, I'm interested in your comments.

But it also strikes me that when physicians go on their continuing education seminars and they're underwritten by drug companies, that could be a bigger issue, in terms of the use of things. And I don't know what the practice is now. I think a lot of them have backed off the "We'll bring you a lunch for your entire staff on Friday." But I do know that when they go to the continuing education things, the open bar is sponsored by "Blank Pharmaceuticals," and you know, some of this other stuff.

Dr. WOLFE. That's a big problem, there is no doubt about it. But—and I don't think that there is any drug-by-drug corruption.

I don't think that's what the drug company money is doing. It's just changed the attitude and the culture there.

And Dr. Krumholz is absolutely right. We should always expect the FDA to be accountable to the public, to the companies that are doing these studies and sending them in. It shouldn't take greasing the wheels with $700 million a year to do that. Good congressional oversight would do that, even if the drug company weren't funding.

But I think the continuing medical education is a disaster. It appears to be getting better. A lot of cosmetic things are being done. But the companies are still spending a fortune, because it works, to influence doctors prescribing——

Dr. KRUMHOLZ. It's still a big problem. They're paying for infomercials, they're funneling the money through CME companies, so that even with the sunshine laws you won't see it. It's the subject of another hearing.

Dr. WOLFE. Yes.

Dr. KRUMHOLZ. I mean it's a huge issue, but it's beyond this issue about what's going on——

Dr. WOLFE. Yes, absolutely.

Dr. KRUMHOLZ. Yes. An important one, though.

Mr. HINCHEY. Well, I think—I just want to thank you for everything that you've done, all that you've said. And I think that this is something that we really will have to deal with. The relationship between the prescription drug companies and too many physicians is not a pleasant set of circumstances——

Dr. WOLFE. Or pharmacists, also.

Mr. HINCHEY. Yes, pharmacists also. This is a situation that——

Dr. KRUMHOLZ. All health care professionals.

Mr. HINCHEY. Amen, yes. It's creating a lot of problem, and it's something that we have to deal with.

Dr. WOLFE. Yes, agreed.

Mr. HINCHEY. Thanks.

Ms. DELAURO. I think I have just got two or three more questions, and then we're just so grateful for your time and your candor with these issues.

This is—and obviously, to the two of you—the OSE, Office of Surveillance in Epidemiology, and the Office of New Drugs signed a memorandum of agreement in June 2008. That states that—FDA's intent for the two offices to contribute equally in determining regulatory actions related to drug safety.

As part of the agreement, FDA transferred authority for one premarket regulatory responsibility from OND to OSE, and plans to transfer authority for two post-market responsibilities, but has not set a time frame for doing so. The authority that was transferred is the pre-market review of proprietary drug names. Proprietary drug names, looking at the names and the brands.

Do you think that this is an important priority for the Office of Surveillance in Epidemiology? Are there higher priority pre-market safety activities that they should—or post-market activities that they ought to be focusing their time and attention on?

Dr. KRUMHOLZ. I'm not sure of the background of the names. There is a lot of interest in patient safety, by the way, and trying to ensure that drugs don't sound the same, so they don't get confused. I'm not sure that that's a major responsibility. It's certainly

important, by the way, that we not lead to systems—that lead to easy confusion between drugs, so that people can be trying to get one and end up with something else. I mean that's happened far too often.

But I think we're coming together on this idea that, first of all, particularly in this post-marketing issue, is that once the drugs are released—and often times, particularly on drugs that are working on surrogate end points—so this is going to, I think, become increasingly important. There is going to be an IOM report next month about surrogate end points, there is going to be a lot of attention to this. Drugs can be approved, based on what they do to lab tests, and the assumption about what that change in lab tests means for their lives.

And yet, we have seen many instances where, as I've said, changes in cholesterol, changes in blood sugar don't translate into the expected benefit for patients. And as we are approving drugs based on that, it puts a great onus on us to figure out what actually happens when people take this drug. Because all of the trials are just about saying, "I gave it to a bunch of people, and this group had a better lab test." But we sometimes can find that, yes, people die more often with better lab results in some of these studies when they're looked at long-term.

And so, it puts a great onus on independence and concentration of resources in tracking what actually happens to people when they take these drugs. We haven't talked much about this issue, but it's relevant to Avandia, because it does make your blood sugar look better. But the truth is, there hasn't been one trial that said, "Does the strategy of using this drug actually improve patient outcomes?" I mean, everything we have said is sort of compared to other things, but there hasn't been a trial that really lets us know that when it was approved, it was approved based on what it did with blood sugar.

And this is—there needs to be a concentration, more hand-off into this area, and they need to—their views need to be respected.

Dr. WOLFE. Just——

Ms. DELAURO. Yes, Dr. Wolfe, because my point was there is that—one of the authorities that was transferred to OSE was the pre-market review of proprietary drug names. So my question there was, you know——

Dr. WOLFE. Aren't there more important——

Ms. DELAURO [continuing]. What else are we talking about here, pre-market and post-market?

Dr. WOLFE. No. I mean what Dr. Krumholz was just talking about, the—the FDA held this hearing after a number of diabetes drugs got into trouble. They said, "Maybe, when we approve a diabetes drug, we should make sure it doesn't harm people," which is different from saying it actually benefits people. And they agreed that that should be done, but unfortunately didn't agree that it needed to be done before a drug comes on the market.

So, it's still the case that a diabetes drug gets approved based on its effect on sugar. And then afterwards—not before—you start doing some studies to find out whether it benefits—or, more likely, because of recent examples—it actually harms people. And the last thing in the world, as I said before, that a diabetic needs is some-

thing that increases their cardiovascular risk, like Avandia seems to do—to a much lesser extent, Actos Pioglitazone does it.

So, I think the kind of—more trivial kind of delegation to OSE is sort of, yes, we're giving them more things to do, but in comparison with the big things, these are not the most important things to do.

Ms. DELAURO. Well, and just to expand on that for a moment, this is the GAO study, the November 2009 GAO study. And this was in conversation with the staff involved in these reviews. The staff involved in these reviews estimated that approximately 90 percent of their time is spent on such pre-market activities, which leaves little time to spend on their other post-market drug safety responsibilities, such as analyzing reports of medication errors.

It makes you wonder that, you know, the reason for just passing this on is just like a pat on the head, "Okay, go over and do this, we're still going to maintain our authority and—over this process."

And I have—and I will ask you both to comment on this, but particularly Dr. Krumholz. This was the American Heart Association and the American College of Cardiology on Avandia. Understanding that the Heart Association, the—are not recommending that doctors prescribe Actos over Avandia. The new story on their view said that the organization said there was inconclusive evidence of cardiovascular concerns.

Now, these are organizations representing the experts in cardiology. Why do they think that the evidence is inconclusive?

Dr. KRUMHOLZ. Well, yes, and I was concerned about that. Actually, I wrote and invited commentary to that statement, which disputed their findings, because I didn't agree with them.

I think it gets to what Representative Kingston said, which is that there are people with different views. I'm not saying it's biased, but different points of view. A person who led that group had published an article which had questioned some of the methods that Nissen had used. I don't think that they were necessarily apprised of all the new information that was out, and they were reluctant to make a call on it, you know, and that's what they came out with.

But again, that's why I think it gets confusing to the practicing doctor when this statement comes out. I think it does show that there is some—there are some experts who remain unconvinced about this, and they came out in that major statement and failed to identify this as a major problem.

Dr. WOLFE. Yes, and you wonder why, after really careful review and looking at least at what was available at the time, which was the end of 2008, all these experts in diabetes, who actually treat these people—they're the experts——

Ms. DELAURO. Right.

Dr. WOLFE [continuing]. Decided that they don't want to use the drug. I mean it may not be——

Ms. DELAURO. That's interesting.

Dr. WOLFE [continuing]. 100 percent conclusive. But from their perspective——

Ms. DELAURO. It's conclusive enough.

Dr. WOLFE [continuing]. It was conclusive enough, and there are other drugs to use. End.

Ms. DELAURO. Right. Okay. This has been enormously helpful. I have a housekeeping thing to do here for a moment, but I want to just say thank you for the dialogue and the back-and-forth and, again, the candor. And I will speak for myself. I'm not a scientist. We do have some in the congress, but I don't know that there are any on this committee. But the way in which you help us to understand these issues is critically important.

My hope is that we can make some of this information available, really, to the FDA. They are going to meet in July—I think it's July 13th and 14th—to do a review here. And I would very, very much like them to have a sense of what was debated or discussed here this morning, and that it would carry some weight.

We also would like to work with you to get your best advice. This committee has an opportunity to make recommendations, or to do some things with our appropriations bill. And, assuming that we will get an appropriations bill out this year—we did last year—that I think we would like to address some of these issues, and see not being authorizers, but appropriators—how far we can go with addressing some of these issues to make the changes that are necessary to ensure the safety of these drugs. So, I thank you very, very much.

And now, if I can, we received this morning a statement from GlaxoSmithKline in response to the hearing, and I ask unanimous consent to put the GlaxoSmithKline statement into the record.

[No response.]

Ms. DELAURO. Without objection.

[The information follows:]

GlaxoSmithKline Statement
House Committee on Appropriations
Subcommittee on Agriculture, Rural Development and Food and Drug Administration and Related Agencies
April 28, 2010

The totality of new and existing data on the cardiovascular safety of Avandia will be presented at the upcoming FDA Advisory Committee meeting on July 13 and 14, 2010. At this two-day hearing, the Committee will provide an "updated assessment of the risks and benefits of Avandia in the treatment of type 2 diabetes." (*See* FDA Announcement, February 22, 2010.) The safety of Avandia should be judged in light of all available scientific data with emphasis on long-term prospective studies.

This includes RECORD, which demonstrated that there is no difference in the risk of cardiovascular hospitalization and cardiovascular death, and no significant increase in cardiac ischemic outcomes with Avandia when compared to metformin and sulfonylureas. RECORD provides the most reliable assessment of the overall cardiovascular safety of Avandia to date. It is a large, long-term prospective randomized controlled trial in 4,447 type 2 diabetic patients.

GSK welcomes additional scientific information that could help guide decisions around clinical trials and ultimately patient safety. Prospectively defined, adjudicated, randomized controlled clinical trials provide the highest level of evidence in assessment of safety. The TIDE trial will provide the best evidence regarding the cardiovascular safety of Avandia and Actos. Despite some reports speculating on differences between these two agents, the American Heart Association (AHA) / American College of Cardiology Foundation (ACCF) said in a recent advisory -- "Thiazolidinedione Drugs and Cardiovascular Risks" – that "insufficient data exist to support the choice of pioglitazone over rosiglitazone."

The TIDE trial design was directed by FDA and the study has been approved by Institutional Review Boards (IRBs) and Ethics Committees around the world whose job it is to assess the safety of conducting the trial. Patient safety in the TIDE trial is monitored by an independent data monitoring committee (IDMC), which includes international experts in cardiovascular disease, diabetes, and statistics. To date, the TIDE IDMC has not expressed any concerns regarding the safety of participants in the study and has recommended that the study continue without modification.

In the years since the FDA convened the joint Advisory Committee Meeting to address questions about the cardiovascular safety of *Avandia*, six large, prospective, randomized, clinical trials have reported results. None of these randomized clinical trials, which remain the gold standard for evaluating scientific and medical questions, shows a statistically significant association between *Avandia* and myocardial infarction (heart attack) or other ischemic cardiovascular events.

GlaxoSmithKline stands behind the safety and efficacy of Avandia when used appropriately and according to its label. Avandia is an important medicine for the treatment of type 2 diabetes, who often need two or three medicines to help maintain their blood sugar levels. It is the most widely studied oral anti-diabetic medicine for the treatment of type 2 diabetes, with experience in over 52,000 patients. Avandia is the only thiazolidinedione to have shown blood sugar control for up to 5 years in clinical trials.

GSK has already responded to the Senate Committee on Finance's January 2010 Staff Report on Avandia. The SFC Report failed to present an accurate, balanced, or complete view of the currently available information on Avandia. The company rejects any allegations of concealing safety information or acting inappropriately on behalf of patients. A fair examination of the company's record will show that GSK has been diligent in its efforts to thoroughly study the safety and effectiveness of rosiglitazone, and to widely communicate that information to governments, regulatory authorities, scientific peers, physicians and others in a variety of ways. To view GSK's complete response, visit http://www.gsk.com/media/GSK-White-Paper-Avandia-23-Feb-2010.pdf).

Ms. DELAURO. Thank you. With that, again, our deepest thanks to you, and for taking the time. And thank you for what you do in your professional lives to ensure the public health.

Dr. WOLFE. Can I just make one comment——

Ms. DELAURO. Please.

Dr. WOLFE [continuing]. Which is back in the 1970s and 1980s, when I first started doing this, there was just a plethora, very importantly, of congressional oversight over the FDA. One Senate small business subcommittee held 135 days of oversight hearings on the drug industry and the FDA in the 1970s and 1980s.

Ms. DELAURO. Wow.

Dr. WOLFE. What this hearing represents to me—well, it seems like too much, but there is almost none. Senator Grassley held a hearing—now six years ago—on Vioxx, and there have just been very few hearings that have actually gotten down to the issue of here is a problem, a drug. What does this say about, A, the drug; and B, about the general process? And I just commend you for having this hearing.

Ms. DELAURO. Thank you.

Dr. WOLFE. And I hope that you have more that hold the FDA to task for what it is doing.

Ms. DELAURO. Yes.

Dr. WOLFE. And the industry, too.

Ms. DELAURO. Yes, we will continue. I promise you that. Thank you.

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