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DISCUSSION DRAFT OF THE FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT LEGISLATION: DEVICE AND COSMETIC SAFETY PROVISIONS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MAY 14, 2008

Serial No. 110–117

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

54–695 PDF WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
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CONTENTS

	Page
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	1
Hon. Nathan Deal, a Representative in Congress from the State of Georgia, opening statement	3
Hon. Anna G. Eshoo, a Representative in Congress from the State of California, opening statement	4
Prepared statement	5
Hon. Gene Green, a Representative in Congress from the State of Texas, opening statement	5
Hon. Joe Barton, a Representative in Congress from the State of Texas, opening statement	6
Hon. John D. Dingell, a Representative in Congress from the State of Michigan, opening statement	7
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, opening statement	10
Hon. Jan Schakowsky, a Representative in Congress from the State of Illinois, opening statement	11
Hon. Marsha Blackburn, a Representative in Congress from the State of Tennessee, opening statement	12
Hon. Lois Capps, a Representative in Congress from the State of California, opening statement	13
Hon. Joseph R. Pitts, a Representative in Congress from the Commonwealth of Pennsylvania, opening statement	14
Hon. Tim Murphy, a Representative in Congress from the Commonwealth of Pennsylvania, opening statement	15
Hon. Edolphus Towns, a Representative in Congress from the State of New York, prepared statement	165
WITNESSES	
Stephen Sundlof, D.V.M., Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration	16
Prepared statement	19
Marcia Crosse, Director of Healthcare, General Accounting Office	35
Prepared statement	37
Stephen J. Ubl, president and chief executive officer, Advanced Medical Technology Association	75
Prepared statement	76
Kelvyn Cullimore, Jr., president and chief executive officer, Dynatronics Corporation; secretary, Medical Devices Manufacturing Association	80
Prepared statement	83
Ami Gadhia, policy counsel, Consumers Union	90
Prepared statement	92
Elizabeth George, vice president, Quality and Regulatory Affairs, Philips Healthcare	102
Prepared statement	104
Pamela Bailey, president and chief executive officer, Personal Care Products Council	116
Prepared statement	118
Jane Houlihan, vice president for research, Environmental Working Group	134
Prepared statement	135
SUBMITTED MATERIAL	
Discussion draft	16

DISCUSSION DRAFT OF THE FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT LEGISLATION: DEVICE AND COSMETIC SAFETY PROVISIONS

WEDNESDAY, MAY 14, 2008

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:09 a.m., in room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Pallone, Eshoo, Green, Capps, Baldwin, Schakowsky, Dingell (ex officio), Deal, Buyer, Pitts, Murphy, Burgess, Blackburn, and Barton (ex officio).

Staff present: Jeanne Ireland, Virgil Miller, Jack Maniko, Melissa Sidman, Chad Grant, Ryan Long, Lauren Bloomberg, and Brin Frazier.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The hearing of the subcommittee is called to order.

Today we are having a hearing, actually the third, on the Food and Drug Administration Globalization Act, the draft bill that Mr. Dingell, myself, Mr. Stupak, and others have proposed, and today this hearing is specifically on medical devices and the cosmetic provisions as well. So I will recognize myself for an opening statement.

Over the last few weeks, as you know, we have discussed the various food and drug-related provisions in this draft, and the focus today or the idea of having a separate hearing, if you will, on medical devices and cosmetics was because we do believe that these do not need to be basically singled out and some emphasis put on those specific provisions as they apply to those industries. In 2006, for example, 183,000 packages of contact lens solution, which is classified as a medical device, were called as a result of bacterial contamination, and this was a product that is classified as low risk, and that simply shouldn't be happening.

While Congress set out to address initial safety concerns with these and similar types of products under MDUFMA, or the Medical Device User Fee and Modernization Act, it is clear to me that more must be done. The FDA is simply incapable of meeting the requirements of that legislation to inspect domestic and foreign de-

vice manufacturing establishments. In MDUFMA, we added a 2-year inspection requirement for device manufacturing companies. However, according to GAO findings, the FDA inspects these establishments on average only every 3 years for high-risk devices and every 5 years for medium-risk devices, and I would be curious to know what the inspection frequency is for low-risk devices.

Perhaps even more disturbing are the inspection rates for international manufacturers of medical devices, which are estimated to be on average every 6 years for high-risk devices and an incredible 27 years for medium-risk devices, and while the market for these products becomes increasingly global, the FDA has no requirement to inspect foreign establishments manufacturing medical devices, again a clear gap in authority, and it is up to us in Congress to act to allow the FDA to do its job and protect the American people.

Of further concern is the FDA's use of a risk-based classification system. While I understand that there are inherently more risks with Class III medically implanted devices as with the class I contact solution, this classification is based only on the nature of the product and does not take into account information related to the actual manufacturers, and this is especially concerning when the FDA appears unable to accurately report information on the number of medical device facilities both in the United States and internationally. Two databases exist at FDA to monitor and track inspections and yet these systems cannot exchange information and are fraught with inaccuracies. One system reports that there are nearly 5,000 foreign establishments registered with the FDA for Class II and III products while the other system reports that there were over 25,000 such establishments internationally. This difference is significant and again illustrates the FDA's inability to meet current and emerging regulatory responsibilities.

These concerns were echoed in a 2007 report issued by the FDA's Science Board that found disparities between the FDA's responsibilities and available resources including inadequate inspection of manufacturers, an obsolete technology infrastructure, an insufficient basis to access, integrate and analyze data, and frequent system failures. These weaknesses jeopardize the FDA's ability to fulfill its mission of protecting the American people and must be addressed.

Now, turning to cosmetics and personal care products, it seems to be basic logic for Congress to include this industry in our discussion today as this industry is largely governed by legislation established way back in 1938. Cosmetics and personal care products are used by Americans each and every day and yet these billion dollar industries have gone largely unregulated. Under current Federal law, the FDA cannot require companies to test cosmetic products for safety before marketing. They cannot review or approve cosmetic products before they are sold to the public. They can't regulate cosmetic products until after they have reached the marketplace, and they cannot require product recalls and they can't require manufacturers to register their cosmetic manufacturers, ingredient information or report cosmetic-related injuries. Instead, the FDA has to rely on a voluntary reporting system that clearly lacks the means for a systematic examination of the safety of the cosmetic industry.

Further, this voluntary system has been used as rationale against calls for reform in the industry. FDA estimates that over the 3 decades during which the voluntary Cosmetic Industry Review, or CIR, process has been in existence, only 11 percent of the ingredients used in cosmetic products have been reviewed. In addition, countries in the European Union have actually banned the use of certain ingredients in cosmetic products yet there are no restrictions in place in the United States, and some studies suggest that there are a vast number of products on the market that contain prohibited chemicals that have been deemed unsafe for use by the industry's own CIR review process. This is to me overwhelming evidence that the FDA must be empowered with the authority to regulate this industry to protect the public.

I just want to thank all the witnesses for appearing today. I know we are going to have a good discussion.

Mr. PALLONE. I now recognize, Mr. Deal, the ranking member, for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman.

We are each reminded every day on a regular basis of potential holes in FDA's current inspection and safety system. As we hear of new threats presented by certain imported products. Just yesterday, I had an interview to discuss the possible lead contamination of dental crowns imported from facilities in China. Some fear these crowns may have contributed to adverse health events in patients who unknowingly were receiving a product made in China.

Events like this one highlight the dwindling confidence the American public has in the FDA's ability to ensure the safety of the products it regulates. As we discuss these issues at today's hearing, I hope we can evaluate whether it is the case that the FDA has adequate authorities but insufficient resources or if the Agency does not even have the authorities necessary to protect the American consumer. My sense from some of our past hearings is, this problem ultimately comes down to insufficient resources at the Agency.

While user fees may seem like the only option to some members of this committee, these fees only further raise questions about an inappropriate relationship between the regulated industry and the Agency. Just last year, this committee significantly increased the fees paid by the device industry for product reviews and it added a facility registration fee. Now it seems we are contemplating even further fee increases well above those negotiated less than a year ago. One aspect in particular of a facility fee structure which has concerned me is the possibility the fees paid by a domestic facility would help pay for the inspection of a foreign facility. If there must be a fee, it seems fair to me that the fee structure would account for the differences in the cost to do the inspections at different facilities. It is also my understanding some device manufacturers have expressed concern about the requirement for a facility inspection prior to marketing approval of certain devices. I would hope our witnesses could elaborate further on this particular subject.

We certainly should be examining these safety issues but I am also afraid our ability to evaluate the effectiveness of the current authorities for the FDA is undermined by their lack of resources to carry out these authorities. While user fees may be the only method to provide this funding available to this committee, we really must question whether or not our dependence on fees from the industry is supplanting money which more rightfully should be provided by appropriations.

With that, Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you, Mr. Deal.

I recognize the gentlewoman from California, Ms. Eshoo, for an opening statement.

OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Thank you, Mr. Chairman. I am very glad that we are having this hearing today. I think it is an important one to address FDA's oversight of medical devices and cosmetics, and I want to thank the witnesses that are here today for being with us to testify.

Medical devices, and I have done a lot of legislative work in this whole area on medical devices to reform our practices at the FDA relative to them. It was complicated work but I think that we did important work on it, established user fees for people that are a part of this. Why? Because it really plays a very important role in healthcare in our country, and I think it is critical that we ensure the safety of the devices as we struggle to do that. I don't think we have accomplished everything on it relative to food and drugs.

It is also important for us not to overlook the unique nature of these devices, which makes them different from drugs, and I think the Congress has come some distance on that, and that a singular regulatory scheme might not be suitable for all types of products. We are all painfully aware of what has made its way into the country and how it harms Americans. The newspapers are full of those stories, so we have a ways to go on this, and I want to be part of getting there.

This legislation, Mr. Chairman, groups drugs and devices and holds them to the same standard of inspection, but I think that we have to look at the components of a device, and I think that this is where we need to hone in, because even a low-risk device has, I think, some other characteristics to it. A low-risk Class II device such as X-ray equipment or an ultrasound machine, there may be hundreds or even thousands of parts that comprise that machine and go into making that into a device. The devices are currently inspected and approved by the FDA as finished products and every component has to work correctly, of course. Otherwise the total of the device is not going to be effective for the patient. Now, under the Globalization Act, each facility which products every nut, each bolt and the circuit boards that go into a device would require an FDA inspection. I think we have to look closer at this. I don't know if that is where we want to go. I don't have the perfect answer but I think that in the draft of this that we have overlooked it. So the number of facilities that would have to come under inspection on

that could be insurmountable, and I don't know whether inspecting every nut and bolt in different facilities is what we intend to do.

So I think that this is an important journey that we are on. I want the highest standards for the American people and I think that that is what we have to keep our eye on, but if we go into semiconductor chips, circuit boards, software, flat panel displays of these sophisticated devices across many facilities, I don't know if that is how we want to spend our time.

So I look forward to working with you. I have some questions obviously for our witnesses. Thank you again for holding this very important hearing.

[The prepared statement of Ms. Eshoo follows:]

STATEMENT OF HON. ANNA G. ESHOO

Thank you Mr. Chairman for holding this important hearing on legislation to address the FDA's oversight of medical devices and cosmetics and my thanks to the witnesses for testifying today.

Medical devices play an increasingly significant role in healthcare and it is critical to ensure the safety of these devices as we do with food and drugs. It's also important for us not to overlook the unique nature of these devices which makes them different from drugs, and that a singular regulatory scheme might not be suitable for all types of products.

I support periodic and consistent inspections of facilities that manufacture active pharmaceutical ingredients as well as fully constituted drugs. We know all too well the dangers of unsafe drugs that have made their way onto pharmacy shelves and the identification of potential hazards from the component ingredients of a drug can be critical. This legislation groups drugs and devices and holds them to the same standard of inspection, requiring that all components of a device, even a low-risk device, have their facilities inspected.

For a low-risk Class II device, such as X-ray equipment or an ultrasound machine, there may be hundreds or even thousands of parts that go into making that device. These devices are currently inspected and approved by the FDA as finished products and every component must work correctly. Under the FDA Globalization Act, each facility which produces every nut, each bolt, and the circuit boards that go into a device would require an FDA inspection. The number of facilities subject to an inspection under such a regime could be insurmountable and cripple the FDA's regulatory process. The unintended consequences of requiring component part inspections will be long and debilitating delays for medical imaging devices to come to market. It's also not clear to me that the FDA has the appropriate expertise to inspect the high-tech equipment such as semi-conductor chips, circuit boards, software, and flat panel displays that go into many of these sophisticated devices.

I look forward to hearing from our witnesses today and the discussion we will have on ensuring the safety of medical devices.

Mr. PALLONE. Thank you, Ms. Eshoo.

The vice chair of the subcommittee, Mr. Green from Texas.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. GREEN. Thank you, Mr. Chairman, for holding the third and final hearing today on the Food and Drug Administration's Globalization Act discussion draft. This week we will be discussing the device and cosmetic provisions in this draft.

As we found in previous hearings, it is clear the FDA does not have the resources or the authority to effectively protect the American people from potential health risks. The FDA is responsible for medical device safety in the United States and for foreign devices entering the country, but as noted in our previous hearing on drug safety, FDA does not have ability to require foreign facilities to

allow inspectors even in the facilities. The GAO estimates the FDA has inspected foreign Class II manufacturers once every 27 years and foreign Class III manufacturers once every 6 years. Clearly the FDA does not have as many inspectors as it needs to conduct these inspections and has not effectively adopted a third-party inspection program.

The GAO has also noted the FDA has two separate databases that are not compatible, which are used to provide the FDA with information on foreign medical device establishments. This has severely limited the FDA's ability to track medical device establishments.

While the FDA has some authority for regulating devices, they have very limited authority when it comes to regulating cosmetics. In fact, the FDA does not have the ability to recall cosmetics. It can monitor companies that issue recalls for a product, but if a company is unwilling to recall an unsafe product, the FDA only has the ability to issue a written request for a recall. The FDA does have the ability to inspect cosmetic manufacturing facilities but does not have a comprehensive or compatible database of manufacturers of product. Currently, registration for the database is voluntary. This means the FDA does not know what products are on the market and what ingredients are even in these products.

It is astounding that the FDA has relied on manufacturers and industry to self-regulate medical devices and cosmetics for this many years. The risk-based approach that FDA has resorted to during this time of limited resources and restrictions seems like a disaster waiting to happen. We need to allocate resources and increase the FDA's authority so they can protect Americans from potential health risks.

Thank you, Mr. Chairman. I yield back my time.

Mr. PALLONE. Thank you, Mr. Green.

Our ranking member of the full committee is here. The gentleman from Texas, Mr. Barton.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. Thank you, Mr. Chairman.

Last evening on the House Floor, I had a very cordial conversation with Full Committee Chairman Dingell in which he strongly encouraged myself and other Republicans to work with you and the other Democrats on the subcommittee to craft a bipartisan food and drug safety bill, or I believe we talked about a food and drug import bill, and I told him that I had some concerns but that I would definitely encourage all Republicans to engage in a good-faith effort to see if we couldn't find a bipartisan bill, and I have instructed my committee staff to do that.

So in the spirit of that, I want to start off today by saying while it is a fact that in the draft that has been out for several months, medical devices were a part of that draft, so it is not that there is a surprise there, but the focus has been in our hearings and the focus has been in our discussions, at least my discussions with Chairman Dingell, that we were going to focus first on food safety, then drug safety, and we really hadn't discussed medical devices. The draft on medical devices, in my opinion, doesn't even deserve

to be a part of the discussion. It doesn't mean we shouldn't look at medical devices but I think there are such differences that we should discuss the medical devices as a stand-alone issue.

I would also say that what is in the draft on medical devices, in my opinion, seems to be overkill and probably non-implementable in the real world. There are between 35 and 50 Class III medical devices that are approved each year. These are complex devices and it might make some sense to require pre-approval inspection. However, there are another 3,500 of less complex Class II medical devices that are approved each year. To require each of those facilities to have a pre-approval inspection is a waste of resources. It will only increase costs to patients and, as far as I can tell, no demonstrable safety benefit, and would needlessly delay these therapies getting to the patients.

The bill would also call for a pre-inspection of all device parts. This is another example of the draft failing to recognize the difference between drugs and devices. A medical device part could be a circuit board. It could be a battery. It could be even a screw. A battery is not the same thing as heparin.

Finally, I want to reiterate a point that I made at the hearing several weeks ago. During the debate on medical device user fee reauthorization last year, I expressed and other members of the Committee expressed serious concern over the level of user fees being paid by the industry. Last year the medical device industry doubled its funding commitment to the FDA from $150 million to $300 million. We should pay some close attention to the clear warnings before we made the FDA even more reliant on the industry that it is supposed to oversee. This bill would create, in addition to that, a new set of user fees for medical devices. I would like to point out to the members of the Committee that the Congress already has, as I just said, a user fee for medical devices.

So I am not trying to be too critical, Mr. Chairman. I just—if we are going to do a food safety bill, let us do a food safety bill. If we want to do drug safety, let us do a drug safety bill. I think you can combine those. I do not think medical devices should be a part of the bill. If we are going to really look at medical devices, I think you should split it up and do that as a stand-alone bill.

And with that, Mr. Chairman, I yield back.

Mr. PALLONE. Thank you.

Next I next recognize the chairman of the full committee, Mr. Dingell.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Mr. Chairman, I thank you for your courtesy and I commend you for your diligence in holding this series of legislative hearings to focus on what resources and authorities the Food and Drug Administration needs to adequately protect the public health.

The third and final hearing today will discuss and focus on the device and cosmetic industry safety provisions in the discussion draft. I want to indicate that the discussion draft has been produced to afford us the opportunity to receive the comments and un-

derstand the concerns and feelings of everyone who would be affected by this legislation, from consumers to manufacturers to importers. And I am very anxious, as I have indicated to my good friend, the ranking Minority member, my friend, Mr. Barton, that we are anxious to work together with him to address this problem, which is a very real one and one which offers real threat and peril to the American people.

The same issues that challenge FDA's ability to properly oversee Food and Drugs in an increasingly global marketplace also plague the Agency's ability to regulate medical devices and cosmetics, and I want to point out that it is not the intention of the authors of the draft to create undue burdens on American industry but rather to see to it that foreigners meet the same standards in terms of safety and efficacy to American consumers as do domestic producers, and I would point out that Food and Drug's total inability to investigate the behavior of foreigners manufacturing goods elsewhere is a matter which hurts American manufacturers by assuring that American manufacturers face unfair, dangerous competition and they face the importation of substances and devices which offer real threat, not just to consumers but, quite frankly, to the goodwill that our manufacturers have been trying to build for so long. I would point out that were it not for the simple fact that our commitments under GAT and WTO force us to treat all marketed commodities in this country whether they are domestic or otherwise alike, we might perhaps be able to address this a little more focused on foreign misbehavior.

It should be noted that the FDA Science Board in 2007 reported that FDA's ability to carry out its mission in the case of medical devices is grossly inadequate and that due to constrained resources, lack of adequate staff, FDA is engaged in reactive regulatory priority setting or a firefighting regulatory posture instead of pursuing a culture of productive regulatory science. In other words, people should be concerned about the inadequacies of Food and Drug to carry out its mission and to protect the American consumers, and parenthetically, to protect American industry from unfair competition by people who are not being regulated by FDA, which unfortunately oftentimes doesn't even know where the people abroad that they are supposed to be looking at might happen to be located or, indeed, who they are.

This unfortunate news has been confirmed in recent testimony of the Government Accountability Office, the GAO, before the Subcommittee on Oversight and Investigations, which found that the FDA was not able to make the required inspection every 2 years of domestic facilities where the highest-risk medical devices are manufactured, and I would point out that in the hearings of this committee in time past, we found that things like heart valves were not being properly and safely manufactured and the result with failure of that kind of device was an instant heart attack with total fatality being the result to the person who happened to have that particular device implanted.

So we need to address this. We need to understand that currently FDA is only able to inspect medium-risk medical device facilities once every 5 years and high-risk device facilities only once every 3 years. American consumers, beware. And the number of in-

spections for foreign producers is much worse. The GAO estimated that FDA inspects foreign manufacturers of Class II devices only once every 27 years, and foreign Class III manufacturers only every 6 years. Despite the fact that there are more registered device manufacturers in China than in any foreign country, Chinese firms can expect FDA to visit them only once every 50 years. And while cosmetics currently represent 9 percent of FDA-regulated products imported into the United States, the number of these imports is growing, and in spite of small budget increases last year, FDA's Office of Cosmetics and Colors has been unable to keep pace with the increasing numbers of foreign cosmetic products, and I would remind all that we are not talking just about finished products but we are talking about raw materials and components, which can offer us greater risk as can the finished products to American consumers. Witness heparin.

We will hear from two FDA officials today, who I hope will be forthright in their testimony about the needs of the Agency. We want to help the Agency, and we look forward to the Agency helping us to help them. We in Congress can do a better job for American consumers if we receive frank, truthful testimony from the people vested with regulatory responsibility.

I want to commend those in the device and in the cosmetic industry who have stepped forward and voiced their willingness to work with us to strengthen FDA, and I want to make it plain that we understand their problems and we are desirous of coming up with something with which they can live and which will enable them to compete fairly in a difficult market.

And as we start this effort, we must all keep in mind that the dire straits which FDA is in and how they impact upon American consumers, and we need to understand that the Federal budget along cannot support the growing demands of the Agency, and we can find time after time where the heads of the Agency has come in to tell us what a good job they were going to do and how we could hope in some distant future that they would have a new and wonderful device and methodology for addressing these problems. We have been disappointed not only in their failures but also in them. Industries that benefit from global marketplace also must share the responsibility of the safety of products that they sell to American consumers, and they must face the same situation and the same regulatory impact that American manufacturers confront.

Lastly, I want to thank the consumer groups and other stakeholders who recognize the crisis at FDA and who are committed to working with us on this effort. Following the conclusion of today's hearing, I intend to begin to work immediately with my good friend, Mr. Barton, and other members of the Committee to try and build a strong, bipartisan piece of legislation using the discussion draft that we are considering at this particular time.

Mr. Chairman, I commend you for this. I thank you for your courtesy. I yield back the balance of my time.

Mr. PALLONE. Thank you, Chairman Dingell.

Next is the gentleman from Texas, Mr. Burgess.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Thank you, Mr. Chairman, and I want to thank the chairman of the full committee, Mr. Dingell, for his draft of the FDA globalization legislation, and I do wish that there could have been more input from the Minority side. I understand I am relatively new, but it seems like if we could be present while you are drafting the draft, it would be easier to get to a true bipartisan compromise. But nevertheless, in a year where process and regular order seem to be jettisoned so easily, I am grateful for this comment and review period. We have got a lot of work to do, but I believe that this committee sincerely wants this to be bipartisan legislation, and I stand ready to offer my assistance to make this a reality. Obviously, while I can't agree with all of the provisions within the chairman's FDA Globalization Act, I do welcome the honest and open discussion about the legislation that will transform the system.

This year, the subcommittees of Energy and Commerce have had hearing after hearing after hearing regarding the resources or lack thereof of the Food and Drug Administration. We have also had many important investigations such as the heparin issue, the melamine issue, the ongoing investigation of lead in dental devices, but while I sit on the Health Subcommittee, Oversight and Investigation Subcommittee, Commerce, Trade, and Consumer Protection, I cannot recall any discussion or any investigation regarding the cosmetic industry. So I am sure that there are some reforms that need to be made within the Office of Cosmetics and Colors and the Center for Food Safety and Applied Nutrition, but I would urge this committee, this subcommittee to move methodically and deliberately. We shouldn't just be passing legislation because we happen to be here.

I would like to address the issue of resources. I respect the fact that this bill attempts to garner more resources for the Agency but I do question some of the attempts. We all know that the Food and Drug Administration, which should be the premiere Federal agency, has been underfunded for decades. It is many administrations, both Republican and Democratic, it is many Congresses, both Republican and Democratic, that bear responsibility for this problem, but this bill seeks to solve that by imposing a pass-through tax to consumers disguised in the form of user fees. So, Mr. Chairman, I call on the leadership of this committee, the leadership of the Appropriations Committee and the Speaker of the House to come together and develop a plan to get the critical resources to this important agency. This is an authorization bill. Under the best of circumstances, when do we expect to see one dime delivered to the Food and Drug Administration? Yet we can do that through the appropriations process this year if we will simply pay attention to the process. This committee doesn't appropriate money but every single member of this committee knows that this year we will be lucky to pass one appropriations bill. Chances are, most appropriations will be passed through on a continuing resolution and so the Agency will receive level funding yet for another year. Consequently, unless we take immediate steps to work within the appropriations process, the Food and Drug Administration will continue to be un-

derfunded regardless of the number of hearings that we hold at the subcommittee level.

So we must act and we must act methodically and deliberately, and Mr. Chairman, you have been generous. I will yield back the balance of my time.

Mr. PALLONE. Thank you.

The gentlewoman from Illinois, Ms. Schakowsky.

OPENING STATEMENT OF HON. JAN SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I appreciate the opportunity to have this hearing today on such an important issue, keeping our devices and cosmetics safe for American consumers. I applaud your leadership on these issues as well as other issues and concerns addressed in your draft Food and Drug Administration Globalization Act.

Today I would like to address some of my concerns about the regulation of cosmetic products at FDA, or rather the lack of regulation. It is under the Food, Drug and Cosmetic Act that FDA receives its authority to regulate drugs, devices, cosmetics, and other products. But what many Americans don't know and in fact, it came as a surprise to me, is that FDA has little to no authority to actually regulate the personal care products we use every single day. Furthermore, the original statute under the FDCA has remained essentially unchanged since 1938. Even the measures that FDA does have the authority to require such as safety substantiations, labeling requirements and facility inspections but without the resources to do so, cosmetics remain widely untested and unregulated. For example, tests for safety are done by the manufacturers themselves and are not overseen by the FDA. Additionally, without an actual standard for what is considered safe, it is hard to imagine what exactly is passing for safe and arriving on shelves across America.

Unfortunately, even when FDA does find a deficiency or violation, it doesn't possess the authority to issue a mandatory recall and often does not pursue legal action because the burden of proof rests on the FDA, which has no resources to carry out investigations or studies of its own. So think about it. How many personal care products does each of us use every day? Ten, 25? My concern is that more and more studies are coming out on the hazards of these products and we simply don't know enough about them and their long-term effects. We are just told that they are safe, trust that the industry's voluntary reporting program works and assume that the FDA has sufficient authority to act if necessary. Yet according to a letter send by the Environmental Working Group to FDA Commissioner von Eschenbach last September, well over 22,000 products—that is 98 percent of all products—contain one or more ingredients that has never been publicly assessed for safety, not by the FDA, not by the Cosmetic Industry Review, which is the industry self-regulation panel, and not by any other publicly accountable U.S. institution.

By contrast, the European Union has required cosmetic companies to remove reproductive toxins, mutagens and carcinogens from personal care products and it now bans more than 1,100 chemicals

from personal care products due to risks associated with cancer, birth defects or reproductive problems. In stark contrast, just nine chemicals are banned from cosmetics in the United States.

That to me is unacceptable and I am so very grateful for the chairman's efforts to rein in this unregulated industry by requiring manufacturers to register their facilities, their products, and their ingredients with the FDA and to submit serious adverse events relating to the use of its cosmetics to a registry. This draft legislation would also establish good manufacturing practices, a big step in the right direction.

So I look forward to working with you, Mr. Chairman, as well as the rest of my colleagues on the Committee to strengthen these provisions further. I think that the improving oversight authority of cosmetics is long overdue, and I look forward to hearing from our witnesses today.

Thank you. I yield back.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Tennessee, Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Ms. BLACKBURN. Thank you, Mr. Chairman, for having this hearing to discuss the device and cosmetic provisions contained in the draft Food and Drug Administration Globalization Act. I do appreciate the goal of the legislation, which is to increase consumer safety in the U.S. import system, and I continue to support increased transparency and enhanced public safety to reduce future incidences of tainted products that are entering the country.

Of course, we have heard, debated, listened to quite a bit of evidence on that issue in this committee this year, and as this committee has learned through those numerous hearings, what we have is the FDA is a broken agency. What we have learned is, there seems to be very little interagency communication, that there are too few inspectors, that there are insufficient resources to complete its core mission, that there are inadequate IT systems, and as far as we know, since we have not heard differently, there seems to be a lack of best practices within the Agency. It seems somewhat out of order for this committee to legislate new requirements for FDA without fixing what appears to be their fundamental and structural underpinning, which is causing problems within the Agency. My hope is that by the time we get around to the final bill, that what we will do is prioritize consumer safety with a balanced approach for consumers and for manufacturers. When legislating in the name of increased consumer safety, it is critical that this legislation achieve its desired effect and not severely restrict the entry of life-saving medical technology into the U.S. healthcare system. This legislation should not limit patients' access to important preventative screenings and diagnostic procedures.

It is well known that the FDA is in need of resources. We have heard they need hundreds of millions of dollars in additional funding to increase inspections on both domestic and foreign manufacturing facilities and to do those in a timely and orderly manner. Last year, user fees, which are taxes and they all get passed to the

consumer, user fees were increased under the Medical Device User Fee and Modernization Act, which was authorized to help defray FDA review costs. Concurrently, some on this committee complained that increased user fees, there again taxes, created FDA dependence on drug and device companies. Well, it concerns me that what we have got is kind of a here-you-go-again with this bill with these user fees and, again, read that as taxes, are further increased and appear to unfairly burden domestic medical imaging manufacturers.

I look forward to discussing the rationale for increased user fees without creating further dependence on the FDA. I know we are going to have quite a discussion on this and I have got more to say, but, Mr. Chairman, I am going to yield back the balance of my time and look forward to the continuing conversation on the legislation.

Mr. PALLONE. Thank you, Ms. Blackburn.

Next recognized for an opening statement, the gentlewoman from California, Ms. Capps.

OPENING STATEMENT OF HON. LOIS CAPPS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. CAPPS. Thank you, Chairman Pallone. I appreciate your holding this hearing today and I want to commend our Chairman Dingell for his continued leadership on this very important issue. As a public health nurse, I believe there is no greater goal than protecting the public's health and well-being, and of course, as part of its mission, the FDA is responsible for regulating all medical devices that are marketed in the United States, including those manufactured on foreign soil.

Inspections are probably the most powerful tool that the FDA has to ensure that these devices are safe and effective, yet growing demands on the Food and Drug Administration have limited the resources it has available to adequately fulfill its mission. As a result, inspections are far too infrequent and unsafe devices have the potential of entering the market undetected.

But device manufacturers also need to be part of this process. We need to form a working partnership in order to guarantee a safe supply. I am pleased that we will have an opportunity to hear today from both FDA and the medical device industry about how to make such a partnership work. It is abundantly clear that the Food and Drug Administration is in desperate need of additional resources. This fact has been acknowledged by colleagues on both sides of the aisle, and it was confirmed by FDA officials testifying before this committee just this month.

Medical devices are not the only products that may be compromised by such limitations. The FDA's authority to regulate the cosmetic industry has been historically limited. The cosmetic products and ingredients are not currently subject to rigorous pre-market FDA inspection and approval. It is left to the cosmetic industry to verify the safety of their products. This limited oversight, combined with a lack of product recall authority, greatly constrains the FDA's ability to protect consumers from potential toxins hidden in cosmetic products. Without sufficient resources, adequate staff and robust regulatory authority, the FDA has been relegated to a reactionary role instead of taking preventive and proactive measures.

This is no way to protect the public's health and safety. Changes do need to be made, and in order to do this, we must make a strong commitment to invest in the Food and Drug Administration, something I have supported throughout my tenure in Congress.

So I thank the witnesses for taking the time to join us today, and I look forward to a productive discussion.

Thank you, and I yield back.

Mr. PALLONE. Thank you.

I recognize the gentleman from Pennsylvania, Mr. Pitts.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Thank you, Mr. Chairman, and thank you for convening this hearing today on the device and cosmetic provisions of the food and drug safety FDA.

I have to admit, however, I am a bit confused as to why drugs and devices have been included in the same title of the discussion draft. The FDA Amendments Act of 2007 recognized the distinct differences between drugs and devices and addressed the two separately, yet several provisions in the draft before us apply the same requirements to both sectors.

I would like to welcome all of the witnesses, particularly those from Avamed and Mita and MDMA. I look forward to all of your comments on this draft legislation.

I think it is important to point out that foreign medical device manufacturing facilities are already subject to international quality and safety inspections at least annually as part of the International Standards Organization, the ISO 13485 standard, a standard virtually identical to the FDA Quality System regulations. Meeting this ISO standard is a requirement for medical device manufacturers in 47 countries worldwide. The FDA should make use of the valuable information gained from these already required inspections.

Also, the discussion draft requires an inspection every time a change is made to a medical device and requires inspections of all component parts. Medical imaging devices, for example, are updated or improved on average once every 18 months. This could be updated software, the device may have an added functionality, or it may be able to image another part of the body. I do not believe that these updates to already approved products warrant an entirely new facility inspection. We have all heard about FDA's lack of resources and lack of inspectors. We can't wait until an FDA inspector comes to a facility to complete a new assessment to give the go-ahead to a product that has effectively an 18-month shelf life. Patients here in the United States need those technologies.

It is also important to note that the FDA classifies medical imaging devices as Class II, which are considered low risk. The FDA inspects and approves medical imaging devices as finished products. I fail to see how inspecting every single component down to the screws used to hold a device together is an efficient use of FDA's time or resources. Every screw, circuit board, and screen must work correctly for the completed device to function properly and pass its rigorous inspections. Examining component parts individ-

ually would be duplicative and not be a prudent use of funds. These new inspection requirements could ultimately end up slowing down the delivery of improved and updated technology to the U.S. market and ultimately to patients.

Finally, medical device manufacturers currently pay a facility registration fee of $1,700 per facility per year to the FDA. They also pay fees for ISO inspections. However, this discussion draft includes additional annual facility registration fees as well as an annual $10,000 importer registration fee. Let us remember that device manufacturers voluntarily agreed to almost double the amount of fees they pay to FDA last year. These new fees are duplicative and do not provide a direct benefit to the manufacturer. I believe we need to be careful not to cross from valid user fees into new taxes on these manufacturers.

I would like to thank all of our witnesses for testifying today. I look forward to your statements, and I yield back the balance of my time.

Mr. PALLONE. Thank you.

The other gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Thank you, Mr. Chairman. It seems as though much of what can be said has been said, and some of my friends say one thing and some another, and I agree with my friends on this, but nonetheless, I want to emphasize here too, and thank you for this hearing, and hope that part of what we get out of this in shaping a bill is one that recognizes we do need to have a more effective system of inspections, not just for its own sake, but on devices and on these other products. I want to make sure we are simply not adding more to the cost burden of these products without yielding results.

In particular, some of the areas I hope our witnesses will talk about is in the areas of finding those who may manufacture or bypass or violate some of these rules, and when we are dealing with foreign companies, it is not hard for them to simply close that company and show up as another name and therefore stay under the radar screen with this. One of the great things about America is, we are able to still be seen as a leader in inspection and having product safety. However, we want to make sure that we maintain that position and not give it up to other countries who are able to bring other products in here that don't have that.

So I look forward to the hearing here and finding how we can carefully balance this issue of making sure that we are able to maintain product safety and not simply overburden the system with regulations that are not leading to that end, and I yield back.

Mr. PALLONE. Thank you. I believe that concludes our opening statements, so we will now turn to our first panel. I would ask our witnesses from the FDA and the GAO to come forward at this time.

Thank you. Let me introduce each of you. On my left is Dr. Sundlof, who is Director of the Center for Food Safety and Applied Nutrition at U.S. FDA. Next to Dr. Sundlof is Lillian Gill, who is Senior Associate Director of the Center for Devices and Radio-

logical Health with FDA. I understand she is not going to be testifying but will answer questions and help us in that respect. And then next is Dr. Marcia Crosse, who is Director of Healthcare for the General Accounting Office.

You know the drill, that we hear 5-minute opening statements they become part of the hearing record, but each witness may in the discretion of the committee submit additional statements in writing for inclusion in the record, and I will start with Dr. Sundlof for 5 minutes. Thank you for being here.

STATEMENT OF STEPHEN SUNDLOF, D.V.M., PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

Dr. SUNDLOF. Thank you, Mr. Chairman and members of the subcommittee. I am Dr. Stephen Sundlof, director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration, and as you indicated, with me today is Dr. Lillian Gill, Senior Associate Director, Center for Devices and Radiological Health at FDA.

Thank you for the opportunity to discuss challenges posed by imported medical products and components of cosmetics. We commend the members of this subcommittee and their staffs for developing the discussion draft entitled, the Food and Drug Administration Globalization Act of 2008. We recognize and appreciate the Committee's efforts to include new authorities requested by the Administration in support of the Action Plan for Import Safety.

Foreign-manufactured medical devices must meet FDA regulatory requirements in order to be imported into the United States or its territories. These requirements include establishing registration device listing, manufacturing in accordance with quality systems regulation, reporting of adverse events and pre-market notification or pre-market approval. Initial importers must register with the FDA. Foreign manufacturers must designate a U.S. agent to, among other things, facilitate interactions between the FDA and the foreign manufacturer. FDA inspects foreign manufacturing sites to assess compliance with FDA requirements and help inform decisions regarding admissibility into U.S. commerce. FDA cooperatively works with Customs and Border Protection in regarding imported products. Products that do not meet FDA's regulatory requirements may be detained at the border.

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. In general, except for color additives and ingredients specifically prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled.

Cosmetic manufacturers are encouraged to register their establishments and file a cosmetic product ingredient statement with FDA's voluntary cosmetic registration program. This program provides FDA with the best information available about the locations, business trade names and types of activities of the establishments that participate in this program. If manufacturers do not remove dangerous products from the market, the Agency can pursue en-

forcement actions against violative products or against firms or individuals who violate the law. FDA works closely with all its partners including the international regulatory authorities on a wide variety of issues important to cosmetic safety including ingredient usage and labeling, marketing surveillance, and areas of emerging science.

The Administration's Action Plan for Import Safety presents broad recommendations and specific action steps to promote the safety of imported products under the organizing principles of prevention, intervention and response. One of the plan's premises is that the United States must transition from an outdated snapshot approach to import safety in which decisions are made at the border into a cost-effective preventive focus model that identifies and targets critical points in the import's life cycle where the risk of the product is greatest and verifies the safety of products at those important phases.

Under the auspices of the Administration's Action Plan for Import Safety, FDA has many initiatives underway to further protect and promote the public health. For example, FDA's Beyond Our Borders initiative is a multi-pronged approach to promote and verify compliance of imported foods, cosmetics and medical devices with the FDA requirements prior to importation. This initiative includes increased FDA presence overseas, increased FDA inspections, greater sharing and use of foreign authority inspection reports and other information, use of third-party certification and increased capacity building with countries that have less-developed regulatory systems to ensure product safety.

In order to target our intervention efforts related to foreign firms, FDA has several plans to enhance its IT systems in ways that will improve databases, enhance interoperability of systems within the Agency and among other regulatory agencies, and provide better analytical function to assess and control risk.

Finally, when a health threat emerges with a regulated product, FDA must have the tools to facilitate the timely recovery of the violative produce, reduce the opportunity for harm, and secure the integrity of the supply. FDA is working to facilitate the adoption by industry of track-and-trace technologies to identify and track the product along the product's life cycle back to the point of origin. Under the Food and Drug Administration Amendments Act of 2007, FDA is working to develop unique identifiers which may support product identification technologies.

Under new authorities, the Action Plan for Import Safety called for providing a number of new authorities in order to enhance the safety of imported products. It requests authority to establish import certification programs using accredited third parties to verify compliance of foreign products with U.S. standards. The plan recommends authorizing FDA to refuse admission of a foreign manufacturer's product when access to the foreign manufacturing site is hampered. The plan also requests authority to expedite destruction of refused medical products, which will prevent unsafe medical products for personal use from entering the U.S. market. Finally, asset forfeiture remedies for certain criminal offenses involving fraudulent or counterfeit products would allow the forfeiture of all vessels, vehicles, aircraft, and other equipment used to aid in the

importing, exporting, transporting, selling, receiving, acquiring, and purchasing of violated products.

We are in the process of reviewing the FDA Globalization Act discussion draft in detail, and we look forward to working with you on this legislation. Let me reiterate some general principles that guided the development of the Action Plan for Import Safety.

Mr. PALLONE. Dr. Sundlof, I hate to stop the FDA witness, in your case, but you are about a minute and a half over. But summarize. We don't want to stop you completely.

Dr. SUNDLOF. Thank you. I think I can stop at this point, Mr. Chairman.

[The prepared statement of Dr. Sundlof follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

STEPHEN F. SUNDLOF, D.V.M., Ph.D.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

"DISCUSSION DRAFT OF THE 'FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT' LEGISLATION: DEVICE AND COSMETICS SAFETY"

MAY 14, 2008

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Stephen F. Sundlof, D.V.M., Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA or the Agency). With me today is Lillian Gill, D.P.A., Senior Associate Director, Center for Devices and Radiological Health. Thank you for the opportunity to discuss FDA's progress in responding to the challenges created by medical devices for the United States (U.S.) market that are either fully manufactured overseas or that are manufactured in the U.S. but contain foreign components. We also appreciate your interest in FDA's cosmetics program by including it as an additional topic of this hearing. FDA's mission is to ensure that products available in the U.S. meet appropriate standards for safety and, for medical products, effectiveness, regardless of where they are produced. In my testimony today, I will outline activities the Agency is undertaking to accomplish this goal.

COSMETICS

Let me first provide some background regarding FDA's cosmetics program. Every day across the country, Americans use a wide variety of cosmetic products, including skin moisturizers, shampoos, perfumes, lipsticks, nail polishes, eye and face make-up, hair colors and deodorants. These consumers expect their cosmetics – and the wide variety of individual ingredients in their cosmetics – to be safe. The FDA's oversight has ensured that the Nation's cosmetics are among the safest in the world.

Cosmetic firms are responsible for substantiating the safety of their products and ingredients before marketing. In general, except for color additives and those

ingredients which are prohibited or restricted from use in cosmetics by regulation[1], a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled. FDA regulations also specify the labeling requirements for cosmetics, including warning statements on the labels of certain types of cosmetics such as coal tar hair dyes. If manufacturers do not remove dangerous products from the market, the Agency can pursue enforcement actions against violative products or against firms or individuals who violate the law.

Cosmetic manufacturers are encouraged to register their establishments and file Cosmetic Product Ingredient Statements with FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing and packaging) of establishments that participate in this program. FDA uses the registration to estimate the size of the cosmetic industry and for conducting on-site establishment inspections. Information from the VCRP database assists the Cosmetic Ingredient Review Expert Panel in determining its priorities for ingredient safety review. Currently, 972 domestic and 612 foreign cosmetic manufacturing establishments are registered with FDA. Though the mix of cosmetic products sold to U.S. consumers is constantly changing, we estimate that the registration system contains product information from a third of all domestic manufacturers.

[1] FDA regulations specifically prohibit or restrict the use of ten types of ingredients in cosmetic products due to safety concerns. 21CFR700Subpart B

Though we believe cosmetics sold in the U.S. are safe, we recognize that the cosmetics industry is expanding and changing. During the past five to ten years, Americans have seen an explosion in the numbers and types of cosmetic products sold annually. The domestic cosmetic industry has annual U.S. sales which are now exceeding $62 billion. To meet demand, cosmetic products and ingredients are also entering the U.S. from a growing number of countries. Though manufacturers are required to ensure the safety of products sold in the U.S., the regulatory systems and standards in many countries are different from those of the U.S. and often from each other. In 2007, cosmetic products and ingredients accounted for nine percent (9%) of all imports under FDA's jurisdiction. From 2000 to 2007, the number of these import entries more than tripled. We expect this upward trend in imported cosmetics and cosmetic ingredients to continue. To address the increasing need for coordination, FDA and its counterparts in the European Union, Canada, and Japan have established a new forum for cooperation and communication on issues of common concern in the cosmetics arena, known as International Cooperation on Cosmetics Regulation.

In addition, the cosmetics industry is rapidly undergoing significant changes as the technologies used in manufacture become increasingly sophisticated and the ingredients, more complex. For example, products that straddle the line between cosmetics and drugs also present new challenges. The industry often refers to these products as "cosmeceuticals," a term which has no legal or regulatory definition in the U.S. Many products in this category are advertised as containing "active ingredients," which are ingredients sometimes used in pharmaceuticals. We note that any product that purports

to treat, cure, or prevent disease (i.e., making a drug claim) would be considered a drug and would need to obtain FDA drug approval. However, we recognize that the use of such ingredients is increasing and we expect this trend to continue. For example, retinol, an ingredient used in cosmetic anti-wrinkle preparations (as well as over-the-counter drug preparations), was not listed in any cosmetic product ingredient statement in FDA's VCRP database in 2003; by 2006 it was listed in almost 50. It is currently listed in 163 cosmetic product ingredient statements. Peptides, a class of cosmetic ingredient also used in skin care preparations and associated with certain drug-like product claims, were not listed in any cosmetic product ingredient statements filed with FDA prior to 2005. Currently, there are over 40 different peptides listed in over 500 cosmetic product ingredient statements.

FDA is committed to ensuring the safety of cosmetics used by consumers across the U.S. FDA will continue to work closely with all of its partners, including international regulatory authorities, on a wide variety of issues important in cosmetic safety, including ingredient usage and labeling, market surveillance, and areas of emerging science.

MEDICAL DEVICES

Foreign-manufactured medical devices must meet FDA regulatory requirements in order to be imported into the U.S. or its territories. These requirements include establishment registration, device listing, manufacturing in accordance with the Quality System Regulation, reporting of adverse events, and Pre-market Notification 510(k) or

Pre-market Approval, if applicable. Foreign manufacturers must also designate a U.S. agent. The responsibilities of the U.S. agent include assisting FDA in communications with the foreign establishment, responding to questions concerning the foreign establishment's devices that are imported or offered for import, assisting FDA in scheduling inspections of the foreign establishment and, if FDA is unable to contact the foreign establishment directly or expeditiously, FDA may provide information or documents to the U.S. agent, which is considered equivalent to providing the same information or documents to the foreign establishment. FDA inspects foreign manufacturing sites to help assess compliance with FDA requirements and to help inform decisions regarding admissibility of products into U.S. commerce. Initial importers also must register with FDA. An initial importer is any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the consumer.

FDA works cooperatively with Customs and Border Protection (CBP) in regulating imported FDA-regulated products. Products that do not meet FDA regulatory requirements may be detained at the border.

Our existing authorities help ensure the safety and effectiveness of medical devices manufactured in foreign establishments and intended for use in the U.S. In addition, FDA has many initiatives underway to further protect and promote the public health under the auspices of the Administration's Action Plan for Import Safety.

ACTION PLAN FOR IMPORT SAFETY

As you know, last year, President Bush issued an Executive Order creating a Cabinet-level Working Group on Import Safety to promote the safety of imported products, and asked Secretary Leavitt to lead the group. The working group, which includes representatives from twelve Federal departments and agencies, reviewed the procedures, regulations, and practices for ensuring that imported food, drugs, and other consumer products are safe.

On November 6, Secretary Leavitt presented the "Action Plan for Import Safety" to the President. This Action Plan presents broad recommendations and specific short- and long-term action steps, categorized under the organizing principles of prevention, intervention, and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. That report concluded that the U.S. must transition from an outdated "snapshot" approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important phases. In the Action Plan, we identified several new legislative authorities that are needed to do this.

Prevention

FDA is seeking to ensure that imported devices are safe and effective and meet all applicable FDA standards *prior* to reaching U.S. ports-of-entry. FDA is pursuing this goal through the following key efforts.

Maximizing Foreign Medical Product Pre-Approval Inspections. Prior to the approval of a medical device pre-market approval application, FDA must determine that the firm's manufacturing processes are adequate to consistently produce a safe and effective device.

Each year, FDA performs foreign device pre-approval inspections which assess data in applications and a firm's GMP compliance. These inspections are designed to evaluate the capability of manufacturing facilities to generate a safe and high-quality product and address manufacturing location, design, source and specifications of components, manufacturing controls, and product labeling and servicing, among other things. FDA conducted more total foreign inspections in Fiscal Year (FY) 2007 than at any other time in the Agency's history. In FY 2007, FDA conducted 289 inspections of foreign device manufacturers, compared to 233 in FY 2005, and 219 in FY 2006. We plan to conduct 392 foreign device manufacturer inspections in FY 2009. It is critical to note, however, that while inspections are an important component to ensuring the safety of imported medical products, simply calling for more inspections is not the solution.

Beyond Our Borders Initiative. The FDA Beyond Our Borders Initiative is a multi-pronged approach to promote and verify compliance of imported food, cosmetics, and medical products with FDA requirements. This Initiative includes increased FDA presence overseas, increased FDA inspections, greater sharing and use of foreign competent authority inspection reports and other information, use of third party certification, and increased capacity building with countries that have less developed regulatory systems to ensure product safety.

Foreign Presence. China is one of the largest exporters of medical products for the U.S. market. Recently, FDA and Department of Health and Human Services leadership, the Department of State, and the U.S. Ambassador to China committed to establishing an FDA office in China this year. On March 8, 2008, the Department of State approved FDA to place 13 total staff in China (eight FDA personnel and five Foreign Nationals). This staff will be responsible for building closer working relationships with our Chinese counterparts, carrying out inspections, and working with Chinese inspectors to provide training. FDA is in the process of making the necessary arrangements and preparing to hire staff. This effort builds on two recently-signed Memoranda of Agreements (MoA) with FDA counterparts. One of the agreements with China's State Food and Drug Administration (SFDA) pertains to medical products, including devices. This MoA will improve regulatory cooperation and information sharing concerning medical products exported from China to the U.S. Starting with products designated in the agreement, SFDA will require registration for products exported to the U.S. and will eventually be able to certify that FDA standards are met for those products. Under the MoA, SFDA is required to respond promptly to information requests about medical products and promptly notify FDA of any serious adverse health consequences associated with Chinese medical products shipped to the U.S. In addition, SFDA will notify FDA of significant non-compliance, including counterfeiting. Furthermore, the agreement provides for a streamlined process for facilitating FDA inspections conducted in China. This aspect of the agreement has already proven effective in gaining FDA prompt access to conduct inspections involving Chinese heparin. This is a significant step toward ensuring the safety and efficacy of medical products produced for the U.S. market.

FDA's efforts will build stronger cooperative relationships with counterpart agencies in China, enhance technical cooperation with these agencies, and foster the flow of information between regulatory systems. Having an overseas presence in China will improve our ability to inspect facilities in China and, very importantly, foster greater interactions between FDA staff and Chinese manufacturers to help ensure that products shipped to the U.S. meet FDA standards for safety and manufacturing quality. In addition, FDA is working to establish beneficial collaborations with India, another large exporter of medical products to the U.S.

Ramping Up Field Efforts. To meet the challenges posed by the increase in the globalization of U.S. drug and device development, FDA must significantly strengthen its field and international inspection operations. Goals for FY 2009 include increasing foreign and domestic inspections and sampling, improving our laboratory infrastructures, continuing to develop tools for rapid analysis, and, as previously mentioned, establishing an in-country presence in China.

Sharing Foreign Inspection Reports. FDA now has over 30 confidentiality arrangements with foreign counterparts, many of which provide mechanisms for sharing inspection reports. FDA intends to increase the use of these arrangements to obtain useful information that can help the Agency make more informed judgments about the safety of foreign-sourced products, in prioritizing our foreign inspection activities, and on detaining unsafe products.

Providing for Certification by Third Parties. As recommended in the President's Action Plan for Import Safety, FDA is pursuing the use of voluntary third party certification to

verify compliance with FDA requirements. These third parties may include foreign government agencies and independent entities who have been accredited by FDA or accreditation organizations recognized by FDA. With proper structuring to stimulate the use of third party certification, this certification would complement, but not supplant, FDA inspectional and other regulatory activities.

Providing Technical Assistance. Another essential element of the Agency Beyond Our Borders Initiative focuses on helping foreign regulators understand FDA standards, laws and regulations by providing technical assistance to counterpart foreign regulators and outreach assistance to foreign industries that engage in trade with the U.S.

Intervention

FDA recognizes the importance of a strong and effective intervention capacity to identify problems as they occur.

Information Technology (IT). FDA has several plans to enhance its IT systems in ways that will enable the Agency to better utilize risk-based information throughout the life-cycle of imported products. These projects will improve databases, enhance interoperability of systems within the Agency and among other regulatory agencies, and provide better analytical function to assess and control risk. We expect these improvements will help to target our intervention efforts related to foreign firms.

Expanding Laboratory Capacity & Development of Rapid Test Methods. FDA must be agile and scientifically sophisticated, with the ability to develop rapid test methods for detection of pathogens and other contaminants in products, and to ensure that these test

methods are available at ports-of-entry to assist in determining whether a product should be admitted into the U.S. FDA research laboratories develop and validate methods, such as the test FDA developed to determine the contaminant in heparin ingredients imported from China. This novel testing method is now accepted and used worldwide to detect the presence of hypersulfated chondroitin sulfate in heparin.

Prioritizing Surveillance Inspections. In addition to pre-approval inspections, FDA conducts surveillance inspections of domestic and foreign manufacturers and uses a risk-based priority model to determine which facilities may pose a risk to the American consumer. FDA staff must consider a number of elements in making a risk-based priority determination, including: the class of device, the date the facility was last inspected, the compliance history of the firm, the firm's shipping volume and history, and information from the local regulatory authorities regarding the manufacturing quality and regulatory status of the establishment.

Response

When a health threat emerges with any FDA-regulated product, whether manufactured domestically or abroad, FDA must be ready to take immediate action.

Making the Border an Integrated Checkpoint. The Action Plan for Import Safety calls for increased FDA and CBP cooperation, including the development of interdepartmental procedures for clearing and controlling shipments at ports-of-entry, co-locating FDA and CBP at locations to improve coordination and efficient use of resources, and greater import information sharing between FDA and CBP through new technology applications.

Rapid Deployment of "For Cause" Inspections. When FDA has information that raises doubts about the safety of a regulated product, it will rapidly conduct domestic or foreign "for cause" inspections. In such cases, the Agency targets a particular firm or product as an inspection priority based on this information and rapidly deploys an inspection team.

Expanded Use of Track-and-Trace Technologies. FDA is working to facilitate the adoption by industry of track-and-trace technologies to identify and track a product along the product's life-cycle. These technologies will facilitate the timely recovery of the violative product and reduce the opportunity for harm, as well as secure the integrity of the supply. The use of track-and-trace technologies provides important life-cycle information back to the point-of-origin. Under the Food and Drug Administration Amendments Act of 2007, FDA is working to develop or recognize unique identifiers which may support product identification technologies.

NEW AUTHORITIES

The Action Plan for Import Safety called for providing a number of new authorities in order to enhance the safety of imported products. It requests authority to establish mandatory import certification programs -- using accredited third parties (which could include federal departments, foreign governments, or private entities) – that are based on product risk to verify compliance with U.S. safety standards. As appropriate, mandatory import certification would include periodic on-site inspections, random testing and certification renewal based on product risk. Product certification could be mandatory for certain high-risk products coming from countries with which the U.S. has entered into agreements. Under the agreements, the countries or accredited third-parties would

certify products as meeting U.S. standards prior to their export to the U.S. Such a procedure would be limited to high-risk products that have been shown to pose a threat to public health.

Additionally, the plan recommends authorizing FDA to refuse admission of a foreign manufacturer's product when FDA encounters undue delay, limits, or denials of access to the foreign manufacturing sites where the product was produced. At present, foreign firms can often deny inspectors access to their facilities without any adverse consequence. The plan also requests authority to expedite destruction of refused medical products, which will prevent unsafe medical products for personal use from entering the U.S. market. Finally, amending the FD&C Act to include asset forfeiture remedies for certain criminal offenses would allow the forfeiture of all vessels, vehicles, aircraft and other equipment used to aid in the importing, exporting, transporting, selling, receiving, acquiring and purchasing of violative products by those who knowingly and willingly violate the Act.

FDA GLOBALIZATION ACT OF 2008

We commend the Members of this Subcommittee and their staffs for developing the discussion draft entitled, the "Food and Drug Administration Globalization Act of 2008." We recognize and appreciate the Committee's efforts to include new authorities requested by the Administration in support of the Action Plan for Import Safety.

We are in the process of reviewing the discussion draft in detail and we look forward to working with you on this legislation. At this time we can, however, describe some general principles that guided the development of the Action Plan for Import Safety

which we believe should also guide the development of product safety legislation.

- Any legislation should move to a more risk-based, cost-effective approach to identify and mitigate risks posed by imported products.
- Given the breadth and scope of products imported into the U.S., as well as those produced domestically, FDA cannot rely on inspection as its primary means of ensuring product safety. Any legislation should build on the framework in the Action Plan for Import Safety, i.e., building in safety measures to address risks throughout a product's life cycle and focus efforts on preventing problems first, and then using risk-based interventions to ensure preventive approaches are effective, coupled with a rapid response as soon as a problem is detected.
- While the Administration is supportive of user fee programs in which regulated industry provides funding for additional performance and efforts or programs designed to recoup the costs of regulatory actions resulting from findings of violations (such as reinspections), the Administration will carefully review any proposed user fee program to ensure that it is being assessed against identifiable recipients of special benefits derived from Federal activities beyond those received by the general public.
- Any legislation should be carefully designed to avoid creating real or perceived trade barriers, and several provisions of the bill may need to be reviewed in light of U.S. trade agreement obligations. We are reaching out to the U.S. Trade Representative for further insight on these.
- Any legislation should empower robust voluntary private sector efforts already underway.

With these in mind, we believe the proposed legislation should be more closely targeted and prioritized according to risk. Several of the legislative sections appear not to be sufficiently focused on high-risk products. Some of these requirements would divert resources, which could detract from important product safety and security priorities. In addition, the legislation should more explicitly incorporate the Administration's strategy of leveraging third party certification and efforts by foreign nations already underway.

CONCLUSION

As you can see, efforts are underway at FDA to ensure that products are safe and medical products are safe and effective regardless of where they are manufactured. We share your interest in enhancing the safety of imported products and look forward to continuing to work with Members and staff on the Committee and Subcommittee. We also look forward to working with you on the Action Plan for Import Safety. Thank you for the opportunity to testify today, and we are happy to respond to any questions you may have.

Mr. PALLONE. Well, now I did stop you. That wasn't my intention.

Dr. Crosse.

STATEMENT OF MARCIA CROSSE, DIRECTOR OF HEALTHCARE, GENERAL ACCOUNTING OFFICE

Dr. CROSSE. Thank you, Mr. Chairman and members of the subcommittee. I am pleased to be here today as you examine FDA's oversight of medical devices.

At the request of the full committee, we have been reviewing a number of issues related to FDA's foreign inspection programs. A variety of medical devices are manufactured in other countries, including high-risk devices designed to be implanted or used in invasive procedures. Our work points to one conclusion: FDA's programs have not kept up with the globalization of manufacturing and the products that FDA regulates. FDA's inspections of foreign establishments are infrequent. The agency's data systems have been rife with errors and lack fundamental capabilities needed to manage the programs, and the Agency has faced several challenges unique to conducting foreign inspections.

Since I first testified about these problems, FDA has announced a number of initiatives to address these concerns, as we have heard today from Dr. Sundlof. FDA's initiatives have the potential to strength FDA's foreign device inspection program but they do not fully address the weaknesses.

FDA is required to inspect every 2 years all domestic establishments manufacturing medical devices classified as being of high risk, or Class III, such as pacemakers and defibrillators, or medium risk, or Class II, such as syringes and hearing aids. There is no comparable time requirement for inspecting foreign establishments, but FDA is responsible for ensuring that they meet the same standards required of domestic establishments. We found that FDA has not met the statutory requirement for domestic inspections of medical device establishments and foreign medical device establishments are inspected less frequently, about every 6 years for Class III devices or 27 years for Class II devices. As of September 2007, there were about 5,000 Class II and III foreign device establishments registered with FDA, of which fewer than 300 were inspected last year.

FDA has faced particular challenges in managing its foreign inspection program. FDA's databases contain inaccurate information about foreign medical device establishments and the products they manufacture. A recent change to FDA's medical device registration process could improve the accuracy of the registration data. The new process includes electronic registration with an annual registration fee currently set at about $1,700.

Another initiative aimed at reducing duplication in its import database is a proposal that FDA has supported to change the data it receives from Customs and Border Protection on products entering the United States. However, the implementation of this proposal is not certain and would require action from multiple Federal agencies. In addition, inspections of foreign medical device establishments pose challenges to FDA in human resources and logistics. FDA depends upon volunteer inspectors, lacks independent trans-

lators and has difficulty altering the travel itinerary if problems are uncovered that might warrant further review. FDA has proposed establishing a dedicated cadre of staff to conduct foreign inspections but the overall time frame associated with this initiative is unclear.

FDA has also announced plans to establish offices overseas with an initial eight FDA staff to be based in China and five Chinese nationals to provide translation and other support. However, the impact that these offices will have on the foreign device inspection program is unknown because these staff would be responsible for all FDA-regulated products.

Finally, over the years there has been interest in using third parties to supplement FDA's inspection resources. We found, however, that few inspections have been conducted through FDA's two accredited third-party inspection programs. In the 4 years since FDA first cleared an accredited organization to conduct independent medical device inspections, a total of 11 inspections have been conducted, 6 of foreign establishments and 5 of domestic establishments.

In conclusion, given the growth in foreign device manufacturing for the U.S. market and the relatively few foreign inspections conducted by FDA, the Agency will need to devote considerable resources to this area if it to increase the rate of inspections. The agency has recently taken some positive steps to improve its foreign inspection program including announcing plans to increase its presence overseas. However, it is too early to tell whether these steps will ultimately enhance the Agency's ability to ensure the safety and effectiveness of medical devices marketed in the United States.

Mr. Chairman, this concludes my prepared remarks. I would be happy to answer any questions that you or other members of the subcommittee may have.

[The prepared statement of Dr. Crosse follows:]

United States Government Accountability Office

GAO

Testimony
Before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

For Release on Delivery Expected at 10:00 a.m. EDT Wednesday, May 14, 2008

MEDICAL DEVICES

FDA Faces Challenges in Conducting Inspections of Foreign Manufacturing Establishments

Statement of Marcia Crosse
Director, Health Care

GAO-08-780T

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you examine the Food and Drug Administration's (FDA) program for inspecting foreign manufacturers of medical devices for the U.S. market. FDA is responsible for the regulation of medical devices[1] marketed in the United States, including those manufactured in foreign establishments.[2] FDA classifies medical devices into one of three classes based on degree of potential risk and level of control needed to reasonably ensure safety and effectiveness.[3] According to FDA data, a wide variety of class II (medium risk) and III (high risk) medical devices may be manufactured for the U.S. market by foreign establishments. Such devices include defibrillators, contact lenses, pacemakers, hip prostheses, and coronary stents.[4] FDA is responsible for inspecting certain foreign and domestic establishments to ensure they meet required manufacturing standards; such inspections are FDA's primary means of assuring that the safety and effectiveness of medical devices are not jeopardized by poor manufacturing practices.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) addressed concerns about FDA's ability to meet its responsibilities for inspecting medical device manufacturing establishments.[5] MDUFMA included provisions designed to (1) increase the number of inspected medical device manufacturing establishments and (2) help medical device manufacturers meet the inspection requirements of both the United States and foreign countries in a single inspection. Specifically, MDUFMA required FDA to

[1]Medical devices include instruments, apparatuses, machines, and implants that are intended for use to diagnose, cure, treat, or prevent disease, or to affect the structure or any function of the body. 21 U.S.C. § 321(h).

[2]FDA regulations define an establishment as a place of business under one management at one general physical location at which a device is manufactured, assembled, or otherwise processed. 21 C.F.R. § 807.3(c) (2007). Medical device manufacturers may have more than one establishment. We use the term "manufacture" to refer to activities including manufacturing, preparing, and processing devices.

[3]21 U.S.C. § 360c. Medical devices are classified into one of three classes. Class I includes "low risk" devices, such as tongue depressors, elastic bandages, and bedpans. Class II includes "medium risk" devices, such as syringes, hearing aids, and electrocardiograph machines. Class III includes "high risk" devices, such as heart valves, pacemakers, and defibrillators.

[4]A coronary stent is a small tube that is placed within a coronary artery to keep the vessel open.

[5]See Pub. L. No. 107-250, § 201, 116 Stat. 1588, 1602-09 (2002) (codified as amended at 21 U.S.C. § 374(g)).

accredit third-party organizations to conduct inspections of certain foreign and domestic establishments.[6] In response, FDA implemented its Accredited Persons Inspection Program, which permits certain establishments to voluntarily request inspections from third-party organizations to meet inspectional requirements. In January 2007, we reported on the status of this program citing, among other things, concerns regarding its implementation and potential incentives and disincentives that may influence manufacturers' participation.[7] Additionally, in partnership with Health Canada,[8] FDA established in September 2006 another program for inspection by accredited third parties—the Pilot Multi-purpose Audit Program (PMAP)—that allows accredited organizations to conduct a single inspection to meet the regulatory requirements of both countries.

My remarks today are based primarily on our January 2008 statement, which updated our January 2007 report, on FDA's management of its medical device inspection program and our April 2008 statement on a number of new FDA initiatives related to foreign inspections of FDA regulated products, including medical devices.[9] My remarks will focus on our assessment of (1) FDA's program for inspecting foreign establishments that manufacture medical devices for the U.S. market and (2) FDA's programs for third-party inspections of foreign medical device manufacturing establishments.

To address these objectives, we used work completed for our January 2008 statement on FDA's medical device inspection program, for which we interviewed officials from FDA's Center for Devices and Radiological Health

[6]In this report, unless otherwise noted, when we discuss inspections, we are referring to those conducted by FDA investigators.

[7]GAO, *Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations*, GAO-07-157 (Washington, D.C.: Jan. 5, 2007).

[8]Health Canada is the governmental entity that regulates medical devices marketed in Canada.

[9]GAO, *Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections*, GAO-08-428T (Washington, D.C.: Jan. 29, 2008) and GAO, *Drug Safety: Preliminary Findings Suggest Recent FDA Initiatives Have Potential, but Do Not Fully Address Weaknesses in Its Foreign Drug Inspection Program*, GAO-08-701T (Washington, D.C.: Apr. 22, 2008).

(CDRH) and Office of Regulatory Affairs (ORA), which have responsibilities for managing the medical device inspection program.[10] To assess FDA's program for inspecting foreign establishments that manufacture medical devices, we obtained information from FDA's Device Registration and Listing System (DRLS), as of September 19, 2007; Field Accomplishments and Compliance Tracking System (FACTS) for fiscal year 2002 through fiscal year 2007; and Operational and Administrative System for Import Support (OASIS) for fiscal year 2007. We assessed the reliability of these data by (1) reviewing existing information about the data and the databases that produced them, (2) interviewing agency officials knowledgeable about the data, and (3) performing electronic testing of data elements from DRLS and FACTS. We found the data in the FACTS database sufficiently reliable for our purposes. We also found that DRLS was sufficiently reliable, to the extent that it accurately reflects information provided by foreign establishments that register to market medical devices in the United States. However, we determined that these data do not necessarily reflect the number of establishments that manufacture medical devices for the U.S. market. In addition, we found that OASIS is likely to overestimate the number of foreign establishments whose medical devices have been imported into the United States because of uncorrected errors in the data. Therefore, we present information from both DRLS and OASIS to illustrate the variability in information that FDA's databases provide on this topic. These data represent the best information available and are what FDA relies on to manage its foreign medical device inspection activities. In addition, in preparation for our April 2008 statement, we obtained information from FDA officials to learn about recent initiatives to improve the agency's program for inspecting establishments manufacturing FDA-regulated products, including medical devices. For today's statement, we obtained additional data from FDA to update selected information from our January 2008 statement.

To examine FDA's programs for third-party inspections of foreign medical device manufacturing establishments, we updated work completed for our January 2008 statement. We obtained FDA data on the number of inspections conducted by accredited third parties from March 11, 2004—the date when FDA first cleared an accredited organization to conduct

[10]Within FDA, the Center for Biologics Evaluation and Research regulates medical devices involved in human immunodeficiency virus (HIV) testing and the collection, processing, testing, manufacture, and administration of licensed blood, blood components, and cellular products. We did not include medical devices regulated by this center in the scope of our work.

inspections—through May 7, 2008. For our January 2008 statement, we also obtained information from FDA about other critical aspects of its programs for inspections by accredited third parties. To gain perspective on recent changes to FDA's programs for inspections by accredited third parties, we contacted representatives of the same 13 affected entities we interviewed for our January 2007 report on this topic.[11] We received responses from 2 of 4 accredited organizations, 1 of 6 medical device manufacturers, and 2 of 3 organizations that represent medical device manufacturers. We shared the facts contained in our current statement with FDA officials. FDA provided technical comments, which are appropriately addressed in the testimony. We conducted audit work for the January 2008 statement from December 2007 to January 2008; for our April 2008 statement, from March 2008 through April 2008; and updated our work on medical devices in early May 2008 for this statement. We conducted this work 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.

In summary, we found that FDA faces challenges in its program to inspect foreign establishments manufacturing medical devices. In January 2008, we testified that two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market contained inaccurate information about establishments subject to FDA inspection and could not exchange information. Since then, FDA has made changes to its registration process that could improve its database and provide the agency with a more accurate count of foreign establishments that manufacture medical devices. While the agency has initiated other steps to improve its databases, it is too soon to know if these changes will improve FDA's management of its foreign inspection program. Another challenge is that FDA conducts relatively few inspections of foreign establishments that manufacture medical devices. Officials estimated the agency had inspected foreign class II manufacturers every 27 years and foreign class III manufacturers every
6 years. Finally, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA, such as difficulties in

[11]These affected entities included accredited organizations, organizations that represent medical device manufacturers, and medical device manufacturers.

recruiting investigators to voluntarily travel to certain countries and in extending trips if problems are identified during inspections. FDA is pursuing initiatives that could address some of these challenges, but it is unclear whether the agency's proposals will increase the frequency with which FDA inspects foreign establishments.

Few inspections of foreign medical device manufacturing establishments have been conducted through FDA's two programs for inspections by accredited third parties—the Accredited Persons Inspection Program and PMAP. Under FDA's Accredited Persons Inspection Program, from March 11, 2004—the date when FDA first cleared an accredited organization to conduct inspections—through May 7, 2008, four inspections of foreign establishments had been conducted by accredited organizations. To participate in this program, manufacturers must decide to request an inspection by an accredited organization, and this decision might be influenced by both potential incentives and disincentives. An incentive to participation in the program is the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. Disincentives include bearing the cost for the inspection, particularly when the consequences of an inspection that otherwise may not occur in the near future could involve regulatory action. The Food and Drug Administration Amendments Act of 2007 (FDAAA) changed the requirements for inspections by accredited third parties in several ways, which could result in increased participation by manufacturers, although it is too soon to tell. For example, a requirement that foreign establishments be periodically inspected by FDA before being eligible for third-party inspections was eliminated. Device manufacturers may also request an inspection by an accredited third party through PMAP, which was established on September 7, 2006, and is limited to a partnership with Canada. As of May 7, 2008, two inspections of foreign establishments had been conducted by an accredited organization through PMAP. The small number of inspections completed by accredited third-party organizations raises questions about the practicality and effectiveness of these programs to help FDA conduct additional foreign inspections.

Background

FDA is responsible for overseeing the safety and effectiveness of medical devices that are marketed in the United States, whether manufactured in domestic or foreign establishments. All establishments that manufacture

medical devices for marketing in the United States are required to register annually with FDA.[12] As part of its efforts to ensure the safety, effectiveness, and quality of medical devices, FDA is responsible for inspecting certain foreign and domestic establishments to ensure that, among other things, they meet manufacturing standards established in FDA's quality system regulation.[13] Within FDA, CDRH is responsible for assuring the safety and effectiveness of medical devices. Among other things, CDRH works with ORA, which conducts inspections of foreign establishments. FDA may conduct inspections before and after medical devices are approved or otherwise cleared to be marketed in the United States.

- Premarket inspections are conducted before FDA approves U.S. marketing of a new medical device that is not substantially equivalent to one that is already on the market.[14] Premarket inspections primarily assess manufacturing facilities, methods, and controls and may verify pertinent records.

- Postmarket inspections are conducted after a medical device has been approved or otherwise cleared to be marketed in the United States and include several types of inspections: (1) Quality system inspections are conducted to assess compliance with applicable FDA regulations, including the quality system regulation to ensure good manufacturing practices and the regulation requiring reporting of adverse events.[15] These inspections may be comprehensive or abbreviated, which differ in the scope of inspectional activity. Comprehensive postmarket inspections assess multiple aspects of the manufacturer's quality system, including management controls, design controls, corrective and preventative actions, and production and process controls. Abbreviated postmarket inspections assess only some of these

[12]21 U.S.C. § 360(b), (i).

[13]21 C.F.R. pt. 820 (2007). The quality system regulation requires, among other things, that domestic or foreign manufacturers have a quality system in place to implement current good manufacturing practices in the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for human use in the United States. A quality system includes the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

[14]Currently, most medical devices are cleared for marketing in the United States because they are determined to be "substantially equivalent" to a marketed device. FDA generally does not conduct premarket inspections of establishments manufacturing these types of medical devices.

[15]21 C.F.R. pt. 803 (2007).

aspects, but always assess corrective and preventative actions. (2) For-cause and compliance follow-up inspections are initiated in response to specific information that raises questions or problems associated with a particular establishment.
(3) Postmarket audit inspections are conducted within 8 to 12 months of a premarket application's approval to examine any changes in the design, manufacturing process, or quality assurance systems.

Requirements governing foreign and domestic inspections differ. Specifically, FDA is required to inspect domestic establishments that manufacture class II or III medical devices every 2 years.[16] There is no comparable requirement to inspect foreign establishments. FDA does not have authority to require foreign establishments to allow the agency to inspect their facilities. However, if an FDA request to inspect is denied, FDA may prevent the importation of medical devices from that foreign establishment into the United States. In addition, FDA has the authority to conduct physical examinations of products offered for import and, if there is sufficient evidence of a violation, prevent their entry at the border.[17] Unlike food, for which FDA primarily relies on inspections at the border, physical inspection of manufacturing establishments is a critical mechanism in FDA's process to ensure that medical devices are safe and effective and that manufacturers adhere to good manufacturing practices.

FDA determines which establishments to inspect using a risk-based strategy. High priority inspections include premarket approval inspections for class III devices, for-cause inspections, inspections of establishments that have had a high frequency of device recalls, and other devices and manufacturers FDA considers high risk. The establishment's inspection history may also be considered. A provision in FDAAA may assist FDA in making decisions about which establishments to inspect because this law authorizes the agency to accept voluntary submissions of audit reports addressing manufacturers' conformance with internationally established standards for the purpose of setting risk-based inspectional priorities.[18]

[16]21 U.S.C. § 360(h). There is no statutory requirement for inspection of class I medical device manufacturing establishments, and FDA does not routinely inspect them. However, FDA periodically inspects establishments manufacturing surgeon's gloves and patient examination gloves, which are both class I medical devices, due to ongoing problems with leakage. FDA also periodically inspects manufacturers of randomly selected class I devices.

[17]21 U.S.C. § 381(a); 21 C.F.R. § 820.1(d) (2007).

[18]Pub. L. No. 110-85, § 228, 121 Stat. 823, 858 (2007).

FDA's programs for foreign and domestic inspections by accredited third parties provide an alternative to the traditional FDA-conducted comprehensive postmarket quality system inspection for eligible manufacturers of class II and III medical devices. MDUFMA required FDA to accredit third persons—which are organizations—to conduct inspections of certain establishments. In describing this requirement, the House of Representatives Committee on Energy and Commerce noted that some manufacturers have faced an increase in the number of inspections required by foreign countries and that the number of inspections could be reduced if the manufacturers could contract with a third-party organization to conduct a single inspection that would satisfy the requirements of both FDA and foreign countries.[19] Manufacturers that meet eligibility requirements may request a postmarket inspection by an FDA-accredited organization.[20] The eligibility criteria for requesting an inspection of an establishment by an accredited organization include that the manufacturer markets a medical device in the United States and markets (or intends to market) a medical device in at least one other country and that the establishment to be inspected must not have received warnings for significant deviations from compliance requirements on its last inspection.[21]

MDUFMA also established minimum requirements for organizations to be accredited to conduct third-party inspections, including protections against financial conflicts of interest and assurances of the competence of the organization to conduct inspections. FDA developed a training program for inspectors from accredited organizations that involves both formal classroom

[19]H.R. Rep. No. 107-728, pt. 1, at 32-36 (2002). Some foreign countries have accredited, certified, or otherwise recognized organizations to conduct inspections. We use the term "single inspection" to mean a complete inspection that covers all requirements of two or more countries, without repeating those activities covered under more than one set of requirements. A complete inspection can be conducted during a single block of time or in multiple phases. Two or more separate inspection reports could be generated on the basis of that single inspection.

[20]Accredited organizations may conduct comprehensive postmarket quality system inspections, but not other types of inspections of establishments that FDA has the authority to conduct, such as premarket or for-cause inspections. FDA may conduct its own inspections of establishments even after inspection by an accredited organization.

[21]See 21 U.S.C. § 374(g)(6). FDAAA eliminated certain previously established eligibility requirements. For example, it eliminated a limitation on the number of consecutive inspections allowed by an accredited organization and a limitation that foreign establishments must be inspected periodically by FDA.

training and completion of three joint training inspections with FDA. Each individual inspector from an accredited organization must complete all training requirements successfully before being cleared to conduct independent inspections. FDA relies on manufacturers to volunteer to host these joint inspections, which count as FDA postmarket quality system inspections.

A manufacturer that is cleared to have an inspection by an accredited third party enters an agreement with the approved accredited organization and schedules an inspection. Once the accredited organization completes its inspection, it prepares a report and submits it to FDA, which makes the final assessment of compliance with applicable requirements. FDAAA added a requirement that accredited organizations notify FDA of any withdrawal, suspension, restriction, or expiration of certificate of conformance with quality systems standards (such as those established by the International Organization for Standardization) for establishments they inspected for FDA.[22]

In addition to the Accredited Persons Inspection Program, FDA has a second program for accredited third-party inspections of medical device establishments. On September 7, 2006, FDA and Health Canada announced the establishment of PMAP. This pilot program was designed to allow qualified third-party organizations to perform a single inspection that would meet the regulatory requirements of both the United States and Canada. The third-party organizations eligible to conduct inspections through PMAP are those that FDA accredited for its Accredited Persons Inspection Program (and that completed all required training for that program) and that are also authorized to conduct inspections of medical device establishments for Health Canada. To be eligible to have a third-party inspection through PMAP, manufacturers must meet all criteria established for the Accredited Persons Inspection Program. As with the Accredited Persons Inspection Program, manufacturers must apply to participate and be willing to pay an accredited organization to conduct the inspection.

FDA relies on multiple databases to manage its program for inspecting medical device manufacturing establishments.

- FDA's medical device registration and listing database contains information on domestic and foreign medical device establishments that have registered

[22] 21 U.S.C. § 374(g)(3)(F).

with FDA. Establishments that are involved in the manufacture of medical devices intended for commercial distribution in the United States are required to register annually with FDA. These establishments provide information to FDA, such as an establishment's name and its address and the medical devices it manufactures. Prior to October 1, 2007, this information was maintained in DRLS. As of October 1, 2007, establishments are required to register electronically through FDA's Unified Registration and Listing System and certain medical device establishments pay an annual establishment registration fee, which in fiscal year 2008 is $1,706.[23]

- OASIS contains information on medical devices and other FDA-regulated products imported into the United States, including information on the establishment that manufactured the medical device. The information in OASIS is automatically generated from data managed by Customs and Border Protection (CBP). These data are originally entered by customs brokers based on the information available from the importer.[24] CBP specifies an algorithm by which customs brokers generate a manufacturer identification number from information about an establishment's name, address, and location.

- FACTS contains information on FDA's inspections, including those of domestic and foreign medical device establishments. FDA investigators enter information into FACTS following completion of an inspection.

According to FDA data, there are more registered establishments in China and Germany reporting that they manufacture class II or III medical devices

[23]21 U.S.C. §§ 360(i)(1), (p), 379i(13), 379j(a)(3), (b), (h). The registration user fee will increase by 8.5 percent per year, to $2,364 in fiscal year 2012. Fees are available for obligation only to the extent and in the amount provided in advance in annual appropriations acts. FDA's authority to assess registration fees terminates on October 1, 2012. Pub. L. No. 110-85, § 217; 121 Stat. 823, 852 (2007).

[24]Customs brokers are private individuals, partnerships, associations, or corporations licensed, regulated, and empowered by CBP to assist in meeting federal requirements governing imports and exports.

than in any other foreign countries.[25] Canada and the United Kingdom also have a large number of registered establishments.

FDA Faces Challenges Conducting Inspections of Foreign Establishments That Manufacture Medical Devices

FDA faces challenges in its program to inspect foreign establishments manufacturing medical devices. The databases that provide FDA with data about the number of foreign establishments manufacturing medical devices for the U.S. market have not provided it with an accurate count of foreign establishments for inspection. In addition, FDA conducted relatively few inspections of foreign establishments. Moreover, inspections of foreign medical device manufacturing establishments pose unique challenges to FDA—both in human resources and logistics.

FDA Lacks Accurate Data on the Number of Foreign Establishments Subject to Inspection, but Has Made Recent Attempts to Improve Its Data

FDA's databases on registration and imported medical devices have not provided an accurate count of establishments subject to inspection, although recent improvements to FDA's medical device registration database may address some weaknesses. In January 2008, we testified that DRLS provided FDA with information about foreign medical device establishments and the products they manufacture for the U.S. market. According to DRLS, as of September 2007, 4,983 foreign establishments that reported manufacturing a class II or III medical device for the U.S. market had registered with FDA.[26] However, these data contained inaccuracies because establishments may register with FDA but not actually manufacture a medical device or may manufacture a medical device that is not marketed in the United States. In addition, FDA did not routinely verify the data within this database.

Recent changes to FDA's medical device establishment registration process could improve the accuracy of its database. In fiscal year 2008, FDA implemented, in addition to its annual user fee, electronic registration and an active re-registration process for medical device establishments.[27]

[25]Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan as these establishments are tracked separately.

[26]DRLS contained one additional registered establishment for which location information was not available.

[27]FDA indicated that it will deactivate the registrations of those establishments that fail to complete the annual registration. Officials noted that many establishments that had previously registered had not updated those registrations in several years.

According to FDA, about half of previously registered establishments had reregistered using the new system as of April 11, 2008.[28] While FDA officials expect that additional establishments will reregister, they expect that the final result will be the elimination of establishments that do not manufacture medical devices for the U.S. market and thus a smaller, more accurate database of medical device establishments. FDA officials indicated that implementation of electronic registration and the annual user fee seemed to have improved the data so FDA can more accurately identify the type of establishment registered, the devices manufactured at an establishment, and whether or not an establishment should be registered. According to FDA officials, the revenue from device registration user fees is applied to the process for the review of device applications, including premarket inspections.[29]

FDA has also proposed, but not yet implemented, the Foreign Vendor Registration Verification Program, which could also help improve the accuracy of information FDA maintains on registered foreign establishments. Through this program, FDA plans to contract with an external organization to conduct on-site verification of the registration data and product listing information of foreign establishments shipping medical devices and other FDA-regulated products to the United States. FDA has solicited proposals for this contract, but it is still developing the specifics of the program. For example, as of April 2008, the agency had not yet established the criteria it would use to determine which establishments would be visited for verification purposes or determined how many establishments it would verify annually. FDA plans to award this contract in June 2008. Given the early stages of this process, it is too soon to determine whether this program will improve the accuracy of the data FDA maintains on foreign medical device establishments.

FDA also obtains information on foreign establishments from OASIS, which tracks the importation of medical devices and other FDA-regulated products.

[28]According to FDA, the agency sent letters on April 11, 2008 and April 14, 2008 to establishments that had registered in the past but had not completed their registration for fiscal year 2008 advising them that they must register using the new system and must pay the registration fee, if applicable, to be considered registered. Establishments that do not reregister within a month of those letters would be considered inactive. As of May 6, 2008, prior to the mid-May deadline, FDA reported that 4,284 registered foreign establishments reported that they manufacture class II or class III medical devices. This total also includes some establishments that may not reregister.

[29]See 21 U.S.C. §§ 379i(8), 379j(h)(1), (2).

While not intended to provide a count of establishments, OASIS does contain information about the medical devices actually being imported into the United States and the establishments manufacturing them. However, inaccuracies in OASIS prevent FDA from using it to develop a list of establishments subject to inspection. OASIS contains an inaccurate count of foreign establishments manufacturing medical devices imported into the United States as a result of unreliable identification numbers generated by customs brokers when the product is offered for entry.[30] FDA officials told us that these errors result in the creation of multiple records for a single establishment, which results in inflated counts of establishments offering medical devices for entry into the U.S. market. According to OASIS, in fiscal year 2007, there were as many as 22,008 foreign establishments that manufactured class II medical devices for the U.S. market and 3,575 foreign establishments that manufactured class III medical devices for the U.S. market.[31]

FDA has supported a proposal with the potential to address weaknesses in OASIS, but FDA does not control the implementation of this proposed change. FDA is pursuing the creation of a governmentwide unique establishment identifier, as part of the Shared Establishment Data Service (SEDS), to address these inaccuracies.[32] Rather than relying on the creation and entry of an identifier at the time of import, SEDS would provide a unique establishment identifier and a centralized service to provide commercially verified information about establishments.[33] The standard identifier would be submitted as part of import entry data when required by FDA or other government agencies. SEDS could thus eliminate the problems that have resulted in multiple identifiers associated with an individual establishment. The implementation of SEDS is dependent on action from multiple federal agencies, including the integration of the

[30]The algorithm currently used by customs brokers to assign the manufacturer identification number does not provide for a number that is reliably reproduced or inherently unique.

[31]According to FDA officials, a single establishment could be manufacturing more than one class of device.

[32]The SEDS concept was developed by a working group with representatives from FDA, the Environmental Protection Agency, and the departments of Agriculture, Commerce, Defense, and Homeland Security.

[33]If an establishment did not already have an identification number, it would request an identification number through SEDS, which would verify the data about the establishment through a commercial service. This commercial service would provide researched and validated records on domestic and foreign establishments.

concept into a CBP import and export system under development and scheduled for implementation in 2010. In addition, once implemented by CBP, participating federal agencies would be responsible for bearing the cost of integrating SEDS with their own operations and systems. FDA officials are not aware of a specific time line for the implementation of SEDS. Developing an implementation plan for SEDS was recommended by the Interagency Working Group on Import Safety.[34]

Although comparing information from its registration and import databases could help FDA determine the number of foreign establishments marketing medical devices in the United States, the databases do not exchange information to be compared electronically and any comparisons are done manually. FDA is in the process of implementing additional initiatives to improve the integration of its databases, and these changes could make it easier for the agency to establish an accurate count of foreign manufacturing establishments subject to inspection. The agency's Mission Accomplishments and Regulatory Compliance Services (MARCS) is intended to help FDA electronically integrate data from multiple systems. It is specifically designed to give individual users more complete information about establishments. FDA officials estimated that MARCS, which is being implemented in stages, could be fully implemented by 2011 or 2012. However, FDA officials told us that implementation has been slow because the agency has been forced to shift resources away from MARCS and toward the maintenance of current systems that are still heavily used, such as FACTS and OASIS. Taken together, changes to FDA's databases could provide the agency with more accurate information on the number of establishments subject to inspection. However, it is too early to tell whether this will improve FDA's management of its inspection program.

FDA Inspects Relatively Few Foreign Medical Device Establishments

From fiscal year 2002 through fiscal year 2007, FDA inspected relatively few foreign medical device establishments and primarily inspected establishments located in the United States. During this period, FDA conducted an average of 247 foreign establishment inspections each year,

[34]Interagency Working Group on Import Safety, *Action Plan for Import Safety: A Roadmap for Continual Improvement* (Nov. 2007) (www.importsafety.gov/report/actionplan.pdf, accessed May 6, 2008).

compared to 1,494 inspections of domestic establishments.[35] This average number of foreign inspections suggests that each year FDA inspects about 6 percent of registered foreign establishments that reported manufacturing class II or class III medical devices.[36] FDA officials estimated the agency had inspected foreign class II manufacturers every 27 years and foreign class III manufacturers every 6 years. The inspected foreign establishments were in 44 foreign countries and more than two-thirds were in 10 countries. Most of the countries with the highest number of inspections were also among those with the largest number of registered establishments that reported manufacturing class II or III medical devices. The lowest rate of inspections in these 10 countries was in China, where 64 inspections were conducted in this 6-year period and 568 establishments were registered as of May 6, 2008. (See table 1.)

Table 1: Number of FDA Inspections of Foreign Medical Device Establishments, Fiscal Year 2002 through Fiscal Year 2007

	Number of inspections[a]							
Country	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	Total	Number of registered class II or III manufacturing establishments[b]
Germany	39	30	34	51	25	52	**231**	460
United Kingdom	25	31	28	14	25	43	**166**	277
Canada	17	17	24	11	13	26	**108**	282

[35]We were unable to differentiate inspections according to medical device classification. FDA's inspection database contains the most recent information available to FDA about the class of device manufactured at the establishment and consequently does not contain readily available information about the class of devices manufactured at the time of a specific inspection. As a result, the data we present include all inspections, regardless of the classification of the manufactured device or devices. According to FDA officials, FDA primarily conducts inspections of establishments manufacturing class II or III medical devices.

[36]This calculation is based on the 4,284 registered establishments that reported that they manufacture class II or III medical devices, as of May 6, 2008.

	Number of inspections[a]							
Country	FY 2002	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	Total	Number of registered class II or III manufacturing establishments[b]
Japan	7	8	20	21	16	25	**97**	210
Ireland	15	22	13	13	16	11	**90**	62
France	16	14	17	14	12	10	**83**	154
Switzerland	6	12	19	9	7	18	**71**	108
China[c]	0	0	21	19	11	13	**64**	568[d]
Mexico	10	7	12	8	12	11	**60**	122
Italy	8	7	10	6	13	11	**55**	170
All other countries	66	83	102	67	69	69	**456**	1,871
Total	**209**	**231**	**300**	**233**	**219**	**289**	**1,481**	**4,284**

Source: GAO analysis of FDA data.

[a]We were unable to differentiate inspections according to medical device classification. FDA's inspection database contains the most recent information available to FDA about the class of device manufactured at the establishment and consequently does not contain readily available information about the class of devices manufactured at the time of a specific inspection. As a result, the data we present include all inspections, regardless of the classification of the manufactured device or devices. According to FDA officials, FDA primarily conducts inspections of establishments manufacturing class II or III medical devices.

[b]These counts represent the number of registered establishments as of May 6, 2008.

[c]The inspection counts for China do not include inspections conducted in Hong Kong or Taiwan because these inspections are tracked separately in FACTS.

[d]Counts of registered establishments in China do not include establishments registered in Hong Kong or Taiwan because these establishments are tracked separately.

FDA's inspections of foreign medical device establishments were primarily postmarket inspections. While premarket inspections were generally FDA's highest priority, relatively few have had to be performed in any given year.[37] Therefore, FDA focused its resources on postmarket inspections. From fiscal year 2002 through fiscal year 2007, 89 percent of the 1,481 foreign establishment inspections were for postmarket purposes.

[37]Currently, most medical devices are cleared for marketing in the United States because they are determined to be "substantially equivalent" to a marketed device. FDA generally does not conduct premarket inspections of establishments manufacturing these types of medical devices.

FDA Faces Unique Challenges in Conducting Foreign Inspections

Inspections of foreign establishments pose unique challenges to FDA—both in human resources and logistics. FDA does not have a dedicated cadre of investigators that only conduct foreign medical device establishment inspections; those staff who inspect foreign establishments also inspect domestic establishments. Among those qualified to inspect foreign establishments,[38] FDA relies on staff to volunteer to conduct inspections. FDA officials told us that it has been difficult to recruit investigators to voluntarily travel to certain countries. However, they added that if the agency could not find an individual to volunteer for a foreign inspection trip, it would mandate the travel. Logistically, foreign medical device establishment inspections are difficult to extend even if problems are identified because the trips are scheduled in advance.[39] Foreign medical device establishment inspections are also logistically challenging because investigators do not receive independent translational support from FDA or the State Department and may rely on English-speaking employees of the inspected establishment or the establishment's U.S. agent to translate during an inspection.

FDA recently announced proposals to address some of the challenges unique to conducting foreign inspections, but specific steps toward implementation and associated time frames are unclear. FDA noted in its report on revitalizing ORA that it was exploring the creation of a cadre of investigators who would be dedicated to conducting foreign inspections.[40] However, the report did not provide any additional details or time frames about this proposal. In addition, FDA announced plans to establish a permanent presence overseas, although little information about these plans is available. FDA intends that its foreign offices will improve cooperation and information exchange with foreign regulatory bodies, improve procedures for expanded inspections, allow it to inspect facilities quickly in an emergency, and facilitate work with private and government agencies to assure standards for quality. FDA's proposed foreign offices are intended to expand the agency's capacity for overseeing, among other things, medical

[38]Staff members must meet certain criteria in terms of their experience and training to conduct inspections of foreign establishments. For example, they are required to take certain training courses and have at least 3 years of experience conducting domestic inspections before they can be considered qualified to conduct a foreign inspection.

[39]Typically, FDA investigators travel abroad for about 3 weeks at a time, during which they inspect approximately three establishments.

[40]See, for example, Food and Drug Administration, *Revitalizing ORA: Protecting the Public Health Together in a Changing World* (Rockville, Md.: January 2008).

devices, drugs, and food that may be imported into the United States. The extent to which the activities conducted by foreign offices are relevant to FDA's foreign medical device inspection program is uncertain. Initially, FDA plans to establish a foreign office in China with three locations—Beijing, Shanghai, and Guangzhou—comprised of a total of eight FDA employees and five Chinese nationals. The Beijing office, which the agency expects will be partially staffed by the end of 2008, will be responsible for coordination between FDA and Chinese regulatory agencies. FDA staff located in Shanghai and Guangzhou, who are to be hired in 2009, will be focused on conducting inspections and working with Chinese inspectors to provide training as necessary. FDA noted that the Chinese nationals will primarily provide support to FDA staff, including translation and interpretation. The agency is also considering setting up offices in other locations, such as India, the Middle East, Latin America, and Europe, but no dates have been specified. While the establishment of both a foreign inspection cadre and offices overseas have the potential for improving FDA's oversight of foreign establishments, it is too early to tell whether these steps will be effective or will increase the number of foreign medical device establishment inspections.

Few Inspections of Foreign Establishments Have Been Conducted Through FDA's Third-Party Programs, but Recent Changes Could Eliminate Some Obstacles to Manufacturers' Participation

Few inspections of foreign medical device manufacturing establishments—a total of six—have been conducted through FDA's two accredited third-party inspection programs, the Accredited Persons Inspection Program and PMAP. FDAAA specified several changes to the requirements for inspections by accredited third parties that could result in increased participation by manufacturers.

Few inspections have been conducted through FDA's Accredited Persons Inspection Program since March 11, 2004—the date when FDA first cleared an accredited organization to conduct independent inspections. Through May 7, 2008, four inspections of foreign establishments had been conducted independently by accredited organizations.[41]

As of May 7, 2008, 16 third-party organizations were accredited, and individuals from 8 of these organizations had completed FDA's training requirements and been cleared to conduct independent inspections.[42] FDA and accredited organizations had conducted 44 joint training inspections. As we previously reported, fewer manufacturers volunteered to host training inspections than have been needed for all of the accredited organizations to complete their training,[43] and scheduling these joint training inspections has been difficult. FDA officials told us that, when appropriate, staff are instructed to ask manufacturers to host a joint training inspection at the time they notify the manufacturers of a pending inspection. FDA schedules inspections a relatively short time prior to an actual inspection,[44] and as we

[41]Two inspections of domestic establishments were also conducted through FDA's Accredited Persons Inspection Program.

[42]Specific foreign jurisdictions that have certified, accredited, or otherwise recognized one or more of the FDA-accredited organizations that have been cleared to conduct independent inspections include all member states of the European Community, Australia, Canada, New Zealand, Norway, Taiwan, and the United Kingdom. Of the eight third-party organizations that have been cleared to conduct independent inspections through the Accredited Persons Inspection Program, four may conduct inspections through PMAP.

[43]As we reported in January 2007, some representatives of affected entities speculated that manufacturers might not have volunteered to host training inspections because they believed that training inspections would require more time and effort for their staff (and would thus be more disruptive) than inspections conducted by fully trained personnel, or that manufacturers might have believed that training inspections would be more rigorous than nontraining inspections if the trainees and FDA personnel were to take particular care to demonstrate their thoroughness to each other.

[44]FDA generally notifies manufacturers about a week in advance of postmarket quality system inspections of domestic establishments and about 6 to 8 weeks in advance of postmarket quality system inspections of foreign establishments.

previously reported, some accredited organizations have not been able to participate because they had prior commitments.

We previously reported that manufacturers' decisions to request an inspection by an accredited organization might be influenced by both potential incentives and disincentives. According to FDA officials and representatives of affected entities, potential incentives to participation include the opportunity to reduce the number of inspections conducted to meet FDA and other countries' requirements. For example, one inspection conducted by an accredited organization was a single inspection designed to meet the requirements of FDA, the European Union, and Canada. Another potential incentive mentioned by FDA officials and representatives of affected entities is the opportunity to control the scheduling of the inspection by an accredited organization by working with the accredited organization. FDA officials and representatives of affected entities also mentioned potential disincentives to having an inspection by an accredited organization. These potential disincentives include bearing the cost for the inspection,[45] doubts about whether accredited organizations can cover multiple requirements in a single inspection, and uncertainty about the potential consequences of an inspection that otherwise may not occur in the near future—consequences that could involve regulatory action.

Changes specified by FDAAA have the potential to eliminate certain obstacles to manufacturers' participation in FDA's programs for inspections by accredited third parties that were associated with manufacturers' eligibility. For example, a requirement that foreign establishments be periodically inspected by FDA before being eligible for third-party inspections was eliminated. Representatives of the two organizations that represent medical device manufacturers with whom we spoke about FDAAA told us that the changes in eligibility requirements could eliminate certain obstacles and therefore potentially increase manufacturers' participation. These representatives also noted that key incentives and disincentives to manufacturers' participation remain. FDA officials told us that they were revising their guidance to industry in light of FDAAA and expected to issue

[45]In January 2007, we reported that representatives of accredited organizations indicated that the cost to manufacturers would vary depending on such factors as the size of the manufacturer and how much extra time would be required to assess compliance with FDA requirements. Representatives suggested that covering FDA's requirements could take 2 or more days in addition to the time spent assessing other countries' requirements, plus time for advance preparation and writing the inspection report. They speculated that they would probably charge manufacturers from $1,700 to $2,500 per day, plus the cost of travel and living expenses.

the revised guidance during fiscal year 2008.[46] It is too soon to tell what impact these changes will have on manufacturers' participation.

FDA officials have acknowledged that manufacturers' participation in the Accredited Persons Inspection Program has been limited. In December 2007, FDA established a working group to assess the successes and failures of this program and to identify ways to increase participation. Representatives of two organizations that represent medical device manufacturers told us that they believe manufacturers remain interested in the Accredited Persons Inspection Program. The representative of one large, global manufacturer of medical devices told us that it was in the process of arranging to have 20 of its domestic and foreign device manufacturing establishments inspected by accredited third parties.

As of May 7, 2008, two inspections of foreign establishments had been conducted through PMAP,[47] FDA's second program for inspections by accredited third parties. Although it is too soon to tell what the benefits of PMAP will be, the program is more limited than the Accredited Persons Inspection Program and may pose additional disincentives to participation by both manufacturers and accredited organizations. Specifically, inspections through PMAP would be designed to meet the requirements of the United States and Canada, whereas inspections conducted through the Accredited Persons Inspection Program could be designed to meet the requirements of other countries. In addition, two of the five representatives of affected entities whom we spoke to for our January 2008 statement noted that in contrast to inspections conducted through the Accredited Persons Inspection Program, inspections conducted through PMAP could undergo additional review by Health Canada. Health Canada will review inspection reports submitted through this pilot program to ensure the inspections meet its standards. This extra review poses a greater risk of unexpected outcomes for the manufacturer and the accredited organization, which could be a disincentive to participation in PMAP that is not present with the Accredited Persons Inspection Program.

[46]As of May 6, 2008, this guidance had not been issued.

[47]Three inspections of domestic establishments were conducted through PMAP.

Concluding Observations

Americans depend on FDA to ensure the safety and effectiveness of medical devices manufactured throughout the world. A variety of medical devices are manufactured in other countries, including high-risk devices designed to be implanted or used in invasive procedures. However, FDA faces challenges in inspecting foreign establishments. Weaknesses in its database prevent it from accurately identifying foreign establishments manufacturing medical devices for the United States and prioritizing those establishments for inspection. In addition, staffing and logistical difficulties associated with foreign inspections complicate FDA's ability to conduct such inspections. The agency has recently taken some positive steps to improve its foreign inspection program, such as initiating changes to improve the accuracy of the data it uses to manage this program and announcing plans to increase its presence overseas. However, it is too early to tell whether these steps will ultimately enhance the agency's ability to select establishments to inspect and increase the number of foreign establishments inspected. To date, FDA's programs for inspections by accredited third parties have not assisted FDA in meeting its regulatory responsibilities nor have these programs provided a rapid or substantial increase in the number of inspections performed by these organizations, as originally intended. Recent statutory changes to the requirements for inspections by accredited third parties may encourage greater participation in these programs. However, the lack of meaningful progress in conducting inspections to this point raises questions about the practicality and effectiveness of these programs to help FDA conduct additional foreign inspections.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or the other Members of the subcommittee may have at this time.

Contacts and Acknowledgments

For further information about this statement, please contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may found on the last page of this statement. Geraldine Redican-Bigott, Assistant Director; Kristen Joan Anderson; Katherine Clark; William Hadley; Cathleen Hamann; Julian Klazkin; and Lisa Motley made key contributions to this statement.

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Mr. PALLONE. Thank you, Dr. Crosse, and I am going to start the questioning by recognizing myself for 5 minutes. I was going to start with Dr. Gill because you are the device person but I guess I am directing it to Dr. Sundlof—to Dr. Gill through Dr. Sundlof. There has been industry interest in the international harmonization of standards for device inspection. Specifically, we have heard that industry would like FDA to adopt International Standards Organization—well, the standards of—they would like them to adopt the International Standards Organization standards. That sounds a little weird but that is what it is. Are there any substantive differences between the FDA's standards and those of the International Standards Organization? And what is your opinion on asking the FDA to move to those standards?

Dr. GILL. Thank you, Mr. Chairman. We have worked for quite a while, the Center for Devices, with the Global Harmonization Task Force. In fact, we chaired that task force this year. We have been working to harmonize our quality system regulation with many of the standards under the GHTF task force. We find that their quality system or their ISO inspection 13485 is pretty close, very similar to ours. In fact, the most recent FDA Modernization Act allowed us to evaluate foreign inspection reports, 13485 ISO inspection reports. So we find them to be very similar. We certainly are developing the criteria under which we could get the reports in, look at them, determine whether or not they have met the foreign standard requirements and to see if they are similar to ours, and we look forward in the future to figuring out how we can use these in lieu of an inspection.

Mr. PALLONE. OK. Thank you.

And then I wanted to ask Dr. Crosse, in your testimony you mentioned the third-party inspection programs that are currently in place and the fact that very few companies have taken advantage of those programs, even after improvements were made. Can you explain why this is and make any recommendations as to how to put in place more incentives for companies to actually partake in those programs? And then does the FDA need additional authorities or basically are there ways to make this work, and how would you go about it?

Dr. CROSSE. Thank you. Yes, we did take a look at the accredited inspection programs and one of the issues that we hear from industry is that it is not clear at this point that a single inspection can meet the requirements of both the FDA and other foreign governments. Is it really that feasible? A few of the companies that had explored using this program had determined from the accredited inspectors that they would actually conduct separate inspections to meet the U.S. requirement from what they would conduct for, for example, the European Union, and so at this point I think there are still some issues to be ironed out. There also is a concern, I think, on the part of some industry organizations that if you are hiring an accredited inspector, you are ensuring then that someone is coming to your door and exposing you to possible regulatory action. Right now, FDA doesn't come that often and so if you just sit back and wait for FDA to show up, it could be many years. So that has worked also as a disincentive for organizations to hire an accredited inspector, to pay for that inspection. Right now an FDA in-

spection does not cost them any money, and then to face possible penalties that might be incurred. I think it is too soon to know whether the changes that were made in the bill last year are going to modify that but at this point under that accredited inspection program, only one additional inspection has been conducted since we testified in January on this. FDA itself has undertaken a separate pilot program with Canada to try to determine if they can iron out some of these problems.

Mr. PALLONE. Thank you.

Let me ask one cosmetic question. Dr. Sundlof, you mentioned several areas of concern with the rapidly growing nature of the cosmetics industry, including increasingly sophisticated technology and more complex ingredients. Will the provisions included in the discussion draft, and I am referencing the mandatory registration, mandatory adverse event reporting, GMP regulations, will they assist FDA in fulfilling its regulatory mission concerning cosmetics?

Dr. SUNDLOF. In terms of requiring that the firms register and report all of the ingredients, it would at least alert us to the fact that there may be new ingredients that we may not otherwise have been aware of were in these cosmetics so in that respect, yes. The other ones I don't think would particularly address that issue of the widely emerging new products that are coming out in terms of new chemicals, new ingredients, et cetera.

Mr. PALLONE. Thank you.

Mr. Deal.

Mr. DEAL. Thank you.

I want to follow up on the ISO issue. First of all, how many countries recognize the ISO 13485 inspections?

Dr. GILL. I don't have that number with me. I would be happy to provide that. But we do know that those that are in European Union recognize that.

Mr. DEAL. Does China recognize those or do they participate?

Dr. GILL. China has attended the last Global Harmonization Task Force meeting. They are scheduled, according to discussions we have had, to attend the next set of GHTF meetings.

Mr. DEAL. But I would assume it takes action on the part of a country to incorporate the ISO inspection standards into their way of doing business in their own country? They have to formally adopt it. Is that correct?

Dr. GILL. That is my understanding.

Mr. DEAL. How long do you anticipate it is going to take to determine whether or not FDA standards can be harmonized with ISO standards?

Dr. GILL. We are currently working through looking at the standards now, looking at the differences and preparing to have a public announcement of our adoption of some of the standards.

Mr. DEAL. I would encourage you to do that as quickly as possible.

The next question is, in the event that you determine that ISO standards are sufficient to cover FDA responsibilities, would it require legislation to allow you to use the ISO inspections as a part of your mandatory, if we go to a mandatory, time frames or numbers of inspections? Will it require that we legislatively build in language that allows you to accept the ISO inspections?

Dr. GILL. I think if they are harmonized inspections and we find that they are very equivalent to ours, I am not sure the legislative changes are absolutely necessary.

Mr. DEAL. I would ask you all if you would look at that because I personally think that is the direction we need to go in.

Second question is, do other countries require on-site inspections of American manufacturing facilities? In other words, the reverse of what we do in overseas inspections.

Dr. GILL. Yes.

Mr. DEAL. How do their fees compare with what we charge?

Dr. GILL. I believe many countries may use the ISO inspectorate. I can certainly find out an answer to that. But that would be an agreement between the third-party inspector and the manufacturers.

Mr. DEAL. In order for that to be accomplished, the reverse of what we normally think of here, would it require formal action on the part of the United States or of FDA to adopt ISO standards as our standard in order for them to accept our inspections under ISO privileges and grant reciprocity, in effect?

Dr. GILL. I would be happy to provide a written response to that.

Mr. DEAL. All right. Thank you.

One of the issues that was mentioned was the Beyond Our Borders initiative that FDA has undertaken. I think it is going to be increasingly important for us to try as best we can to harmonize with other countries that are trying to do the right thing and be able to work cooperatively in that effort, and I think it is also going to require that we continue to apply pressure for those countries that do not move in that direction, and in that regard, reference was made in Mr. Dingell's opening statement that we could not—we have to be careful, I guess under WTO, that we do not differentiate between domestic and foreign inspection costs, et cetera. But isn't it true that it is significantly more expensive to do overseas inspections under our current system than it is to do domestic inspections?

Dr. GILL. I do believe there are costs associated with travel in foreign inspections that we don't have to pay for domestic inspections but we do try to cover at least three inspections while we are there to minimize that travel cost.

Mr. DEAL. One of the things that the Administration asks us under their safety plan, has asked Congress to grant FDA the authority to refuse to admit for import products that were manufactured in facilities that denied FDA inspectors or hampered their ability to do inspections. Is it true that there is no authority to discriminate against those countries and products where you have been, in effect, denied or hampered in your inspections that we don't have any authority to discriminate against them currently?

Dr. GILL. Allowing an FDA investigator into a foreign facility is voluntary, so we—

Mr. DEAL. No, I am talking about on our end. What I read is that apparently you are asking Congress to give you the authority to discriminate against those products from those countries or from those plants that have interfered with your ability to inspect their product. Is that something that needs statutory changes?

Dr. SUNDLOF. Yes, I believe it is, and right now we can detain product if we have reason to believe that it is adulterated but we have to establish at the port of entry that it is adulterated. Then we can issue an import alert, and that prevents it. But we don't have that authority just on the basis—we can't initiate an import alert on the basis that the country of origin refused our inspection.

Mr. DEAL. Thank you.

Mr. PALLONE. Chairman Dingell for questions.

Mr. DINGELL. Thank you.

Does FDA currently have an accurate, verified count of how many foreign device facilities are selling products to the American people, yes or no?

Dr. GILL. Our new database will help us determine how many foreign facilities—

Mr. DINGELL. So the answer is, you do not have such information?

Dr. GILL. At this time, I don't believe we have an exact number.

Mr. DINGELL. All right. Now, you have got two—is it two or three databases?

Dr. GILL. We have about three or four databases.

Mr. DINGELL. OK. How many of them talk to each other and how many of them are integrated?

Dr. GILL. Currently, we are working to make sure that they talk to each other, but as of—

Mr. DINGELL. So at this time you have none of them are integrated and none of them can talk to each other?

Dr. GILL. Well, we are integrating the electronic registration database.

Mr. DINGELL. So the answer to the question is yes?

Dr. GILL. We do have one or two.

Mr. DINGELL. All right. Now, how much is it going to cost and when will this be done? First of all, how much is it going to cost, and second, when will it be done?

Dr. GILL. I can certainly provide you an answer with the cost.

Mr. DINGELL. Please submit that for the record. I have a grand total of 5 minutes here.

Now, does FDA currently have an accurate and verified accounting of what products these companies are making? The answer to that question is no, is it not?

Dr. GILL. Until our new system is in and they can list their products—

Mr. DINGELL. I have a limited amount of time. Yes or no?

Dr. GILL. I believe we don't have the accurate account.

Mr. DINGELL. Does FDA currently know how many foreign facilities are actually subject to inspection, yes or no?

Dr. GILL. We are finding that out daily, Mr. Chairman.

Mr. DINGELL. Now, Dr. Gill, as we move forward producing bipartisan legislation to this concern, it would be very helpful to have the Committee have the Agency's plan of action for improving its device information system, both its funding needs and timelines. Does such a plan exist, yes or no?

Dr. GILL. We are developing that plan.

Mr. DINGELL. You are developing it, but you do not have it. When will you have it and when can you submit it to the committee?

Dr. GILL. I can certainly submit to you the dates when we will have the plan completed.

Mr. DINGELL. You will submit that to us for the record.

Now, Dr. Woodcock said that meeting the Agency's obligations when she was here before the committee would cost an additional $100 million. Can you tell us how much you need to meet the required frequency for domestic device inspections?

Dr. GILL. That also could be provided for you.

Mr. DINGELL. Please submit that for the record.

I am told here, according to Dr. Crosse, FDA inspects relatively few foreign medical device establishments despite the fact that over 4,200 foreign facilities have been registered to sell medium- and high-risk devices to American consumers. Is that accurate?

Dr. GILL. Could you repeat that question?

Mr. DINGELL. FDA inspects relatively few foreign device establishments, according to Dr. Crosse, despite the fact that over 4,200 foreign facilities have been registered to sell medium- and high-risk devices to American consumers. Is that accurate?

Dr. GILL. Yes, that is what we have reported.

Mr. DINGELL. Dr. Woodcock testified at the previous hearing that FDA would need another $225 million to inspect foreign drug facilities at the same rate that is required currently to investigate domestic facilities. Can you tell us what the figure would be for foreign device facilities?

Dr. GILL. We will certainly make that part of the answer we supply to you.

Mr. DINGELL. Now, have you seen the GAO study?

Dr. GILL. Yes, we have.

Mr. DINGELL. I want you to submit any criticisms to this committee you have with regard to the factual and other questions associated with this study, and I will ask that the record be kept open so that that may be done.

Now, they said this: "In summary, we found that FDA faces challenges in its program to inspect foreign establishments manufacturing medical devices. In January 2008, we testified that the two databases that provide FDA with information about foreign medical device establishments and the products they manufacture for U.S. market contain inaccurate information about establishments subject to FDA inspection and could not exchange information." Is that true?

Dr. GILL. According to the report, yes.

Mr. DINGELL. All right. They went on to say this: "Few inspections of foreign device manufacturing establishments have been conducted through FDA's two programs for inspections by accredited third parties." Is that statement true?

Dr. GILL. According to the report, yes, we responded.

Mr. DINGELL. All right. Now, in this, they further say this: "FDA faces challenges conducting inspections of foreign establishments that manufacture medical devices," and they go on to say, "FDA lacks accurate data on the number of foreign establishments subject to inspection." Are those statements true?

Dr. GILL. I think our data is becoming more accurate with the electronic registration and listing, and we are finding—

Mr. DINGELL. Are these statements true?

Dr. GILL. As of the time of the report, yes.

Mr. DINGELL. They are true?

Dr. GILL. Yes.

Mr. DINGELL. All right. I have so many questions, Mr. Chairman, I am sort of floundering in a morass.

They go on to say this: "FDA inspects relatively few foreign medical device establishments." Is that statement true?

Dr. GILL. It is correct.

Mr. DINGELL. Then they go on and say, "FDA officials told us it has been difficult to recruit investigators to voluntarily travel to foreign countries. However, they added that if the Agency could not find an individual to volunteer for a foreign inspection trip, it would mandate the travel. Logistically, foreign medical device establishment inspections are difficult to extend even if problems are identified because the trips are scheduled in advance." Is that true?

Dr. GILL. Yes, they are pre-announced inspections.

Mr. DINGELL. Now, what are you doing about that?

Dr. GILL. Well, we are certainly cleaning up the database and finding out the inspections that are warranted, the Class II and Class III who actually registered with us who are actually exporting product to the United States that we should go inspect.

Mr. DINGELL. Mr. Chairman, I am going to ask that I be permitted to submit additional questions in writing. I thank you for your courtesy to me, witnesses. I thank you, and I am sorry I can't ask more friendly questions of you. Yours is a great agency, and regrettably, you are crippled by your inability to carry out your responsibilities.

Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, and without objection, so ordered to submit those questions.

We do have a vote, 11 minutes left. I was going to ask the ranking member, Mr. Barton, to ask his questions and then we will recess and come back. There is just the one vote. Mr. Barton.

Mr. BARTON. I just have two or three questions, Mr. Chairman.

As I said in my opening statement, I am a little confused about medical devices being included in this particular bill. We have had major problems with food imports from China, we had major problems with drug imports from China, but I am not aware that we have had major problems from medical device imports from China. Dr. Gill, are you aware of any major medical device issues in terms of medical devices that are manufactured in China and sent to the United States?

Dr. GILL. Well, the most recent with the heparin issues but—

Mr. BARTON. Well, heparin is not a medical device.

Dr. GILL. Well, it is used on medical devices but we did not have any serious issues with those devices.

Mr. BARTON. I would ask our witness from the GAO, are you aware of that?

Dr. CROSSE. No, sir, not specifically of devices manufactured in China, although, as Dr. Gill indicated—

Mr. BARTON. Are you aware of any major medical device issues in terms of medical devices that are manufactured in China and sent to the United States?

Dr. GILL. Well, the most recent with the heparin issues but we did not—

Mr. BARTON. But heparin, though, is not a medical device.

Dr. GILL. Well, it is used on medical devices, but we did not have any serious issues with those devices.

Mr. BARTON. I would ask our witness from the GAO, are you aware of that?

Dr. CROSSE. No, sir, not specifically of devices manufactured in China, although as Dr. Gill indicated, the heparin has affected a number of devices that are now being recalled.

Mr. BARTON. But heparin is a drug.

Dr. CROSSE. Yes, but it is used to coat certain things like catheters that are sometimes used in invasive procedures to keep clots from forming. And so there is some heparin that is used in some of the medical—

Mr. BARTON. And you are saying the heparin is coated on the medical device in China?

Dr. CROSSE. On certain medical devices. The heparin manufactured in China has been used to coat certain medical devices.

Mr. BARTON. But if we solve the heparin problem, the device itself is not—

Dr. CROSSE. With those devices, that is correct.

Mr. BARTON. OK. Now, on the issue of the number of inspections that are done on these facilities, I think each of you testified FDA doesn't conduct its own inspections as frequently overseas as it does in the United States, and we have a law that allows the company to ask for a third-party inspection, but many companies don't do that because they say, well, if the FDA is not inspecting me, why should I ask for a third-party inspection that then may result in an FDA inspection. What if we reversed that and allowed the FDA to direct a third-party inspection as a substitute for an FDA inspection? How would that work?

Dr. GILL. Well, certainly in the Import Safety Action Plan we looked at what would help us to get more information about foreign facilities, and certainly asking for those foreign inspections reports would give us that information.

Mr. BARTON. But currently the FDA can't direct a third-party inspection. It has to be done at the request of the facility, isn't that correct?

Dr. GILL. It is all voluntary.

Mr. BARTON. So if we changed it, you could still ask for the voluntary but if you gave the FDA the authority because of whatever reason, limited resources, limited time, probable cause, you name it, to direct a third-party inspector, would that help address this issue of lack of frequency of FDA inspections? That is my question.

Dr. GILL. I think we would want to make sure that the third parties are trained to conduct them so we get the same quality in the inspection that we get with our own FDA inspections. It might help.

Dr. CROSSE. I would just add that at the current time, there aren't enough to fill the gap. There are not enough trained, accred-

ited inspectors to be able to fill the gap to get inspections up to the level that is required, and also you would be asking the company then to bear the cost of that inspection. An accredited inspection program requires the company to pay.

Mr. BARTON. But the concept on the face of it doesn't seem unworkable?

Dr. CROSSE. The accredited inspection program is set up with the goal that that inspection is equivalent to an inspection by FDA.

Mr. BARTON. And we wouldn't change that. That is all my questions, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Barton. We will take a recess. There is only one vote, so we should be back fairly quickly, and then we can take the rest of the questions for this panel. The Subcommittee stands in recess.

[Recess.]

Mr. PALLONE. The Subcommittee will reconvene, and we left off with Mr. Barton, so I recognize the gentlewoman from California, Ms. Eshoo, for questions.

Ms. ESHOO. Thank you, Mr. Chairman. Let me ask the following questions. In the legislation, I believe there is a pathway for inspections, and how we operate today and where we want to go obviously, the legislation puts forth the way. What I would like to examine with the FDA is, what are the ISO standards today? How high are they? Do they meet with FDA standards? And what you bring to inspections of devices sent into our country, is it better to inspect in the facilities abroad? How effective is your inspection here? And so I would like to examine that area because most frankly I am not so sure how it works, how well it works, and what you think of it.

What I want to say, and this is just a general observation, and we don't have very many members here so I am going to be speaking to three other people. Most frankly, I think if I were the FDA Commissioner, I would bring forward a list to the Congress and this Committee and say, these are all of the responsibilities that you have charged us with in order to protect the American people. We have the resources to do the following. You know, we may have given the FDA 79 things to do, all very, very, important, and the Agency not having the resources to carry the rest out. I have said consistently here, we cannot remain content with user fees. They are important. I helped to establish them. But having said that, I don't believe the Congress is funding the Agency the way it needs to be funded in order to carry out these all-important mandates including the ones that we are looking at in this legislation.

So can you take us through the inspections? How robust are they and compare and contrast the two standards for us. I think Dr. Gill is going to address this.

Dr. GILL. Yes.

Ms. ESHOO. Thank you.

Dr. GILL. First of all, we have our quality system inspection that we use to conduct our G&P inspection. There is an ISO standard that is very similar, and that is the 13485 that looks at many of the same components that our quality system inspection looks at. Where I think the major differences lie and it is what is covered in the FDA inspections. We include not only G&P—

Ms. ESHOO. Is it a higher standard? That is what I want to know.

Dr. GILL. It includes many more element—

Ms. ESHOO. It does?

Dr. GILL [continuing]. And some of the difference is also in the depth of our inspection. We inspect to the regulation. We of course look at whether or not they have—

Ms. ESHOO. And how often do you do that?

Dr. GILL. We do the FDA inspection every time we go, and we have two levels of inspection. We have an abbreviated quality system inspection and we have a full inspection.

Ms. ESHOO. This is when products are coming into the United States?

Dr. GILL. This is the inspection technique process that we use regardless. We use it in foreign manufacturers, we use that in domestic manufacturers. We don't inspect product at the border as it is coming in, we inspect the manufacturing facility.

Ms. ESHOO. How often do you do that?

Dr. GILL. As the report says, we are conducting domestic inspections for Class III devices about once every three years and Class II—

Ms. ESHOO. Are you satisfied with that statement?

Dr. GILL [continuing]. Every five. According to our risk-based scenario, it is covering our most critical high-risk issues.

Ms. ESHOO. OK. Let me just get another question in. I still think this still needs some more exploration. I raised in my opening statement the whole issue of the component parts for medical devices, circuit boards, software, et cetera. Do you want to comment on that? I don't think FDA knows how to inspect those things?

Dr. GILL. Our current law requires the manufacturers to be responsible. Devices, as you stated, are made up of multiple components, and we have, in our law, said the manufacturer is responsible for making sure that the components that they purchased to include in the finished product—

Ms. ESHOO. So if the device fails—

Dr. GILL [continuing]. Still qualify for—

Ms. ESHOO. If the device fails, then the responsibility is on the company?

Dr. GILL. It is on the company. We do go in and inspect whether or not they have looked at all components to their product to make sure that they were acceptable according to the standard.

Ms. ESHOO. Thank you. And my time is up. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. The gentleman from Indiana.

Mr. BUYER. Thank you. I would like to do some follow-up on the question that Mr. Deal had asked earlier just for clarity purposes to the FDA. During these inspections and you have a foreign government that will not cooperate or you have a company in a foreign country that doesn't cooperate with an inspection, are you asking us for specific statutory authority so that you could prevent those products from entering into the United States market?

Dr. SUNDLOF. Yes, sir. The Import Safety Action Plan specifically asks for authority to deny importation of products if we are denied access to those foreign firms.

Mr. BUYER. And if this Committee were to take affirmative action to include that in this bill, that provision, of course, you would support that?

Dr. SUNDLOF. Could you repeat the question, please?

Mr. BUYER. If we took that and put this in the bill, obviously that is something that you would support?

Dr. SUNDLOF. The administration has support—now obviously, we would have to see exactly what the language said but—

Mr. BUYER. All right. You don't have to dance. I just want you to know, we are trying to help you, right? OK.

Dr. SUNDLOF. Thank you, sir.

Mr. BUYER. You don't have to do that kind of answer. Are you aware of any trade agreement issues that might arise from the bill's $10,000 import registration fee on how that could be interpreted?

Dr. SUNDLOF. I don't have the answer to that. We can get you an answer in writing. I think the kind of trade agreement concerns that we had specifically looked at having higher standards for imported products than we do for our domestic products. We need to make sure that any legislative language would not interfere with our trade agreement.

Mr. BUYER. Well, that would be my hope also. To be helpful to us and to the GAO, if you, in cooperation with other departments or agencies, recognize that if we were to actually put a $10,000 import registration fee and it is against any of our trade agreements, we need to know about that. So please let the Committee know in writing.

I have some concerns that there are approximately 3,800 premarket notifications a year and the majority are Class II devices, given your testimony on the drug side of this bill and how much effort it is going to take for you to do staffing and resources necessary to inspect on the drug provisions of this bill, what are your concerns regarding the provisions in the bill with regard to—how are you going to be able to do the staffing and how are you going to be able to do all of what is required in this bill given your present level of appropriations?

Dr. SUNDLOF. I believe with all the new authorities that this bill would offer, we would need additional resources to be able to accomplish all of the new authorities that we would have. And exactly what that is, the dollar amount, I can't say. One of the things that we say in our Import Safety Action Plan and that has been addressed in this bill as well, the use of third parties. Depending upon how extensively we took advantage of those third parties would have a major impact on what we need to staff. In other words, FDA inspectors versus what we would be relying on third parties to accomplish without us having to fund them.

Mr. BUYER. Section 210 of the bill provides for civil penalties, and civil penalties were placed in the Food, Drug and Cosmetic Act of 1990. Are you aware of how many civil cases the FDA has brought against the device industry since 1990?

Dr. GILL. I don't have that number offhand, but I know we have taken some civil money penalty cases.

Mr. BUYER. Would you please provide in writing the number of civil penalty cases since 1990 and at what amounts and why they were—

Dr. GILL. We certainly will.

Mr. BUYER. —by industry? You don't have to do it by industry, I only want it for the device industry.

At this moment, I am going to yield to Mr. Deal if he has any further questions he may have with regard to those foreign inspections so we can get the right and appropriate language given the questions he had asked earlier. I yield to the gentleman.

Mr. DEAL. I thank the gentleman for yielding. I understand that there was a letter written to the Committee by the European Union. Do you have that here? I am trying to get a staff to get it for us. Apparently they are claiming that any import fee would be in violation of WTO rules. Are any of you aware of that issue being raised by the European Union?

Dr. GILL. I am not aware of that issue.

Mr. DEAL. I think it is a concern that we need to be looking at. Dr Crosse?

Dr. CROSSE. No, I am not aware of that issue, either. There currently is a registration fee that is being charged to all medical device firms.

Mr. DEAL. And I had earlier asked if foreign countries were also coming in and charging fees of our manufacturers, and I have had several people during the break assure me that they are and that the fees that they are charging to American manufacturers are significantly more than they are charging to their own domestic manufacturers. Hopefully I will have that copy of the letter and we will put it in the record perhaps before the end of the hearing. I would ask you all if you would take a look at that issue. We don't need to do something that is going to provoke a WTO fight or retaliation and all the things that we know go along with those kind of disputes. If there is a way we can achieve our purposes short of that, then I would think we would all hopefully work toward that; and I would follow up, too, with Mr. Buyer on that line of questioning as to your action plan as it relates to the statutory language. I have not personally seen any suggested language on that. This would be the appropriate place in my opinion for us to try to get that statutory authorization that you think is appropriate, and I would urge you to make that available to us as soon as possible because I assume we are going to be marking this bill up some time in the very near future in this committee.

I appreciate the gentleman yielding. Thank you. I will yield back.

Mr. PALLONE. The gentlewoman from Illinois, Ms. Schakowsky, for questions.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. Do any of you know whether or not balloon catheters are imported ever?

Dr. GILL. I will check on that and get back to you.

Dr. CROSSE. According to the registration date, certain types of balloon catheters used in angioplasty are among the top devices imported from foreign countries.

Ms. SCHAKOWSKY. There was a Supreme Court case, Regal v. Medtronic, where the Regals sued the medical device company for injuries that Mr. Regal sustained when the balloon catheter that

was used by this physician burst in angioplasty. And the Supreme Court ruled in favor of Medtronic and found that FDA regulations preempted state civil matters. And my concern is this. If we are doing an inadequate job of inspecting, of assuring the safety of the devices, and yet any other actions, either state actions or court actions, are precluded because the FDA is the final authority, then it seems to me that we are leaving people without options and at risk, and important ability for states and individuals through a private right of action that might be an incentive for these products to be safer is precluded. So I just wondered if anybody had a comment on whether or not the ultimate authority—if consumers can really depend now on the FDA to be the ultimate authority on the safety of these products.

Dr. GILL. I don't have any current comment on that. I think many of our products of our safe. We do have a reporting system that lets us know from all users as well as consumers when there are problems with products, and for the most part, we are finding devices are safe and we are actively investigating those that are not.

Ms. SCHAKOWSKY. Would you argue, Dr. Crosse, that the GAO report would endorse that assessment?

Dr. CROSSE. I think we have concerns about the current level of oversight that FDA is able to employ, both for medical devices and for drugs.

Ms. SCHAKOWSKY. Let me ask about cosmetics. It is my understanding, Dr. Sundlof, that in response to an Environmental Working Group Petition in 2005 that the FDA responded, "The Food, Drug and Cosmetics Act contains no provision that requires demonstration to FDA of the safety of ingredients of cosmetic products prior to the marketing of the product." Is that correct?

Dr. SUNDLOF. That is correct. There is no pre-market review of cosmetics.

Ms. SCHAKOWSKY. But you do have a requirement that manufacturers adequately substantiate their products for safety, is that not correct?

Dr. SUNDLOF. Yes, that is correct.

Ms. SCHAKOWSKY. Are you able to provide our Subcommittee with FDA's definition of safe?

Dr. SUNDLOF. I can provide that to you in writing.

Ms. SCHAKOWSKY. My understanding is that there is no FDA definition of safe.

Dr. SUNDLOF. In the area of cosmetics, I will have to go back and look into that. There certainly are definitions of safe for foods and medical products.

Ms. SCHAKOWSKY. Check that. I would be interested because I have been told that there is no definition for safe for these cosmetics. Does the Agency develop guidelines for industry and what should be done on their part to substantiate safety?

Dr. SUNDLOF. I am sorry, could you repeat that?

Ms. SCHAKOWSKY. Are there guidelines developed by the FDA to substantiate safety that manufacturers have to follow?

Dr. SUNDLOF. The FDA participates in the international community with programs that establish what the criteria are, what kind

of testing criteria are used to demonstrate certain kinds of safety, and those have been in effect for a number of years.

Ms. SCHAKOWSKY. And when the companies substantiate their products before they are sold, who do they submit the data to, the FDA?

Dr. SUNDLOF. They are not required to submit data to the FDA. If it turns out that there is a safety issue associated with a particular cosmetic, the FDA has the authority to inspect that facility and determine whether or not the company has done an adequate job of demonstrating the safety before they entered the product in the market.

Ms. SCHAKOWSKY. Thank you. Mr. Chairman, may I ask one more question? It is my understanding that the industry-funded safety panel, the Cosmetic Ingredient Review Panel, has only reviewed 11 percent of the over 12,000 ingredients in personal care products over its 30-year history. So I am concerned that this panel might not be up to the job. And in your testimony you state that FDA estimates that within their voluntary registration system, there is product information from just a third of all domestic manufacturers. So what do you think it would take to review all ingredients used in personal care products, what kind of data does FDA currently have on chemical ingredients most commonly used in personal care products, and I guess finally, do you think that the work that is being done to guarantee safety currently is sufficient?

Dr. SUNDLOF. Certainly, the law as it currently is written allows virtually anything to be incorporated into cosmetics with certain exceptions that are specifically prohibited under the Act. The reminder of your questions I think we would need to go back and we can provide you with an answer in writing.

Ms. SCHAKOWSKY. I just wondered, Dr. Crosse, if I haven't read the whole report, if you deal with that in your report?

Dr. CROSSE. No, I am sorry, we do not look at cosmetics at all.

Ms. SCHAKOWSKY. Thank you. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. And that concludes our questions of the first panel. I want to thank you very much for answering the questions and for your testimony. As you know, we do intend to move toward the marking of this bill at some time in the near future. So we will continue to get back to you. Thank you.

And if the next panel could come forward at this time? Well, welcome again. I am going to introduce each of you. Starting on my left, some of you, maybe all of you but certainly a lot of you have been here before. You are no strangers to the Committee. First is Stephen Ubl. Did I pronounce it right?

Mr. UBL. Ubl.

Mr. PALLONE. Ubl. OK. Stephen Ubl. I have met you many times. Stephen Ubl is president and CEO of the Advanced Medical Technology Association. And then is Kelvyn Cullimore. He is President and CEO of MDMA Secretary. Is that the organization?

Mr. CULLIMORE. I am Secretary of the MDMA—

Mr. PALLONE. Oh, I see. You are President and CEO and also Secretary of the MDMA of the Dynatronics Corporation.

Mr. CULLIMORE. Dynatronics is the company. We are a member of MDMA, and I am on the—

Mr. PALLONE. Oh, I see. You are doing both. OK. And then we have Ms. Ami Gadhia with the Consumers Union. She is the Policy Counsel. She was here recently. And then we have Elisabeth George who is Vice-President for Quality and Regulatory Affairs at Philips Healthcare, and Pamela Bailey who is President and CEO of Personal Care Products Council, and Jane Houlihan who is Vice-President for Research of the Environmental Working Group here in D.C.

Thank you all for being here. You know the rules: 5 minutes opening statement. They become part of the record, and we may submit additional questions in writing that we would ask you to get back to us about. And I will start out with Mr. Ubl.

Mr. UBL. Thank you.

Mr. PALLONE. Is that on?

Mr. UBL. It is on now.

Mr. PALLONE. OK.

STATEMENT OF STEPHEN J. UBL, PRESIDENT AND CEO, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

Mr. UBL. Thank you, Mr. Chairman, Ranking Member Deal. I appreciate the opportunity to share our views on the discussion draft of the FDA Globalization Act of 2008.

Medical technology is one of the few manufacturing industries where there remains a strong, vibrant balance of trade. Every day our member companies export more medical devices that are imported to the United States. In fact, more than three-and-a-half times more exports than imports. In 2007, medical device exports were approximately $4.7 billion and imports were barely a third of that at $1.5 billion.

Before I address our specific comments on the discussion draft, I would like to first emphasize the broad range of medical devices and the risk-based approach currently used by the FDA to effectively regulate devices. As you know, FDA classifies devices into three risk categories ranging from low-risk products in Class I to high-risk devices in Class III. Since its inception in 1976, the legislative framework, the Medical Device Law, has been to regulate based on risk. FDA's regulatory regime, whether it is the approval process or setting of inspectional priorities, are based on a level of risk associated with the device. We believe FDA's risk-based approach effectively focuses the Agency and its resources on the right areas to ensure public health and safety.

I would like to now address three primary issues with regard to the discussion draft. First, we have concerns with the proposed new broad-based industry fee, but we are open to exploring a more targeted approach to inspections. Our view is that inspections are a core function of the FDA, and funding should come from the appropriations process, not industry fees. As has been mentioned earlier, last year's FDA Amendments Act resulted in a 91 percent increase in industry user fees, including the establishment of the first-ever facility registration fee. A new, broad-based user fee would impose a potentially significant financial burden on top of the increased user fees enacted into law last year. We also believe there could be unintended consequences with a broad-based user fee. Many of our members, particularly small companies, do not even have foreign

facilities. Yet, through their fees, they would effectively subsidize inspections of foreign companies exporting their products to the United States. Consider that high-risk medical device imports overwhelmingly come from countries with established regulatory systems. According to our analysis of U.S. Customs data from 2007, 93.7 percent of imported medical device implants come from the highly developed countries of the European Union, Canada, Australia, and Japan. In this category of devices, 0.01 percent come from China. I want to emphasize that we are willing to explore a targeted funding mechanism for inspections of foreign facilities that are located in countries with less developed regulatory systems and actually export products to the United States.

Our second issue is with the proposed pre-approval inspection for Class II and Class III devices. As you know, FDA already conducts pre-approval inspections of all new Class III medical devices. There has been mention with regard to Class II devices, there are more than 3,600 approved each year. Simply put, the FDA approval process would come to a screeching halt if this proposal were implemented. Requiring a pre-approval inspection for this number of products before they are permitted to be marketed could inhibit the availability of lifesaving and life-enhancing devices.

The third issue is with the catch-up inspections for all Class II and Class III facilities. According to the GAO, there are 10,600 facilities manufacturing Class II and Class III devices. Having FDA inspect all of these facilities within the next 2 years is an unrealistic expectation. We support FDA's risk-based approach in determining its inspectional priorities. Moreover, for the purpose of setting those priorities, the recently enacted FDA Amendments Act permits FDA to accept submissions from companies of certifications through internationally accepted quality system standards set by the International Organization for Standardization, or ISO. To explain, ISO is an international standard-setting independent organization consisting of technical experts including FDA. FDA personnel are active participants in the ISO technical committees developing these important standards. We support a change in law that would go one step further by allowing FDA to accept ISO quality system standard as equivalent to FDA's current quality systems regulation. Doing so would allow FDA to use a company's compliance with the ISO standards in place of an FDA inspection. This also would bring FDA into harmonization with the internationally recognized and accepted quality systems regulations.

In closing, we support a strong FDA and appreciate the Committee's leadership in offering the discussion draft under consideration. Our members are committed to providing safe and effective products, and we look forward to working with you.

[The prepared statement of Mr. Ubl follows:]

STATEMENT OF STEPHEN J. UBL

Good Morning. My name is Stephen J. Ubl. I am President and Chief Executive Office of the Advanced Medical Technology Association, known as AdvaMed. I am pleased to be here today to comment from a medical device perspective on the Committee's discussion draft of the FDA Globalization Act of 2008. Thank you, Chairman Dingell, Congressman Barton, and other members of the Committee for giving us the opportunity to share our views on this important topic.

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed's members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of the health care technology purchased annually around the world. AdvaMed members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

OVERVIEW

AdvaMed very much appreciates the Committee's process of providing the public with an opportunity to comment on the Committee's preliminary thoughts as the Congress considers how to address major challenges in our increasingly global economy. I would like to begin by making several general points. First, our members are committed to assuring that the medical devices we manufacture are safe and effective, perform as intended, and meet all the rigorous quality system requirements established by the FDA.

Second, we share the Committee's view that a robust and effective FDA inspection program is an essential element of FDA's regulatory system. We believe that such a program can be achieved with a multi-faceted approach by leveraging FDA's resources and expanding FDA's existing risk-based analysis model that currently guides device facility inspections. We are willing to explore ways in which FDA's resources can be leveraged with use of third party inspection information and mechanisms for financing foreign facilities inspections.

Third, we share the Committee's goal of increasing funding for FDA activities. This is why AdvaMed partnered with you last year during the FDA Amendments Act, and why it is a member of the Alliance for a Stronger FDA. We look forward to working with the Committee on finding innovative ways to assure the effectiveness of FDA's inspection regime. However, while we understand the goals expressed in the Committee draft, we do have a number of concerns about specific provisions and we appreciate your interest in our suggestions. Our greatest concerns relate to requirements for pre-marketing inspection of plants making class II products, use of the two year statutory standard rather than a risk-based approach as the guide for frequency of FDA inspections of Class II product plants, and imposition of a broad-based facility user fee to pay for expanded foreign and domestic inspections.

Fourth, as additional regulatory or cost requirements are considered by the Congress, it is important to keep the unique story of the industry in mind. Medical devices represent one of the few manufacturing industries where there remains a strong and vibrant balance of trade. According to 2007 data from the International Trade Commission, medical device exports approximated $4.7 billion. In contrast, imports were barely one-third of that amount, or approximately $1.5 billion. According to a 2007 analysis by the Lewin Group, these exports supported 357,000 domestic jobs, with average annual wages of $45,600, based on 2002 data, versus $40,300 for the average U. S. manufacturing job. At the same time, medical device imports overwhelmingly come from developed countries with established inspection systems. For example, roughly 93.7% of imported medical device implants and 97.6% of imported medical device instruments and appliances came from the highly developed countries of Canada, Australia, the European Union, and Japan. In these categories of imported medical devices, only .01% are imported from China. This does not mean that inspections of foreign facilities should not be increased, but it does mean that there is no immediate cause for alarm. Clearly, in a global marketplace, significant changes to the cost structure of our companies could impact this very positive story for an industry in which the United States leads the world.

SUMMARY OF CONCERNS

In order to properly consider changes to the FDA inspection process for medical devices, it is important to first understand the broad range of medical device products. This understanding is important as it logically leads to a view that different types of devices warrant various levels of regulation. The law currently anticipates these differences with respect to, for example, market access.

The FDA currently classifies devices into three risk based categories: I, II, and III. Class I are the lowest risk devices such as tongue depressors, bedpans, and bandages. Class II devices are moderate risk devices such as contact lenses, tracheal tubes, and glucose test meters. Class III are high risk devices such as pacemakers, heart valves, and implantable cardiodefibrillators.

There has been no demonstrated public health need for pre-marketing inspection of facilities making Class II products. Implementation of such a system would actu-

ally harm the public health, by drastically slowing the introduction and availability of improved medical devices. FDA currently conducts pre-approval inspection of approximately 50 class III devices a year, and pre-approval inspection is appropriate for these high risk devices. Requiring FDA to conduct pre-approval inspections of the 3,600 plus class II devices that are approved every year would bring the approval process to a grinding halt. Appropriately, FDA inspects facilities that make class II products on a risk-based schedule.

While we understand that the goals outlined in the draft will require a significant increase in FDA's ability to gather inspections data, imposition of a broad-based user fee to pay for inspections would represent a serious departure from the principles that have governed device user fees. User fees were assessed under MDUFMA and FDAAA, based on negotiations between FDA and industry and approved by the Congress. These fees are used to finance improvements in the device approval process that benefit both industry and the public. Establishing a user fee to finance domestic inspections would transfer financial responsibility from the appropriations process to industry for what has rightfully been a public function. The industry just negotiated a new user fee agreement with the FDA and the Congress last year that have raised total fees by 91% and established a facility registration fee for the first time. An important premise of that negotiation was that user fees would remain stable for the 5-year life of the reauthorization. Under these circumstances, the industry would find it difficult to bear the increased burden of a new broad-based user fee program—particularly one that shifts the financing of public functions to its shoulders.

In addition, a proposal to assess a broad-based user fee to fund an inspection program would raise a number of questions for our member companies:

1. The costs of inspection would certainly vary significantly for a domestic facility versus a foreign facility in a developed country versus the cost of inspection in a less developed country. Is it fair to charge one price for these different facilities and potentially have domestic companies subsidizing the costs of inspections for foreign facilities?

2. What guarantees would there be that the fees be additive to FDA's current or future level of appropriated funds, rather than financing, in part or in whole, the current level of effort supported by general treasury funds? And what assurance is there that this change in the philosophy of user fees to support the device center would not, in tight budget times, be used to shift more and more of the burden of financing the center to industry?

3. How would fees for FDA inspections interact with the existing third party inspection program for medical devices?

ADDITIONAL COMMENTS

The proposed pre-inspection requirement for all class II devices. Section 202 of the discussion draft calls for a new FDA inspection requirement for all class II medical devices. FDA already conducts such inspections for class III products. Under this proposal, an FDA inspection would be required prior to the distribution of all new products, and FDA would have just 2 years to inspect all facilities marketing such products today. This new requirement is not justified on public health and safety grounds, would be impractical to implement, and is premature, given the potential benefits of the third-party inspection program just streamlined through the FDAAA.

Since its inception in 1976, the legislative framework of the medical device law has always been to regulate based on risk. This risk-based philosophy is embedded within the three classes of medical devices and particularly in the very different risk profiles of class II and class III medical devices. FDA already routinely conducts pre-approval inspections of new class III medical devices, but rightfully inspects facilities that make class II products on a risk-based schedule. If the current provisions of the draft bill were to be implemented, it would inevitably delay the availability to patients of thousands of new safe and effective therapeutic and diagnostic medical device products. To appreciate the order of magnitude involved, FDA currently conducts pre-approval inspections for about 50 class III devices approved annually, but more than three thousand six hundred class II devices are approved each year.

Moreover, the "catch-up" requirement for FDA to go back and inspect the thousands of current class II facilities is also simply not feasible. The mere process of hiring, training, and deploying new inspectors could not realistically be accomplished during that time.

Should more inspections of domestic medical device facilities be needed, one approach would be for FDA to fully implement the third-party inspection provisions of the FDAAA. Although Congress first authorized FDA accredited third parties to

conduct inspections of medical device establishments in the original MDUFMA legislation in 2002, legislative changes were needed and instituted in 2007 to make that process more attractive and feasible from both an agency and industry standpoint. We are hopeful that this program will free up significant FDA resources.

Finally, we do not believe that the case has been made for an exponential increase in FDA inspections of domestic medical device facilities, such as the discussion draft envisions. There should be a well-documented public health and safety benefit from this expenditure of resources. It would be a more prudent course of action, as described further below, for Congress to allow the opportunity for the third-party inspection process that was streamlined in the FDAAA to work. As with many other times when Congress considers new legislation, we ask that any legislation addressing medical devices be geared specifically and uniquely to the existing legal and factual circumstances surrounding medical devices and that medical devices not be swept in with pharmaceutical and other products regulated by FDA.

IMPORTER FEES

We believe the annual fee of $10,000 per importer may violate World Trade Organization (WTO) rules and respectfully suggest that the Committee examine this issue carefully before moving forward.

"COUNTRY-OF-MANUFACTURE" LABELING REQUIREMENT

We believe additional legislation is unnecessary and potentially counterproductive due to existing rules under U.S. Customs law. Under existing Customs law, any company that imports products, including medical devices, is already required to disclose the country of origin on shipping cartons, individual packaging, and, in some cases, the product itself. There are already sanctions in place for violating the Customs law, including both civil and criminal sanctions. See, e.g. 19 U.S.C. Section 1304(h) and (k), Section 1592(a) and Section 1595a.

The Customs "Country of Origin" marking requirement focuses on the individual unit so that the ultimate purchaser or user of the device can be informed of the country of origin. In addition, the entry documents for imported products state the country of origin. Therefore, an amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act) that requires device products to identify "country of manufacture," as proposed by section 206 of the discussion draft, would be duplicative, costly, and potentially confusing if the regulations promulgated by FDA under a new FD&C Act mandate differ in any way from the standards used under Customs rules.

UNIQUE FACILITY IDENTIFIER

We do not believe there is a need for additional legislation on this subject. FDA already assigns a unique identification number as part of its mandatory registration process for all establishments involved in the production and distribution of medical devices intended for commercial distribution in the United States when those facilities register with the FDA. This process provides FDA with the location of medical device manufacturing facilities and importers. To the extent that Congress wishes to authorize FDA to use the facility registration numbers for "purposes other than for registration," as provided in the discussion draft, FDA also does that currently. For example, FDA already requires a medical device company to include its unique facility registration number on the Premarket Review Submission Cover Sheet, when being submitted to FDA's Center for Devices and Radiological Health (CDRH), to identify where the product will be manufactured.

CONCLUSION

AdvaMed appreciates the opportunity to share its views with the Committee on the discussion draft of the FDA Globalization Act of 2008. We share your goal of an effective, risk-based inspection system that applies to both foreign and domestic manufacturers and is adequately funded. As I have outlined in my testimony, we have a number of concerns about specific provisions of the bill, and serious questions about the concept of a broad-based user fee to fund inspection activities. However, we share the overarching goals of the Committee as it pertains to safety in the global supply chain, and look forward to working with the Committee to achieve them.

Mr. PALLONE. Thank you, Mr. Ubl. Mr. Cullimore?

Mr. CULLIMORE. Thank you.

Mr. PALLONE. Mr. Cullimore, let me just say, I just wanted to make it clear for the record that you are the President and CEO of Dynatronics Corporation, but you are the Secretary of MDMA, which is the Medical and Devices Manufacturing Association.

Mr. CULLIMORE. Thank you.

Mr. PALLONE. Did I get that right?

Mr. CULLIMORE. Thank you for that verification. Our President got very nervous when you made that announcement.

Mr. PALLONE. OK.

STATEMENT OF KELVYN CULLIMORE, JR., PRESIDENT AND CEO, DYNATRONICS CORPORATION; SECRETARY, MEDICAL AND DEVICES MANUFACTURING ASSOCIATION

Mr. CULLIMORE. Chairman Pallone and Ranking Member Deal, thank you for having me here today to testify. Many of my comments echo those of Mr. Ubl. We appreciate the opportunity to comment on this draft legislation. We recognize and acknowledge the sincerity of concerns that motivate this legislation, and we really do support additional appropriations for FDA to accomplish their assigned mission. But I would like to spend my 5 minutes focusing on a few concerns about the draft legislation. As was mentioned, my name is Kelvyn Cullimore, and I am the President and Chief Executive Officer of Dynatronics Corporation which is a small publicly traded medical device company headquartered in Cottonwood Heights, Utah. We also have manufacturing facilities in Tennessee.

Today I am here to testify on behalf of the MDMA, Medical and Devices Manufacturing Association, which is a national organization of more than 180 member companies representing the innovative, entrepreneurial sector of the medical technology industry. MDMA's mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small research-driven medical device companies. MDMA was actually founded in 1992 to oppose attempts by Congress and large manufacturers to institute a device user fee program. While MDMA recognizes the appropriate role of government in regulating the industry, the Association believed that the government should fund such regulation through appropriations, not user fees. However, in 2002, as we know, MDUFMA I was passed and it established user fees. While MDUFMA I did include important provisions to ensure that smaller companies received fee relief, it did start the slippery slope of government reliance on industry fees.

In 2007, this Committee led efforts to reauthorize the user fee program for an additional 5 years. The result was fees paid by industry almost doubled from $150 million under MDUFMA I to $300 million under MDUFMA II. The reauthorization also expanded fees beyond just device applications to include annual registration fees of $1,700 applicable to every registered manufacturer and fees for filing of annual reports. If we continue to add more and more fees, it will create a significant financial burden for the majority of small medical device companies that could literally mean the difference between success and failure to those companies.

In light of the doubling of the medical device user fees under MDUFMA reauthorization last year, the current draft legislation's

proposal to seek even more fees from industry is very alarming. While these fees may not be viewed as a hardship for multi-billion dollar drug and device companies, I can say for certain that it will be a hardship for the thousands of small medical device companies in this country which are responsible for much of the medical device innovation. Levying additional fees will further erode R&D budgets and have a serious detrimental effect on the operation and sustainability of these small companies.

Enhancing FDA's stewardship and oversight of importation of regulated products is a worthy pursuit, but such efforts that benefit the public at large should be funded from congressional appropriations, not additional user fees, particularly given that proposed paradigm that requires domestic and non-importing manufacturers to subsidize such efforts. When I testified before this committee last year, concerns were raised about FDA becoming too reliant on industry user fees for funding. I shared these concerns and strongly advocate for additional congressional appropriations to fund this proposed legislation.

I would like to take a moment to discuss the bill's provisions dealing with inspections. Congress and FDA have recognized the importance of establishing risk-based classifications for medical devices based upon the level of FDA control necessary to establish and assure the safety and effectiveness of the medical device. However, Section 202 of the draft legislation ignores the important distinction between Class II and III medical devices and proposes to subject all of these medical devices to equal, pre-approval, and pre-clearance inspection regardless of risk. The proposed Section 202 appears to require FDA to conduct pre-clearance inspections of all 510(k) pre-market notifications. Such a requirement would create a logistical nightmare for FDA and would effectively impose additional indeterminate delays on the applicant while awaiting for an FDA inspection, regardless of whether FDA determines that such a pre-clearance inspection was necessary. It could also result in manufacturers being inspected multiple times per year. Adding an additional waiting period for an FDA pre-clearance inspection would result in unacceptable and unnecessary delays for both patients and manufacturers, not to mention the untold pressure on FDA resources to conduct thousands of additional inspections each year.

Finally, let me briefly address the issue of the proposed civil monetary penalties outlined in the draft bill. In particular, as currently drafted, Section 210 could be read as mandating the imposition of penalties for any violation. This section would appear to impose penalties on situations where FDA and manufacturers have historically worked cooperatively to remedy minor and technical violations. The legislation should permit FDA the flexibility and discretion to determine when civil penalties should be imposed and should specifically clarify that penalties would not be imposed for violations that can be addressed by the cooperative efforts of FDA and the industry.

Thank you for providing me with the opportunity to testify today before the Committee. We look forward to working with you and your staff to improve the current FDA inspection process in an efficient and effective manner.

[The prepared statement of Mr. Cullimore, Jr., follows:]

Hearing Testimony

Kelvyn Cullimore Jr.
President and Chief Executive Officer
Dynatronics Corporation

On Behalf Of
The Medical Device Manufacturers Association (MDMA)

Before the House Energy and Commerce
Subcommittee on Health

"Food and Drug Administration Globalization Act"

May 14, 2008

Chairman Pallone, Ranking Member Deal and Members of the Health Subcommittee:

Thank you for inviting me to testify before you today on the discussion draft of the "Food and Drug Administration Globalization Act.[1]"

My name is Kelvyn Cullimore and I am the President and Chief Executive Officer of Dynatronics Corporation. Dynatronics Corporation manufactures, markets, and distributes advanced-technology medical devices, orthopedic soft goods, and rehabilitation equipment for the physical therapy and sports medicine markets as well as devices and equipment for the cosmetic and aesthetics market. Dynatronics was founded in 1979 and is headquartered in Cottonwood Heights, Utah, a suburb of Salt Lake City with manufacturing and distribution operations also located in Chattanooga, Tennessee and Pleasanton, California. Between all operations, Dynatronics has 200 employees, with 90 employees in Utah, 50 employees in

[1] I have included a single-page summary of my testimony as Attachment I to this testimony.

Tennessee, 25 employees in California and 35 employees at satellite sales offices in other states throughout the country.

Dynatronics manufactures medical devices primarily regulated under section 510(k) of the Federal Food, Drug and Cosmetic Act ("FFDCA"). The company is an ISO certified manufacturer with products sold domestically and internationally totaling approximately $33,000,000 in annual sales.

Today, I am here to testify on behalf of the Medical Device Manufacturers Association ("MDMA"), a national organization with over 180 member companies, representing the innovative, entrepreneurial sector of the medical technology industry. MDMA's mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

As a representative of the medical device industry, I thank you for allowing me to share with you my perspectives on the Food and Drug Administration Globalization Act ("FDAGA").

Background of User Fees

As you may know, MDMA was founded in 1992 primarily to oppose attempts to institute a device user fee program. While MDMA recognized the appropriate role of government regulation of the industry, the association believed and continues to believe that the government should fund itself and not look towards the industry to fund its efforts. However, in 2002, the Medical Device User Fee Modernization Act of 2002 ("MDUFMA I") was enacted which established a user fee program. While MDUFMA I did include important provisions to ensure that smaller companies received fee relief, including a one-time waiver of fees for an

initial premarket approval application ("PMA") and reduced application fees for 510(k)s, PMAs and PMA supplements, it started the slippery slope of government reliance on industry fees.

In 2007, this Committee led efforts to reauthorize the user fee program for an additional five years. In the end, the user fee reauthorization doubled industry's contribution to FDA from approximately $150M from 2002-2007 to nearly $300M from 2008-2012. The reauthorization also expanded fees beyond submission to include an annual registration fee of $1,704 which increases at an annual rate of 8.5%.

Proposed New User Fees

In light of the doubling of the medical device user fees last year, the draft legislation's proposal to seek even more fees from industry is very troubling. While these fees may not be viewed as a hardship for multi-billion dollar drug companies, I can say for certain that it will be a hardship for the thousands of small medical technology companies in this country which are responsible for a majority of medical device innovation that eventually comes to market. It is worth noting that 80% of the medical device companies have fewer than 50 employees and 98% have fewer than 500 employees. Levying an additional fee will further erode R&D budgets and have a detrimental effect on the operation and sustainability of these small companies.

This legislation has its genesis in the belief that more funding is required to enable FDA to perform additional oversight with regards to importation of foods, drugs and devices. Such sweeping stewardship will clearly benefit the public at large, but should be funded from congressional appropriations, not additional industry user fees.

When I testified before this committee last year, concerns were raised about FDA becoming too reliant on the industry for funding. I share these concerns. Therefore, I strongly advocate for additional congressional appropriations to fund this proposed legislation.

FDA Inspections

Section 202 of the legislation ignores the risk-based classification system for medical devices, and would require FDA to reallocate its resources from life-supporting or life-sustaining devices to those that pose fewer risks. Congress and FDA have historically recognized the importance of allocating FDA's review of and regulatory control over medical devices according to the device's intended use, indications for use, and significantly, the risk the device poses to the patient. Instead of subjecting every medical device to the same pre-market and post-market regulatory review and oversight, Congress and FDA have recognized the importance of establishing risk-based classifications for medical devices based upon the level of FDA control necessary to establish and assure the safety and effectiveness of the medical device. However, as drafted, Section 202 of the proposed legislation ignores the important distinctions between class II and class III medical devices and proposes to subject all of these medical devices to equal pre-approval or pre-clearance inspection scrutiny regardless of need.

For example, the proposed Section 202 appears to require FDA to conduct pre-clearance inspections for all 510(k) premarket notifications. Such a requirement would create a logistical nightmare for FDA and would effectively impose an additional indeterminate delay on the applicant while waiting for an FDA inspection, regardless of whether FDA determined that such a pre-clearance inspection was necessary – a delay that could add months or even a year beyond the current time to market. As it is, delays in getting a product to market through the traditional 510(k) process can significantly hinder patient access. Adding an additional waiting period for an FDA pre-clearance inspection would result in unacceptable and unnecessary delays for both patients and manufacturers – not to mention untold pressure on FDA resources to conduct thousands of additional inspections each year.

In addition to unnecessarily delaying the availability of medical devices for patients, the pre-clearance inspections currently contemplated in the draft legislation will discourage innovation and product development thus potentially eliminating the future availability of some medical devices entirely by adding cost prohibitive delays and the expense of additional, repetitive, and unnecessary inspections. For example, manufacturers of devices which are commercially available through the 510(k) clearance process regularly modify devices and submit additional 510(k) notifications for the same device for expanded indications or modifications to the device. If, as the current legislation appears to require, a manufacturer is subject to an FDA inspection prior to the introduction of the modified device (which presumably would not satisfy the ambiguously worded "minor modification" of the legislation), manufacturers could potentially be subject to numerous inspections in a single year. Conversely, manufacturers could delay innovation and advancement of their products in order to avoid being subjected to multiple repetitive, costly inspections in a single year. These repetitive inspections would also appear to be a misallocation of FDA resources as they are arbitrarily applied to all class II and class III medical devices irrespective of the risk-based approach to medical devices outlined in the FFDCA and FDA regulations, are not directed at facilities with cGMP violations, and are not otherwise associated with some need - other than being triggered by FDA approval or clearance of a new device.

Penalties

In addition to the issues outlined above, I am concerned with the draft legislation's proposed civil monetary penalties. In particular, as currently drafted, Section 210 could be read as mandating the imposition of penalties for any violation of any requirement of the FFDCA. As drafted, this appears to be an incredibly broad, heavy-handed, ambiguous and arbitrary provision.

The legislation does not appear to provide FDA any discretion in imposing a civil penalty - the wording is that "[a]ny person who violates a requirement of [the FFDCA] that relates to drugs and devices for human use shall be liable to the United States for a civil penalty not to exceed $100,000." This section would appear to impose penalties in situations where FDA and manufacturers have historically worked cooperatively to remedy minor, technical violations. For example, this section would appear to subject every manufacturer who receives an inspectional observation on an FDA Form 483 to a mandatory penalty. Furthermore, this provision appears to require FDA to impose civil penalties on manufacturers (indeed, any person) who unintentionally, without knowledge, or even mistakenly violates a provision of the FFDCA.

The legislation should permit FDA with the flexibility and discretion to determine when civil penalties should be imposed and should specifically clarify that penalties would not be imposed for violations that can be addressed by the cooperative efforts of FDA and the industry.

Again, thank you for providing me with the opportunity to testify today before the Committee and we look forward to working with you and your staff to improve the current FDA inspection process in an efficient and effective manner.

Attachment I

User Fees

- While MDMA recognizes the appropriate role of government regulation of the industry, the association believes that any additional resources from FDA must come from Congressional appropriations and not from industry user fees.

- The device industry has seen its user fee totals jump from approximately $150M from 2002-2007 to nearly $300M from 2008-2012.

- The device industry is composed primarily of small companies (80% less than 50 employees and 98% less than 500 employees) who cannot afford to pay additional user fees.

Inspections

- Section 202 of the legislation ignores the risk-based classification system for medical devices, and would require FDA to reallocate its resources from life-supporting or life-sustaining devices to those that pose fewer risks.

- Congress and FDA have historically recognized the importance of allocating FDA's review of and regulatory control over medical devices according to the device's intended use, indications for use, and significantly, the risk the device poses to the patient. Instead of subjecting every medical device to the same pre-market and post-market regulatory review and oversight, Congress and FDA have recognized the importance of establishing risk-based classifications for medical devices based upon the level of FDA control necessary to establish and assure the safety and effectiveness of the medical device.

- Adding an additional waiting period for an FDA pre-clearance inspection would result in unacceptable and unnecessary delays for both patients and manufacturers.

Penalties

- As currently drafted, Section 210 could be read as mandating the imposition of penalties for any violation of any requirement of the FFDCA. This section would appear to impose penalties in situations where FDA and manufacturers have historically worked cooperatively to remedy minor, technical violations. The legislation should permit FDA the flexibility and discretion to determine when civil penalties should be imposed and should specifically clarify that penalties would not be imposed for violations that can be addressed by the cooperative efforts of FDA and the industry.

Conclusion

- MDMA looks forward to working with Congress to improve the current FDA inspection process in an efficient and effective manner.

Mr. PALLONE. Thank you, Mr. Cullimore. Ms. Gadhia?

STATEMENT OF AMI GADHIA, POLICY COUNSEL, CONSUMERS UNION

Ms. GADHIA. Good afternoon, Subcommittee Chairman Pallone, Ranking Member Deal, and members of the Subcommittee. My name is Ami Gadhia and I am Policy Counsel with Consumers Union, the non-profit publisher of Consumer Reports Magazine.

I am here today to testify about the medical device and cosmetic safety provisions of the discussion draft of the FDA Globalization Act. Consumers Union applauds Chairman Dingell for his leadership on the proposed legislation and commends members of the Energy and Commerce Committee for holding today's hearing on this critical consumer safety issue.

Some of the more high-profile failures of our medical device and cosmetics regulatory system are well-known at this point. The 2006 recall of 183,000 packages of contact lens solution manufactured in China because of bacterial contamination and the June 2007 import alert about toothpaste made in China that contains the very dangerous chemical, diethylene glycol, which is used in antifreeze and as a solvent. Other frightening stories of recalls of medical devices include balloon catheters that failed to deflate and cause a heart attack and heparin lock flush syringes that were contaminated with bacteria.

FDA is charged with overseeing these products, but due to a lack of resources and political will, the Agency has dropped the ball. There have not been enough inspections, enough authority, or enough enforcement of existing regulations, and consumers are paying the price.

Consumers Union believes that the discussion draft of the FDA Globalization bill contains a number of strong provisions that will help make consumers safer. With regards to medical devices, CU supports the provisions of the bill that would require mandatory inspection of both domestic and foreign medical device facilities every 2 years. This inspection provision, if implemented with protections against conflicts of interest, should help improve compliance with existing FDA safety regulations. We would respectfully recommend that this inspection occur annually and more often if there are problems, given the host of serious public health risks that have emerged from foreign facilities in particular.

With regards to cosmetics, CU is in support of the provisions addressed in the FDA's Cosmetic Adverse Event Reporting System, CAERS. In addition to mandatory reporting of adverse events by manufacturers, it is important that FDA's processing and publicizing of these events occurs in a timely manner.

With regards to both device and cosmetic safety, we are pleased that under the draft legislation FDA would track all registered establishments and, at least with regards to medical devices, have a firm number of establishments subject to inspection. Currently, the number of establishments the FDA should be inspecting is a ballpark figure with many establishments completely off FDA's radar.

The discussion draft would require destruction of adulterated, misbranded, or counterfeit drugs that a company attempts to import into the United States. However, a similar safeguard does not

exist for unsafe medical devices, and we would recommend that it be added. We also support the provisions in the bill creating a fee requirement for importers of cosmetics. It is not sufficient for FDA's inspection resources to stay at their current extremely inadequate level with regard to imported cosmetics. This importer fee requirement is one step toward addressing this problem.

There are, however, some provisions in the discussion draft affecting both medical devices and cosmetics that Consumers Union would encourage the Committee to consider strengthening. We would recommend shortening the timeframes for implementation. It appears that the effective dates of a number of the bill's provisions are too far out into the future, sometimes 2 or 3 years out. These should be shortened.

We support the provision creating a user fee schedule for various new FDA functions. However, we urge the Committee to ensure that the user fees do not turn into a pay-for-play scenario. We would not want to see regulated entities have the ability to exert undue influence over the FDA in its decision-making or other functions.

In addition, like the user fees for food safety importation, the fees pertaining to device and cosmetic safety should be indexed for inflation.

Consumers Union also believes that the monetary civil penalties for violations of the medical device protections in the bill are set too low. For a large manufacturer, producer, or other multi-national, a penalty of $100,000 is simply a cost of doing business or a few hours' worth of profit. For the penalties to serve as a true deterrent against illegal actions, they should be set higher.

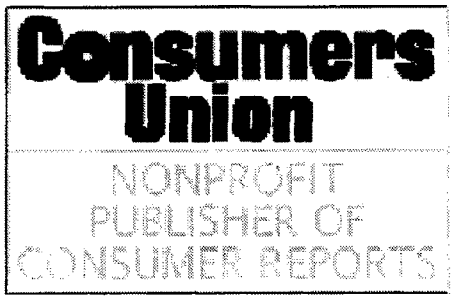
FDA must also have the ability to perform unannounced inspections of foreign facilities. Because of advanced warning, these foreign manufacturers, unlike domestic companies, are able to clean up to ensure that they pass inspection, even if they are out of compliance every other day of the year. In addition, any provisions in the final bill that permit FDA to outsource any agency task to a third party should include protections against such tasks being performed by entities with a conflict of interest.

We have a number of other concerns and recommendations about the draft bill that we would also like to bring to the Committee's attention. These particular concerns are presented in detail in my written testimony.

We wholeheartedly support providing FDA with new authority and resources. We are pleased that this discussion draft gives FDA a number of new and very necessary powers to better ensure the safety of our medical devices and cosmetics. We also urge that manufacturers and others who profit from the sale of medical devices and cosmetics to American consumers fairly shoulder their full responsibility for improving the safety and quality of the products that they sell.

I thank the Committee for the opportunity to testify today, and we at Consumers Union look forward to looking with the Committee to help move forward on the strongest FDA reform bill possible.

[The prepared statement of Ms. Gadhia follows:]



Statement of Ami Gadhia

Concerning Discussion Draft of "FDA Globalization Act"

Subcommittee on Health, Energy & Commerce Committee

U.S. House of Representatives

May 14, 2008

Good morning, Chairman Dingell, Ranking Member Barton, Subcommittee Chairman Pallone, Subcommittee Ranking Member Deal, and members of the Subcommittee. My name is Ami Gadhia, and I am Policy Counsel with Consumers Union[1], the non-profit publisher of *Consumer Reports* magazine. I am here today to testify about the Medical Device and Cosmetic Safety provisions of the Discussion Draft of the Food and Drug Administration (FDA) Globalization Act. Consumers Union applauds the Chairman for his leadership on the proposed legislation, and commends members of the Energy and Commerce Committee for holding today's hearing on this critical consumer safety issue.

I. INTRODUCTION

Some of the more high-profile failures of our medical device and cosmetics regulatory system are well known at this point: for example, the 2006 recall of 183,000 packages of contact lens solution, manufactured in China, because of bacterial contamination; and a June 2007 import alert about toothpaste made in China that contained the very dangerous chemical diethylene glycol, which is used in antifreeze and as a solvent. Other frightening stories of unsafe medical devices also serve as cautionary tales. Just a few examples of so-called "Class I" recalls of medical devices – those that pose a significant risk of injury or death – include balloon catheters that could fail to deflate and cause a heart attack, automatic external defibrillators that could fail to analyze

[1] Consumers Union (CU) is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finance. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* and its other publications and websites have a total subscription of approximately 8.6 million. *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

a patient's electrocardiogram result, and heparin lock flush syringes that were contaminated with bacteria.

FDA is charged with overseeing these products. But due to a lack of resources – and political will – the agency has dropped the ball. There have not been enough inspections, enough authority, and enough enforcement of existing regulations, and consumers are paying the price.

Consider the ineffective oversight of cosmetics and personal care products. Like most drugs, they are often used on a daily basis, designed for frequent direct contact, in the mouth and on the skin. Many are also inhaled. Yet, consumers are almost always disturbed to learn that unlike for drugs, the safety of cosmetic ingredients and their production is not subject to FDA scrutiny before they enter the marketplace. [2] Further, many would be shocked to know that even the ingredients used in cosmetic products are not known to the FDA and sometimes even the Poison Control Centers, leaving both unprepared to act effectively when faced with reports of counterfeiting or contamination.

FDA maintains the Voluntary Cosmetic Registration Program, or VCRP, for cosmetic establishments and formulations. "As its name indicates, this program is voluntary. In contrast, it is mandatory for drug firms to register their establishments and list their drug products with FDA."[3]

Because of these important differences in FDA regulation of cosmetics – in contrast to its regulation of drugs - and the likely perception of consumers of the relative safety of cosmetics, it is very important particularly, in this era of increasing imports, that

[2] http://www.cfsan.fda.gov/~dms/cos-218.html
[3] http://www.cfsan.fda.gov/~dms/cos-218.html

the FDA be given the tools and resources to protect consumers from unsafe cosmetics, in addition to increased regulation and oversight of medical devices.

II. PROVISIONS IN THE DISCUSSION DRAFT SUPPORTED BY CONSUMERS UNION

Consumers Union believes that the Discussion Draft of the FDA Globalization bill contains a number of strong provisions that will help make consumers safer. With regards to medical devices, CU supports the provisions of the bill that would require mandatory inspection of both domestic and foreign medical device facilities every two years. This inspection provision – if implemented with protections against conflicts of interest – should help improve compliance with existing FDA safety regulations. Consumers Union would respectfully recommend that this inspection occur annually (and more frequently, if there are problems), given the host of serious public health risks that have emerged from foreign facilities in particular. However, recognizing the time and resources involved in inspections, the annual inspection requirement could be modified to include a graduated inspection schedule depending on the category of device (e.g., tongue depressor facilities may be inspected less frequently than an establishment that manufactures cardiac pacemakers).

With regards to cosmetics, CU is in support of the provisions addressing the FDA's Cosmetic Adverse Event Reporting System (CAERS). However, there are two changes that we feel are necessary to this provision. Instead of requiring reporting of adverse events from each *facility*, the requirement should apply to *manufacturers*, since a facility can be a very small overseas shop that produces one ingredient in the product, and which may not adhere to the reporting requirement; the manufacturer should be responsible for all the ingredients/components of the product. In addition to mandatory

reporting of adverse events by manufacturers, it is important that FDA's processing and publicizing of these events occurs in a timely manner. We have reported on significant problems with this system. In the Winter 2007 issue of Consumer Reports' magazine *ShopSmart,* we reported the problems encountered by a health care provider when attempting to use CAERS. Dr. Amy Newberger, a dermatologist at St. Luke's-Roosevelt Hospital Center in New York City and a former member of the FDA's General and Plastic Surgery Devices Panel, reported a rash with blisters associated with the use of an anti-aging treatment, and she filed the report both over the phone and on the CAERS system. However, it wasn't until a year later, in November 2006, that the FDA sent her an email asking her to complete some forms. Such delays slow the availability of critical safety information to those who can protect the public health.

With regards to both device and cosmetic safety, we are pleased that under the draft legislation, FDA would track all registered establishments and, at least with regards to medical devices, have a firm number of establishments subject to inspection. Currently, the number of establishments the FDA should be inspecting is a ball-park figure, with many establishments completely off FDA's radar. However, although Sections 201 and 301 require drug, device and cosmetic establishments to register with FDA, the legislation does not provide (and FDA does not presently have) the authority to block products and ingredients from unregistered establishments at the border. In order to fix this loophole, importers should be required to prove at the border that the product's supply chain is composed of only registered establishments, and products that cannot document its supply chain should be refused entry. Although such a requirement may be

the intent of the Discussion Draft, we are concerned that such intent may need clarification in the actual bill language.

III. AREAS OF CONCERN

The Discussion Draft would require destruction of adulterated, misbranded, or counterfeit drugs that a company attempts to import into the United States. However, a similar safeguard does not exist for unsafe medical devices. Such a provision is necessary to prevent importers from "shopping" until they find a port that will admit entry for their products, and will help to keep dangerous products out of the U.S. The destruction of these unsafe drugs will also prevent importers from simply "dumping" them on the citizens of countries outside U.S. borders – particularly those with lax regulation. The dangers from such devices are no less than those from adulterated, misbranded, or counterfeit drugs. We would therefore also recommend that the bill provide for a similar destruction of unsafe medical devices.

We support the provisions in the bill addressing the safety of cosmetics. As mentioned above, in June 2007, FDA issued an import alert against imported toothpaste that contained diethylene glycol. Other cosmetics may also contain this or other harmful chemicals. It is not sufficient for FDA's inspection resources to stay at their current extremely inadequate level with regard to imported cosmetics. Creating a fee requirement for importers of cosmetics is one step towards addressing this problem.

There are, however, some provisions in the Discussion Draft affecting both medical devices and cosmetics that Consumers Union would urge the Committee to consider strengthening. We would recommend shortening the timeframes for implementation. It appears that the effective dates of a number of the bill's provisions

are too far out into the future. There is a two-year delay after enactment of the Act before foreign producers are required to undergo inspection of their facilities as a pre-condition to importation, and before the country-of-origin labeling requirement is enacted. In addition, there is a three-year delay in the requirement to produce documentation. These time intervals to implementation should be shortened.

Consumers Union supports the Discussion draft's provision creating a "user fees" schedule for various new FDA functions such as registration, certification, and inspection as a reasonable way to pay for FDA's increased inspections and enhanced oversight of both devices and cosmetics. However, CU urges the Committee to ensure that the user fees do not turn into a "pay-for-play" scenario. That is, we would not want to see regulated entities have the ability, through the user fee program, to exert undue influence over the FDA in its decision-making or other functions.

We are also concerned that the fees for registration of importers of both devices and cosmetics, as established by Section 401(c) of the Draft, are not indexed for inflation. Like the user fees for food safety importation, the drug and device importer fees should be indexed.

Consumers Union also believes the monetary civil penalties for violations of the medical device protections in the bill, in Section 210, are set too low.[4] For a large manufacturer, producer, or other multi-national, a penalty of $100,000 is simply a cost of doing business. The drug and device industry is a multi-billion dollar industry, and a $100,000 fine may simply be a few hours' worth of profit for some companies. For the

[4] Please note that the Discussion Draft does not create monetary civil penalties for violations of cosmetic safety provisions, so our concerns can pertain only to penalties for device safety violations.

penalties to serve as a true deterrent against unsafe or illegal actions, they should be set higher.

We also urge inclusion of one particular GAO recommendation from its November 2007 report that is not currently in the Discussion Draft: FDA must have the ability to perform unannounced inspections of foreign facilities. Currently, since FDA gives foreign manufacturers advanced warning of inspections, these manufacturers – unlike domestic companies – are able to "clean up" to ensure they pass inspection, even if they are not in compliance every other day of the year. A dedicated foreign inspectorate (which the bill provides for) and regular FDA presence overseas, as well as adequate resources to staff these overseas offices, may be the best way to ensure random inspections.

In addition, any provisions in the final bill that permit FDA to outsource inspection, certification, registration, or any other agency tasks to a third party should include protections against such tasks being performed by entities with a conflict of interest. That is, any third party entities engaged by FDA to conduct safety and quality tasks should not be in any way connected with, related to, or otherwise influenced by any company within the supply chain.

Finally, we have four concerns about cosmetic safety that they would also like to bring to the Committee's attention. These particular concerns are presented on behalf of CU and of the Consumer Federation of America (CFA). In the Winter 2007 issue of *ShopSmart* CU also reported that phthalates, a family of chemicals that may be linked to developmental and reproductive health risks, are found in many cosmetics, including perfumes and deodorants. CU tested eight perfumes – including five top sellers – and

found phthalates in all of them, *including* perfumes that the manufacturer stated were phthalate-free. However, companies are not required to list phthalates in their ingredient lists. What is more, there is currently only a voluntary program for manufacturers to report the ingredients in their cosmetics. Because of the voluntary nature of the program, many companies do not report their ingredients, and it is difficult for researchers to conduct thorough studies on the effects of chemicals in cosmetics upon humans. In order to advance our understanding of the effects of the various chemicals in cosmetic products upon our bodies, it should be made mandatory for companies to report the ingredients and their concentrations for all cosmetics to the FDA. Second, CU and CFA believe that the FDA needs to do a better job of enforcement with regards to cosmetic ingredients that are not approved as safe for use but that still exist in products. Companies that are using such non-approved ingredients in products must, by regulation, put a label on the product to inform the consumer of the ingredient's presence. However, such labeling is often missing. CU and CFA support giving FDA better enforcement authority to make sure that all cosmetics – both those manufactured domestically and abroad – bear such labels.

Third, CU and CFA feel that Discussion Draft should also contain, or direct the FDA to create by rulemaking, a definition of the word "safe" as used with regards to cosmetics. Finally, our organizations feel that FDA should be given the authority to regulate and oversee, in a comprehensive fashion, ingredients that appear across the various kinds of products that they regulate. Phthalates are a prime example of such an ingredient: they appear in medical devices, drug coatings, cosmetics, and in food packaging, for example.

IV. CONCLUSION

We wholeheartedly support providing FDA with new authority and resources. We are pleased that this Discussion Draft gives FDA a number of new – and very necessary –powers to better ensure the safety of our medical devices and cosmetics. We also urge that manufacturers and others who profit from the sale of medical devices and cosmetics to American consumers fairly shoulder their full responsibility for improving the safety and quality of the products they sell.

I thank the Committee for the opportunity to testify today, and we at Consumers Union look forward to working with the Committee to help move forward on the strongest FDA reform bill possible.

Mr. PALLONE. Thank you again. Ms. George?

STATEMENT OF ELISABETH GEORGE, VICE PRESIDENT, QUALITY AND REGULATORY AFFAIRS, PHILIPS HEALTHCARE

Ms. GEORGE. Mr. Chairman, Ranking Member Deal, and members of the Committee, thank you for the opportunity to testify today. My name is Elisabeth George, Vice President of Quality, Regulatory, Sustainability, and Product Security at Philips Healthcare. I am testifying today on behalf of Medical Imaging and Technology Alliance, MITA, where I serve as a member of the board of directors.

MITA understands and has a record of supporting the Committee's desire to ensure that FDA is well-funded and that medical devices imported into the United States are safe for U.S. patients.

MITA is the collective voice of medical imaging equipment manufacturers, innovators, and product developers whose sales comprise more than 95 percent of the global market. Medical imaging encompasses X-ray, CT scans, radiation therapy, ultrasound, PET, and MRI. Our members make the products that detect and treat serious illnesses such as heart disease, cancer, stroke, and osteoporosis. The equipment our member companies manufacture empowers doctors and medical professionals to view the human body with stunning and ever-increasing clarity and accuracy. This enables better diagnosis and more effective medical care for patients, often reducing the need for costly medical services and evasive surgical procedures. In fact, it is not an exaggeration at all to say the term exploratory surgery will become obsolete in medicine due to the power of medical imaging.

The medical imaging industry is a net exporter economic engine and employs tens of thousands of skilled workers here in the United States. The research and development that led to the innovative technologies were invented right here in communities across America.

As we continue working together to reduce healthcare spending, improve patient care and outcomes, MITA appreciates the support from leadership and members of this committee to protect medical imaging from further Medicare reimbursement cuts. We understand that there are significant concerns about drug ingredients and food that have been imported from foreign countries. However, we believe the device industry, a highly regulated industry globally, is vastly different. Medical devices are classified into Class I, II, and III based on the level of risk. Medical imaging devices are Class II. Our members' foreign and domestic facilities are subject to international quality and safety inspections at least annually as a part of the International Standards Organization, ISO 13485 standard. This inspection is virtually identical to the FDA quality system regulation system inspections. Meeting the ISO 13485 standard is a requirement for medical imaging manufacturers in 47 countries. MITA believes that the FDA should avail itself of valuable information gained from these inspections that are required by every other industrialized nation.

I would like to turn to the discussion draft before us today. We believe the discussion draft places new unnecessary regulatory burdens on our products without taking into account the unique na-

ture of how our devices are manufactured and extensively regulated. For example, the draft would require an FDA inspection for nearly every modification of the device. MITA believes this inspection requirement unduly stalls delivery of improved technology that benefits patients. On average, each medical imaging device is updated with improved technology once every 18 months. For example, a manufacturer may submit a device change to the FDA based on the fact that we can image another part of the body, we have updated the software, or added new functionality. These updates do not warrant a new facility inspection which will halt production of already-approved products until an FDA inspector completes the new assessment.

Secondly, we are concerned that requiring registration and inspection of component parts may be duplicative and imprudent. Medical imaging devices are inspected and approved by the FDA as finished products. Components, including screws, circuit boards, monitors, and so forth, must work correctly for the device to function properly.

Finally, we believe significant new fees are duplicative and are unnecessary. Last year, FDAA Act, the industry agreed to a 90 percent increase in user fees in order to provide stability to the Agency and ensure the life-saving medical devices would proceed to market. Medical device manufacturers currently pay fees for ISO inspections as well as for FDA-mandated facility registration fees. However, the draft includes additional annual facility registration and importer fees. These new fees unfairly burden domestic medical imaging manufacturers. MITA understands the need to fund the FDA, but any fees should be targeted at funding the actual inspection of the foreign facilities.

In conclusion, medical imaging has become integral to best practices across so many disease states and plays a critical role in providing high-quality patient care. It is critical that patients have access to innovative medical imaging technology to help fight serious illnesses.

Again, thank you for the opportunity to testify at today's hearing, and I welcome your questions later.

[The prepared statement of Ms. George follows:]

Testimony of
Elisabeth George, Vice President, Quality, Regulatory, Sustainability & Product Security
Philips Healthcare
On Behalf of Medical Imaging & Technology Alliance (MITA)
A Division of the National Electrical Manufacturers Association (NEMA)

Before the
Subcommittee on Health
Committee on Energy & Commerce
United States House of Representatives

Hearing on
Discussion Draft of the "Food and Drug Administration Globalization Act" Legislation: Device and Cosmetic Safety Provisions

May 14, 2008
2123 Rayburn House Office Building

Mr. Chairman, Chairman Dingell, Ranking Member Barton, Ranking Member Deal and Members of the Committee, thank you for the opportunity to testify before the Committee today on the important topic of the Food and Drug Administration's (FDA) inspections of foreign manufacturing facilities. My name is Elisabeth George, Vice President, Quality, Regulatory, Sustainability & Product Security of Philips Healthcare. I am testifying today on behalf of the Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA) where I serve as a Member of the Board of Directors. MITA is the collective voice of medical imaging equipment manufacturers, innovators, and product developers. It represents companies whose sales comprise more than 95 percent of the global market for medical imaging technology. Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, nuclear medical imaging (including (PET)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with serious diseases including heart disease, cancer and stroke, often reducing the need for costly medical services and invasive surgical procedures.[1] In addition, medical imaging equipment is often used to facilitate effective treatment, for example, by guiding physicians as they carry out a medical or surgical intervention, to ensure high-quality clinical results for the patient.[2]

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[1] Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005. Further, in reviewing the clinical literature, MITA recommends that CMS consider the positive findings on the cost-effectiveness of PET in the diagnosis of lung cancer. Muller A., Stratmann-Schone D, Klose T, Leidl, Overview of Economic Evaluation of Positron-Emission Tomograpy. Eur J Health Econ 3:59-65 2002.

[2] Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731 - 737.

MITA represents large, mid-size and small manufacturers who manufacture and conduct most of their research and development right here in the United States. The medical imaging industry is a net exporter and a positive industry for the U.S. economy. Our industry employs tens of thousands of skilled workers here in the U.S. The research and development that led to the innovative technologies such as magnetic resonance imaging MRI, CT and PET, which detect, and are instrumental to the treatment of, serious illnesses, were invented in the U.S.

Importance of Medical Imaging

MITA applauds and appreciates the support from leadership and members on this Committee to protect medical imaging from further reimbursement cuts. Medical imaging empowers doctors and medical professionals to view the human body with ever increasing clarity and accuracy. This enables better diagnoses and more effective medical care for patients. In addition, medical imaging is integral to best practices across many disease states. It is essential to the continuum of care – from prevention, to diagnosis, to treatment –and the result is improved outcomes for patients. In fact, the *New England Journal of Medicine* has acknowledged the value of medical imaging, calling it **one of the top 11 innovations of the past 1,000 years**. Medical imaging allows for less invasive, highly-targeted medical surgeries and therapies that translate to shorter hospital stays, fewer complications, and greater comfort for patients.

Medical imaging is essential to many widely-accepted quality and screening guidelines for a variety of diseases, including breast cancer. For example, the American Cancer Society recommends that every woman 40 years old and older receive an annual mammogram. In fact, when breast cancer is detected early, while still confined to the breast, the five-year survival rate

increases to more than 98 percent. Consequently, these devices help millions of Americans more effectively fight and survive serious illnesses such as breast, ovarian, cervical, colorectal, lung and prostate cancers, heart disease and osteoporosis. Detecting these critical illnesses at their most curable stage is essential. Medical imaging saves money – by reducing or eliminating unnecessary surgery and post-operative care. It also often replaces more costly tests or treatments. CT scans, for example, have all but eliminated the practice of exploratory surgery with its associated risks and lengthy recovery periods.

The Device Industry is Highly Regulated Both Domestically and Internationally

We understand that there are significant concerns about drug ingredients and food that have been imported from foreign countries. However, we believe the device industry, a highly regulated industry globally, is vastly different. Before we turn to the specific differences between drugs and devices, it is important to note that not all devices are the same.

Regulatory Classification of Devices Based on Risk

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III based on the level of risk. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.

Device classification depends on the *intended use* of the device and also upon *indications for use*. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product. A discussion of the meaning of intended use is contained in Premarket Notification Review Programs.

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk, Class II with moderate risk, and Class III includes those with the greatest risk. Medical imaging and radiation therapy devices are Class II devices that require filing a 510(k) to demonstrate that they are substantially equivalent to a predicate device, but are not considered high risk. As a result, when FDA considers its inspectional priorities, if a manufacturer of a Class II device has a good inspectional history, they receive inspections less frequently. According to the Government Accountability Office (GAO), domestic manufacturers of Class II devices are inspected on average of once every 5 years. However, at Philips Healthcare and at other imaging device manufacturers, inspections occur on a much more frequent basis, in spite of our excellent inspectional history and low relative product risk.

Global Inspection Process

MITA members' foreign and domestic manufacturing facilities are subject to international quality and safety inspections **at least annually** as part of the International Standards Organization (ISO) 13485 standard, a standard virtually identical to FDA Quality System

Regulations (QSR). Meeting the ISO 13485 standard is a requirement for medical imaging manufacturers in 47 countries and all major regulatory agencies worldwide[3].

The slight differences between FDA's QSR and the ISO 13485 standard fall into four categories. However, the spirit and substance of the requirements are the same.

- **Recall regulations** – As part of the Corrective and Preventive Action (CAPA) regulations present in QSR and ISO, FDA may also follow up on product recalls. However, recall reporting is mandated outside the inspection requirements (as part of 21 CFR 806) and requires separate reporting by manufacturers to FDA. FDA may follow up on these at any time; inspections are not needed to enforce these requirements.

- **Medical Device Reporting (MDR) regulations** – As a follow up to certain complaints, FDA may evaluate the manufacturer for their MDR content. However, the MDR requirements are not managed by the inspection process (actually part of 21 CFR 803) and require direct reporting to the agency.

- **Design History Files** – Design History Files include information on how a product was developed by a company. Both the ISO and QSR require this information to be maintained for inspection. The same information is required, but the terminology varies slightly.

[3] List of countries attached as Appendix A

- **Device History Records** – Device History Records include information on how a product is manufactured and show that specific quality assurance steps are taken in the manufacturing process. The ISO and QSR requirements for Device History Records are virtually identical. But similar to the regulations for Design History Files, the only difference is in the terminology used.

MITA believes that the FDA should avail itself of the valuable information gained from these inspections that are already required by every other industrialized nation. Beyond these four minor points, the remaining variations between the QSR and ISO 13485 entail definitions of terms and other minor wording differences. Indeed, as the FDA is intricately involved in the development of the ISO standards, FDA should be able to readily adopt the ISO 13485 quality system standard as the basis for its regulatory process.

Drugs v. Imaging Devices

As opposed to drugs, medical imaging devices are inspected and approved by the FDA as finished products. Component parts for devices, that include screws, circuit boards and screens must work correctly for the completed device to function properly and pass its rigorous inspections. Each component part must meet stringent individual international standards that are established by regulatory bodies. While we understand the concern over component drug ingredients, in the medical imaging industry, if components do not function correctly, the device does not operate properly. Imaging devices are tested throughout the production process and in final inspection. Any malfunctioning that may arise as a result of

faulty component parts is identified during mid-product testing or in the testing of finished devices.

The FDA's inspection process and the international regulatory structure for devices are both based on the fact that a properly designed and implemented quality system will ensure quality of components for the finished product to operate correctly. Examining component parts would be duplicative, unnecessary and not be a prudent use of FDA resources in this arena. Requiring the inspection of each component part is a wholesale change in the way imaging devices are regulated by the FDA currently and could grind manufacturing to a halt.

Food & Drug Administration Amendments Act of 2007 and User Fees

The Food & Drug Administration Amendments Act of 2007 (FDAAA) was the result of a carefully crafted negotiation between FDA and industry that resulted in providing much needed resources to the FDA. FDAAA represented an increase of nearly 90% in user fees to the industry over 5 years. User fees went from approximately $150 million to nearly $300 million from the original Medical Device User Fee Amendments (MDUFMA) to FDAAA. The industry agreed on the increase in order to provide stability to the agency and ensure that life-saving medical devices would proceed to market. There is a shared goal by the FDA and industry to provide new resources to the FDA so that innovative products can be expeditiously reviewed and patients can continue receiving access to critical diagnosis and treatment equipment.

FDAAA also included, for the first time, an annual fee of $1700 per facility (domestic and foreign) as part of a carefully negotiated compromise to bring needed resources into a specific part of the agency, FDA's Center for Devices and Radiological Health (CDRH). The new fees

included in the Discussion Draft provide no obvious link to the FDA's work on medical devices. In addition, these new fees unfairly burden domestic medical imaging manufacturers, which comprise 52 percent of the global market. The effectiveness of added fees is questionable, given that over 90 percent of medical imaging and oncology treatment devices are manufactured in industrialized nations such as the U.S., European Union, and Japan.

As part of the FDAAA, manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. All establishment registrations must be submitted electronically unless a waiver has been granted by FDA.

It is important to note that FDAAA also included statutory revisions to the third-party inspection program which is intended to increase participation while maintaining all of the stringent conflict of interest requirements. As a result, Philips Healthcare has signed up for 22 new third-party inspections. Prior to the modifications we had conducted two inspections. These third party inspections we believe will achieve the goal, much as the Committee has done in the Food section of this Discussion draft, of providing a greater window of transparency into the inspection process and get more inspection information to the FDA. In order to participate in the program, a manufacturer needs to have a good inspectional record conducted by the FDA.

FDA Globalization Bill

MITA understands the Committee's desire to ensure that FDA is well funded and that medical products imported into the United States are safe for U.S. patients. However, MITA has a number of concerns about the FDA Globalization Bill discussion draft. As mentioned above, we

do not believe the bill takes into account the unique nature of medical devices, specifically how they are regulated and manufactured. In summary, MITA's concerns are as follows:

- The Discussion Draft would require an FDA inspection for each "minor modification" in a medical device prior to importation into the U.S. MITA believes this inspection requirement will unduly stall delivery of improved technology into the U.S. market. On average, each medical imaging device is updated with improved technology once every 18 months. For example, a manufacturer may submit a device change to the FDA based on the fact that it now can image another part of the body, has updated software, change the monitor screen, or has added functionality. These updates do not warrant a mandated new facility inspection, which will halt production of already approved products until an FDA inspector completes the new assessment. This would also create a strain on Agency resources, requiring FDA to divert resources to products that have changes with no or limited risk to the patient. FDA should be focusing their resources on known or potential risk. This would benefit not only the FDA, but also patient safety. This will adversely affect innovation in an industry where the U.S. is the global leader, and will prevent patients from having access to the very best available technology.

- As previously mentioned, included among MITA members are small and mid-size companies here in the U.S. that are at the forefront of innovation and development. Many of our small members do not have the resources to pay a $10,000 importer fee as well as an increased registration fee. We are concerned that the increased registration fees will also be a significant burden on all domestic manufacturers. MITA understands

the need to fund FDA, but any fees should be targeted at funding the actual inspection of foreign medical device facilities rather than general fees. We look forward to working with the Committee to come up with a fair and equitable system to increase the FDA's resources while ensuring that imported devices are safe and effective.

- Also referenced earlier, inclusion of component parts in the inspection requirement for medical devices would be duplicative, unnecessary and an imprudent use of funds.

Conclusion

Medical imaging has become integral to best practices across so many disease states and plays a critical role in providing high quality patient care. It is critical that patients have access to innovative medical imaging technology to help fight serious illnesses such as heart disease, cancer, stroke and osteoporosis. We look forward to working with the Committee as it continues to develop this important legislation.

Appendix A: Countries requiring ISO 13485 Certificates

Austria	Ireland	Poland
Belarus	Italy	Portugal
Belgium	Japan	Romania
Brazil	Kyrgyzstan	Russia
Bulgaria	Latvia	Serbia
Canada	Libya	Slovakia
Cyprus	Lithuania	Slovenia
Czech Republic	Luxembourg	South Korea
Denmark	Malaysia	Spain
Estonia	Malta	Sweden
Finland	Mexico	Taiwan
France	Mongolia	Turkey
Germany	Netherlands	Ukraine
Greece	Panama	United Kingdom
Hungary	Peru	Uzbekistan

Mr. PALLONE. Thank you. Ms. Bailey?

STATEMENT OF PAMELA BAILEY, PRESIDENT AND CEO, PERSONAL CARE PRODUCTS COUNCIL

Ms. BAILEY. Thank you, Chairman Pallone, Ranking Member Deal. I am pleased to be able to testify today on behalf of the Personal Care Products Council and to discuss the longstanding safety record of our personal care products companies.

The Council is the leading national trade association representing the global cosmetic and personal care products industry, and our 600-member companies are the manufacturers, suppliers, and distributors of the vast majority of finished personal care products marketed in the United States.

We would like to state up front that we appreciate and support the goal of this Committee in the cosmetic section in the pending legislation to ensure the FDA has the authority to provide strong oversight so that American consumers can be assured that imported products are safe. I also appreciate the opportunity today to provide additional information to the Committee on the existing nature of the regulatory framework governing personal care products.

Consumer safety has always been the number one priority of our companies. Under the Federal Food, Drug, and Cosmetic Act, it is a crime to market an unsafe cosmetic product in the United States. Cosmetic products imported into the United States are subject to the same substantive standards as those produced in the United States and face an even higher regulatory threshold upon entry in that an appearance of adulteration or misbranding may subject them to detention at the border. They must be safe and contain no prohibitive ingredients, and all labeling and packaging must be in compliance with U.S. regulations.

In addition, all colors must be listed and are pre-approved by FDA, and a number of color additives in addition must be pre-approved, batch tested, before they can be added to a personal care product either within the United States or outside.

In addition, if a product contains an active ingredient that qualifies it for regulation under our OTC drug rules, then they are subjected to the stricter drug review standards that govern drugs in the U.S. What this means, Mr. Chairman, is that if a product is a sunscreen, an antiperspirant, and a dandruff shampoo, toothpaste, mouthwash, it must go through the pre-approval standards of the OTC program. In addition, any colors added to products must be pre-approved. So a product as simple as a lipstick that has SPF in it will be subject to pre-approval standards both for the colors and for the SPF.

Product safety in a global marketplace is not only a matter of law for our members, it is the primary commitment for each of them and for our Association. For 40 years our companies have invested millions of dollars through our trade association in safety programs to enhance the regulatory responsibilities at FDA including our consumer commitment code, the Cosmetic Ingredient Review Panel, our FDA Company Registration Program, the International Cosmetic Ingredient Dictionary, our consumer information Web site, and our Import Safety Committee. The result of these

safety practices and initiatives, cosmetics and personal care products are the safest category of products regulated by FDA. This means, for example, that of the 11 billion individual personal care products sold in the United State each year, less than 200 instances of product adverse events are reported to FDA. It means that between the years of 2000 and 2005 of the warning letters issued by CFSAN, some 1,400 of them related to food and only three related to cosmetics.

We recognize that ours is now a global industry and that our products and our ingredients are manufactured and sourced throughout the world. We agree with the Committee that FDA needs basic information about the safety of products and where and how they are manufactured. That is why three years ago, when we wrote our Consumer Commitment Code, we required member companies signing the code to register their cosmetic facilities with FDA and to report serious and unexpected adverse events to FDA.

We are proud that in the first 16 months of its implementation, 80 percent of all U.S. annual sales are covered by our board member companies who have certified to the code and are registered with FDA and have agreed to report their adverse events to FDA. We are proud that our industry helped craft global manufacturing standards and have worked with international regulatory agencies to encourage each nation to adopt those G&P standards, and we have encouraged FDA to issue guidance incorporating ISO G&P standards into current practice in the United States.

The Committee and the draft bill challenge us to take the next step. Exactly how that is done is important. We have been working with the bipartisan staff to provide technical details on the draft's regulatory provisions, and we appreciate the opportunity to continue those discussions.

We believe the most effective way to enhance cosmetic safety is to provide additional resources to FDA. The budget for FDA for cosmetics in 1974 was $2.7 million. In real dollar terms, that would be $14.5 million today. In reality, it was $3.5 million last year before we successfully lobbied for an additional $1 million in appropriations. We are going to continue those efforts and urge the Committee to support additional appropriations.

Mr. Chairman, I want to close with a note on the registration and import fees. Our industry has never been subject to fees. This is a topic of significant discussion. We are continuing to discuss that. We are going to continue to discuss it with the Committee, but we are going to need more time on that and other issues.

In conclusion, we want to thank the Committee for the opportunity to work on this legislation. Our industry has always put safety first. We have always been aware of the necessity to take additional steps whenever that may be, and we look forward to discussing with the Committee the most effective way to take the next steps so that we can continue to ensure the American consumer that our products are safe. Thank you.

[The prepared statement of Ms. Bailey follows:]

Prepared Written Testimony of Pamela G. Bailey

Chief Executive Officer and President

The Personal Care Products Council

UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE

MAY 14th, 2008

Chairman Pallone, Ranking Member Deal, and distinguished Members of the Committee:

I am here today on behalf of the Personal Care Products Council, formerly the Cosmetic, Toiletry, and Fragrance Association. I appreciate the opportunity to appear before you to discuss the long-standing commitment to safety that personal care product companies have demonstrated and the resulting strong record of safety for our products.

Founded in 1894 and based in Washington, D.C., the Council is the leading national trade association representing the global cosmetic and personal care products industry. We represent over 600 member companies, including leading U.S. and global brands like L'Oreal, Procter & Gamble, Mary Kay, Avon, The Dial Corporation, Johnson & Johnson, Unilever, Estee Lauder, Revlon, and several hundred small businesses with annual revenue under ten million dollars.

From sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, our companies manufacture, supply, and distribute the vast majority of finished personal care

products marketed in the U.S. As the makers of a diverse range of products millions of consumers rely on everyday, personal care products companies are global leaders committed to product safety, quality, and innovation.

We would like to state upfront that we appreciate and support the goal of this legislation and the cosmetic section – to ensure that FDA has the authority to provide strong oversight so that American consumers can be assured that imported products are safe.

Consumer safety has always been the number one priority of our cosmetics and personal care products companies. The most important law pertaining to the safety of cosmetics marketed in the United States is the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, as currently amended.

Under this law, the organizing principles of cosmetic safety were established. There is a strong, existing regulatory framework. Under this law, it is a crime to market an unsafe cosmetic product. Let me restate that: it is a crime to market an unsafe cosmetic product. Cosmetic companies are responsible for substantiating the safety of their products and the individual ingredients before marketing. The FDA's responsibility is to provide regulatory oversight through the creation and enforcement of safety and labeling regulations that hold industry accountable and to conduct post-market surveillance to determine whether a cosmetic is in violation of the FD&C Act and should be removed from the marketplace. In addition, FDA collects samples for examination and analysis as part of its plant inspections, inspects imported goods, and conducts follow-up to

complaints of adverse reactions. FDA may also conduct research on cosmetic products and ingredients to address safety concerns.

It is also important to note that under the FD&C Act, any cosmetic that contains an active ingredient - - such as sunscreens, anti-caries toothpaste, mouthwash, antiperspirants and anti-dandruff shampoo - - is also categorized as a drug and as such is regulated under the stricter FDA drug safety regime. It is also significant that color additives used in cosmetics are carved out under the FD&C Act for a strict system of FDA pre-market approval.

Cosmetics products imported into the U.S. are subject to the same substantive standards as those produced in the U.S., and face an even higher regulatory threshold upon entry into the U.S., in that an "appearance" of adulteration or misbranding may subject them to detention at the border. They must be safe and contain no prohibited ingredients, and all labeling and packaging must be in compliance with U.S. regulations. All colors must be listed and pre-approved by FDA, and a number of color additives must be batch certified by FDA. If the product has an intended use that causes it to be considered an over-the-counter (OTC) drug, it must comply with the regulations for drugs, including establishment registration and drug listing.

The issue of product safety in a global marketplace is not only a matter of law for our members, but it is the primary commitment for each of them and for our trade association. That's why our companies invest substantial resources every year in

scientific research and safety processes to ensure product safety. They work diligently with thousands of expert chemists, toxicologists, and biologists to evaluate the safety of cosmetic products before they go to market.

In addition to their own individual efforts, for nearly forty years our companies have invested millions of dollars through our trade association in programs to enhance and supplement the safety commitments of each individual company by providing additional safety and technical resources and information through initiatives such as:

The FDA Company Registration Program (VCRP) through which FDA collects information on manufacturers, packers, and distributors of cosmetic products in commercial distribution in the U.S. **The Cosmetic Ingredient Review (CIR)** – an independent expert panel of scientists and physicians that evaluate safety data for the most commonly-used cosmetic ingredients. **The Cosmetic Ingredient Dictionary** that has been cited by the FDA as the primary source of ingredient names for the FDA regulation requiring cosmetic ingredient labeling. **Technical Guidelines** for the industry that provide information on microbiological testing, quality assurance, and safety testing.

A Consumer Commitment Code that requires our member companies to go beyond the requirements of the law by agreeing to open their scientific data and information to FDA scrutiny; to report to FDA serious and unexpected adverse consumer experiences with a cosmetic product; and to register their manufacturing establishments and thousands of formulas with the FDA Registration Program.

The Establishment of International Consumer Safety Standards through the International Organization for Standardization (ISO) program, and a **Global Harmonization of Regulations process called** ICCR, an official dialogue of international cosmetics regulatory authorities joined by the cosmetics industry trade associations.

At the direction of our Board, the Council also created an **Import Safety Committee** last year to benchmark our industry's best practices and policy objectives with respect to import safety with the goal of developing additional industry guidelines.

In addition to the numerous industry regulatory programs in place, the Personal Care Products Council also developed a **Consumer Information Website, CosmeticsInfo.org.** The site, launched in 2007, was created to provide consumers with easy access to in-depth, scientifically-based information about cosmetic and personal care products and ingredients.

The result of these manufacturer safety practices and voluntary initiatives under a framework of Federal law has been an outstanding safety record that has been commended by previous FDA Commissioners.. Cosmetics and personal care products are the safest category of products regulated by the FDA.

We recognize, just as the Committee has, that ours is now a global industry with products and ingredients manufactured and sourced across the world.

In this global era, we agree with the Committee that FDA needs basic information about the safety of products and where and how they are manufactured. That's why three years ago, when we wrote our Consumer Commitment Code, which took effect in January 2007, we required member companies signing on to the Code to both register cosmetic facilities and to report serious and unexpected adverse reactions to the FDA.

We are proud that in just the first sixteen months of it's implementation, eighty (80) percent of all U.S. annual sales are covered by our board member companies who have signed this Code and that all have registered their manufacturing facilities and products with the FDA.

We are proud that a majority of our members have signed the Consumer Commitment Code, and that those who have signed are required to report serious and unexpected adverse events.

We are proud that the industry has helped craft standards for Good Manufacturing Practices that are now being adopted by the countries that lead international standard setting.

We are proud too of our work to put key scientific safety information in the hands of consumers through our new consumer information site. But we want to do more.

We have a multi-year plan to enhance and expand the CIR processes, adding expertise, expanding capacity for ingredient safety reviews, and increasing transparency.

The Committee and the draft bill have challenged us to take the next step. Exactly how that is done is important. We have been working with the bipartisan staff to provide technical details on the draft's regulatory provisions, and we appreciate this opportunity.

Unfortunately, while the industry has consistently expanded its voluntary initiatives to enhance consumer safety, FDA resources allocated for cosmetics oversight have declined. We understand that FDA prioritizes its scarce budget resources and cosmetics are the lowest risk category, yet we believe the most effective way to enhance cosmetic safety is to provide additional federal resources for FDA. FDA as the "tough cop on the beat" is the best preventative measure for companies who might be tempted to not do the right thing and to help hold all companies accountable.

In 1974, FDA's cosmetics program had 87 full-time equivalents (FTEs) – that number was down to 18 last year. The budget for cosmetics at FDA in 1974 was $2.7 million, a real dollar equivalent of $14.5 million today. FDA's actual cosmetic budget for 2007 was only $3.5 million.

Because we support a strong and vigilant FDA, in 2007, we actively lobbied on Capitol Hill to secure additional funding for the Office of Cosmetics and Colors, and these efforts were a success. This past Fall, the House of Representatives led the way by voting to add $2 million to the FDA cosmetics budget, a number that was subsequently lowered to $1 million in conference, leading to a current budget of $4.5 million. This is still too little. In 2008, we will continue to lobby for an additional $1 million increase in funding.

Mr. Chairman, I want to close with a note on the registration and import fees. The Committee knows that our industry has never been subject to fees. This is a fundamentally new issue for us. Our member companies have been meeting and working around the clock to address this issue, but today, we neither oppose nor support the proposals in the draft bill. We need additional time to address this and other issues.

Chairman Pallone, Ranking Member Deal, and distinguished Members of the Committee, thank you again for the opportunity to work with the Committee staff on this legislation. Our industry has always put safety first. We have done that by always being willing to take the next step, and we look forward to working with you on this next step: to continue to ensure the safety of consumers in America.

Thank you.

APPENDIX A: Personal Care Products Council Consumer Safety Initiatives

- **FDA Company Registration Program (VCRP):** In 1974, when what was then CTFA recognized the FDA's need to have basic information about cosmetic manufacturing and products, this trade association petitioned the agency to establish regulations for the voluntary submission of establishment registration, product listing, and adverse event reporting. Under the Voluntary Cosmetic Registration Program (VCRP), FDA collects information on manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the U.S., including: company and parent company names, type of product, brand name of product, ingredient and chemical name, discontinuance of a product, and other key data. As noted by FDA, "[t]he VCRP helps FDA in its mission to protect consumers, while also helping cosmetic manufacturers and distributors make informed decisions." In this way, each company is telling FDA where they are located and what products they make.

  Based on information received through the Voluntary Cosmetic Registration Program, FDA can determine if a cosmetic ingredient being used is harmful and

should be removed from product use and then notify the manufacturers and distributors of affected products by using the VCRP database. The VCRP applies to all cosmetic products being sold to consumers in the United States.

Participation in this important program is a key component of the Personal Care Products Council Consumer Commitment Code. Every member of the Personal Care Products Council's Board of Directors has signed onto the Council's Consumer Commitment Code, instituted last year, which requires complete participation in the FDA registry program. Together, these companies' sales volume represents more than 80 percent of the U.S. market and 94 percent of Council member sales.

The Voluntary Cosmetic Registration Program also supports the independent safety evaluation of cosmetic ingredients. Information from the VCRP database assists the CIR in determining its priorities for ingredient safety review.

Two years ago, the Council was a vocal advocate for updating the program to an electronic filing system in order to achieve a more efficient registration process.

- **Cosmetic Ingredient Review (CIR):** In 1976, our trade association founded the CIR – the Cosmetic Ingredient Review program – to evaluate safety data for the most commonly-used cosmetic ingredients. CIR helps manufacturers meet their obligations to ensure that each ingredient used in a cosmetic and each finished

cosmetic product is safe before it is marketed. Members of the CIR expert panel are seven leading academic scientists and physicians who must meet the same conflict of interest requirements as special non-government advisory panels to FDA. They represent the disciplines of dermatology, pharmacology, chemistry, toxicology and oncology. The panel includes non-voting participation by an industry representative, an FDA liaison for the Office of Cosmetics and Colors, and a consumer representative from the Consumer Federation of America.

We are proud that both FDA and the Consumer Federation of America have been part of the CIR comment and discussion process from the beginning. For 30 years, this independent, non-profit panel has contributed to product safety by evaluating more than 1,300 ingredients and publishing their findings in peer-reviewed scientific literature. Final reports are also transmitted to the FDA Commissioner and the Panel conclusions are available on the CIR website for the public.

While the CIR is independent from any association with the industry, it is funded entirely by the cosmetic industry and does not place a resource burden on FDA. The industry is in the process of expanding the activities of this effort by possibly doubling its investment in CIR to increase the output of the expert panel.

As we move forward in 2008, the Council has outlined a multi-year action plan to enhance and expand on CIR because we believe firmly that the regulatory process

is fluid and ongoing and requires constant updating and improvements in order to be most effective. We plan to add additional experts to the Panel, increase greater capacity for staff, and expand the scope of ingredient evaluation.

- **Cosmetic Ingredient Dictionary:** The Council established in 1973, and today still maintains, an International Cosmetic Ingredient Dictionary (ICID) that makes ingredient labeling meaningful. The dictionary has been cited by the FDA as the primary source of ingredient names for the FDA regulation requiring cosmetic ingredient labeling, and has become the principal reference for ingredient names in efforts to harmonize labeling requirements between the EU, US, Canada, Australia and other countries.

The dictionary, published by the Council through an international committee of experts, provides a comprehensive listing of ingredients that might be used in cosmetic and personal care products and the names by which they must be declared on product labels. The dictionary is an important resource prepared for the benefit of consumers, the FDA, and manufacturers. The combined dictionary and handbook contains more than 14,000 International Nomenclature Cosmetic Ingredient (INCI) labeling names for the United States, the European Union, and other countries. These are cross-referenced to nearly 60,000 trade and technical names and 3,000 suppliers from 91 countries.

The ICID is an industry-sponsored effort to establish an orderly process for the designation of ingredients and has become the primary source used for selecting

acceptable ingredient names for label declaration. The need for uniformity in cosmetic ingredient nomenclature has been recognized in countries around the world. There are numerous benefits to a global system of labeling names for cosmetic ingredients, including the consistency and transparency provided to consumers as ingredients are identified by a single labeling name regardless of the national origin of the product. Scientists and dermatologists are also ensured that information will be referenced by a uniform name, eliminating the possibility of confusion or misidentification from the use of multiple names for the same material.

- **Technical Guidelines:** Our trade association in 1969 established Technical Guidelines for the industry to help assure safe, high-quality products. These guidelines provide information on microbiological testing, quality assurance and safety testing. The publication of Technical Guidelines to assist domestic and foreign manufacturers in the development and marketing of safe products has been an important association activity for more than 35 years.

- **Consumer Commitment Code (Established January 2007):** The Council's Board of Directors resolved two years ago to establish the Consumer Commitment Code as a key industry program supporting product safety. Put into effect January of 2007, the Code requires our member companies who have signed the Code to formalize and strengthen the product safety practices that are followed for most personal care product companies. Under the Code, companies must go beyond the requirements of the law by agreeing to open their scientific

data and information to FDA scrutiny; to report to FDA serious and unexpected adverse consumer experiences with a cosmetic product; and make a positive commitment to register their manufacturing establishments and thousands of formulas with the FDA voluntary registration program.

All members of the Council's Board of Directors have signed the Code on behalf of their companies. Together, their companies' sales volume represents more than 80 percent of the U.S. market and 93 percent of Council member sales.

- **Establishment of International Standards:** Our companies have been in the forefront of efforts to develop international safety standards through the International Organization for Standardization (ISO) program. In this capacity, the Personal Care Products Council has taken the lead in representing U.S. industry. ISO has developed or is working on standards for microbiology test methods, product labeling, analytical test methods for contaminants, Good Manufacturing Practices, and sunscreen test methods. These guidelines offer organizational and practical advice on the management of the human, technical, and administrative factors affecting product quality of cosmetics with a global view.

- **Global Harmonization of Regulations & ICCR (Initiated 2007):** In response to the globalization of our marketplace and divergent safety standards worldwide, in 2007, the Council proposed that global regulators launch and FDA participate

in the International Cooperation on Cosmetics Regulation (ICCR), which held its first meeting in Brussels this past September. ICCR is an official dialogue of cosmetics regulatory authorities from Canada, European Union, Japan and the U.S. joined by the cosmetics industry trade associations Colipa (Europe), CCTFA (Canada), JCIA (Japan) and the CTFA (United States).

The ICCR is actively working to create consistent global safety and regulatory standards especially in the areas of ingredient labeling, nanotechnology and alternatives to animal testing. Taking advantage of work already accomplished by industry and global regulatory authorities to establish a global Good Manufacturing Practices (GMP) standard under ISO, one of the first ICCR work items was to agree that all participating regulating authorities would adopt the ISO GMP standards for cosmetics. This would mean that companies operating in ICCR markets will have a consistent reference on GMPs. The Council has urged FDA to issue guidance on cosmetics GMPs in the U.S., that refer to these ISO standards, consistent with their ICCR agreement.

- **Import Safety Committee:** Established in 2007, at the direction of the Board, to benchmark our industry's best practices and policy objectives with respect to import safety. This Committee is made up of senior industry representatives with responsibility for global quality assurance, supply chain management, purchasing and other disciplines. We are aggressively reviewing current industry procedures

around assuring the safety of the total supply chain and identifying best practices with the express goal of developing additional industry guidelines and practice.

We intend for these guidelines to serve as the basis for new programs to educate and to assist smaller and medium sized companies. As we move forward, these efforts will also give us the tools to determine the need for any additional measures, such as third party certifications, international cooperation or other steps that will allow us to further enhance our import safety practices.

- **In-Depth Scientific Consumer Information Website (Launched December 2007):** In the fall of 2007, the Council completed an intensive two year effort and launched our consumer information website, CosmeticsInfo.org, which we created to provide consumers with easy access to in-depth, scientifically-based information about personal care products. Linked to government sites, CosmeticsInfo.Org provides information on 13 personal care product categories and more than 1,500 ingredients, representing the majority of ingredients most commonly used in personal care products today.

The information provided on the site also shows consumers how to read cosmetic labels, how cosmetics are regulated, and the complex, multi-step process companies use to assess the safety of cosmetic ingredients and finished products. The site will be continually updated and expanded to provide consumers with latest information available on personal care products and ingredients.

Mr. PALLONE. Thank you very much. Ms. Houlihan?

STATEMENT OF JANE HOULIHAN, VICE PRESIDENT FOR RESEARCH, ENVIRONMENTAL WORKING GROUP

Ms. HOULIHAN. Chairman Pallone and Ranking Member Deal, thank you for the opportunity to testify. My name is Jane Houlihan. I am Vice-President for Research at the Environmental Working Group. We are a non-profit research and advocacy organization based in Washington, D.C. We appreciate the interest of the Committee in addressing the regulation of cosmetics for the first time in a long time.

Cosmetics, or personal care products, are essentially unregulated under the Federal Food, Drug, and Cosmetics Act. FDA can't require companies to test products and can't review or approve products or ingredients before they are sold. FDA can't require product recalls. They must go to court to remove misbranded and adulterated products from the market. FDA can't require manufacturers to register cosmetic establishments, file data on ingredients, or report cosmetic-related injuries. Instead, they rely on voluntary reporting for this data. And in the absence of government authority, the safety of personal care product ingredients is evaluated through a voluntary industry program, the Cosmetic Ingredient Review.

This absence of accountability to a responsible government agency has created a culture of ignorance. Far too little is known about ingredient safety, and the FDA and industry maintain that everything is safe, even without full knowledge.

In the committee discussion draft, you are taking vital steps that we support to close some of these gaps requiring that companies register and report their facilities, products, ingredients, and cosmetic-related injuries to the FDA and follow good manufacturing practices.

We look forward to working with you on additional efforts as well. I want to tell you about seven major gaps in cosmetics safety that show why it is important to act.

First of all, the vast majority of ingredients have not been assessed for safety by any publicly accountable body. Through three decades, the CIR has reviewed only 11 percent of ingredients in products, and at this pace, it will require another two-and-a-half centuries to complete reviews for all ingredients.

Second, companies are free to use almost any ingredient they choose in personal care products. FDA has prohibited or restricted only nine ingredients in personal care products. In contrast, 244 ingredients are restricted and prohibited in Japan, more than 600 in Canada, more than 1,100 in the E.U.

The third major gap in cosmetic safety, these ingredients can penetrate the skin, they can pose health risks, particularly for children. Americans use an average of nine products every day with 126 unique ingredients. Cosmetic ingredients are found in blood, urine, breast milk, even in breast tumor tissue. These ingredients are linked to birth defects, allergies, thyroid problems and more. And children are particularly at risk. Their skin is thinner than an adult's, their exposures are higher, their bodies are more vulnerable.

The fourth gap in cosmetic safety, despite these potential health risks, the FDA doesn't even know how many ingredients are used in cosmetics. They have records of 4,100 product ingredients. We found an additional 5,000 ingredients not on record at FDA at all in our survey of products on the market.

The fifth major gap in cosmetic safety, FDA doesn't know where and how many companies make and distribute personal care products. Facility inspections are FDA's primary enforcement tool for overseeing this industry according to GAO, and yet, FDA doesn't even know where all these facilities are and they can't mandate registration.

The sixth major gap in cosmetic safety is that FDA doesn't know the extent of health impacts from harmful ingredients in cosmetics. Companies aren't required to report adverse events, and companies that have experienced major problems may be least likely to report them voluntarily.

The seventh gap in cosmetic safety, consumers' right to know, is hampered by lack of standards and labeling loopholes. Not all ingredients appear on labels, like ingredients in fragrance; and companies can use terms like natural and hypoallergenic to mean anything or nothing at all. More than a third of all children's products marked as natural in fact contain artificial preservatives linked to allergic reactions and nervous system problems.

We support the Committee's discussion draft with mandatory reporting and manufacturing standards, but we also support safety standards for cosmetics and enforcement authority for FDA. These should be brought up to par with FDA's authority over pesticides and food and color additives which meet a safety standard under the Act. Cosmetic ingredients are found in cord blood, they pollute the bodies of almost everyone in the population, and they should be as safe as pesticides, food, and color additives. FDA needs the mandate to ensure that ingredients are safe and the authority to demand the study it needs to make this finding.

Thank you very much.

[The prepared statement of Ms. Houlihan follows:]

STATEMENT OF JANE HOULIHAN

Vice President for Research
Environmental Working Group

Hearing on

"Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Device and Cosmetic Safety"

Before the

Subcommittee on Health of the
Committee on Energy and Commerce
United States House of Representatives

Wednesday, May 14, 2008, at 10 a.m.

Submitted for the Record

Mr. Chairman, Ranking Member, distinguished Members of the Committee, thank you for this opportunity to testify on the "Discussion Draft of the 'Food and Drug Administration Globalization Act' Legislation: Device and Cosmetic Safety." My name is Jane Houlihan, and I am the Vice President for Research at the Environmental Working Group (EWG), a nonprofit research and advocacy organization based in Washington, DC and Oakland, California. We appreciate the Committee's interest in, and commitment to, seriously addressing the regulation of cosmetics for the first time in decades. Unfortunately, the cosmetics industry has enjoyed a largely unwatched and unregulated status that raises serious concerns for public health.

Cosmetics, or personal care products, are essentially unregulated under the Federal Food, Drug, and Cosmetics Act (FFDCA). The Act includes 112 pages of standards for food and drugs, but just a single page for cosmetics (Tolchin 1990). This page provides the Food and Drug Administration (FDA) with virtually no power to perform even the most rudimentary functions needed to ensure the

safety of an estimated $35 billion of personal care products purchased by consumers annually.

Under federal law and regulation, FDA (FDA 1995, 2005):

- Cannot require companies to test cosmetic products for safety before marketing.
- Does not review or approve cosmetic products and cosmetic ingredients before they are sold to the public.
- Cannot regulate cosmetic products until after they are released to the marketplace, and even then the process is extremely cumbersome.
- Cannot require product recalls. The agency must to go to court to remove misbranded and adulterated products from the market
- Cannot require manufacturers to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries. Instead, FDA relies on voluntary reporting of ingredients, injuries and establishments.

In the absence of government authority, the safety of personal care product ingredients is evaluated through a voluntary industry program known as the Cosmetic Industry Review (CIR) process. In the words of John Bailey, former head of the FDA's Office of Cosmetics and Color and now head of the personal care products lobby group's science division, "In the absence of the CIR program, there would be no systematic examination of the safety of individual cosmetic ingredients" (FDA 1992).

This complete absence of accountability to a responsible government agency has not served the American public well. Instead, it has created a culture of ignorance around personal care products, where far too little is known about ingredient safety, while the industry and the FDA steadfastly maintain that all products and their ingredients are safe.

In the Committee Discussion Draft, you are taking vital steps to close these gaps by requiring cosmetic facilities to comply with some of the same requirements as other facilities: registration with the US Food and Drug Administration (FDA), requiring cosmetic manufacturers to report all anticipated and unanticipated serious adverse effects to FDA, and requiring good manufacturing practices. These actions are needed to close serious gaps in information on personal care products.

My testimony will focus largely on what we do and do not know about cosmetics. Unfortunately, what we do not know is much greater than what we do know. But, we do know enough to urge this committee to act expeditiously on the Discussion Draft. In addition, we look forward to working with the Committee as we move forward on additional efforts to ensure that cosmetics are safe for consumers.

The vast majority of ingredients have not been assessed for safety by the CIR, the FDA, or any other publicly accountable body.

The regulation of cosmetics is woefully outdated. The basic law regulating cosmetics has not been significantly updated for many

decades. For the last 32 years, voluntary programs like the CIR, which companies are free to follow or ignore, have been used to deflect calls for reform and fend off the much-needed expansion of FDA authority to include review of ingredient safety. Through 3 decades the CIR has reviewed only about 11% of the ingredients in products, or 1,400 out of what FDA estimates is a total of 12,500 ingredients in personal care products (FDA 2007). At this pace, it will require another two and a half centuries to review the safety of all the ingredients in use by the cosmetics industry, assuming nothing new is introduced.

Companies are free to use almost any ingredient they choose in personal care products, with no proof of safety required.

FDA has prohibited or restricted by regulation only 9 ingredients in personal care products (FDA 2000a). The CIR has recommended restrictions on some uses of some additional ingredients, mostly to minimize skin irritation and allergic reactions, but has found only 9 ingredients unsafe for use in personal care products (a different 9 from FDA) (CIR 2006).

Companies are free to use any other ingredient they choose in cosmetics. Environmental Working Group's 2007 survey of products sold in the U.S. found nearly 400 products on the market that contain chemicals prohibited for use in cosmetics in other countries, and over 400 products containing ingredients that industry assessments have found unsafe when used as directed on product labels according to reviews by the CIR and the International Fragrance Association (EWG 2007a).

EWG's assessments of product ingredients reveal:

- A wide range of nano-materials may be common in personal care products (EWG 2007b). The safety of these ingredients is in question and is currently under study by multiple government public health agencies (NNI 2008).
- Phthalate plasticizers linked to birth defects of the male reproductive system and other health problems remain in common use in nail care products (EWG 2008a, EWG 2000, Houlihan et al. 2002).
- Companies still use hydroquinone in skin lighteners, despite FDA's proposed restrictions and warnings that the ingredient can lead to permanent skin disfigurement and may be linked to cancer and reproductive problems (FR 2006).
- Products contain a wide variety of ingredients derived from animal organs and tissues, including placenta expelled from cows (EWG 2008c), ingredients that raise concerns for the transmission of bovine spongiform encephalopathy (FDA 2007), ingredients restricted in other countries (Health Canada 2007), and "ethically sourced" human placenta (Earthscience 2008).
- Studies show lead contamination in lipstick (CSC 2008) and cancer-causing impurities in children's products and products labeled as "natural" (OCA 2008, EWG 2007c, Steinman 2007).

Since 2000, EWG has analyzed the safety of personal care product ingredients and the laws and regulations that govern them. We publish the results of this work as a part of our Skin Deep

website, a searchable consumer tool that evaluates the safety of ingredients in 29,000 personal care products (EWG 2008b). An EWG analysis of product ingredients against definitive government, industry, and academic databases of hazardous chemicals finds that more than 1 in 5 of all products contain chemicals linked to cancer, 80% contain ingredients that commonly contain hazardous impurities, and 56% contain penetration enhancers that help deliver ingredients deeper into the skin.

Cosmetic ingredients penetrate the skin and may pose health risks, particularly for children.

Personal care products may be the primary exposure route for many chemicals that raise significant health concerns. Consumers can be exposed through skin absorption, inhalation, and ingestion. A personal care product use survey of more than 2,300 people, conducted by EWG and a coalition of public interest and environmental health organizations, shows that the average adult uses 9 personal care products each day, with 126 unique chemical ingredients. More than a quarter of all women and 1 of every 100 men use at least 15 products daily. The average woman uses 12 products containing 168 unique ingredients every day. Men, on the other hand, use 6 products daily with 85 unique ingredients, on average (EWG 2004).

Children are at particular risk from exposures to personal care product ingredients. Their skin is significantly thinner than an adult's, their ability to detoxify and excrete chemicals can be limited, and at birth the blood-brain barrier that can block chemicals' access to brain tissue is not complete (NRC 1993, EWG

2007d). In short, their developing bodies are more vulnerable to damage from hazardous chemicals.

Yet children's products are not assessed for their risks to children. In July and August of 2007, EWG surveyed more than 3,300 parents to find out what shampoos, lotions, bath soaps and other personal care products their children use. Based on the specific products named by these parents, we found that children are exposed to an average of 61 different chemical ingredients every day, and that on average 27 of these ingredients have not been found safe for children by the government or the cosmetic industry's expert safety panel (EWG 2007d, *see* attached Executive Summary).

Over the past decade, a steady stream of peer-reviewed scientific studies and reports from the Centers for Disease Control and Prevention (CDC) has documented the presence of chemicals from personal care products in the blood and tissues of most Americans, including young children. Many of these chemicals present serious health risks, and most have not been evaluated by the CIR or any authoritative body.

Scientists have found many common cosmetic ingredients in human tissues, including industrial plasticizers called phthalates in urine (CDC 2005), preservatives called parabens in breast tumor tissue and urine (Darbre et al. 2004, Ye et al. 2006), and persistent fragrance components like musk xylene in human fat, blood, and breast milk (Müller et al. 1996, Eisenhardt et al. 2001, Reiner et al. 2007).

Scientists at the Centers for Disease Control and Prevention (CDC) detected phthalates in urine samples from all but 12 of 2,790 people tested (CDC 2005), with six or more phthalates found in 84% of people tested. A recent study establishes a link between the use of shampoos and lotions on infants and the presence of a group of chemicals called phthalates in infants' bodies (as measured in urine). All babies in the study had at least one phthalate in them; 80% had seven or more (Sathyanarayana et al. 2008).

Over the past four years scientists have published at least 10 epidemiology studies linking phthalates to birth defects in baby boys, reproductive problems in men, abdominal obesity, increased diabetes risk, thyroid problems, as well as asthma and dermal diseases in children (Stahlhut et al. 2007, Meeker et al. 2007, Huang et al. 2007, Duty et al. 2003a, 2003b, 2004, and 2005, Hauser et al. 2007, Hauser et al. 2006, Wormuth et al. 2006, Marsee et al. 2006, Swan et al. 2005, Bornehag et al. 2004, Lottrup et al. 2006). This evidence joins many dozens of laboratory studies proving phthalates to be potent reproductive toxicants that target the male reproductive system, posing the greatest risks during development (Matsumoto et al. 2008, Gray et al. 2006, Frederiksen et al. 2007).

Some phthalates are banned from personal care product use in the EU; none are restricted in the U.S.

A 2008 study by the CDC found that 97% of Americans are

contaminated with a widely used sunscreen ingredient called oxybenzone that has been linked to allergies, hormone disruption, and cell damage (Calafat et al. 2008b). A companion study published just one day earlier revealed that this chemical is linked to low birth weight in baby girls whose mothers are exposed during pregnancy (Wolff et al. 2008). Oxybenzone is also a penetration enhancer, a chemical that helps other chemicals penetrate the skin.

Triclosan, a common ingredient in anti-microbial soaps, was found in the urine of 61% of 90 girls age 6 to 8 by researchers from Mt. Sinai School of Medicine (Wolff et al. 2007). CDC found triclosan in 75% of the U.S. population in a recent study (Calafat et al. 2008a). Triclosan tends to bioaccumulate (Samsøe-Petersen 2003), or become more concentrated in the fatty tissues of humans and other animals. As a result, this chemical has been detected in human breast milk, and in blood samples as well (Adolfsson-Erici 2002; TNO 2005; Allmyr 2008. 2006a,b; Dayan 2007). Higher levels of triclosan in blood and breast milk are linked to use of body care products containing triclosan (Allmyr 2006a).

The overwhelming weight of the evidence indicates that chemicals in personal care products may be a serious health threat to the American public, and the FDA does not have the statutory authority or the resources to step in and protect the public.

Despite the potential risks, FDA does not even know how many ingredients are used in cosmetics.

The FDA does not have a basic understanding of the size and scope of the potential health risks from cosmetic ingredients, in no small part because the agency does not know how many ingredients are in cosmetics. And the cosmetic industry does not seem to know, either.

In 2000, FDA stated that, "It has been estimated that consumer expenditures for cosmetics exceed 35 billion dollars annually. It is further estimated that the marketed cosmetics are being produced in more than 1400 domestic manufacturing and repacking establishments and represent more than 25,000 product formulations. About 10,500 different cosmetic ingredients and a similar number of fragrance ingredients are being used by the cosmetic industry" (FDA 2000b). In 2007 FDA altered their estimate of ingredients to 12,500 (FDA 2007).

Cosmetics industry officials, on the other hand, have variously estimated that the total number of ingredients used is "probably around 2,000" (Solomon 2004) or "really less than 4,000" (Bender 2005).

FDA sources show that the agency has records of 4,066 ingredients, as published in their ingredient dictionary and in the product database FDA has compiled through its Voluntary Cosmetic Registration Program (FDA 2008a, FDA 2008b). EWG has compiled ingredient listings for 29,037 products in our online product database (EWG 2008b), and as of May 12 2008 we find a total of 8,821 unique ingredients in our product database and FDA sources altogether, including 4,755 ingredients for which FDA has

no record.

Clearly, the industry's voluntary program for providing FDA with product ingredient listings is leaving FDA with grossly incomplete data on the full scope of ingredients used in products.

FDA does not know where and how many companies make and distribute personal care products.

FDA cannot require companies to register their cosmetics establishments with the agency, although they encourage companies to do so voluntarily. The absence of mandatory registration is a significant limiting factor in FDA's ability to ensure that cosmetics are not harming public health.

Without the ability to require pre-market safety testing, FDA must rely on facility inspections to assess product safety. A 1990 General Accounting Office study found that facility inspections are FDA's "primary enforcement tool for overseeing the cosmetics industry" (GAO 1990). Yet without mandatory registration, FDA does not know where and how many companies make and distribute personal care products. It is impossible for FDA to inspect facilities if their existence is not on record. And as the GAO noted, "Because FDA cannot mandate participation, it cannot accurately assess how many companies may be avoiding registration" (GAO 1990). FDA has estimated that marketed cosmetics are being produced in more than 1,400 domestic manufacturing and repacking establishments (FDA 2007), but their registration system for these establishments is purely voluntary.

FDA does not know the extent of health impacts from harmful ingredients in cosmetics.

Twenty years ago the cosmetic industry staved off the threat of federal regulation with renewed pledges to increase the number of companies reporting adverse health effects from their products to FDA's voluntary reporting system. At the time, FDA reported that only 3% of distributors were filing injury reports. Though the industry claimed this was sufficient, since large companies with large market shares were participating, FDA noted that without injury data for each specific product on the market, they would be unable to identify all those that present safety problems (GAO 1990).

GAO found that voluntary injury reporting will fail: "FDA will never be able to require reporting from all companies, particularly those that may be least likely to report because they have experienced problems with their cosmetics" (GAO 1990).

In 2007 the cosmetic trade association launched a renewed effort to boost company participation in voluntary reporting, a program called the Consumer Commitment Code, again staving off renewed interest in stronger federal regulations. By signing the Code, a company agrees, among other things, to calculate "the incidence of adverse health effects in the United States (e.g., number per 100,000 or million units distributed) that have been medically confirmed as caused by the product in question" and to provide this information to FDA for inspection at a "mutually agreed location" when an FDA District Director submits a written

request to the company's CEO or other designated official that is based on an explicit, legitimate, and specific safety concern with regard to the product (PPCP 2008).

This agreement might help mitigate the long-standing problem of companies refusing to disclose health information to FDA on their products (GAO 1990). But while better reporting of adverse events is a necessary first step to ensuring product safety, it alone will not give FDA the data it needs to understand the full range of health impacts from harmful cosmetic ingredients, even if the entire cosmetic industry participates and if FDA spends enormous resources sending staff to "mutually agreed locations" to inspect ingredient safety reports.

Consumers and their doctors might recognize skin irritation or allergic reactions as linked to particular products. But those cases will be the exceptions. Chronic health effects from chemicals in personal care products, like cancer, reproductive or nervous system effects are driven by genetic susceptibility, the timing of exposures, and aggregate exposures over a lifetime, and can almost never be traced back to individual consumer products. Exposures in the womb or early childhood, for instance, can lead to health problems much later in life (Lau et al. 2004). An injury reporting system that focuses only on acute, immediately observable adverse reactions will never help FDA understand other kinds of health risks. Only mandatory reporting systems, pre-market safety testing, and stronger safety standards for cosmetics will provide the information needed to ensure that personal care products are truly safe.

Consumers' right-to-know is hampered by lack of standards and labeling loopholes.

With no required safety testing for products, consumers must rely on labels for clues about a product's safety. Unfortunately, though, not all ingredients appear on labels, and not all claims printed on products must be backed by proof.

There is almost no regulation of marketing terms and other product claims. When FDA tried to establish definitions for the use of terms such as "natural" and "hypoallergenic," its regulations were overturned in court. Companies can use these and many other claims on cosmetic labels "to mean anything or nothing at all" (FDA 1998).

EWG's analysis (EWG 2007c) shows that 35% of all children's products marked as "natural" on the label are not completely natural, but instead contain one or more artificial preservatives linked to allergic reactions, hormone disruption, or nervous system problems in laboratory studies. Four out of five children's products marked as gentle and non-irritating (gentle, soothing, non-irritating, dermatologist approved, or free of harsh ingredients) instead contain ingredients linked to allergies and skin or eye irritation according to government and industry sources.

When the cosmetic trade association's chief scientist was head of FDA's color and cosmetic office, he noted: "Most cosmetics contain ingredients that are promoted with exaggerated claims of

beauty or long-lasting effects to create an image… Image is what the cosmetic industry sells through its products, and it's up to the consumer to believe it or not" (FDA 1992).

Likewise, consumers' ability to make wise purchasing decisions is hampered by significant ingredient labeling loopholes. Federal law requires that all ingredients in a product appear in order of prevalence, but does not require that the ingredients in the "fragrance" added to a product appear on the label. Fragrances are usually complex mixtures of many chemicals. EWG's research shows that 44% of all products list the word "fragrance" on the ingredient label but fail to list what's in it (EWG 2008d). FDA has estimated that there are 12,500 ingredients in cosmetics, and an additional 12,500 chemicals used as fragrances (FDA 2007), none of which are required to be listed on product labels.

Additionally, nanomaterials do not have to appear as such on product labels. Many ingredients are now produced in both conventional and nano-scale forms that may pose greater potential for exposure and health risks. Because there are no labeling requirements for nanomaterials, consumers have no way to know the difference.

Recommendations

The cosmetics industry has renewed efforts to boost participation in voluntary programs through its new Consumer Commitment Code. But the industry's 70-year track record in self-regulation shows that this effort will fail to provide FDA with the information and authority it needs to protect public health. To fill the

gaps, states are taking actions to restrict some of the most hazardous chemicals from products, independent certifications programs are increasing in number in attempts to provide meaningful standards for consumers, and groups and coalitions like the national Campaign for Safe Cosmetics are educating consumers on cosmetic safety and working directly with manufacturers to encourage the production of safer products. Until FDA can take enforceable actions when problems arise, the agency will remain unable to protect public health. EWG looks forward to working with the committee to address the following issues to ensure that personal care products are safe, particularly for those most vulnerable to the harmful effects of hazardous chemicals:

- Mandatory registration of facilities. FDA needs to know who is making personal care products, and what products they are making, as a basic first step to protecting the public health.
- Mandatory, public injury reports (adverse event reporting). FDA needs to know exactly which products may be endangering public health so that they can take the appropriate actions.
- Registration of products and ingredients must be mandatory. FDA must know what is in products if it is to protect the public from ingredients that may pose health risks.
- Meaningful and proven labeling. Product claims and marketing terms must be backed up by tests and must meet explicit definitions set by FDA.
- Safety standards for cosmetics and FDA enforcement

authority. FDA's safety standard for cosmetics and its authority over cosmetic safety must be brought up to par with the agency's authority over pesticides and food and color additives under the Federal Food, Drug, & Cosmetic Act (FFDCA). FDA must have the mandate to ensure that ingredients are safe and the authority to demand the studies that it needs to make this finding. Cosmetic ingredients have been found in cord blood and they pollute the bodies of nearly everyone in the population; they should be as safe as pesticides, and food and color additives that meet safety standards under FFDCA.

Thank you.

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Mr. PALLONE. Thank you, Ms. Houlihan. OK. We will have some questions from the members, and I will start out with myself.

I wanted to first ask some questions relative to cosmetics, and I will start with Ms. Bailey. You mentioned the Cosmetic Industry Review, CIR. Actually, several of you mentioned it, but you mentioned it in your testimony. Can you elaborate a bit on this CIR? For example, how is the panel determined? How are the conflict-of-interest considerations made? How are decisions disseminated?

Ms. BAILEY. Sure. Thank you, Mr. Chairman. The panel was set up in 1976, and at that time it was designed to mirror the same standards supplied for OTC drug reviews at FDA. In fact, my understanding is it was set up by the industry because the FDA did not then have the resources to do it itself. The conflict of interest standards are indeed as strict if not stricter. Nobody on the expert panel can have any tie whatsoever to the industry. The panelists are all chosen by existing panelists. The Chair, Dr. Wilma Bergfeld, is considered first lady, if you will, of dermatology and chairs the Department of Dermatology at the Cleveland Clinic.

Mr. PALLONE. OK. I am still with you, Ms. Bailey. Now, Ms. Houlihan mentioned the CIR as well and also noted that they have identified 9 unsafe ingredients that are actually different from the 9 or 10 unsafe ingredients that the FDA has identified. What has been the response from the cosmetic industry in reaction to those restriction recommendations, both from the CIR as well as the FDA, and are those ingredients found in products on the market today?

Ms. BAILEY. I am sorry, are those ingredients found—

Mr. PALLONE. Found on the market today in products that are on the market today?

Ms. BAILEY. An ingredient that is unsafe, Mr. Chairman, should not be in any cosmetic product because the company cannot substantiate the safety of it. So the ingredients FDA has found to be unsafe should not be in any product, nor should the ones CIR has deemed unsafe.

Mr. PALLONE. OK. Did Ms. Gadhia or Ms. Houlihan, do you want to add anything to what Ms. Bailey said or comment further? Go ahead.

Ms. HOULIHAN. I would say that one shortcoming of the CIR process is that it is dominated by dermatologists who are primarily interested in allergic reactions and irritations with ingredients, and that means that a huge wealth of health impacts doesn't get proper consideration by that panel. And it is one reason, in addition to many others, that we feel like the authority for assessing ingredient safety needs to be mandatory, needs to belong with FDA so we have a consistent, national standard, an FDA authority over cosmetic safety.

Mr. PALLONE. Did you want to add anything, Ms. Gadhia?

Ms. GADHIA. I would concur with what Ms. Houlihan said. The only thing I would add is that there is only one dedicated consumer representative on CIR representing that standpoint.

Mr. PALLONE. All right. Let me ask Ms. Houlihan, do you think the provisions included in our discussion draft will assist the FDA in regulating the cosmetic industry which is growing rapidly?

Ms. HOULIHAN. I do and we support the provisions in the discussion draft that would make mandatory the registration of facilities, ingredients, products, and adverse effects. I think it is a great first step to get FDA that very basic data that it needs to determine the range of unsafe products that might be on the market and take action.

Mr. PALLONE. With regard to ingredients, how many ingredients do you estimate are currently being used in cosmetic products, currently being used by American consumers? In other words, of those ingredients, how many would you say have been tested by FDA or other independent bodies for their safety?

Ms. HOULIHAN. There is no mandatory reporting of ingredients to FDA, so it is not known the full range of ingredients that are on the market. FDA has estimated 12,500, but cosmetic industry officials have estimated it is only between 2,000 and 4,000. When we surveyed products on the market, we found 8,800 unique ingredients. It is an open question, and it is one reason that mandatory ingredient reporting needs to happen so that FDA has an understanding of what is on the market. We do know that of the estimated 12,500 ingredients that FDA thinks are on the market, the industry has reviewed only about 1,400 or 11 percent.

Mr. PALLONE. OK. I wanted to get one more thing in but—that is all right. Go ahead, and then I will ask the other.

Ms. BAILEY. Thank you, Mr. Chairman. The number 12,500 indeed refers to the number that the discreet ingredient names that are listed in the cosmetic dictionary that we in fact publish. Not all of those ingredients are used in cosmetic products. By our count, 5,500 ingredients are commonly used in U.S. products. Of them, some 3,000 are ingredients such as botanicals. They would not reach the threshold of risk for the full peer-reviewed study. That leaves 2,500. By the end of this year, 2008, CIR will have reviewed 2,000. They are chosen by level of risk and complexity and by use on the common use. So that would leave some 500 that would be of lower risk, and CIR as I understand it is now reviewing how the best way would be to review those ingredients. But they are now reviewing them at the rate of 200 a year. If I could add, the issue of how many ingredients and what is commonly in use is also a reflection of the database problem that FDA has because until 2005, all of these files were made by paper and they have yet been able to complete the transfer of the paper filings into their new electronic system.

Mr. PALLONE. I had a medical device question, but let us hear from the other two members, and then we will see if we have time. Mr. Deal?

Mr. DEAL. I will try to go quickly. You all do the same. Going down the list of all of you there, do any of you disagree with the proposition that FDA needs greater resources in order to carry out the responsibilities they currently have and would particularly need more resources if they were given the responsibilities under this proposed legislation? Anybody disagree with the concept that they need more money? Apparently not. Let me go down the list, though. What should be the source of that revenue? Should it be further appropriations by Congress or should it be user fees or some combination thereof? Mr. Ubl, I will start with you.

Mr. UBL. We believe inspections are a core function of the Agency and as a result should be funded by appropriated dollars. In addition, I think FDA's risk-based approach, together with greater reliance or leveraging of the ISO standard that has been discussed is our preferred approach for addressing the legitimate gap that has been raised as a result.

Mr. DEAL. So primarily appropriations then?

Mr. UBL. Yes.

Mr. DEAL. Mr. Cullimore?

Mr. CULLIMORE. We agree, appropriations are the way to do it. We feel that user fees have the risk of undermining a very essential element in regulatory prioritization and that is fiscal restraint. When there is no fiscal restraint, the regulatory prioritization is much more difficult to do.

Mr. DEAL. Ms. Gadhia?

Ms. GADHIA. Some combination of appropriations and user fees with the conflict of interest protections would be best in our judgment.

Ms. GEORGE. I think one of the first ways better would be to leverage all of the ISO certificate reports that we are already paying for as an industry and get annually, and that would be a significant amount of information and data to the FDA to help them make that risk determination and determine whether they need to do further inspections of us.

Ms. BAILEY. As I pointed out, we have a long way to go on the federal side of funding of cosmetics. The fee issue is one that is new to the industry, and we are under discussion about that right now. But it is a very difficult issue, and certainly the federal funding side needs to be significantly increased.

Mr. DEAL. Ms. Houlihan?

Ms. HOULIHAN. We would agree with Consumers Union on this point that a combination of appropriations and user fees would be appropriate with conflict of interest protections.

Mr. DEAL. Most of you have sort of I think agreed that appropriations needs to be one of the primary, if not the primary source. I'm going to get Mr. Pallone to agree to sign a letter with me I am sure to our appropriators asking that they consider that proposition.

Before I go further on questions, I do now have the European Union letter that I mentioned earlier. I would ask unanimous consent that it be admitted for the record.

Mr. PALLONE. Without objection so ordered.

[This information was unavailable at time of printing.]

Mr. DEAL. Let me go back to the proposition that several of you have alluded to and I asked questions about and that is ISO. First of all, understand there are 47 countries and China is not one of them as I understand, those 47 countries that already require each of you to comply with ISO standards, I assume that they, in many instances, if you are exporting, they send inspectors to your facilities here in the United States and charge fees associated with that. Is that true? Yes, yes, yes. All right. Now, it would seem to me that we do need harmonization of these efforts, and I think if you could all help us in later responses or written documentation as to how do we harmonize what FDA is trying to do with what ISO regula-

tions are already doing? That would be very helpful. That seems to me to be a great way of saving a lot of money on both sides of the ocean, so to speak, in terms of what it costs to get products to the consumer.

Now, Ms. George, your company has a lot of experience dealing with this, and you indicated that you participated in the ISO standard-making process, is that correct?

Ms. GEORGE. Yes, we do. We have members that are on the committees that actually help define those as well as our members are on the Global Harmonization Task Force along with the FDA as well as other country members.

Mr. DEAL. So FDA is also participating in that process already?

Ms. GEORGE. Yes, they are.

Mr. DEAL. I would just hope that all of us would work toward trying to achieve this purpose. I think it would safe a lot of money.

The last thing I want to make mention of is I understand that since we did electronic registration that there have been like 11,000 facilities that have electronically registered with FDA. Ms. Gadhia, am I pronouncing that correctly?

Ms. GADHIA. Yes.

Mr. DEAL. You indicated that you felt that everybody ought to be inspected at least once every 2 years. If there are 11,000 of those, and I don't think that even includes what this bill would contemplate on component manufacturers that would be added to that list, is that a realistic thing that we can achieve or is it just pie in the sky to think we can inspect them all within a 2-year period?

Ms. GADHIA. Something that is in my written testimony but for time purposes I could not fit in my oral testimony, we recognize that there are a lot of differing devices out there, a lot of things are classified as devices. We would support an approach that differentiates between say tongue depressors and how often those facilities are inspected versus, say, cardiac pacemakers. We recognize that there is a difference in—

Mr. DEAL. A risk level?

Ms. GADHIA. I don't know if I would go as far as saying a risk assessment basis, but we recognize the differences of different types of devices.

Mr. DEAL. OK. My time is up. Thank you.

Mr. PALLONE. The gentlewoman from Illinois.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. Ms. Bailey, you were talking about the large number of personal care products that are used. I was told you said something like billions? I mean, there are a lot. I use a lot of them myself. And you said that of that number, only 200 adverse events were reported. First of all, where would they be reported?

Ms. BAILEY. I am talking about to FDA, and this is a number that has remained fairly consistent over any number of years.

Ms. SCHAKOWSKY. OK. Do you really think that that is the extent of adverse effects? Do you think it is representative of a true number?

Ms. BAILEY. We do because in fact, adverse events are very rare with these products because they are inherently safe. And let me also point out that OTC cosmetics, for example, sunscreens, antiperspirants, anti-dandruff shampoos that have an active ingredient

are regulated. It is over the counter, drugs are, and those adverse reactions would be reported to the drug side of FDA on a mandatory basis.

Ms. SCHAKOWSKY. Well, none of the research—does anybody else want to comment on that, that the 200 represents in fact a reasonable assessment of adverse reactions? Ms. Houlihan?

Ms. HOULIHAN. Thank you, Representative. It is an absolute underestimate because adverse event reporting is not mandatory, and the GAO found that companies that experience the most serious effects from their products may be disinclined to report voluntarily, and until we have mandatory reporting, we won't see the full scope. I will just give you one example is that fragrance in personal care products is considered one of the top allergens in the world, and we are certainly not seeing all allergic reactions to fragranced personal care products reported to FDA's database.

Ms. SCHAKOWSKY. Yeah, I would really caution against using that number. I mean, even when there are adverse effects, so few people actually end up reporting at all. But are you aware, Ms. Bailey, of any studies that have been done on the lifetime effects of your company's products? Do we know how safe it is to use any one personal care product over the course of a person's life, every single day?

Ms. BAILEY. In fact, companies are obligated to substantiate the safety of individual ingredients and the safety of the product before it is marketed, and those assessments taken into account the knowledge that these products were used in combination with other products and may be used over the lifetime.

Ms. SCHAKOWSKY. OK. I have other questions that I wanted to ask. Ms. Houlihan, in your testimony you state the cosmetics industry review only 11 percent of the ingredients or 1,400 out of the 12,500. And you go on to say that at this pace, it will require two-and-a-half centuries to review all the products, assuming nothing new is introduced. So what can we do to reduce this timeframe of two-and-a-half centuries for reviewing the safety of these ingredients?

Ms. HOULIHAN. Well, clearly, one thing we need is a consistent safety standard and a law that would mandate pre-market safety testing of cosmetic ingredients and products before they go on the market, and that testing could be done by manufacturers. It should be public, it should be reviewed by FDA, and with so many ingredients on the market, one thing that can be considered is a prioritization system that would target first ingredients that might pose the highest risk, that would cross the placenta would be a risk to developing children that are known or suspected hazardous chemicals. But we certainly need to see the pace picked up to have an assurance that products on the market are safe.

Ms. SCHAKOWSKY. And I wonder if anybody wants to comment on this. The European Union has required cosmetics companies to remove reproductive toxins, mutagens and carcinogens from personal care products and now bans 1,100 chemicals from the personal care products due to serious adverse effects, cancer, birth defects, reproductive problems, and just 9 chemicals, not 900 or 90, but 9 chemicals are banned from cosmetics in the United States. How do we account for this difference and does that mean that personal care

product consumers are at risk in the United States? Why has the E.U. banned 1,100 and we only nine? How do we explain that?

Ms. BAILEY. Well, in fact, the list of chemicals that you are referring to includes many ingredients that aren't even used in cosmetics either in Europe or in the United States. The reality is in the United States and Europe, there is the same principle that a company must substantiate the safety of its product before it is put on the—

Ms. SCHAKOWSKY. How do we get the—OK. So what do we subtract?

Ms. BAILEY. Yes, and so if there is an ingredient that has been proven under a peer-reviewed science-based basis to cause cancer or be a toxin and cannot be substantiated for safety, it cannot be included in a finished product. And FDA has the authority to ban certain ingredients any time it wants to. It has a list. The CIR findings are peer reviewed, published in peer-reviewed journals, and there is a substantial body of science in the United States behind every ingredient that is included in a finished product.

Ms. SCHAKOWSKY. How do we get that big difference? Does anybody want to speak to that? It would seem like even if we don't use all those, that it is not explained sufficiently.

Ms. HOULIHAN. What has happened in the United States is that for the past three decades we have had a voluntary industry system for evaluating ingredient safety, and FDA has stepped back and let that be the de facto safety standard in the United States. And one of the major problems is yes, there is a requirement in the law that ingredients and products be substantiated for safety, but there is no definition or guidance that FDA has provided to industry for what that means. And so when we look at ingredients that are on the market here in the United States, we see one in five products contain ingredients of chemicals linked to cancer. We see 60 percent of all products contain estrogenic chemicals that can cause hormone problems, we find lead contamination in lipstick and cancer-causing impurities in baby products and in natural products. So companies are making very different decisions about what is safe enough to sell because they don't have FDA guidance on the issue.

Ms. SCHAKOWSKY. Thank you. My time is more than expired. Thank you.

Mr. PALLONE. Thank you, and the bells have run for our votes, so I guess we just finished up in time to go to the floor. And I just wanted to thank all of you again. As you know and I said before, you have the discussion draft and it is still a work in progress, and so we may very well get back to you with additional questions or comments as we move forward to a markup. If we get additional questions submitted in writing, they will be submitted within the next 10 days and then we will get back to you so that you can hopefully answer them.

Thank you again. This is a very important issue, and this concludes our third and final hearing on the discussion draft. And without objection, this meeting of the Subcommittee is adjourned.

[Whereupon, at 1:15 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF HON. EDOLPHUS TOWNS

I thank Chairman Pallone and Ranking Member Deal for today's hearing and applaud Chairman Dingell, Ranking Member Barton, and my colleagues for these much needed efforts to protect the American public from unsafe products manufactured outside of the United States.

I find it interesting that in 2006, FDA-regulated manufacturers of medical devices sold $110 billion dollars worth of medical device products. Medical device imports to the United States have steadily increased since 2005. In 2007, the U.S. imported roughly $1.5 billion dollars worth of medical devices. The domestic cosmetic industry is also doing well and increasing use of foreign ingredients. The cosmetic industry has annual U.S. sales which are now exceeding $62 billion, according to current FDA figures. World imports have lifted the U.S. economy and supports U.S. jobs. But it hasn't lifted all boats and may be responsible for sinking a few, since lives were lost because of bad products. We should proceed with caution. It's also unfortunate that the FDA can't keep pace with globalization and is not having success with two databases that supply inconsistent information about foreign manufacturers. FDA inspections of class 2 foreign manufactured medical devices, or mid-level risks devices, happen once in 27 years, but for class 3 medical devices that pose the greatest risks, the FDA inspects about every 6 years. Clearly, these inspection times are inadequate and do not come near what the U.S. has set as the bar for domestic standards.

Today, I hope to hear more about user fees, third party certification and use of international standards organizations for product certification and inspections. I hope we are taking small business considerations into account, as well. I remain open to solutions and am committed to working with this committee, the administration, the industry, our foreign trade partners, consumers, and the public to get the FDA fully functional and actively protecting the safety of the American public. I thank the chairman and yield back.

1 **SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CON-**
2 **TENTS.**

3 (a) SHORT TITLE.—This Act may be cited as the
4 "Food and Drug Administration Globalization Act of
5 2008".

6 (b) REFERENCES TO THE FEDERAL FOOD, DRUG,
7 AND COSMETIC ACT.—Except as otherwise specified,
8 whenever in this Act an amendment is expressed in terms
9 of an amendment to a section or other provision, the ref-
10 erence shall be considered to be made to a section or other
11 provision of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 301 et seq.).

13 (c) TABLE OF CONTENTS.—The table of contents of
14 this Act is as follows:

Sec. 1. Short title; references; table of contents.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

Sec. 101. Changes in registration of food facilities.
Sec. 102. Food safety plan; process controls; and performance standards.
Sec. 103. Safety standards for fresh produce.
Sec. 104. Periodic inspections of food facilities.
Sec. 105. Reinspection fee applicable to facilities.
Sec. 106. Food facility certification program.
Sec. 107. Testing of food shipments; accredited laboratories.
Sec. 108. Safe and secure food importation program.

Subtitle B—Intervention

Sec. 111. Imports and commercial food importation through specific ports of entry.
Sec. 112. Research on testing techniques for use in inspections of imported food safety; priority regarding detection of intentional adulteration.

Sec. 113. Notification, nondistribution, and recall of adulterated or misbranded articles of food.

Subtitle C—Response

Sec. 121. Civil penalties relating to food.
Sec. 122. Enforcement and recall.

Subtitle D—Miscellaneous

Sec. 131. Labeling requirement for meat, poultry products, and seafood that contain carbon monoxide.
Sec. 132. Food substances generally recognized as safe.
Sec. 133. Country of origin labeling; disclosure of source of ingredients.
Sec. 134. New food and animal feed export certification fee to improve the ability of United States firms to export their products.

TITLE II—DRUG AND DEVICE SAFETY

Sec. 201. Registration fee applicable to producers of drugs and devices.
Sec. 202. Inspection of producers of drugs, active pharmaceutical ingredients, devices, and device parts.
Sec. 203. Documentation for admissibility of drug imports.
Sec. 204. Origin of ingredients.
Sec. 205. Testing for drug purity and identity.
Sec. 206. Country of origin labeling.
Sec. 207. Recall authority for drugs.
Sec. 208. Destruction of adulterated, misbranded or counterfeit drugs offered for import.
Sec. 209. Administrative detention of drugs that appear to violate the law.
Sec. 210. Civil money penalties for violative drugs and devices and improper import entry filings.

TITLE III—COSMETIC SAFETY

Sec. 301. Registration of cosmetic facilities.

TITLE IV—MISCELLANEOUS

Sec. 401. Registration and fee for commercial importers of food, drugs, devices, and cosmetics.
Sec. 402. Unique identification number for food, drug, and device facilities and establishments.
Sec. 403. Dedicated foreign inspectorate.
Sec. 404. Continued operation of field laboratories.
Sec. 405. False or misleading reporting to FDA.
Sec. 406. Application to biological products.
Sec. 407. Limitation to commercial importation.

TITLE I—FOOD SAFETY

Subtitle A—Prevention

SEC. 101. CHANGES IN REGISTRATION OF FOOD FACILITIES.

(a) PROHIBITED ACTS.—Subsection (p) of section 301 (21 U.S.C. 331) is amended by inserting "or section 415, or to pay a registration fee in accordance with section 741" after "the failure to register under section 510".

(b) ANNUAL REGISTRATION AND PAYMENT OF REGISTRATION FEE.—

(1) IN GENERAL.—Section 415(a) (21 U.S.C. 350d(a)) is amended—

(A) in the first sentence of paragraph (1), by inserting "annually" after "be registered";

(B) in paragraph (1), by inserting "and pay the registration fee required under section 741" after "submit a registration to the Secretary" each place it appears in subparagraphs (A) and (B); and

(C) in paragraph (4), by inserting after the first sentence the following: "The Secretary shall remove from such list the name of any facility that fails to reregister in accordance with this section and shall treat such removal as a suspension of the facility's registration.".

1 (2) REGISTRATION FEE.—Chapter VII (21
2 U.S.C. 371 et seq.) is amended—
3 (A) by redesignating sections 741 and 742
4 as sections 744 and 745, respectively; and
5 (B) by adding at the end of subchapter C
6 the following:

7 **"PART 3—FEES RELATING TO FOOD**

8 **"SEC. 741. FACILITY REGISTRATION FEE.**

9 "(a) IN GENERAL.—The Secretary shall assess and
10 collect a fee for a facility registration under section 415
11 for food safety activities under this Act.
12 "(b) AMOUNT OF FEE.—
13 "(1) IN GENERAL.—Subject to paragraph (2),
14 the amount of the fee under this section shall be
15 $2,000 for the initial registration and each rereg-
16 istration under section 415 of each facility operated
17 by the registrant.
18 "(2) ANNUAL INCREASE.—
19 "(A) IN GENERAL.—Subject to the limita-
20 tion specified in subparagraph (B), the amount
21 of the fee under this section for registrations
22 and re-registrations for a fiscal year after 2009
23 shall be the amount of such fee under this sec-
24 tion for the previous fiscal year increased by the
25 same percentage as the percentage inflation ad-

1 justment described in section 736(c)(1) for the
2 fiscal year.
3 "(B) LIMITATION.—An increase in the
4 amount of the fee under this paragraph shall
5 not be made under this section for any fiscal
6 year unless—
7 "(i) the amount appropriated for sala-
8 ries and expenses of the Center for Food
9 Safety and Applied Nutrition within Food
10 and Drug Administration for such fiscal
11 year is equal to or greater than the
12 amount appropriated for salaries and ex-
13 penses of such Center for fiscal year 2008
14 multiplied by the adjustment factor appli-
15 cable to the fiscal year involved under sec-
16 tion 736(c); and
17 "(ii) the amount appropriated for sal-
18 aries and expenses of the Food and Drug
19 Administration for such fiscal year is equal
20 to or greater than the amount appro-
21 priated for salaries and expenses of such
22 Administration for fiscal year 2008 multi-
23 plied by the adjustment factor applicable
24 to the fiscal year involved under section
25 736(c); and, except that in making deter-

1 minations under this subparagraph for the
2 fiscal year involved there shall be excluded
3 the amounts of fees collected under this
4 part, section 736, section 738, and section
5 740.
6 In applying clauses (i) and (ii) there shall not
7 be taken into account salaries or expenses that
8 are paid from fees, including those collected
9 under subsection (a), section 736, 738, 740,
10 741B, and 741D.".
11 (c) CONTENTS OF REGISTRATION.—Paragraph (2) of
12 section 415(a) (21 U.S.C. 350d(a)) is amended by striking
13 "containing information" and all that follows and insert-
14 ing the following: "containing information that identifies
15 the following:
16 "(A) The name, address, and emergency
17 contact information of each facility engaged in
18 manufacturing, processing, packing, or holding
19 food for consumption in the United States that
20 the registrant operates.
21 "(B) The primary purpose and business
22 activity of each such facility, including the dates
23 of operation if the facility is seasonal.
24 "(C) The general food category (as listed
25 under section 170.3(n) of title 21, Code of Fed-

1 eral Regulations, or as the Secretary may other-
2 wise designate for purposes of evaluating poten-
3 tial threats to food protection) of any food man-
4 ufactured, processed, packed, or held at each
5 such facility.
6 "(D) All trade names under which each
7 such facility conducts business related to food.
8 "(E) The name, address, and 24-hour
9 emergency contact information of the United
10 States distribution agent for each such facility,
11 which agent shall maintain information on the
12 wholesale and retail distribution of food.
13 Such registration shall also include an assurance
14 that the registrant will notify the Secretary of any
15 change in the products, function, or legal status of
16 each such facility (including cessation of business ac-
17 tivities) not later than 30 days after the date of such
18 change.".
19 (d) SUSPENSION AUTHORITY.—Such section is fur-
20 ther amended by adding at the end the following:
21 "(6) SUSPENSION OF REGISTRATION.—
22 "(A) IN GENERAL.—The Secretary may
23 suspend the registration of any facility reg-
24 istered under this section, including the facility
25 of an importer—

1 "(i) for violation of this Act that could
2 result in serious adverse health con-
3 sequences or death to humans or animals;
4 or
5 "(ii) if the facility, or employee of the
6 facility, delays, limits, or denies an inspec-
7 tion by the Secretary under this Act.
8 "(B) NOTICE AND OPPORTUNITY FOR
9 HEARING.—Before suspending the registration
10 of a facility under this paragraph, the Secretary
11 shall provide notice to a registrant of an intent
12 to suspend the registration and provide the reg-
13 istrant with an opportunity for an informal
14 hearing. The Secretary may issue a written
15 order of suspension following the hearing, if the
16 Secretary finds that a violation described in
17 subparagraph (A) has occurred.
18 "(C) REINSTATEMENT.—A registration
19 that is suspended under this section may be re-
20 instated pursuant to criteria published by the
21 Secretary in the Federal Register and on a pub-
22 lic website of the Food and Drug Administra-
23 tion.
24 "(D) APPEAL.—Any registrant whose reg-
25 istration is suspended under this section may

1 appeal that action in any appropriate district
2 court of the United States.".
3 (e) EFFECTIVE DATE.—
4 (1) MODIFICATION OF REGISTRATION FORM.—
5 Not later than 30 days after the date of the enact-
6 ment of this Act, the Secretary of Health and
7 Human Services shall modify the registration form
8 under section 415 of the Federal Food, Drug, and
9 Cosmetic Act to comply with the amendments made
10 by subsection (c).
11 (2) APPLICATION.—The amendments made by
12 this section, other than by subsection (c), shall take
13 effect on the date that is 30 days after the date on
14 which such modified registration form takes effect,
15 but not later than 60 days after the date of the en-
16 actment of this Act.
17 **SEC. 102. FOOD SAFETY PLAN; PROCESS CONTROLS; AND**
18 **PERFORMANCE STANDARDS.**
19 (a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et
20 seq.) is amended by adding at the end the following:
21 **"SEC. 418. FOOD SAFETY PLAN; PROCESS CONTROLS; AND**
22 **PERFORMANCE STANDARDS.**
23 "(a) IMPLEMENTATION OF FOOD SAFETY PLAN.—
24 "(1) IN GENERAL.—Before a facility (as de-
25 fined in section 415(b)) introduces or delivers for in-

1 troduction into interstate commerce any shipment of
2 food, the owner, operator, or agent in charge of the
3 facility shall develop and implement a written food
4 safety plan (in this section referred to as a 'food
5 safety plan') that is based on an analysis of—
6 "(A) the specific practices for—
7 "(i) obtaining and ensuring the safety
8 of raw materials and ingredients for food
9 produced, manufactured, processed,
10 packed, or held at a facility;
11 "(ii) producing, manufacturing, proc-
12 essing, packing, and holding food at the fa-
13 cility; and
14 "(iii) transporting food to and from
15 the facility; and
16 "(B) any hazard that has been present in
17 or on, or is reasonably likely to be present in
18 or on, any food that is manufactured, proc-
19 essed, packed, or held at the facility.
20 "(2) CONTENTS.—The food safety plan shall in-
21 clude each of the following elements:
22 "(A) A description of the preventive con-
23 trols being implemented that are reasonably ap-
24 propriate to control or limit identified hazards
25 and to comply with applicable hazard-specific

1 performance standards and other food safety
2 regulatory requirements.
3 "(B) Validation that such preventive con-
4 trols are effective to reduce, control, or elimi-
5 nate such hazard.
6 "(C) A description of monitoring of such
7 preventive controls being implemented, includ-
8 ing sampling and testing relating to the control
9 of hazards where appropriate to verify that the
10 controls are effective.
11 "(D) A description of the recordkeeping
12 being conducted, including evidence of correc-
13 tive actions, sampling and testing records, mon-
14 itoring and verification records, and validation
15 records.
16 "(E) A description of established proce-
17 dures for the recall of such articles of food,
18 whether voluntarily or when required under sec-
19 tion 423.
20 "(b) FOOD SAFETY PLAN REVISIONS.—
21 "(1) IN GENERAL.—The food safety plan shall
22 be revised—
23 "(A) when major changes have been made
24 by the owner facility; and

1 "(B) as deemed appropriate by the Sec-
2 retary.
3 "(2) INCLUSION OF SPECIFIC HAZARD CON-
4 TROLS.—The Secretary may require that a food
5 safety plan for a facility include specific hazard con-
6 trols, if such controls are needed to ensure the pro-
7 tection of the public health including to prevent in-
8 tentional adulteration of food.
9 "(c) INSPECTION OF FOOD SAFETY PLAN IN COURSE
10 OF FACILITY INSPECTION.—In the course of a facility in-
11 spection under section 704A, the Secretary shall conduct
12 a review of the food safety plan to ensure the plan—
13 "(1) is based on a thorough hazard analysis
14 and is adequate to protect the public health;
15 "(2) meets relevant regulatory and food safety
16 standards; and
17 "(3) limits the presence and growth of contami-
18 nants in food prepared in a facility to meet perform-
19 ance standards of subsection (d).
20 "(d) PERFORMANCE STANDARDS.—
21 "(1) IN GENERAL.—To protect the public
22 health, the Secretary may establish by regulation
23 and enforce performance standards that define, with
24 respect to specific foods and contaminants in food,

1 the level of food safety performance that a facility
2 shall meet.
3 "(2) CONSULTATION.—In establishing perform-
4 ance standards under this subsection, the Secretary
5 shall consult with the Centers for Disease Control
6 and Prevention and infectious disease experts out-
7 side the federal government, and hold public meet-
8 ings for the purpose of receiving public input and
9 comment.".
10 (b) EFFECTIVE DATE.—The amendment made by
11 subsection (a) shall apply to food shipments introduced
12 or delivered for introduction into interstate commerce on
13 and after the date that is 2 years after the date of the
14 enactment of this Act.
15 **SEC. 103. SAFETY STANDARDS FOR FRESH PRODUCE.**
16 Chapter IV (21 U.S.C. 341 et seq.), as amended by
17 section 102(a), is further amended by adding at the end
18 the following:
19 **"SEC. 419. SAFETY STANDARDS FOR FRESH PRODUCE.**
20 "(a) IN GENERAL.—Section 418 (relating to food
21 safety plan; process controls; and performance standards)
22 shall apply with respect to the production of a type of
23 fresh produce for consumption in the United States 1 year
24 after the date on which the Secretary by regulation de-

1 scribes how a producer of such type of fresh produce may
2 comply with such section.
3 "(b) LOCAL GROWING CONDITIONS.—The Secretary
4 shall assist a State or foreign country in identifying how,
5 considering local growing conditions, producers in such
6 State or foreign country may comply with section 418, as
7 applied under subsection (a).
8 "(c) VARIANCES.—If the Secretary issues a regula-
9 tion under subsection (a) with respect to the production
10 of a type of fresh produce, the Secretary shall provide for
11 a variance from such a regulation for producers in a State
12 or foreign country if the State or foreign country deter-
13 mines, and the Secretary concurs, that the variance—
14 "(1) is necessary in light of local growing condi-
15 tions; and
16 "(2) will be at least as effective in controlling
17 hazards as if the variance had not been provided.
18 "(d) FRESH PRODUCE DEFINED.—In this section,
19 the term 'fresh produce' means any fruit or vegetable that
20 is intended to be sold to the consumer—
21 "(1) in its unpeeled, natural form; or
22 "(2) with minimal processing (such as peeling,
23 chopping, or trimming).".

1 **SEC. 104. PERIODIC INSPECTIONS OF FOOD FACILITIES.**

2 (a) IN GENERAL.—Chapter VII is amended by add-
3 ing after section 704 the following:

4 **"SEC. 704A. PERIODIC INSPECTIONS OF FOOD FACILITIES.**

5 "(a) NATURE OF INSPECTIONS.—

6 "(1) IN GENERAL.—The Secretary shall provide
7 for an inspection system for the conduct of unan-
8 nounced inspections of facilities (as defined in sec-
9 tion 415(b)) to determine whether such facilities are
10 operating in compliance with this Act and with good
11 manufacturing practices, including the requirements
12 of section 419. Inspections shall include review of
13 records and sampling of food products.

14 "(2) TIMING OF INSPECTIONS.—

15 "(A) IN GENERAL.—Subject to subpara-
16 graph (B), inspections of facilities shall be con-
17 ducted every 4 years.

18 "(B) NONCERTIFIED FACILITIES.—Inspec-
19 tions of facilities that are not certified under
20 section 418 shall be conducted every 2 years.

21 "(3) SANCTION FOR INTERFERENCE WITH IN-
22 SPECTIONS.—If a facility or employee of a facility
23 delays, limits, or denies an inspection of the facility
24 under this section, the Secretary shall make a deter-
25 mination that may result in the facility losing its
26 registration under section 415.

1 "(b) CONDUCT OF INSPECTIONS.—

2 "(1) SCOPE.—An inspection under subsection
3 (a) of any facility shall extend to all things therein
4 that bear on whether food products are in compli-
5 ance with this Act. Access to records may include
6 the copying of such records.

7 "(2) AUTHORITY.—In conducting such inspec-
8 tions, officers or employees duly designated by the
9 Secretary, upon presenting appropriate credentials
10 to the owner, operator, or agent in charge, are au-
11 thorized—

12 "(A) to enter at reasonable times any facil-
13 ity in or to enter any vehicle being used to
14 transport or hold such food products;

15 "(B) to inspect in a reasonable manner
16 such facility or vehicle and all pertinent equip-
17 ment, finished and unfinished materials, con-
18 tainers, labeling, processes, controls, and prem-
19 ises;

20 "(C) to collect and retain samples of food
21 products or ingredients or of any other items
22 found during an inspection that may contribute
23 to a finding of whether such food products are
24 unsafe for human consumption or adulterated
25 or misbranded under this Act;

1 "(D) to review food safety plan established
2 under section 418; and
3 "(E) may take photographs and such pho-
4 tographs shall be treated as documents subject
5 to section 301(j).
6 "(3) WRITTEN REPORT.—Within 24 hours after
7 completion of inspection, the Secretary or certifying
8 agent making the inspection shall give to the owner,
9 operator, or agent in charge a report in writing set-
10 ting forth any conditions or practices observed which
11 indicate that either processing controls are inad-
12 equate to prevent or minimize food safety hazards or
13 that any food from such facility is unsafe for human
14 consumption, or adulterated or misbranded under
15 this Act.
16 "(c) PRODUCT DETENTION AND CONDEMNATION.—
17 "(1) ORDERS.—If, during an inspection con-
18 ducted under this section, the Secretary or certifying
19 agent has reason to believe that a food product is
20 unsafe for human or animal consumption, or adul-
21 terated or misbranded under this Act, the Secretary
22 may order the food product segregated, impounded,
23 and if objection is not made within 48 hours, con-
24 demned. If objection is made, such food products
25 that are in perishable form may be processed to the

1 extent necessary to prevent spoilage, and a hearing
2 shall be commenced expeditiously.
3 "(2) RELABELING.—If the Secretary deter-
4 mines that, through re-labeling or other action, such
5 food products can be brought into compliance with
6 this Act , the food may be released following a deter-
7 mination by the Secretary that such re-labeling or
8 other action as specified by the Secretary has been
9 performed.
10 "(3) DESTRUCTION OF CONDEMNED FOOD.—
11 Any food product condemned without objection, or
12 after an informal hearing, shall be destroyed under
13 supervision of the Secretary.".
14 (b) CONFORMING AMENDMENTS.—
15 (1) Section 415(a) (21 U.S.C. 350d(a)), as
16 amended by section 101(b), is amended by adding at
17 the end the following:
18 "(7) INSPECTION.—Every facility that is reg-
19 istered under this section shall be subject to inspec-
20 tion pursuant to section 704A.".
21 (2) OTHER INSPECTION RIGHTS AND DUTIES.—
22 Section 704 (21 U.S.C. 374) is amended by adding
23 at the end the following new subsection:
24 "(h) The rights and duties under this section of duly
25 designated officers and employees and of other persons

1 shall apply to the exercise of authority under section
2 704A.".

3 **SEC. 105. REINSPECTION FEE APPLICABLE TO FACILITIES.**

4 (a) IN GENERAL.—Part 3 of chapter VII (21 U.S.C.
5 371 et seq.), as added by section 101(b)(2), is further
6 amended by adding at the end the following:

7 **"SEC. 741A. REINSPECTION FEE APPLICABLE TO FACILI-**
8 **TIES.**

9 "(a) IN GENERAL.—The Secretary shall assess and
10 collect fees from each facility (as defined in section
11 415(b)) that—

12 "(1) during such fiscal year, commits a viola-
13 tion of any requirement of this Act relating to food,
14 including any such requirement relating to good
15 manufacturing practices; and

16 "(2) because of such violation, undergoes addi-
17 tional inspection by the Food and Drug Administra-
18 tion.

19 "(b) AMOUNT OF FEES.—The Secretary shall set the
20 amount of the fees under this section to fully defray the
21 costs of conducting the additional inspections referred to
22 in subsection (a)(2).

23 "(c) USE OF FEES.—The Secretary shall make all
24 of the fees collected pursuant to this section available sole-

1 ly to pay for the costs of additional inspections referred
2 to in subsection (a)(2).".
3 (b) EFFECTIVE DATE.—The amendment made by
4 subsection (a) shall apply to additional inspections occur-
5 ring after the date of the enactment of this Act.
6 **SEC. 106. FOOD FACILITY CERTIFICATION PROGRAM.**
7 (a) IN GENERAL.—Chapter IV (21 U.S.C. 341 et
8 seq.), as amended by sections 102(a) and 103, is amended
9 by adding at the end the following:
10 **"SEC. 420. FOOD FACILITY CERTIFICATION PROGRAM.**
11 "(a) IN GENERAL.—
12 "(1) CERTIFICATION.—The Secretary shall es-
13 tablish a program for the certification of a facility
14 as being in compliance with the applicable require-
15 ments of this Act. Such program shall provide for—
16 "(A) direct certification by the Secretary;
17 or
18 "(B) certification by a certifying agent
19 that has been accredited under subsection (b).
20 "(2) VOLUNTARY CERTIFICATION.—Any facility
21 may apply to be certified to the Secretary under this
22 section.
23 "(3) FACILITY DEFINED.—For purposes of this
24 section, the term 'facility' has the meaning given

1 such term in section 415(b), and includes both for-
2 eign and domestic facilities.
3 "(4) CERTIFIED FACILITY DEFINED.—For pur-
4 poses of this chapter, the term 'certified facility'
5 means a facility that has been certified under the
6 program established under this subsection.
7 "(b) LISTING AND NOTICES.—
8 "(1) PUBLIC LISTING OF CERTIFIED FACILI-
9 TIES.—The Secretary shall make available to the
10 public through the Internet Web Site of the Food
11 and Drug Administration a list of each facility that
12 is certified under this section and the date on which
13 such certification will no longer be in effect.
14 "(2) DURATION OF CERTIFICATION.—The cer-
15 tification for a facility under this section shall be in
16 effect for 2 years from the date the Secretary or cer-
17 tifying agent approves the application for such cer-
18 tification of the facility.
19 "(3) REQUIRED INSPECTION.—No facility shall
20 be certified without having been inspected by the
21 Secretary or a certifying agent.
22 "(4) NOTICES OF VIOLATIONS.—
23 "(A) IN GENERAL.—If a certifying agent
24 in the process of inspecting a facility for certifi-
25 cation determines that the facility's food safety

1 plan is in violation of this Act and that the fa-
2 cility has failed to take corrective action within
3 30 days, the agent shall notify the Secretary of
4 such violation and such failure.
5 "(B) IMMEDIATE NOTICE.—A certifying
6 agent shall notify the Secretary immediately
7 during inspection of a facility if the food at the
8 facility appears to be unsafe for human or ani-
9 mal consumption or adulterated or misbranded
10 "(5) SUSPENSION OF CERTIFICATION.—The
11 Secretary may suspend the certification of a facility
12 under this section if, after opportunity for an infor-
13 mal hearing, the Secretary finds that—
14 "(A) the food safety plan of the facility
15 fails to comply with requirements of section
16 418; or
17 "(B) the facility is found on inspection not
18 to be in compliance with other applicable re-
19 quirements of this Act.
20 "(c) ACCREDITATION OF FOREIGN GOVERNMENTS
21 AND CERTIFYING AGENTS.—
22 "(1) IN GENERAL.—Beginning not later than 2
23 years after the date of enactment of this section, the
24 Secretary shall establish and implement an accredi-
25 tation system under which a foreign government, a

1 State or regional food authority, a foreign or domes-
2 tic cooperative that aggregates the products of grow-
3 ers or processors, or any other third party that the
4 Secretary determines appropriate, may request per-
5 mission to certify that facilities meet the applicable
6 requirements of this Act.

7 "(2) REQUEST BY FOREIGN GOVERNMENT.—
8 Prior to accrediting a foreign government as a certi-
9 fying agent under this paragraph (1)(A), the Sec-
10 retary shall perform such reviews and audits of food
11 safety programs, systems, and standards of the gov-
12 ernment (including all statutes, regulations, and in-
13 spection authority) as the Secretary deems necessary
14 to determine that they are adequate to ensure that
15 facilities certified by such government meet the re-
16 quirements of this Act with respect to food manufac-
17 tured, processed, packed, or held for import to the
18 United States.

19 "(3) REQUEST BY OTHER THIRD PARTY.—Prior
20 to accrediting a third party under paragraph (1)(B),
21 the Secretary shall perform such reviews and audits
22 of the training and qualifications of inspectors used
23 by the agent and conduct such reviews of internal
24 systems and such other investigation of the party as
25 the Secretary deems necessary to determine that

1 each facility certified by the party has systems and
2 standards in use to ensure that such facility meets
3 the requirements of this Act.
4 "(d) IMPORTATION.—As condition of accrediting
5 such government or certifying agent, the government or
6 certifying agent shall agree to issue a written and elec-
7 tronic certification to accompany each food shipment made
8 for import from a facility certified by such government or
9 certifying agent, subject to requirements set forth by the
10 Secretary.
11 "(e) MONITORING.—Following any accreditation of a
12 certifying agent under subsection (b), the Secretary may
13 at any time—
14 "(1) conduct an on-site audit of any facility cer-
15 tified by the agent, with or without the certifying
16 agent present; or
17 "(2) require the agent to submit to the Sec-
18 retary, for any facility certified by the agent, an on-
19 site inspection report and such other reports or doc-
20 uments the agent requires as part of the audit proc-
21 ess, including for a facility located outside the
22 United States documentation that the facility is in
23 compliance with registration requirements and prior
24 notice requirements for food imported to the United
25 States.

1 "(f) DEFINITIONS.—For purposes of this section:

2 "(1) CERTIFYING AGENT.—The term 'certifying
3 agent' means a foreign government or other third
4 party that conducts certification of facilities.

5 "(2) INSPECTOR.—The term 'inspector' means
6 a person who has completed training as required by
7 the Secretary in the conduct of food safety inspec-
8 tions.

9 "(g) LIMITATION.—

10 "(1) TO SPECIFIED FOOD PRODUCTS.—The
11 Secretary may limit the accreditation of a foreign
12 government or a third party under this section to
13 the certification of facilities for the import to the
14 United States only of specified food products (or
15 specified categories of food products), as determined
16 by the Secretary.

17 "(2) TO AVOID CONFLICTS OF INTEREST WITH
18 CERTIFYING AGENTS.—The Secretary shall promul-
19 gate regulations to ensure that there are adequate
20 protections against conflicts of interest between a
21 certifying agent and the facility to be certified by
22 such agent.

23 "(h) WITHDRAWAL OF ACCREDITATION.—The Sec-
24 retary may withdraw accreditation from a certifying agent
25 under subsection (b)—

1 "(1) if food from facilities certified by such
2 agent is linked to an outbreak of human or animal
3 illness;
4 "(2) following an investigation and finding by
5 the Secretary that the agent no longer meet the re-
6 quirements of subsection (b) for accreditation; or
7 "(3) following a refusal to allow United States
8 officials to conduct such audits and investigations as
9 may be necessary to ensure continued compliance
10 with the requirements set forth in this section.
11 "(i) RENEWAL OF ACCREDITATION.—The Secretary
12 shall audit accredited certifying agents whenever needed,
13 but no less than once every three years, to ensure the con-
14 tinued compliance with the requirements set forth in this
15 section. Renewal of accreditation shall occur following
16 each satisfactory audit.".
17 (b) FEE.—Part 3 of chapter VII, as added by section
18 101(b) and amended by section 105(a), is amended by
19 adding at the end the following:
20 **"SEC. 741B. CERTIFYING AGENT FEE.**
21 "(a) IN GENERAL.—The Secretary shall assess and
22 collect a fee for the accreditation of a foreign government
23 or third party as a certifying agent under section 420 for
24 the purpose of defraying the costs of the implementation

1 of the accreditation programs required to carry out such
2 section.
3 "(b) AMOUNT OF FEE.—The amount of a fee under
4 this section shall be as determined by the Secretary.".

5 **SEC. 107. TESTING OF FOOD SHIPMENTS; ACCREDITED LAB-**
6 **ORATORIES.**

7 (a) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)
8 is amended by adding at the end the following:
9 "(oo) The introduction or delivery for introduction
10 into interstate commerce by facility that is not certified
11 under section 420 of any shipment of food before arrang-
12 ing for sampling and testing of such shipment and submit-
13 ting the results of such sampling and testing to the Sec-
14 retary in accordance with section 421.".
15 (b) TESTING OF FOOD SHIPMENTS; ACCREDITED
16 LABORATORIES.—Chapter IV (21 U.S.C. 341 et seq.),
17 amended by sections 102(a), 103, and 106(a), is further
18 amended by adding at the end the following:

19 **"SEC. 421. TESTING OF FOOD SHIPMENTS; ACCREDITED**
20 **LABORATORIES.**

21 "(a) TESTING IN NON-CERTIFIED FACILITIES.—Be-
22 fore introducing or delivering for introduction into inter-
23 state commerce any shipment of food, a facility (as defined
24 in section 415(b)) that is engaged in manufacturing, proc-
25 essing, packaging, or holding such food and that is not

1 certified under section 420 with respect to such food shall
2 arrange for a laboratory accredited under subsection (c)—
3 "(1) to conduct sampling and testing of such
4 shipment to ensure compliance with applicable food
5 safety standards; and
6 "(2) to simultaneously submit electronically the
7 results of such sampling and testing to the Secretary
8 and to the owner of such facility.
9 "(b) TESTING IN CERTIFIED FACILITIES.—A facility
10 certified under section 420 that is engaged with manufac-
11 turing, processing, packaging, or holding food shall ar-
12 range for a laboratory accredited under subsection (c)—
13 "(1) to conduct, on a periodic basis specified by
14 the Secretary, sampling and testing of shipments of
15 food being introduced or delivered for introduction
16 into interstate commerce to ensure compliance with
17 applicable food safety standards; and
18 "(2) to submit electronically the results of such
19 sampling and testing to the Secretary and to the
20 owner of such facility.
21 "(c) ACCREDITATION OF LABORATORIES.—
22 "(1) IN GENERAL.—The Secretary shall ac-
23 credit laboratories for the purpose of conducting
24 sampling and testing under subsections (a) and (b).

1 "(2) STANDARDS.—Not later than 1 year after
2 the date of the enactment of this section, the Sec-
3 retary shall establish and publish in the Federal
4 Register standards to accredit or deny accreditation
5 to laboratories under this subsection. A laboratory
6 shall not be accredited unless it has paid the accredi-
7 tation fee required under section 741C.
8 "(3) AUDITS.—To ensure that laboratories ac-
9 credited under this subsection continue to meet the
10 standards of accreditation, the Secretary shall—
11 "(A) make onsite visits on an annual basis
12 to each accredited laboratory to audit the per-
13 formance of such laboratory; and
14 "(B) take such additional measures as the
15 Secretary determines to be appropriate.".
16 (c) ACCREDITATION FEE.—Part 3 of chapter VII, as
17 added by section 101(b) and amended by sections 105(a)
18 and 106(b), is amended by adding at the end the fol-
19 lowing:
20 **"SEC. 741C. LABORATORY ACCREDITATION FEE.**
21 "The Secretary shall assess and collect an annual fee,
22 specified by the Secretary, for accreditation under section
23 421(c) for the purpose of defraying the costs of the accred-
24 itation activities under such section.".

1 (d) EFFECTIVE DATE.—Sections 301(oo) and 421(a)
2 of the Federal Food, Drug, and Cosmetic Act, as added
3 by subsections (a) and (b), shall apply to shipments of
4 food introduced or delivered for introduction into inter-
5 state commerce on or after such date, not later than 3
6 years after the date of the enactment of this Act, as the
7 Secretary of Health and Human Services shall specify.

8 **SEC. 108. SAFE AND SECURE FOOD IMPORTATION PRO-**
9 **GRAM.**

10 Chapter VIII (21 U.S.C. 381 et seq.) is amended by
11 adding at the end the following:

12 **"SEC. 805. SAFE AND SECURE FOOD IMPORTATION PRO-**
13 **GRAM.**

14 "(a) IN GENERAL.—Beginning not later than 2 years
15 after the date of the enactment of this section, the Sec-
16 retary shall establish by regulation and carry out a pro-
17 gram under which the Secretary expedites the movement
18 of food through the importation process under this Act
19 if each facility involved in the production, manufacture,
20 processing, packaging, and holding of the food—

21 "(1) is certified under section 420; and

22 "(2) has agreed to abide by, and has been de-
23 termined by the Secretary to be in compliance with,
24 the food safety and security guidelines developed
25 under subsection (b) with respect to such food.

1 "(b) GUIDELINES.—

2 "(1) DEVELOPMENT.—For purposes of the pro-
3 gram established under subsection (a), the Secretary
4 shall develop safety and security guidelines applica-
5 ble to the importation of food.

6 "(2) FACTORS.—Such guidelines shall take into
7 account the following factors:

8 "(A) The personnel of the person import-
9 ing the food.

10 "(B) The physical and procedural safety
11 and security of such person's food supply chain.

12 "(C) The sufficiency of access controls for
13 food and ingredients purchased by such person.

14 "(D) The need for tracking and maintain-
15 ing records on food and ingredients purchased
16 by such person or moved through the supply
17 chain.

18 "(E) Documentation processing through
19 such person's supply chain.

20 "(F) Access by the Secretary to such per-
21 son's business records for review.

22 "(G) Vendor and supplier information.

23 "(H) Such other factors as the Secretary
24 determines necessary.".

1 **Subtitle B—Intervention**

2 **SEC. 111. IMPORTS AND COMMERCIAL FOOD IMPORTATION**
3 **THROUGH SPECIFIC PORTS OF ENTRY.**

4 Chapter IV (21 U.S.C. 341 et seq.), as amended by
5 sections 102(a), 103, 106(a), and 107(b), is further
6 amended by adding at the end the following:

7 **"SEC. 422. IMPORTS AND COMMERCIAL FOOD IMPORTA-**
8 **TION THROUGH SPECIFIC PORTS OF ENTRY.**

9 "Beginning on a date (not later than 5 years after
10 the date of enactment of this section) specified by the Sec-
11 retary, food shall only enter the United States, other than
12 only for personal use, through a port of entry that is lo-
13 cated in a metropolitan area with a federal laboratory, un-
14 less each facility (as defined in section 415(b)) that has
15 manufactured, processed, packed, and held the food is cer-
16 tified under section 420.".

17 **SEC. 112. RESEARCH ON TESTING TECHNIQUES FOR USE IN**
18 **INSPECTIONS OF IMPORTED FOOD SAFETY;**
19 **PRIORITY REGARDING DETECTION OF INTEN-**
20 **TIONAL ADULTERATION.**

21 Section 801 (21 U.S.C. 381) is amended by adding
22 at the end the following: "

23 "(p) RESEARCH ON TESTING TECHNIQUES FOR USE
24 IN INSPECTIONS OF IMPORTED FOOD SAFETY.—

1 "(1) IN GENERAL.—The Secretary shall (di-
2 rectly or through grants or contracts) provide for re-
3 search on the development of tests and sampling
4 methodologies, for use in inspections of food under
5 this section—
6 "(A) whose purpose is to determine wheth-
7 er food is adulterated by reason of being con-
8 taminated with microorganisms, chemical tox-
9 ins, or pesticide chemicals or related residues;
10 and
11 "(B) whose results are available not later
12 than approximately 60 minutes after the ad-
13 ministration of the tests.
14 "(2) PRIORITY.—
15 "(A) IN GENERAL.—In providing for re-
16 search under paragraph (1), the Secretary shall
17 give priority to conducting research on the de-
18 velopment of tests that are suitable for inspec-
19 tions of food at ports of entry into the United
20 States, with the greatest priority given to the
21 development of such tests that the Secretary de-
22 termines would be useful in detecting the inten-
23 tional adulteration of food.
24 "(B) SPECIFIC PRIORITIES.— In providing
25 for such research, the Secretary shall give pri-

1 ority under this paragraph to conducting re-
2 search on the development of tests and sam-
3 pling methodology for detecting the presence in
4 or on food of—
5 "(i) pathogens, including Escherichia
6 coli (STEC) 0157, salmonella, cyclospora,
7 cryptosporidium, hepatitis A, Clostridium
8 botulinum, or listeria;
9 "(ii) pesticide chemicals and related
10 residues;
11 "(iii) chemical toxins; and
12 "(iv) such other pathogens or sub-
13 stances as the Secretary determines to be
14 appropriate, including any pathogen or
15 substance that the Secretary determines is
16 a candidate for use to intentionally adul-
17 terate food.
18 "(C) GOAL.—The Secretary shall establish
19 the goal of developing, by the expiration of the
20 3-year period beginning on the date of the en-
21 actment of this subsection, tests and methodolo-
22 gies under paragraph (1) for each of the patho-
23 gens and substances receiving priority under
24 this paragraph.
25 "(3) PERIODIC REPORTS.—

1 "(A) IN GENERAL.—The Secretary shall
2 submit to the Congress periodic reports describ-
3 ing the progress that has been made toward the
4 goal referred to in paragraph (1)(C) and de-
5 scribing plans for future research toward the
6 goal.
7 "(B) CONTENTS.— Each of the reports
8 shall provide an estimate by the Secretary of
9 the amount of funds needed to meet such goal,
10 and shall provide a determination by the Sec-
11 retary of whether there is a need for further re-
12 search under this subsection.
13 "(C) DEADLINES.— The first report under
14 this paragraph shall be submitted not later
15 than 2 years after the date of the enactment of
16 this subsection. Subsequent reports shall be
17 submitted annually until such goal is met.
18 "(4) CONSULTATION.—The Secretary shall
19 carry out the program of research under paragraph
20 (1) in consultation with the Director of the Centers
21 for Disease Control and Prevention, the Director of
22 the National Institutes of Health, and the Adminis-
23 trator of the Environmental Protection Agency. The
24 Secretary shall with respect to such research coordi-
25 nate the activities of the Department of Health and

1 Human Services. The Secretary shall in addition
2 consult with the Secretary of Agriculture (acting
3 through the Food Safety and Inspection Service of
4 the Department of Agriculture) in carrying out the
5 program.".

6 **SEC. 113. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
7 **OF ADULTERATED OR MISBRANDED ARTI-**
8 **CLES OF FOOD.**

9 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.
10 331), as amended by section 107(a), is amended by adding
11 at the end the following:

12 "(pp)(1) The failure to notify the Secretary in viola-
13 tion of section 423(a).

14 "(2) The failure to comply with—

15 "(A) an order issued under section 423(b) fol-
16 lowing any hearing requested under section 423(c);
17 or

18 "(B) an amended order issued under section
19 423(d)(1).".

20 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
21 OF ADULTERATED OR MISBRANDED ARTICLES OF
22 FOOD.—Chapter IV (21 U.S.C. 341 et seq.), as amended
23 by sections 102(a), 103, 106(a), 107(b), and 111, is fur-
24 ther amended by adding at the end the following:

1 **"SEC. 423. NOTIFICATION, NONDISTRIBUTION, AND RECALL**
2 **OF ADULTERATED OR MISBRANDED ARTI-**
3 **CLES OF FOOD.**
4 "(a) NOTIFICATION TO SECRETARY OF VIOLATION.—
5 "(1) IN GENERAL.—A person (other than a
6 household consumer or other individual who is the
7 intended consumer of an article of food) that has
8 reason to believe that an article of food when intro-
9 duced into or while in interstate commerce, or while
10 held for sale (regardless of whether the first sale)
11 after shipment in interstate commerce, is adulter-
12 ated or misbranded in a manner that, if consumed,
13 may result in illness or injury shall, as soon as prac-
14 ticable, notify the Secretary of the identity and loca-
15 tion of the article.
16 "(2) MANNER OF NOTIFICATION.—Notification
17 under paragraph (1) shall be made in such manner
18 and by such means as the Secretary may require by
19 regulation.
20 "(b) RECALL AND CONSUMER NOTIFICATION.—
21 "(1) VOLUNTARY ACTIONS.—On receiving noti-
22 fication under subsection (a) or by other means of
23 a suspected adulteration or misbranding of food, if
24 the Secretary finds that an article of food when in-
25 troduced into or while in interstate commerce, or
26 while held for sale (regardless of whether the first

1 sale) after shipment in interstate commerce, is adul-
2 terated or misbranded in a manner that, if con-
3 sumed, may result in illness or injury (as determined
4 by the Secretary), the Secretary shall provide all ap-
5 propriate persons (including the manufacturer, im-
6 porter, distributor, or retailer of the article) with an
7 opportunity (as determined by the Secretary)—
8 "(A) to cease distribution of the article;
9 "(B) to notify all persons—
10 "(i) that produce, manufacture, pack,
11 process, prepare, treat, package, distribute,
12 or hold the article, to cease immediately
13 those activities with respect to the article;
14 or
15 "(ii) to which the article has been dis-
16 tributed, transported, or sold, to cease im-
17 mediately distribution of the article;
18 "(C) to recall the article;
19 "(D) in consultation with the Secretary, to
20 provide notice of the finding of the Secretary to
21 all consumers to which the article was, or may
22 have been, distributed and to appropriate State
23 and local health officials; and
24 "(E) to notify State and local public health
25 officials.

1 "(2) MANDATORY ACTIONS.—If the appropriate
2 person referred to in paragraph (1) does not carry
3 out the actions described in that paragraph with re-
4 spect to an article within the time period and in the
5 manner prescribed by the Secretary, the Secretary—
6 "(A) shall issue an order requiring the per-
7 son—
8 "(i) to immediately cease distribution
9 of the article; and
10 "(ii) to immediately make the notifica-
11 tion described in paragraph (1)(B); and
12 "(B) may take control or possession of the
13 article.
14 "(3) NOTICE TO CONSUMERS AND HEALTH OF-
15 FICIALS.—The Secretary shall, as the Secretary de-
16 termines to be necessary, provide notice of the find-
17 ing of the Secretary under paragraph (1) to con-
18 sumers to which the article was, or may have been,
19 distributed and to appropriate State and local health
20 officials.
21 "(c) HEARINGS ON ORDERS.—
22 "(1) IN GENERAL.—The Secretary shall provide
23 a person subject to an order under subsection (b)(2)
24 with an opportunity for a hearing on—
25 "(A) the actions required by the order; and

1 "(B) any reasons why the article of food
2 that is the subject of the order should not be
3 recalled.
4 "(2) TIMING OF HEARINGS.—If a hearing is re-
5 quested under paragraph (1) with respect to an
6 order, the Secretary shall hold the hearing as soon
7 as practicable, but not later than 2 business days,
8 after the date of issuance of the order.
9 "(d) POST-HEARING RECALL ORDERS.—
10 "(1) AMENDMENT OF ORDERS.—If, after pro-
11 viding an opportunity for a hearing (and a hearing
12 if requested) under subsection (c), the Secretary de-
13 termines that an article of food when introduced into
14 or while in interstate commerce, or while held for
15 sale (regardless of whether the first sale) after ship-
16 ment in interstate commerce, is adulterated or mis-
17 branded in a manner that, if consumed, may result
18 in illness or injury, the Secretary may, as the Sec-
19 retary determines to be necessary—
20 "(A) amend the order under subsection
21 (b)(2)—
22 "(i) to require recall of the article or
23 other appropriate action; and
24 "(ii) to specify a timetable during
25 which the recall shall occur;

1 "(B) require periodic reports to the Sec-
2 retary describing the progress of any such re-
3 call; and
4 "(C) provide notice of such a recall to con-
5 sumers to which the article was, or may have
6 been, distributed.
7 "(2) VACATION OF ORDERS.—If, after providing
8 an opportunity for a hearing (and a hearing if re-
9 quested) under subsection (c), the Secretary deter-
10 mines that adequate grounds do not exist to con-
11 tinue the actions required by the order, the Sec-
12 retary shall vacate the order.
13 "(e) REMEDIES NOT EXCLUSIVE.—The remedies au-
14 thorized by this section shall be in addition to any other
15 remedies that may be available.".
16 (c) EFFECTIVE DATE.—Sections 301(pp)(1) and
17 423(a) of the Federal Food, Drug, and Cosmetic Act, as
18 added by subsections (a) and (b), shall apply with respect
19 to articles of food as of such date, not later than 1 year
20 after the date of the enactment of this Act, as the Sec-
21 retary of Health and Human Services shall specify.

22 **Subtitle C—Response**

23 **SEC. 121. CIVIL PENALTIES RELATING TO FOOD.**

24 (a) IN GENERAL.—Chapter III (21 U.S.C. 331 et
25 seq.) is amended by adding after section 303 the following:

1 **"SEC. 303A. CIVIL PENALTIES RELATING TO FOODS.**

2 "(a) IN GENERAL.—

3 "(1) ASSESSMENT.—The Secretary may assess
4 against a person that commits an act prohibited by
5 section 301 with respect to an article of food a civil
6 penalty for each such act of not more than—

7 "(A) $100,000, in the case of an indi-
8 vidual; and

9 "(B) $500,000, in the case of any other
10 person.

11 "(2) SEPARATE OFFENSES.—Each prohibited
12 act described in paragraph (1) and each day during
13 which the act continues shall be considered to be a
14 separate offense.

15 "(3) NOTICE AND OPPORTUNITY FOR HEAR-
16 ING.—The Secretary shall not assess a civil penalty
17 under this section against a person unless the person
18 is given notice and opportunity for a hearing on the
19 record before the Secretary in accordance with sec-
20 tions 554 and 556 of title 5, United States Code.

21 "(4) DETERMINATION OF CIVIL PENALTY
22 AMOUNT.—The amount of a civil penalty under this
23 section—

24 "(A) shall be assessed by the Secretary by
25 written order, taking into account—

26 "(i) the gravity of the violation;

1 "(ii) the degree of culpability of the
2 person;
3 "(iii) the size and type of the business
4 of the person; and
5 "(iv) any history of prior offenses by
6 the person; and
7 "(B) shall be reviewed only in accordance
8 with subsection (b).
9 "(b) JUDICIAL REVIEW.—
10 "(1) IN GENERAL.—An order assessing a civil
11 penalty against a person under subsection (a) shall
12 be final unless the person—
13 "(A) not later than 30 days after the effec-
14 tive date of the order, files a petition for judi-
15 cial review of the order in—
16 "(i) the United States court of ap-
17 peals for the circuit in which the person re-
18 sides or has its principal place of business;
19 or
20 "(ii) the United States Court of Ap-
21 peals for the District of Columbia Circuit;
22 and
23 "(B) simultaneously sends a copy of the
24 petition by certified mail to the Secretary.

1 "(2) FILING OF COPY OF RECORD.—The Sec-
2 retary shall promptly file in the court a certified
3 copy of the record on which the order was issued.
4 "(3) STANDARD OF REVIEW.—The findings of
5 the Secretary relating to the order shall be set aside
6 only if the findings are found to be unsupported by
7 substantial evidence on the record as a whole.
8 "(c) COLLECTION ACTIONS FOR FAILURE TO PAY
9 ASSESSMENT.—
10 "(1) REFERRAL TO ATTORNEY GENERAL.—If a
11 person fails to pay a civil penalty assessed under
12 subsection (a) after the order assessing the civil pen-
13 alty has become a final order, or after the court of
14 appeals has entered final judgment in favor of the
15 Secretary, the Secretary may refer the matter to the
16 Attorney General.
17 "(2) ACTION BY ATTORNEY GENERAL.—The
18 Attorney General shall bring a civil action to recover
19 the amount of the civil penalty in United States dis-
20 trict court.
21 "(3) SCOPE OF REVIEW.—In a civil action
22 under paragraph (2), the validity and appropriate-
23 ness of the order of the Secretary assessing the civil
24 penalty shall not be subject to review.

1 "(d) PENALTIES DEPOSITED IN TREASURY.—All
2 amounts collected as civil penalties under this section shall
3 be deposited in the Treasury of the United States and
4 shall be available to cover costs of the Administration in
5 carrying out food safety activities under this Act.

6 "(e) PENALTIES IN LIEU OF OTHER ACTIONS.—
7 Nothing in this Act requires the Secretary to report for
8 prosecution, or for the commencement of any libel or in-
9 junction proceeding, any violation of this Act in any case
10 in which the Secretary believes that the public interest will
11 be adequately served by the assessment of a civil penalty
12 under this section.

13 "(f) REMEDIES NOT EXCLUSIVE.—The remedies au-
14 thorized by this section shall be in addition to any other
15 remedies that may be available.".

16 (b) EFFECTIVE DATE.—The amendment made by
17 subsection (a) shall apply to prohibited acts committed on
18 or after the date of the enactment of this Act .

19 **SEC. 122. ENFORCEMENT AND RECALL.**

20 Section 801 (21 U.S.C. 381), as amended by section
21 112, is further amended by adding at the end the fol-
22 lowing:

23 "(q)(1) The Secretary may deny importation of food,
24 other than only for personal use, from any foreign country,
25 or which is manufactured, processed, packed, or held by

1 a facility (as defined in section 415), if the government
2 of such country, or such facility, respectively, does not
3 timely consent to an investigation by the Administration
4 when food from that country or facility is linked to a food-
5 borne illness outbreak or is otherwise found to be adulter-
6 ated or mislabeled. Any food imported for consumption in
7 the United States may be detained and condemned pursu-
8 ant to section 704A(c) or recalled pursuant to section
9 423.".

10 **Subtitle D—Miscellaneous**

11 **SEC. 131. LABELING REQUIREMENT FOR MEAT, POULTRY**
12 **PRODUCTS, AND SEAFOOD THAT CONTAIN**
13 **CARBON MONOXIDE.**

14 (a) LABELING REQUIREMENT.—

15 (1) IN GENERAL.—Paragraph (t) of section 201
16 (21 U.S.C. 321) is amended by adding at the end
17 the following:

18 "(4) In the case of food that is meat within the mean-
19 ing of the Federal Meat Inspection Act, a poultry product
20 within the meaning of the Poultry Products Inspection
21 Act, or seafood (including all fresh or saltwater fish,
22 molluscan shellfish, crustaceans, and other forms of
23 aquatic animal life) intended for human consumption as
24 food within the meaning of section 201(f) (referred to col-
25 lectively in this paragraph as 'seafood'), the term 'color

1 additive' shall include carbon monoxide under conditions
2 of use that may impart, maintain, preserve, stabilize, fix,
3 or otherwise affect the color of fresh meat, poultry prod-
4 ucts, or seafood, unless the label of such food bears,
5 prominently and conspicuously in such place and in such
6 manner as to render it likely to be read and understood
7 by the ordinary person, the following statement to prevent
8 consumer deception and serious risks to the public health:
9 'CONSUMER NOTICE: Carbon monoxide has been used
10 to preserve the color of this product. Do not rely on color
11 or the "use or freeze by" date alone to judge the freshness
12 of the product.' ".

13 (2) EFFECTIVE DATE.—The amendment made
14 by this subsection shall apply to food labeled on or
15 after the date that is 30 days after the date of the
16 enactment of this Act.

17 (b) DISCRETIONARY AUTHORITY.—If, not earlier
18 than 5 years after the effective date described in sub-
19 section (a)(2), the Secretary of Health and Human Serv-
20 ices finds, based on competent and reliable scientific evi-
21 dence, that the statement prescribed in section 201(t)(4)
22 of the Federal Food, Drug, and Cosmetic Act is no longer
23 required to prevent consumer deception and other harms,
24 then the Secretary is authorized to issue regulations estab-
25 lishing alternative labeling requirements that are shown

1 to be adequate and effective in preventing consumer de-
2 ception and other harms related to the conditions of use
3 of carbon monoxide, including with respect to preventing
4 any consumer deception or other harm that may result
5 from the actual conditions of carbon monoxide use and
6 its potential to impart a persistent color to meat, poultry
7 products, or seafood described in such section through a
8 reaction with natural pigment.

9 **SEC. 132. FOOD SUBSTANCES GENERALLY RECOGNIZED AS**
10 **SAFE.**

11 Section 409 (21 U.S.C. 348) is amended by adding
12 at the end the following:

13 "Substances Generally Recognized as Safe

14 "(k)(1) Not later than 60 days after the date of re-
15 ceipt by the Secretary after the date of the enactment of
16 this subsection of a request for a substance to be deter-
17 mined by the Secretary to be a GRAS food substance, the
18 Secretary shall publish such notice in the Federal Reg-
19 ister.

20 "(2) Not later than 90 days after the date of publica-
21 tion of a notice concerning a GRAS food substance, the
22 Secretary shall determine whether the substance is consid-
23 ered generally recognized as safe.

24 "(3) In this subsection, the term 'GRAS food sub-
25 stance' means a substance excluded from the definition of

1 the term 'food additive' in section 201(s) because such
2 substance is generally recognized, among experts qualified
3 by scientific training and experience to evaluate its safety,
4 as having been adequately shown through scientific proce-
5 dures (or, in the case of a substances used in food prior
6 to January 1, 1958, through either scientific procedures
7 or experience based on common use in food) to be safe
8 under the conditions of its intended use.

9 "(4) A determination whether a substance is gen-
10 erally recognized as safe by the Secretary shall be pub-
11 lished in the Federal Register.".

12 **SEC. 133. COUNTRY OF ORIGIN LABELING; DISCLOSURE OF**
13 **SOURCE OF INGREDIENTS.**

14 (a) FOOD.—Section 403 (21 U.S.C. 343) is amended
15 by adding at the end the following:

16 "(z) In the case of a processed food if—

17 "(1) the labeling of the food fails to identify the
18 country in which the final processing of the food oc-
19 curs; and

20 "(2) the website for the manufacturer of the
21 food fails to identify the country (or countries) of or-
22 igin for each ingredient in the food.

23 "(aa) In the case of non-processed food if—

24 "(1) the labeling of the food fails to identify the
25 country of origin of the food; and

1 "(2) the website for the original packer of the
2 food fails to identify the country of origin for the
3 food.".
4 (b) REGULATIONS.—Not later than 180 days after
5 the date of the enactment of this Act, the Secretary of
6 Health and Human Services shall promulgate final regula-
7 tions to carry out the paragraphs (z) and (aa) of section
8 403(z) of the Federal Food, Drug, and Cosmetic Act, as
9 added by subsection (a).
10 (c) EFFECTIVE DATE.—The requirements of para-
11 graphs (z) and (aa) of section 403 of the Federal Food,
12 Drug, and Cosmetic Act, as added by subsection (a), takes
13 effect on the date that is 2 years after the date of the
14 enactment of this Act.
15 **SEC. 134. NEW FOOD AND ANIMAL FEED EXPORT CERTIFI-**
16 **CATION FEE TO IMPROVE THE ABILITY OF**
17 **UNITED STATES FIRMS TO EXPORT THEIR**
18 **PRODUCTS.**
19 Part 3 of chapter VII (21 U.S.C. 371 et seq.), , as
20 added by section 101(b) and amended by sections 105(a),
21 106(b), and 107(c), is further amended by adding at the
22 end the following:

1 **"SEC. 741D. NEW FOOD AND ANIMAL FEED EXPORT CER-**
2 **TIFICATION FEE TO IMPROVE THE ABILITY**
3 **OF UNITED STATES FIRMS TO EXPORT THEIR**
4 **PRODUCTS.**

5 "(a) IN GENERAL.—If the Secretary provides for the
6 issuance of export certificates for foods and animal feeds
7 in cases where exportation is restricted without such a cer-
8 tificate, the Secretary may impose a fee for the issuance
9 of such a certificate.

10 "(b) AMOUNT.—The amount of the fee under this
11 section shall be an amount that is reasonably related to
12 the cost of issuing such certificates.

13 "(c) USE OF FEES.—The Secretary shall make all
14 of the fees collected pursuant to this section available sole-
15 ly to pay for the costs of issuance of such certificates.".

16 **TITLE II—DRUG AND DEVICE**
17 **SAFETY**

18 **SEC. 201. REGISTRATION FEE APPLICABLE TO PRODUCERS**
19 **OF DRUGS AND DEVICES.**

20 (a) PROHIBITED ACT.—Subsection (p) of section 301
21 (21 U.S.C. 331), as amended by section 101(a), is amend-
22 ed by striking "501(k);" and inserting "501(k), the failure
23 to pay an annual registration fee in violation of 736C,".

24 (b) REGISTRATION FEE.—Part 2 of subchapter C of
25 chapter VII is amended by adding at the end the following:

1 **"SEC. 736C. REGISTRATION FEE.**

2 "(a) IN GENERAL.—The Secretary shall assess and
3 collect an annual fee for registration under subsection (b),
4 (c), (d), or (i) of section 510 for the purpose of defraying
5 the costs of inspecting establishments registered under
6 such subsection to ensure that such establishments are in
7 compliance with the requirements of this Act relating to
8 drugs and devices.

9 "(b) AMOUNT OF FEE.—The amount of a fee under
10 this section shall be—

11 "(1) such amount as the Secretary determines
12 for establishments with respect to drugs; and

13 "(2) such amount as the Secretary determines
14 for establishments with respect to devices.".

15 (c) EFFECTIVE DATE.—The Secretary of Health and
16 Human Services shall first impose the fee established
17 under section 736C of the Federal Food, Drug, and Cos-
18 metic Act, as added by subsection (b), for fiscal years be-
19 ginning with fiscal year 2009.

20 **SEC. 202. INSPECTION OF PRODUCERS OF DRUGS, ACTIVE**
21 **PHARMACEUTICAL INGREDIENTS, DEVICES,**
22 **AND DEVICE PARTS.**

23 (a) PROHIBITED ACT.—Subsection (p) of section 301
24 (21 U.S.C. 331), as amended by sections 101(a) and
25 201(a), is amended by inserting before "or the failure to
26 provide a notice required by section 510(j)(2)" the fol-

1 lowing: "the introduction or delivery for introduction into
2 interstate commerce of any drug, any active pharma-
3 ceutical ingredient, any class II or III device, or device
4 part to such a device, as determined by the Secretary, be-
5 fore an initial inspection is complete in violation of section
6 510(h)(2),".

7 (b) INSPECTION.—Subsection (h) of section 510 (21
8 U.S.C. 351) is amended—

9 (1) by striking "(h)" and inserting "(h)(1)";

10 (2) by striking "Every establishment in any
11 State registered with the Secretary pursuant to this
12 section" and inserting "Every establishment reg-
13 istered with the Secretary pursuant to subsection
14 (b), (c), (d), or (i)"; and

15 (3) by adding at the end the following:

16 "(2) Upon receipt of an initial registration under sub-
17 section (b), (c), (d), or (i) for an establishment, the Sec-
18 retary shall ensure that such establishment is promptly
19 inspected pursuant to section 704. Until such initial in-
20 spection is complete, any drug (including any active phar-
21 maceutical ingredient) or class II or III device or any de-
22 vice part of such a device (as determined by the Secretary
23 that is manufactured, prepared, propagated, compounded,
24 or processed by such establishment shall not be introduced
25 or delivered for introduction into interstate commerce.

1 There shall be a new initial inspection of a drug or device
2 establishment when the establishment begins to manufac-
3 ture, prepare, propagate, compound, or process a drug, ac-
4 tive pharmaceutical ingredient, class II or III device, or
5 a part of such a device (as determined by the Secretary)
6 before its introduction or delivery into interstate commerce
7 unless the product constitutes only a minor modification
8 to a product previously manufactured, prepared, propa-
9 gated, compounded, or processed at the establishment..
10 "(3) A drug or device establishment, or employee of
11 such an establishment, that delays, limits, or denies an
12 inspection under this Act is subject to suspension of reg-
13 istration under section 510. If the Secretary determines
14 that such an establishment delays, limits, or denies such
15 an inspection, the establishment shall not place into inter-
16 state commerce any drug or device it manufactures, pre-
17 pares, propagates, compounds, or processes.".
18 (c) EFFECTIVE DATE.—
19 (1) IN GENERAL.—The amendments made by
20 this section shall apply to drugs introduced or deliv-
21 ered for introduction into interstate commerce on or
22 after the date that is 2 years after the date of the
23 enactment of this Act
24 (2) ESTABLISHMENTS ALREADY REGISTERED,
25 BUT NOT INSPECTED.—In the case of any establish-

1 ment that is registered under subsection (b), (c),
2 (d), or (i) of section 510 of the Federal Food, Drug,
3 and Cosmetic Act (21 U.S.C. 351) as of the effective
4 date specified in paragraph (1) but has not been in-
5 spected pursuant to section 704 of such Act (21
6 U.S.C. 374) as of such date, such amendments shall
7 not apply until 2 years after such effective date.

8 **SEC. 203. DOCUMENTATION FOR ADMISSIBILITY OF DRUG**
9 **IMPORTS.**

10 Section 801 (21 U.S.C. 381), as amended by sections
11 112 and 122, is amended by adding at the end the fol-
12 lowing:

13 "(r) Beginning 3 years after the date of enactment
14 of this subsection, a drug shall only enter the United
15 States, other than only for personal use, through a port
16 of entry that is located in a metropolitan area with a fed-
17 eral testing laboratory, unless the party offering that drug
18 for import provides the Secretary, at the time of offering
19 the drug for import, documentation demonstrating compli-
20 ance with applicable requirements pertaining to identity,
21 strength, quality, purity, approval, listing, labeling, and
22 registration. The Secretary may require that such docu-
23 mentation include verification of compliance by an accred-
24 ited third party or by the Secretary during an inspection
25 within the past two years, and such other information as

1 the Secretary determines is necessary for protection of the
2 public health.".

3 **SEC. 204. ORIGIN OF INGREDIENTS.**

4 (a) IN GENERAL.—Section 501(a)(2) (21 U.S.C.
5 351(a)(2)) is amended by inserting after "; or" at the end
6 the following: "or (D) if it is a drug and it bears, contains,
7 or consists of an active or inactive ingredient and the man-
8 ufacturer of that ingredient and of each drug that contains
9 that ingredient does not have, and provide to the Secretary
10 upon request, adequate documentation to establish where
11 the ingredient was made, including all previous producers
12 and manufacturers, that the ingredient is not adulterated
13 or misbranded, that the ingredient will perform in accord-
14 ance with specifications, is not contaminated, and does not
15 have any undisclosed additives, and that the ingredient
16 was manufactured, distributed, shipped, warehoused,
17 processed, brokered, imported, and conveyed under condi-
18 tions that ensure the identity, strength, quality, and purity
19 of the drug; or".

20 (b) EFFECTIVE DATE.—The amendment made by
21 subsection (a) shall take effect on a date, specified by the
22 Secretary of Health and Human Services, not later than
23 3 years after the date of the enactment of this Act.

1 **SEC. 205. TESTING FOR DRUG PURITY AND IDENTITY.**

2 (a) IN GENERAL.—Section 501(a)(2) (21 U.S.C.
3 351(a)(2)), as amended section 204(a), is amended by in-
4 serting after "; or" at the end the following: "or (E) if
5 it is a drug, unless each manufacturer of the finished dos-
6 age form, active ingredients, and inactive ingredients con-
7 tained in or consisting of that drug verifies its product's
8 purity and identity using scientifically sound and appro-
9 priate methods of sufficient analytical precision and speci-
10 ficity to detect and quantify the product separate from
11 contaminants, impurities, and adulterants; or (F) if it is
12 a drug, unless each manufacturer of an active pharma-
13 ceutical ingredient contained in or consisting of that drug
14 periodically evaluates its ingredient's impurity profile to
15 verify that it remains substantially similar to or better
16 than the profile of the lot (or lots) used in the clinical
17 studies and/or toxicological evaluation. If no clinical stud-
18 ies or toxicological evaluation was conducted, then the im-
19 purity profile shall determined according to standards to
20 be established by the Secretary; or".

21 (b) EFFECTIVE DATE.—The amendment made by
22 subsection (a) shall take effect on a date, specified by the
23 Secretary of Health and Human Services, not later than
24 3 years after the date of the enactment of this Act.

1 **SEC. 206. COUNTRY OF ORIGIN LABELING.**

2 (a) DRUGS AND DEVICES.—Section 502 (21 U.S.C.
3 352) is amended by adding at the end the following:

4 "(y) If it is a drug or device and—

5 "(1) its labeling fails to identify the country (or
6 countries) which is the source of the active pharma-
7 ceutical ingredient in whole or in part and of its
8 place of manufacture in the case of a drug, or the
9 country of manufacture in the case of a device; or

10 "(2) in the case of a drug the website of the
11 manufacturer of the drug does not list the country
12 of origin for any drug ingredient of such drug.".

13 (b) REGULATIONS.—Not later than 180 days after
14 the date of the enactment of this Act, the Secretary shall
15 promulgate final regulations to carry out section 502(y)
16 of the Federal Food, Drug, and Cosmetic Act, as added
17 by subsection (a).

18 (c) EFFECTIVE DATE.—The requirement of section
19 502(y) of the Federal Food, Drug, and Cosmetic Act, as
20 added by subsection (a), takes effect 2 years after the date
21 of the enactment of this Act.

22 **SEC. 207. RECALL AUTHORITY FOR DRUGS.**

23 Subchapter E of chapter V is amended by adding at
24 the end the following:

1 **"SEC. 568. RECALL AUTHORITY FOR DRUGS.**

2 "The Secretary shall have the same authority with
3 respect to drugs as the Secretary has with respect to de-
4 vices under section 518(e). In applying the previous sen-
5 tence, any reference in such section to a device shall be
6 deemed a reference to a drug.".

7 **SEC. 208. DESTRUCTION OF ADULTERATED, MISBRANDED**
8 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**
9 **PORT.**

10 (a) IN GENERAL.—The fifth sentence of section
11 801(a) (21 U.S.C. 381(a)) is amended by inserting before
12 the period at the end the following: ", except that any
13 product that is refused admission may, at the discretion
14 of the Secretary, be destroyed and not exported if (1) it
15 appears to pose a risk of injury or death, or (2) has a
16 value of less than $2,000, as determined by the Sec-
17 retary".

18 (b) EFFECTIVE DATE.—The amendment made by
19 subsection (a) shall take effect the date of the enactment
20 of this Act, regardless of when the product may have been
21 refused admission.

22 **SEC. 209. ADMINISTRATIVE DETENTION OF DRUGS THAT**
23 **APPEAR TO VIOLATE THE LAW.**

24 (a) IN GENERAL.—Section 304(g) (21 U.S.C.
25 334(g)) is amended—

1 (1) by inserting "drug or" before "device" each
2 place it appears; and
3 (2) in paragraph (1), by inserting after "adul-
4 terated or misbranded" the following: "or, in the
5 case of a drug, which in the determination of the of-
6 ficer or employee making the inspection appears to
7 be in violation of section 505,".
8 (b) EFFECTIVE DATE.—The amendments made by
9 subsection (a) shall take effect on a date, specified by the
10 Secretary of Health and Human Services, not later than
11 1 year after the date of the enactment of this Act.
12 (c) TRANSITION.—Until such time as the Food and
13 Drug Administration issues regulations to carry out the
14 amendments made by subsection (a), the regulations ap-
15 plicable under section 304(g) of the Federal Food, Drug,
16 and Cosmetic Act shall apply to drugs, as included by the
17 amendment made by such amendments.
18 **SEC. 210. CIVIL MONEY PENALTIES FOR VIOLATIVE DRUGS**
19 **AND DEVICES AND IMPROPER IMPORT**
20 **ENTRY FILINGS.**
21 (a) IN GENERAL.—Section 303 (21 U.S.C. 333) is
22 amended by adding at the end the following:
23 "(h)(1) Any person who violates a requirement of this
24 Act that relates to drugs and devices for human use shall
25 be liable to the United States for a civil penalty not to

1 exceed $100,000 per violation. Each day during which a
2 violation continues shall be considered a separate viola-
3 tion.

4 "(2) Any person, including a manufacturer, dis-
5 tributor, importer, broker, or filer, who knowingly reports
6 or enters false data on documents related to the introduc-
7 tion of drugs and devices in interstate commerce shall be
8 liable to the United States for a civil penalty not to exceed
9 $150,000. Each act of reporting or entering false data
10 shall be considered a separate violation.

11 "(3) The provisions of paragraphs (2), (5), (6), and
12 (7) of subsection (g) shall apply to a civil money penalty
13 under paragraph (1) or (2) of this subsection in the same
14 manner as they apply to a civil money penalty under sub-
15 section (g)(1).".

16 (b) EFFECTIVE DATE.—The amendment made by
17 subsection (a) shall apply to violations occurring on or
18 after the date of the enactment of this Act.

19 TITLE III—COSMETIC SAFETY

20 **SEC. 301. REGISTRATION OF COSMETIC FACILITIES.**

21 (a) IN GENERAL.—Chapter VI is amended by adding
22 at the end the following new section:

23 **"SEC. 604. REGISTRATION OF FACILITIES.**

24 "(a) IN GENERAL.—The Secretary shall by regula-
25 tion require that any facility engaged in manufacturing,

1 processing, packing, or holding of cosmetics in the United
2 States or for import to the United States be registered
3 with the Secretary.

4 "(b) APPLICATION OF FOOD REGISTRATION RULES
5 AND REGISTRATION FEE.—Except as provided in this sec-
6 tion, the provisions of section 415 and section 741 shall
7 apply to registration of cosmetic facilities under subsection
8 (a) in the same manner as they apply to registration of
9 facilities (as defined in section 415(b)) under such respec-
10 tive section, except that, with respect to registration fees
11 imposed under this subsection, any reference in section
12 741 to 'food' is deemed a reference to 'cosmetics'. Each
13 facility shall list in the registration the cosmetic products
14 it manufactures, processes, packs, or holds and, in the
15 case of a manufacturing facility, a list of the ingredients
16 for each product so listed that it manufactures.

17 "(c) ADVERSE EVENT REGISTRY.—The Secretary
18 shall by regulation require a facility that manufactures
19 cosmetics to report to the Secretary all anticipated and
20 unanticipated serious adverse events relating to the use
21 of cosmetics it has manufactured.

22 "(d) GOOD MANUFACTURING PRACTICES.—The Sec-
23 retary shall by regulation require that the methods used
24 in, and the facilities and controls used for the manufac-
25 ture, process, packing, or holding of a cosmetic conform

1 to good manufacturing practices as prescribed in such reg-
2 ulations.".
3 (b) EFFECTIVE DATES.—
4 (1) REGISTRATION AND FEES.—Cosmetic facili-
5 ties shall be required to register (and pay registra-
6 tion fees) under subsections (a) and (b) of section
7 604 of the Federal Food, Drug, and Cosmetic Act,
8 as added by subsection (a), beginning 6 months
9 after the date of the enactment of this Act.
10 (2) ADVERSE EVENT REGISTRY AND GOOD MAN-
11 UFACTURING PRACTICES.—The Secretary of Health
12 and Human Services shall establish the adverse
13 event registry and the good manufacturing practices
14 under the amendment made by subsection (a) not
15 later than 18 months after the date of the enact-
16 ment of this Act.

17 TITLE IV—MISCELLANEOUS

18 SEC. 401. REGISTRATION AND FEE FOR COMMERCIAL IM-
19 PORTERS OF FOOD, DRUGS, DEVICES, AND
20 COSMETICS.

21 (a) PROHIBITIONS.—Section 301 (21 U.S.C. 331), as
22 amended by sections 107(a) and 113(a), is further amend-
23 ed by adding at the end the following:
24 "(qq) The importation of food, drugs, devices, or cos-
25 metics other than only for personal use by an importer

1 that is not registered with respect to such food, drugs,
2 devices, or cosmetics under section 415, 510, or 604, re-
3 spectively, unless the importer is registered under section
4 801(s).".

5 (b) REGISTRATION.—Section 801, as amended by
6 sections 112, 122, and 203, is amended by adding at the
7 end the following:

8 "(s) The Secretary shall by regulation require that
9 an importer of food, drugs, devices, or cosmetics, other
10 than only for personal use, that is not registered with re-
11 spect to such food, drugs, devices, or cosmetics under sec-
12 tion 415, 510, or 604, respectively, shall be registered with
13 the Secretary in a form and manner specified by the Sec-
14 retary. The Secretary shall assign a unique identification
15 number to each importer so registered.".

16 (c) FEE.—Subchapter C of chapter VII is amended
17 by adding at the end the following:

18 **"PART 6—IMPORTERS OF FOOD, DRUGS,**
19 **DEVICES, AND COSMETICS**

20 **"SEC. 742. IMPORTERS OF FOOD, DRUGS, DEVICES, AND**
21 **COSMETICS.**

22 "(a) IN GENERAL.—The Secretary shall assess and
23 collect an annual fee for the registration of an importer
24 of food, drugs, devices, or cosmetics under section 801(s).

1 "(b) AMOUNT OF FEE.—The amount of the fee under
2 this section shall be $10,000.".
3 (d) EFFECTIVE DATE.—
4 (1) REGISTRATION.—Not later than 1 year
5 after the date of the enactment of this Act, the Sec-
6 retary of Health and Human Services shall establish
7 procedures for the registration of importers under
8 section 801(s) of the Federal Food, Drug, and Cos-
9 metic Act, as added by subsection (a).
10 (2) REGISTRATION.—The amendments made by
11 this section shall first apply not later than 1 year
12 after the date of the enactment of this Act.
13 **SEC. 402. UNIQUE IDENTIFICATION NUMBER FOR FOOD,**
14 **DRUG, AND DEVICE FACILITIES AND ESTAB-**
15 **LISHMENTS.**
16 (a) FOOD AND COSMETICS.—Section 415(a)(3) (21
17 U.S.C. 350d(a)(3)) is amended by adding at the end the
18 following: "Such a registration number shall be a unique
19 identification number for each such facility that may be
20 used for purposes other than registration under this sub-
21 section.".
22 (b) DRUGS AND DEVICES.—Section 510(e) (21
23 U.S.C. 360(e)) is amended by adding after the first sen-
24 tence the following: "Such a registration number shall be
25 a unique identification number for each such establish-

1 ment that may be used for purposes other than registra-
2 tion under this subsection.".

3 (c) APPLICATION TO COSMETICS.—The amendment
4 made by subsection (a) applies to cosmetics through the
5 operation of section 604 of the Federal Food, Drug, and
6 Cosmetic Act, as added by section 301(a).

7 (d) APPLICATION TO IMPORTERS.—See section
8 402(b) of this Act for the requirement for a unique identi-
9 fication number for importers that are registered.

10 (e) EFFECTIVE DATE.—The Secretary of Health and
11 Human Services shall implement the amendments made
12 by this section not later than 1 year after the date of the
13 enactment of this Act.

14 **SEC. 403. DEDICATED FOREIGN INSPECTORATE.**

15 Section 704 (21 U.S.C. 374) is amended by adding
16 at the end the following:

17 "(h) The Secretary shall establish and maintain a
18 corps of inspectors dedicated to inspections of foreign
19 food, drug, device, and cosmetics facilities and establish-
20 ments. This corps shall be staffed and funded by the Sec-
21 retary at a level sufficient to allow it to conduct inspec-
22 tions of foreign food, drug, device and cosmetic facilities
23 and establishments at a frequency at least equivalent to
24 the inspection rate of domestic food, drug, device, and cos-
25 metic facilities and establishments.".

1 **SEC. 404. CONTINUED OPERATION OF FIELD LABORA-**
2 **TORIES.**
3 (a) IN GENERAL.—Subject to subsections (b) and
4 (d), the Secretary of Health and Human Services (in this
5 section referred to as the "Secretary") shall not—
6 (1) terminate any of the 13 field laboratories
7 that were operated by the Office of Regulatory Af-
8 fairs of the Food and Drug Administration as of
9 January 1, 2007;
10 (2) consolidate any such laboratory with any
11 other laboratory;
12 (3) terminate any of the 20 district offices or
13 any of the inspection or compliance functions of any
14 of the 20 district offices of the Food and Drug Ad-
15 ministration functioning as of January 1, 2007; or
16 (4) consolidate—
17 (A) any such district office with an office
18 in any other district; or
19 (B) transfer any of the compliance or in-
20 spection functions of any such district office to
21 any other district.
22 (b) REPORT BY SECRETARY.—
23 (1) SUBMISSION.—The Secretary shall submit a
24 reorganization plan involving the termination or con-
25 solidation of the laboratories, the district offices, or
26 the functions of such district offices specified in sub-

1 section (a) to the Comptroller General of the United
2 States, the Committee on Energy and Commerce of
3 the House of Representatives, and the Committee on
4 Health, Education, Labor, and Pensions of the Sen-
5 ate.
6 (2) CONSULTATION.—In preparing the reorga-
7 nization plan described in paragraph (1), the Sec-
8 retary shall consult with personnel and unions to be
9 affected by the plan.
10 (c) REPORT BY GAO.—The Comptroller General
11 shall study the cost effectiveness of the reorganization
12 plan described in subsection (b) and its impact on the
13 safety of food, drug, and other products regulated under
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
15 et seq.) and the Public Health Service Act (42 U.S.C. 201
16 et seq.) and report to the Committee on Energy and Com-
17 merce of the House of Representatives and the Committee
18 on Health, Education, Labor, and Pensions of the Senate.
19 (d) REORGANIZATION.—
20 (1) CONGRESSIONAL REVIEW.—The reorganiza-
21 tion plan described in subsection (b) is deemed to be
22 a major rule (as defined in section 804(2) of title 5,
23 United States Code) for purposes of chapter 8 of
24 such title.

1 (2) EFFECTIVE DATE.—Notwithstanding sec-
2 tion 801(a)(3) of title 5, United States Code, the re-
3 organization plan described in subsection (b) shall
4 take effect (unless disapproved under section 802 of
5 such title) on the date that is specified in such plan,
6 but not earlier than 180 days after the date on
7 which the Comptroller General submits the report
8 required by subsection (c).

9 **SEC. 405. FALSE OR MISLEADING REPORTING TO FDA.**

10 (a) IN GENERAL.—Section 301(q)(2) (21 U.S.C.
11 331(q)(2)) is amended by inserting after "device" the fol-
12 lowing: "food, drug, or biological product".

13 (b) EFFECTIVE DATE.— The amendment made by
14 subsection (a) shall apply to submissions made on or after
15 the date of the enactment of this Act.

16 **SEC. 406. APPLICATION TO BIOLOGICAL PRODUCTS.**

17 Under section 351(j) of the Public Health Service Act
18 (42 U.S.C. 262(j)), the amendments made to the Federal
19 Food, Drug, and Cosmetic Act by this Act shall also apply
20 to biological products.

21 **SEC. 407. LIMITATION TO COMMERCIAL IMPORTATION.**

22 Nothing in this Act, or the amendments made by this
23 Act, shall be construed as applying to importation other
24 than commercial (and not personal) importation.