REAUTHORIZATION OF THE MEDICAL DEVICE USER FEE AND MODERNIZATION ACT

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BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

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WEDNESDAY, MAY 16, 2007

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

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2322 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. (chairman) presiding.

Members present: Representatives Pallone, Waxman, Eshoo, Green, DeGette, Capps, Hooley, Matheson, Deal, Shadegg, Pitts, Ferguson, Murphy, and Burgess.

Staff present: John Ford, Jack Mariho, Bobby York, Virgil Miller, Melissa Sidman, Ryan Long, Nandan Kenkeremath, and Chad Grant.

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

Mr. PALLONE. We will call the meeting to order. Today we are having a hearing on the reauthorization of the Medical Device User Fee and Modernization Act and I will recognize myself for an opening statement. First of all, good morning and thank you for being here today. I know we have two panels and you are the first one. We will start out with opening statements, though, and then we will go to the panel.

Recent innovations in medical devices have provided us with new possibilities in treating illness and delivering healthcare services. Today we are witnessing medical innovations that would have been considered unthinkable just a few years ago but now are considered commonplace. New breakthroughs in medical device technology have empowered patients and providers to achieve better clinical outcomes with less invasive procedures and shorter recovery times. As the medical device industry continues to innovate, we, as policymakers, have a responsibility to ensure that the FDA has the financial and human resources necessary to provide for a timely review of the latest inventions in medical technology.

In an attempt to achieve this goal, Congress passed the Medical Device User Fee and Modernization Act, or MDUFMA, of 2002, which established for the first time a user fee program for medical devices that was modeled after the Prescription Drug User Fee Program, which we are also working to reauthorize this year. This legislation was necessary due to inadequate resources at the FDA.

As applications began to pile up, it became clear that there was a need to implement a new revenue stream to improve the time in which new and innovative medical devices could be approved by FDA, and that is as true today as it was 5 years ago.

While FDA has been meeting its performance goals under MDUFMA I, the demand on FDA to ensure that devices are safe and effective has grown significantly in the past few years and will continue to do so. Innovations in the medical device industry that will transform our healthcare system will continue to rapidly develop and will likely require even greater resources from the FDA. But accordingly, it is important that this committee reauthorize MDUFMA so that FDA can continue to fulfill its job of regulating medical devices and safeguarding the public health.

I want to thank all of the people that worked hard to bring this proposal together. Having had the chance to review it, though, I do have some concerns. First and foremost, noticeably absent from the proposals appears to be any provisions relating to post-market surveillance of medical devices. In MDUFMA I, there was an authorization for appropriations for post-market surveillance activities. Even though these funds were never appropriated under the previous Republican-led Congresses, at least there was some recognition about the need to fund post-market surveillance activities. There are no such provisions in the MDUFMA II proposal that I am aware of.

This obviously raises some concerns for me. Most importantly, for anyone who has been paying attention to the Prescription Drug User Fee Act, PDUFA, which has been reauthorized a number of times, that in the first few reauthorizations to that program, user fees were mostly set aside to fund pre-market activities, largely ignoring any of the post-market responsibilities at FDA to ensure that drugs are safe once they are already on the market. Under the MDUFMA II proposal, I see a recurring pattern where, once again, FDA and the industry have managed to agree on performance goals for achieving expedited review of medical devices, but failed to address the post-market surveillance issues, which are equally as important, so we will have to take a long and hard look at this and it may be necessary to ensure some of the user fees collected under MDUFMA II are designated for post-market surveillance activities.

On another issue, I am also concerned about the reprocessing of single-use devices, or SUDs. MDUFMA I attempted to address the potential risk of infection and device malfunction that might arise from the reprocessing of single-use devices. Over the past year I have been following this issue closely, especially in my home State of New Jersey, and I continue to be alarmed about the reprocessing of SUDs and at a minimum believe that patients should be made aware of when a single-use device that has been reprocessed is being used on them during a procedure. As this problem persists, I am worried that the MDUFMA II proposal does not focus on SUDs at all, with the exception that SUD reprocessors pay the proposed annual establishment fee, and further regulation may be required.

In closing, I just want to say that I know, during the first MDUFMA authorization, there was tremendous bipartisan support within our committee to reach an agreement on behalf of patients,

providers and the industry. I hope that we can proceed in a similar fashion as we move forward with reauthorizing this program, because the health and wellbeing of many of my friends, family and constituents certainly depend upon it. And I would like to now recognize the ranking member, Mr. Deal.

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

Mr. DEAL. Thank you, Mr. Chairman. I will be brief. The Medical Device User Fee Program was first enacted in 2002 to try to improve FDA's device review capabilities to get safe and effective devices to patients more quickly. Like any new program, it has experienced its own challenges in achieving that goal, some of which Congress has already had to address through legislation.

As we evaluate reauthorization for the first time, I know some of the problems like funding adequacy and fee predictability have helped to form changes in the reauthorization proposal before us. Small businesses are a vital component of the medical device industry and I was pleased to see that the agreement reached between the FDA and industry sought to balance the diverse needs of both small and large manufacturers.

I look forward to hearing the witnesses' thoughts on some of the successes and shortcomings of the program and I am sure their testimony will be helpful to our committee as we attempt to reauthorize the legislation. I yield back.

Mr. PALLONE. Thank you. Mr. Waxman.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman. Medical devices are certainly important and they are growing in importance and in complexity. We need these devices for so many different purposes. Contact lenses improve our vision, artificial joints help people walk, and pacemakers keep many alive and well. With this growth in medical devices, the challenges are growing as well for the Food and Drug Administration and FDA needs adequate resources to meet these challenges.

Under the 2007 negotiated package, the Device Center would receive an increase in user fees, but I am concerned, however, that that is not nearly enough to make up for what has been years of underfunding. I am worried that exchange for what is only a modest increase in user fees, FDA is now making a commitment to conduct even faster reviews of medical devices. If the effect of these performance goals is to hinder FDA's ability to conduct thorough and complete reviews, it is the American public that will suffer from an exposure to unsafe and ineffective devices. Now that is before the drug is approved. But we also need to be aware of the fact that there must be a surveillance after the device—I said drug—device has been approved, but we need to be aware of and to deal with the post-marketing problems in this area, as we must in the pharmaceutical area.

If FDA is seeking to speed up its review of device applications, I think we need to examine whether there are adequate resources

to effectively monitor and oversee the safety of these devices once they are on the market. The attention and resources directed at conducted speedier reviews has apparently detracted from other responsibilities like inspections. More than 20,000 firms now produce medical devices for the U.S. market and at the current rate, FDA will inspect a device firm only about once every 10 years on average, this despite the fact that FDA is required by law to conduct inspections once every 2 years.

I am also troubled by the proposed changes to FDA's Third-Party Inspection Program. Under this program companies can pay a fee to get an inspection by an outside person accredited by FDA. To date we have seen very poor results from this. FDA has spent $3 million implementing it and there have been a total of three inspections by these third parties and I am concerned that we are allowing outsiders to do what is essentially an FDA job. Yet the negotiated proposal contains provisions that would expand its use. Instead of putting resources into training outsider parties to conduct inspections, we should be getting those desperately needed dollars into FDA's own inspection program.

We owe it to FDA and the American public to ensure FDA has the resources and authority it needs to guarantee our medical devices are safe and effective, both before they go on the market and throughout their lifecycle. I look forward to hearing from witnesses on this subject and how we can accomplish these goals. I wish we weren't even asking for user fees. We ought to pony up the appropriations necessary because of the essential government purpose of having an FDA. If user fees are going supplement those appropriations, we ought to make sure that there are enough appropriations to go along with the user fees so FDA can do the job before it. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Waxman. Mr. Ferguson.

OPENING STATEMENT OF HON. MIKE FERGUSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. FERGUSON. Thank you, Mr. Chairman, and thanks for holding this hearing and I know we have two distinguished panels of witnesses today, so I too will be brief.

I was listening to Mr. Waxman talk about the different devices and products that fall under this program and I am thinking to myself, my dad has two artificial hips, my father-in-law has two artificial knees, I think I am a ticking time bomb, but I think every one of us, if we haven't in our life had an opportunity to use or benefit from one of these devices, we certainly will, probably, sometime in the future and it really highlights how important the Medical Device User Fee Program has become.

It has been successful. It has facilitated the approval and the breakthrough for medical devices and allowing them to reach the market and to benefit patients. It is essential that we reauthorize this program soon, so that the FDA has the resources it needs to ensure that the public and our constituents have access to safe and effective medical devices. I certainly look forward to hearing from our two panels of witnesses today and thank you, Mr. Chairman, for holding this hearing and I yield back.

Mr. PALLONE. Thank you. Mrs. Capps.

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

Mrs. CAPPS. Thank you, Chairman Pallone, for holding this hearing, and to our witnesses for your testimony. I have served in Congress 9 years now and even during this time, we have all seen such an incredible jump in the number of medical devices being created and put out on the market. Those of us who represent districts in California note that our State has been a leader in this industry and it is not going down, it is continuing to advance.

Clearly the spike in applications has created a drain on FDA and thus, this Congress has enacted MDUFMA, but of course, the formulas were unpredictable and we had to come in and institute last-minute fixes to ensure predictable revenues for the Food and Drug Administration. And I think this is really important to keep in mind as we move to reauthorize MDUFMA, because it highlights the need to place more weight on appropriated funding rather than on user fees.

In my opinion, we have allowed PDUFA fees to control too great a percentage of the Food and Drug Administration's budget for drug approval and I hope our colleagues will join me in ensuring that we keep the user fees for device approval at a lower percentage so that we can better ensure integrity and avoid conflicts of interest. And speaking of conflicts of interest, I think we need to be extremely careful in how we address the issue of third-party inspections. Anything we can do to address and enhance the safety of devices is welcomed by all of us, but we need to make sure that we ensure that safety inspections are conducted by truly independent actors. And not be those with the financial interest in having the product out on the market. The consequences are way more expensive if we don't do that. It is basic common sense.

Finally, I hope that we can discuss disparities in the medical device field. We have found that devices are being manufactured with adult males in mind, even though women and children have a need for them as well. Our committee is slated to discuss pediatric devices on another day, but I hope we can discuss the ways in which we can utilize MDUFMA reauthorization process to encourage innovation in devices that suit the needs of women. So I hope, Mr. Chairman, that you are going to be amenable to that and again, thank you in advance to our witnesses and I look forward to the discussions today and I yield back.

Mr. PALLONE. Thank you. Mr. Pitts.

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

Mr. PITTS. Thank you, Mr. Chairman, and thank you for convening this hearing today on MDUFMA reauthorization.

Before 2002, the government funded the approval process for medical devices. It was really a mess. It significantly delayed FDA approval of new lifesaving medical devices and prevented patients from benefiting from new technologies, and to end this delay, as was noted, Congress unanimously passed the MDUFMA act in

2002 and it overcame the obstacles at the FDA that prevented timely approval of new lifesaving medical technologies without compromising the safety of consumers, and created a stable funding base for FDA, combining industry-paid user fees and congressional appropriations and as a result, the device approval time has been virtually cut in half.

And as we all know, unless Congress acts to reauthorize this successful program, it will sunset on October 1 of this year. And if we do not reauthorize the program in a timely fashion, FDA may be forced to issue a reduction-in-force notices to its employees. Federal regulations mandate that FDA must issue these notices at least 60 days prior to the expiration of the current MDUFMA program and this possibility could lead to a loss of highly qualified staff, staff who could easily find more lucrative employment elsewhere.

So on the whole, I believe the agreement reached between FDA and the industry is a good one and I would urge my colleagues to work toward a speedy reauthorization. And I would like to thank all of the witnesses who have come today. We look forward to your testimony and I hope that we don't find our self in the situation that I have talked about, in the future, and I yield back the balance of time.

Mr. PALLONE. Thank you. The gentlewoman from California, Ms. Eshoo.

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

Ms. ESHOO. Good morning, Mr. Chairman, and to our witnesses. Thank you for holding this important hearing on reauthorizing MDUFMA. As my colleagues know, I worked very hard with Mr. Barton and Mr. Greenwood, our former colleague, to enact the first authorization of MDUFMA 5 years ago and I think that it has been a success. Reauthorizations are very important because it gives us the opportunity to strengthen legislation, having the opportunity of looking over our shoulders to see how the original legislation has worked.

In the last 5 years, since the original authorization was passed, user fees have substantially increased the financial resources that FDA needs to review new products. FDA has been able to hire more employees, upgrade its equipment and increase its personnel expertise, which is very, very important in a complex area. In fact, the American people depend on that. The establishment of a third-party inspection program has helped ensure that manufacturing plants are inspected on a more regular basis by allowing FDA to utilize outside accredited inspectors to conduct inspections and provide reports to FDA. That was a real point of contention when we first authorized and it should be, because it is a very, very important determination to be made. So while I think that that was important and we did, I think, a pretty solid job in coming to consensus, I don't think that it is entirely safe to say that the program is perfect, but we have the opportunity to do that.

So with authorization, I think that we can improve, overall, the operations at FDA. I think we need to take a careful look at the length of time it takes for new devices to come to market, consider

ways that will expedite the approval process without compromising, of course, patient safety. I think we need to increase the industry's participation in the Third-Party Inspection Program and also improve the quality and the type of information FDA has access to regarding medical devices that are manufactured and marketed in our country.

Another area, Mr. Chairman, that I have a lot of concern about is that of pediatric device safety and we know that because children are still in stages of development, that that presents a difficult challenge for companies developing and manufacturing devices to keep up with growing bones and organs. And children experience unique side effects that we don't see in adult populations. So I think Congress has made some progress in enacting and enforcing pediatric drug testing laws, which I have had my hand in, but I think that we can do better with regard to devices. Mr. Markey and Mr. Rogers have offered legislation in this area and I hope that we will address the pediatric device issue in our reauthorization of MDUFMA.

So in closing, I would like reiterate my support for this. I have some ideas about how to make it stronger and better and I think that all of the stakeholders in this have done an initial good job of reaching some consensus and I look forward to working with everyone to not only reauthorize but be one of the real cheerleaders after we finish with it in saying job well done. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I think most of you know, but I will just mention it again, that next Tuesday we are going to have a hearing on the pediatric bills that need to be reauthorized. That is not to suggest that you can't get into that today, but we are going to have a separate hearing on the pediatric bills that need to be reauthorized next Tuesday. Next is Mr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman. I will submit my statement for the record. I do want to thank the witnesses for participating in this with us this morning and I think it is going to be lively and instructional and I look forward to their testimony. I yield back.

Mr. PALLONE. Thank you. Ms. DeGette.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman, for holding this hearing today. As the parent of a child who uses two medical devices every day to manage her Type I diabetes, I am acutely aware of how important they are to the health and wellbeing of millions of Americans. It is important, therefore, that we provide a stable source of funding to the FDA to assess the safety and efficacy of these devices before they can be marketed.

When the committee originally authorized MDUFMA in 2002, I authored the language that was added to the bill requiring the Institute of Medicine to conduct a study to determine whether the FDA system for post-market surveillance of medical devices provides adequate safeguards for their use in pediatric populations. Mr. Chairman, I know we are talking about pediatrics next week.

I won't be here because I have the honor of attending my elder daughter's high school graduation next week. So I just want to talk for a minute about my views on pediatrics today.

The IOM study which was released in 2005 details a number of important recommendations for further protection of children using medical devices. Specifically, the report cited a number of recommendations for Congress, including requiring the FDA to establish a system for monitoring and publicly reporting the status of post-market study commitments involving medical devices. Permitting the FDA to order post-market studies as a condition of clearance for the categories of devices, for which section 522 post-market surveillance studies are now allowed, and allowing the FDA to extend those studies for those devices with expected high pediatric use beyond the current 3-year limit. I look forward to hearing from our witnesses today about how these recommendations are or should be incorporated into the reauthorization of MDUFMA.

The report also highlighted several recommendations for the FDA that would not require statutory authority. These recommendations include collaboration with the NIH and the Agency for Healthcare Research and Quality to define a research agenda and priorities for the evaluation of the short and long-term safety and effectiveness of medical device use with growing and developing children; promoting the development and use of standards and approaches for capturing and linking use in outcomes data for medical devices; collaborating with industry, healthcare professionals and organizations and parent and patient advocates to improve adverse event reporting; overseeing the management of high-profile medical device safety issues, similar to the independent Drug Safety Oversight Board within the FDA; and establishing a central point of responsibility for pediatric issues, within the Center for Devices and Radiological Health, to evaluate the adequacy of the Center's use of pediatric expertise and its attention to pediatric issues in all aspects of its work.

Mr. Chairman, as we consider the reauthorization of MDUFMA, I look forward to hearing from witnesses about whether the FDA has adopted these recommendations and whether the MDUFMA package negotiated by the administration reflects further necessary changes. And with that, I yield back my time. Thank you.

Mr. PALLONE. Thank you. The gentlewoman from New Mexico, Mrs. Wilson.

OPENING STATEMENT OF HON. HEATHER WILSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW MEXICO

Mrs. WILSON. Thank you, Mr. Chairman. I appreciate your having this hearing today. The Medical Device User Fee Program is really important and I think it is much less controversial than the Prescription Drug User Fee Program that we had hearings on last week, and I hope that we can very rapidly reauthorize this program to provide some stability for the folks who are work on this.

There are two companies in my district that rely upon this legislation in order to get rapid approval for the devices that they manufacture, Johnson & Johnson, which has Ethicon Endo-Surgery and I have visited their plant where they package and sterilize surgical

products and medical devices, as well as, surprisingly for some folks, Intel Corporation, because anything that has a computer chip that is an implantable device has to get approval under MDUFMA.

My colleague from Denver has been one of the leaders on childhood diabetes in the Congress and that is particularly important in New Mexico, where the epidemic of diabetes has a disproportionate effect on the people that I represent and I represent a city with one of the highest percentages of Native Americans in the country and also a very high percentage of Hispanic citizens, and the increases in diabetes that we are seeing is really overwhelming. So one of the issues that I hope we will be looking at is whether there is priority given to those devices that might have a disproportionate public health effect. In other words, are there ways to make sure that things like continuous glucose monitoring devices, and things that have—is there a way to concentrate approvals or attention and resources on those devices that have a disproportionate effect on public health? And the answer to that may be no, but it is an issue that I would like to see us at least discuss and address.

I join my colleagues in agreeing that these medical innovations need to be kept moving forward and going through the pipeline so that they are brought to the market and that they are safe and effective, people can have confidence in them and they get to people who need them as quickly as possible. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. The gentlewoman from Oregon, Ms. Hooley.

OPENING STATEMENT OF HON. DARLENE HOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. HOOLEY. Thank you, Mr. Chairman. Although the first iteration of Medical Device User Fee and Modernization Act, MDUFMA, has encountered a number of challenges, the legislation has shown results. The FDA, industry, and most importantly, consumers benefit from a faster approval process enabled by MDUFMA's increased revenues. Timely approval of medical devices means that lifesaving devices get to patients more quickly. However, safety must be FDA's No. 1 priority. Increased resources and reauthorization of MDUFMA should enable the FDA to strengthen its review process to get devices to market more quickly and safely. More high-profile safety features have occurred on the drug side of FDA's review process than with devices. However, serious safety concerns have also arisen in recent years with a number of devices. We must ensure that FDA has the resources and authority to protect the public health. Investments and enhanced information technology, and hiring of more specialized experts enabled by MDUFMA's increased user fee, must be maximized to help better protect consumers.

Although user fees have increased as a percentage of the Center for Devices and Radiological Health budget, the proportion of user fees to appropriated funds remain much lower for devices than for drugs. It is critical to maintain that appropriate balance and I believe MDUFMA accomplishes that objective. MDUFMA's reauthorization also takes important steps to stabilize user fee funding. Increased predictability in user fee revenues will be beneficial to both

the FDA and industry, because regulators and industry will better be able to plan for their needs under the new fee structure.

Moreover, I am glad to see MDUFMA has recognized the vital role small businesses play in our robust medical device industry. According to the Government Accountability Office, small businesses account for approximately 20 percent of device applications in 2006. Fee reduction for small medical device businesses will help keep that important segment of the industry competitive. Finally, like with PDUFA, it is important to pass MDUFMA in a timely manner so FDA does not lose its best scientists. Thank you, Mr. Chairman, and I yield back.

Mr. PALLONE. Thank you. Mrs. Blackburn.

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

Mrs. BLACKBURN. Thank you, Mr. Chairman. Thank you for the hearing and I want to apologize to you and to our witnesses. We have an O&I Subcommittee hearing going on downstairs and I am going to need to step back to that. But I am pleased, as are my colleagues, to be talking about the reauthorization of MDUFMA.

I am amazed by the innovation that is taking place in this industry and I have seen it firsthand in my district, and many of the medical technology companies in my district are, as Ms. Hooley was saying, they are small business companies and it is imperative and so very important to them that this process work as smoothly, that we have an expedient process when they make their filings, and that they receive timely answers. We have one Tennessee device company that created a state-of-the-art mobile medical device training center, equipped with six surgical stations, highly advanced technology to train medical professionals on new orthopedic devices and it is an amazing technology and quite frankly, I think this is one of the most exciting areas of science and it is important for us to act responsibly and to make certain that we move forward with this legislation quickly.

I think that it is important for us to note that medical device research and development has more than doubled in terms of sales in the past 15 years and investment is continuing to grow, and what this tells me is that this is an area that consumers and our constituents are looking to for options to improve their quality of life and it is something that they are paying close attention to, so it is imperative that we continue to provide incentives for this innovation. We have seen some major breakthroughs due to medical devices and we must support initiatives such as health information technology, medical technology, will continue to transform our health delivery systems and the care that is available to our constituents.

I appreciate that the device industry and the FDA have reached an agreement on a reauthorization package. I am looking forward to hearing more about that today. I think we all have a few little questions that we would like to have answered and it is my hope that we will move forward in an expedient manner. Thank you again, Mr. Chairman, and I yield back.

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

Mr. SHADEGG. Mr. Chairman, I want to thank you for holding this hearing and I want to express my appreciation to our witnesses and with that, I will waive.

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

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

Mr. MURPHY. Thank you very much, Mr. Chairman, and I also appreciate this hearing. I too have a simultaneous hearing and I am going back and forth between these. But I wanted to thank you for an ongoing hearing that continues to deal with issues of patient-centered healthcare and these aspects of dealing with medical devices is quite important because it allows us to continue to focus on the issues of patient quality, patient safety and patient choice.

Along these lines, my hope is that as we move forward on any of these issues, that one of the aspects that we address has to do with reprocessed and reused medical devices that are brought under the regulation of the FDA. One of the concerns I have about reusing medical devices is that these devices were designed for optimum performance and safety under intended conditions of use and not necessarily the ease of cleaning or secondary use, which can oftentimes make them extremely difficult to sterilize and I worry sometimes that reusing medical devices can compromise their safety, and push for some review of devices for which they were never intended.

For example, a 2001 study of reuse of catheters found an increased risk of infection. Even after rigorous cleaning and sterilization, virus and bacteria were still present in the catheter, which, of course, can be deadly to a patient. We have to be reminded that some 90,000 lives are lost every year from infections in hospitals, some 2 million people are infected in hospitals and healthcare centers every year, and some $50 billion is spent annually dealing with, in many cases, preventable infections. I think patients have a right to know and to choose whether or not a medical device was designed for single use and has already been used in other patients and if they are going to be exposed to unnecessary risks.

One of the reasons I have introduced a bill, H.R. 1174, the Healthy Hospitals Act, would require all hospitals to publicly report their infection rates, which could easily apply to medical devices and in illness stemming from reuse of medical devices. So I look forward to hearing from the FDA and our witnesses today, specifically on how we can avoid unnecessary infections from medical devices, ways to incorporate patient safety and patient quality, and to this committee's efforts to ensure that new and existing medical devices are both effective and safe. And with that, I yield back my time.

Mr. PALLONE. Thank you. And I recognize our vice chairman, Mr. Green.

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

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing on the reauthorization of Medical Device User Fee and Modernization. I apologize for being late, but we have an Oversight and In-

vestigation Subcommittee hearing on British Petroleum downstairs and since 15 people near my district were killed 2 years ago, we have a real interest in that.

Congress first authorized FDA to collect user fees for the review of medical devices in 2002. While we have enacted a couple of bills to correct and stabilize the user fee for medical devices, we face our first comprehensive reauthorization of these fees. For regulatory purposes, medical devices are everything from the gloves that doctors wear when examining a patient, to heart valves implanted in individuals for the rest of their lives. The wide variety of medical devices regulated under the system necessitates that review and approval of post-market surveillance be appropriate for the type of device under regulation, all the while ensuring that we balance safety with a desire to bring these lifesaving devices to market in a timely manner.

In our first authorization, we sought to strike a balance by specifying that the FDA would utilize user fees for the pre-market reviews and inspection, the monitoring and research and evaluation of post-market studies, among other things. By providing user fee exceptions for small business, we attempted to facilitate their participation in the medical device industry. Likewise, the user fee exemptions for pediatric devices and humanitarian-use devices sought to ensure that children and individuals with rare diseases were able to benefit from the innovation within the device industry.

A perfect example is the FDA's approval of the DeBakey VAD, the name for renowned Houston surgeon, Dr. Michael DeBakey. His device, which is a miniature valveless blood pump used in children, was approved in February 2004 under the humanitarian-use exemption. The next month, a 6-year-old Houston girl was the first pediatric patient in the world who received this device which helps to improve blood flow for patients awaiting heart transplants. The device that a Houston company manufactures is a lifesaving device. Its first use was in Texas Children's Hospital on a child from Houston. It gives me pride in the innovation in medical miracles taking place in our community.

As we begin our work on reauthorization, we need to make sure that the user fee system continues to spur that innovation, but we also need to make sure that the pressure at the FDA to meet the increased performance goals doesn't create a culture of swift approval at the expense of safety. I would like to see an increased focus on post-market surveillance and safety at the Center and I look forward to hearing what resources we can provide to make sure we appropriately strike that balance when we bring devices to market and protecting the health of Americans. I look forward to hearing our witnesses. And Mr. Chairman, I yield back my time.

Mr. PALLONE. Thank you. I think we completed the opening statements of the Members. Any other statements for the record will be accepted at this time.

[The prepared statement of Mr. Dingell follows:]

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

Mr. Chairman, thank you for holding this hearing today. We are here to discuss the reauthorization of a very important piece of legislation, the Medical Device User Fee and Modernization Act, also known as MDUFMA. Originally passed in 2002,

this program provides valuable resources to the Food and Drug Administration to allow timely approval of safe and effective new medical devices. Additionally, MDUFMA includes important provisions that address standards for the reuse of single-use devices; that allow third-party inspections; that provide incentives for the industry to study the application of their devices on children; and that include a number of additional regulatory reforms.

While MDUFMA has worked well, we have twice made adjustments to the program through the 2004 Medical Devices Technical Corrections Act and the Medical Device User Fee Stabilization Act of 2005 to ensure its effectiveness and sustainability. Under current law, FDA's authority to collect medical device user fees expires on October 1, 2007.

FDA's proposal to reauthorize the medical device user fee program includes a variety of provisions that Congress will need to study. New fees would be established to provide sustainability and a sense of predictability; fees paid by small businesses would be further reduced; the third-party inspection program would be changed; performance goals would be shifted; and new innovative diagnostic tests would be developed.

In addition to these proposed device program changes, we must also discuss the issue of device safety. According to the Wall Street Journal, an internal report by FDA critiqued the agency's practices to ensure the safety of medical devices, such as defibrillators and pacemakers. The agency concluded that the monitoring system at the Center for Devices and Radiological Health lacked quality information on approved devices. At the same time, the agency concluded that the volume of information received exceeded the center's ability to consistently enter or review data in a routine matter. While the medical device user fee program was created to improve timeliness of device approvals, timeliness must not come at the cost of safety.

I understand that FDA is required to do much with limited resources. Because it does not receive adequate resources from Congress, the user fee program continues to increase as a percentage of FDA's resources. From fiscal year 2003 to 2008, MDUFMA funding has increased at a much faster rate (220.1 percent) than FDA's program level device review budget (31.3 percent). As a result, FDA becomes increasingly more dependent on the very industry it was created to regulate.

We must ensure that adequate enforcement tools, resources, and processes are in place to ensure that devices are safe and effective. When I supported the Medical Device User Fee and Modernization Act in 2002, I envisioned this program providing a down payment on an increased level of post-market surveillance. The current reauthorization provides us with a process to increase safety and compliance activity. FDA on its own has taken some steps to increase post-market safety, such as its "Post-market Transformation Initiative." We now have an opportunity to explore other ways to enhance safety.

We recognize that we must act fairly quickly to prevent a possible exodus of qualified staff and other experienced medical officers at FDA whose positions are funded by user fees. We ran into an unusual situation in 2005 when uncertainty as to whether corrective legislation would be enacted before the October 1, 2005, appropriations "trigger" date, required FDA to impose a hiring freeze in its Center for Devices and Radiological Health. In response to this problem, we passed the Medical Device User Fee Stabilization Act of 2005.

I appreciate the importance of this hearing. I look forward to the testimony of witnesses and the input of our Members as we discuss the MDUFMA reauthorization.

Mr. PALLONE. We will turn to our witnesses and I see our first panel is already seated, but welcome again. Let me introduce you briefly here. First, we have Dr. Jeffrey Shuren, who is Assistant Commissioner for Policy for the FDA, and he is accompanied by Dr. Daniel Schultz, who is Director of the Center for Devices and Radiological Health at the FDA. Thanks again for being here. We have 5-minute opening statements. They become part of the record. And if you want to, at the discretion of the committee, submit additional statements or comments, you can still do that later. So I will begin by recognizing Dr. Shuren.

STATEMENTS OF JEFFREY SHUREN, M.D., J.D., ASSISTANT COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY DANIEL G. SCHULTZ, M.D., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION

Dr. SHUREN. Thank you, Mr. Chairman and members of the subcommittee. We are pleased to be here today to discuss the importance of reauthorizing the Medical Device User Fee and Modernization Act before it expires on October 1, 2007.

In 2002, Congress enacted MDUFMA to improve the timeliness and predictability of device application review to help get safe and effective medical devices to patients and practitioners more quickly. Under MDUFMA, FDA receives user fees from industry, in addition to appropriated funds for the Medical Device Review Program, and in return for these additional resources, FDA is expected to meet performance goals that became more ambitious each year of the legislation.

In August 2005, Congress amended MDUFMA to provide more predictability for industry in the amount of user fees they pay by statutorily locking in a fixed annual fee increase of 8½ percent. MDUFMA I was about growth, progressively increasing the size of the Device Review Program through rapidly increasing funding linked to progressively more aggressive performance goals. For MDUFMA II, we are recommending changes to fine-tune the program, including funding to maintain a stable Device Review Program, while continuing to improve performance as a result of investments in a seasoned review staff and process efficiencies.

While my written testimony describes all of FDA's legislative recommendations, I would like to highlight three areas for refinement. First, for pre-market review performance, we are proposing to meet more rigorous goals that build on the progress we made in the first Medical Device User Fee Program. The result would be a shortened decision time for several types of applications, including those for the most innovative devices. In addition, we are proposing several qualitative goals to continue to enhance the device review process and to make it more transparent. For example, we are proposing additional steps to facilitate the informal interactions with manufacturers, what we call interactive review, providing guidance on the pathway to market for imaging devices that use contrast agents or radiopharmaceuticals, making public more information about our performance, and enhancing the review process for in vitro diagnostic tests, because they will play a critical role in personalized medicine.

Second, to ensure financial stability for the review program, we are recommending a reasoned increased in user fee revenues in the first year, followed by annual increases of 8½ percent for the 4 years thereafter. This will help ensure that we have adequate resources to maintain a stable device review program, while providing the predictability in the fees that industry pays for the duration of MDUFMA II.

We are also proposing two new fees that will generate about 50 percent of the total fee revenue, an annual establishment registration fee and an annual fee for filing period reports. The large number of device-making establishments that would pay a fee, an esti-

mated total of about 13,000, would stabilize our funding as well as allow us to lower the application fees and provide a larger fee discount for small businesses. The fee proposed is modest, about $1,700 in fiscal year 2008, but it would reduce the fiscal year 2008 standard fee for pre-market approval application, and that is those for the highest risk devices, to 65 percent of the 2007 rate. And the 2008 for small businesses for pre-market approval application would be reduced to 43 percent of the 2007 rate.

Third, we are recommending modest changes to the Third-Party Inspection Program to encourage industry participation while maintaining the strong safeguards against conflict of interest, because we are concerned about that as well.

FDA believes that reauthorization of the user fee legislation, with the improvements I just outlined, will result in benefits to public health. Continued improvement in device review times and greater transparency of the review process will mean that patients and practitioners will have access to safe and effective medical devices more quickly. Adequate and stable funding for FDA will provide FDA with the resources to maintain the cutting-edge expertise necessary to provide timely review and ensure the safety of increasingly complex devices of tomorrow. Finally, a successful Third-Party Inspection Program will enable FDA to better focus its inspectional resources on higher risk devices.

We thank all of you for your commitment to the mission of FDA and the continued success of our Medical Device Review Program and we look forward to working with you on MDUFMA II legislation. We would be happy to answer any questions you may have.

[The prepared statement of Dr. Shuren follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT BY

JEFFREY E. SHUREN, M.D., J.D.
ASSISTANT COMMISSIONER FOR POLICY

FOOD AND DRUG ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

May 16, 2007

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Jeffrey Shuren, Assistant Commissioner for Policy at the Food and Drug Administration (FDA or the Agency) and beside me is Daniel Schultz, Director of FDA's Center for Devices and Radiological Health. We are pleased to be here today to discuss the Agency's success in implementing the Medical Device User Fee and Modernization Act and to emphasize the importance of reauthorizing this law in advance of its October 1, expiration date.

BACKGROUND

MDUFMA I

As you know, in 2002, Congress enacted the Medical Device User Fee and Modernization Act (P.L. 107-250, October 26, 2002) (MDUFMA), aimed primarily at improving the timeliness, quality, and predictability of medical device application review. The House Report to the MDUFMA legislation commented that FDA's device review program lacked the resources to keep up with a rapidly growing industry and increasingly complex technology. (U.S. Congress, House Committee on Energy and Commerce, Medical Device User Fee and Modernization Act of 2002, report to accompany H.R. 3580, 107th Cong., 2nd sess., part 1 [Washington: GPO, 2002], pp.23).

Under MDUFMA, the industry provides additional funds through user fees that are available to FDA, to supplement appropriated funds, to spend on the device review process. Our

authority to collect and spend user fees is linked to – or "triggered" by – increased appropriations. We can collect and spend user fees only in years when the amount Congress appropriates for our entire medical device program keeps pace with a measure of inflation specified in MDUFMA.

The additional resources provided by medical device user fees allow FDA to meet performance goals defined in a letter from the Secretary of the Department of Health and Human Services to Congress. These goals include "FDA decision" goals, which require FDA to make a specific decision on most types of pre-market applications within a specified time (and similar goals that require FDA to "review and act on" certain biologics applications within a specified time), and cycle goals, which refer to FDA actions prior to a final Agency decision on a submission. These goals were progressively more ambitious each year for the duration of the legislation.

In addition to its provisions relating to medical device user fees and performance goals, MDUFMA contained other significant provisions. These include:

- Authorization for a program that allows establishment inspections to be conducted by third party accredited persons (APs), under carefully prescribed conditions.
- Establishment of a new office in the Office of the Commissioner to coordinate the review of combination products;

- Authorization to require electronic registration of device establishments, once FDA finds that electronic registration is feasible; and
- Explicit authorization for the "modular" review of pre-market approval applications (PMAs).

MDUFSA

In August 2005, Congress passed the Medical Device User Fee Stabilization Act (Public Law 109-43, August 1, 2005) (MDUFSA). MDUFSA modified several provisions of MDUFMA as follows:

- Repealed the fiscal year (FY) 2003 and FY 2004 appropriations trigger requirements;
- Modified the 2005-2007 minimum appropriation requirements for the device and radiological health line of FDA's appropriation to be within 1 percent of the calculated appropriations trigger;
- Specified user fee rates for FY 2006 and FY 2007, using 8.5 percent rate of increase each year;
- Expanded the definition of "small business" for FY 2006 and FY 2007, making more firms eligible for small business fees; and
- Repealed the "compensating adjustment" that allowed FDA to adjust user fee rates to make up for revenue lost when user fee revenues did not meet projections in a prior year.

MDUFMA ACHIEVEMENTS

The user fees provided by MDUFMA, and the annual appropriations, have allowed us to make significant improvements in the device review program. FDA's progress towards meeting MDUFMA's performance goals has been accomplished through:

- Targeted hiring, including medical specialists, statisticians, software experts, and engineers;
- Increased use of outside experts, particularly for novel technologies;
- Improvements to the IT systems, such as enhanced tracking of applications and reporting systems; and
- Additional guidance documents that assist industry in preparing their applications to better address regulatory and scientific issues, such as how to obtain expedited review of a pre-market submission, and how to use new statistical tools to enhance the value of clinical trial data.

These actions have led to improved FDA review times and greater predictability in the device review process.

In addition, we have made significant progress towards meeting other fundamental objectives of MDUFMA. For example, FDA established an Office of Combination Products that is improving coordination of combination product reviews. And, FDA met the statutory requirement to establish a third-party inspection program. This option may be particularly useful to U.S. firms who compete in international markets and are faced with multiple sets of

regulatory requirements, since a single third party inspection may satisfy both U.S. and foreign requirements and also may meet International Organization for Standardization (ISO) or other international standards requirements.

The program has produced significant benefits for public health. A better resourced device program has enhanced our abilities to keep pace with the increasing complexity of technology and changes in clinical practice. Since MDUFMA was enacted, FDA has approved more than 150 original PMAs. These have included devices intended to address unmet needs in the pediatric population, such as the first pediatric left-ventricular assist device, a cooling cap to treat severe hypoxic-ischemic encephalopathy in infants, and an expandable prosthetic rib to treat growing children with Thoracic Insufficiency Syndrome.

The device program also has approved important new laboratory tests, including the first test for use as an aid in diagnosing West Nile Virus, tests for diabetes management and newborn screening, tests for diagnosing cystic fibrosis, and a rapid screening test for lead poisoning that can be used at health care clinics, mobile health units, and schools. Device reviews have significantly contributed to the very important trend towards personalized medicine through clearance of test systems that can identify an individual's DNA to evaluate likely response to drug therapy.

In the area of women's health, FDA's device program approved an optical detection system to identify areas of potential cervical cancer, a non-invasive therapy system to treat uterine

fibroids with high-frequency ultrasound, and a clinical laboratory test to determine if a woman with breast cancer is a good candidate for Herceptin therapy.

Other important devices include the first carotid-stenting systems, a hip resurfacing system intended to treat younger patients who are not ready for hip replacements, and the first over-the-counter automatic external defibrillators.

REAUTHORIZATION

The user fee provisions of MDUFMA will sunset on October 1, 2007, if not reauthorized. In preparing our proposed recommendations for MDUFMA reauthorization, we have conducted technical discussions with regulated industry and have consulted each year with stakeholders at a public meeting as required by law. We published proposed recommendations for reauthorization on April 18, 2007; the comment period closes on May 18, 2007. We also held a public meeting on April 30, 2007, to obtain public input from all interested parties, including regulated industry, appropriate scientific and academic experts, health care professionals, and representatives of patient and consumer advocacy groups, on the proposed recommendations. Testimony at that meeting was generally supportive of our published recommendations.

PROPOSALS FOR MDUFMA II

Our goal for the legislative package to reauthorize medical device user fees and to make other improvements (MDUFMA II) is to build upon the performance goals we are pursuing for FY 2007 while providing reasonable and predictable user fees for industry and adequate and stable funding for FDA. Our proposed recommendations fall into two major categories: proposals to ensure sound financial footing for the device review program and proposals to enhance the process for pre-market review of device applications. We also are recommending modifications to the third party inspection program authorized by MDUFMA.

Proposed Recommendations to Ensure Sound Financial Footing

Although user fees have provided additional resources to FDA since the beginning of the program, resources for device review have not kept up with increasing costs. FDA as a whole has experienced an increase in its costs per FTE (including pay, benefits, and contract support) averaging 5.8 percent per year over the most recent five years. Non-salary costs, including the costs of rent and contract support, have also increased at the same rate per FTE. At the same time, our user fee revenue, which has been entirely dependent on the number of fee-paying applications submitted by industry, has not reached the levels anticipated when MDUFMA was enacted. These factors have impeded our business planning and delayed additional improvements to the device review program. We are proposing changes to the financial provisions of MDUFMA to place FDA on more sound financial footing, while providing industry with lower fees per application for most submissions. We believe these changes will help us continue and enhance the program.

1. Adjustment of Total Revenue for Device Review to Ensure a 6.4 percent Increase From Year to Year Over the Next Five Years

Detailed analysis of FDA's recent costs history, and increased costs FDA is anticipating over the next five years due to increased costs related to moving the Center for Devices and Radiological Health to the new White Oak facility necessitate annual increases of 6.4 percent just for FDA to maintain the current level of staff to support the device review process. The primary drivers of this rate of increase are rent, security, and statutorily mandated payroll and benefit increases. The industry has agreed to a fee structure designed to provide $287 million over the next five years. This will provide an approximately 31 percent increase in total fee revenue for 2008 and an 8.5 percent increase each subsequent year through 2012.

2. More Stable Fee Structure

Under MDUFMA I, fee revenues repeatedly fell short of expectations. All fee revenues were derived solely from application fees, which fluctuated significantly from year to year. For MDUFMA II, industry has agreed to two new fees that will generate about 50 percent of the total fee revenue and that will create a more stable structure than relying solely on application fees. They are an annual establishment registration fee and an annual fee for filing periodic reports. The addition of these new fees will allow for a significant reduction of existing application fees.

The establishment fee will be paid once each year by each device manufacturer, single-use device reprocessor, and specification developer. It is proposed to start at $1,706 in 2008 and

will generate about $21.8 million for FY 2008 (45 percent of total revenues), assuming that 12,750 establishments pay this fee. A firm will not be considered to be legally registered each year without the payment of this fee. An establishment's registration, listing, and registration fee payment would be completed electronically through a single on-line system.

The standard annual fee for filing periodic reports is proposed to start at $6,475 in 2008 and will generate about $2.5 million in FY 2008, or about 5 percent of fee revenues, assuming that we receive reports on 425 devices subject to periodic reporting and 10 percent pay the reduced small business fee of $1,619.

The remaining 50 percent of revenues will come from application fees. All proposed application fees will be significantly lower than they were in FY 2007. For example, the proposed fee for a Pre-Market Application (PMA) or Biologics Licensing Application (BLA) will be reduced from $281,600 in FY 2007 to $185,000 in FY 2008 and the fee for a 510(k) pre-market notification submission will be reduced from $4,158 in FY 2007 to $3,404 in FY 2008.

FDA is proposing two new application fees. They are (1) a fee for 30-day notices (making modifications to manufacturing procedures or methods) that will be 1.6 percent of the fee for a full PMA, and (2) a fee for a request for classification information under section 513(g) that will be 1.35 percent of the cost of a full PMA. Both of these applications require significant work for FDA, and the proposed fees reflect the work that they involve, on average. As

stated above, all of the fees will increase each year by 8.5 percent to ensure that fee revenues contribute their expected share to total program costs.

3. Changes in the Fee Structure for Small Businesses

To reduce the burden on small businesses, FDA is proposing to reduce small business fee rates for certain submissions. We are proposing to reduce the rates for small businesses for pre-market application, panel-track PMA applications, BLA efficacy supplements, 180-day PMA supplements, real-time PMA supplements, and annual reports from 38 percent to 25 percent of the full fee. We also are proposing to reduce the rates for small businesses for 30-day notices, 510(k) pre-market notification submissions, and 513(g) requests for classification information from 80 percent to 50 percent of the full fee. We are not proposing to change the criteria to qualify for small business status. However, we are proposing to expand the small business provisions to provide a way for foreign firms that do not file tax returns with the United States Internal Revenue Service to qualify for small business rates.

4. Electronic Registration and Listing

FDA believes electronic registration and listing are essential for efficient implementation of any proposal for an establishment registration fee. Therefore, we are proposing to change section 510(p) of the FD&C Act (21 U.S.C. 360(p)) to require all establishments to submit their registration and listing information by electronic means, except in those situations where FDA agrees that electronic registration is not reasonable. Electronic registration and listing will be faster and more efficient for industry and FDA.

5. Technical Changes to Increase Administrative Efficiency of the User Fee Program

We are also proposing to change the current offset provision of MDUFMA which requires us to reduce fees in a subsequent year if collections in any year exceed the amount appropriated. There currently is no parallel provision in MDUFMA to increase fees in a subsequent year if collections fall short of amounts appropriated from fees. We propose to aggregate all fees paid over the first four years of MDUFMA II and compare that amount to aggregate appropriations for the same period. A reduction will be made in fees in the final year only if the amount collected in the four-year period exceeds the amount appropriated for the same period. We believe aggregation over four years is fairer than treating each year separately. There would still be no parallel provision for increasing revenues if fees collected fall below appropriated amounts in aggregate.

Enhancing the Process for Pre-market Review

In the area of pre-market review, FDA is proposing enhancements in a number of areas:

- Improved performance goals;
- Interactive review;
- Guidance document development;
- Diagnostic imaging products;
- In vitro diagnostics;
- Meetings;
- Quarterly performance reports; and
- Reviewer training.

1. Improved Performance Goals

FDA is proposing goals for MDUFMA II that build on the progress made in MDUFMA I, taking into account the presence of more seasoned review staff and efficiencies accomplished in MDUFMA I and planned for in MDUFMA II. These efficiencies include additional scientific, regulatory and leadership training; additional staff, including those with expertise demanded by increasingly complex device reviews; expanded use of outside experts; and IT improvements.

In MDUFMA II, we propose to eliminate cycle goals, which we believe serve as an impediment to reaching the ultimate objective of getting safe and effective devices to patients and health care professionals more quickly. We believe that an unintended consequence of the cycle goals is that, because we must determine whether or not to send a major deficiency letter, "not approvable" letter, or other interim action earlier in the review process, we are less likely to have sufficient time to engage in informal interactions with industry to resolve outstanding questions before making that determination. Consequently, we are more likely to issue a formal interim letter. Because both FDA and industry would like to see greater informal interactions, we propose to eliminate cycle goals and focus our performance goals more closely on FDA decisions.

In MDUFMA II, we propose to improve our performance in reaching a final decision for expedited and non-expedited PMAs, panel track PMA supplements, and 510(k)s. We also propose to add a goal for PMA modules in MDUFMA II. And, where specific quantitative

goals have not been established (for example, Investigational Device Exemptions, or IDEs), we propose to maintain current review performance.

2. Interactive Review

We will continue to incorporate an interactive review process using all forms of communication and intended to: (a) prevent unnecessary delays in the completion of the review; (b) avoid surprises to the sponsor at the end of the review process; (c) minimize the number of review cycles and extent of review questions conveyed through formal requests for additional information; and (d) ensure timely and adequate responses from sponsors. Strengthening interactive review can help sponsors address Agency concerns and provide additional data, when necessary, earlier in the review process.

3. Guidance Document Development

We will continue to develop guidance documents to the extent possible without adversely impacting the review timeliness on MDUFMA-related submissions. In addition, FDA will post a list of guidance documents it is considering for development and provide stakeholders an opportunity to provide comments and suggestions for those topics as well as suggestions for new or different guidances.

4. Diagnostic Imaging Products

Diagnostic imaging devices are sometimes used concurrently with diagnostic drug and biological products (such as contrast agents and radiopharmaceuticals) in a way that does not meet the regulatory definition of a combination product. Nevertheless, such "concomitant

use products" present important questions of efficient regulation and consultation because multiple FDA review Centers and regulatory authorities may be involved as is often the case with combination products. To help ensure the timely and effective review of these products, and consistent and appropriate post-market regulation and product labeling requirements, FDA is proposing to develop a guidance document for diagnostic imaging devices used with approved imaging contrast agents and/or radiopharmaceuticals.

5. *In Vitro* Diagnostics (IVDs)

IVDs are devices used to diagnose diseases and other conditions. They will play an important role in personalized medicine. To facilitate the development of IVD devices, FDA will continue to explore ways to clarify the regulatory requirements and reduce regulatory burden. FDA proposes to:

- Draft or revise guidance on the conduct of clinical trials involving de-identified leftover specimens, clinical trial design issues for molecular diagnostic tests, migration studies, herpes simplex virus, enterovirus, and influenza testing;
- Conduct a pilot program of voluntary participants to evaluate the 510(k) review and Clinical Laboratory Improvement Amendments (CLIA) waiver application review processes for possible increased efficiencies through concurrent review;
- Consider industry proposals on acceptable CLIA waiver study protocols, develop acceptable protocol designs, and make them available by adding appendices to the CLIA waiver guidance or by posting redacted protocols on the OIVD website;

- Track our performance on CLIA waiver applications and evaluate whether CLIA waiver user fees and performance goals should be considered for MDUFMA III;
- Review a list of class I and II low risk IVD devices, provided by industry, to determine whether any could be exempted from pre-market notification and allow interested parties to petition for exemptions consistent with 510(m)(2); and
- Conduct a review of the pre-IDE program.

6. Meetings

FDA will make every effort to schedule both informal and formal meetings, including pre-submission meetings, determination meetings, agreement meetings, and 100-day meetings, held both before and during the review process, in a timely way. Industry will make every effort to provide timely and relevant information to make the meetings as productive as possible.

7. Quarterly Performance Reports

FDA will report quarterly on its progress toward meeting the quantitative goals described in the commitment letter. In addition, for all submission types, we will track total time (time with FDA plus time with the company) from receipt or filing to final decision. We also will provide de-identified review branch performance data for 510(k)s, 180-day supplements, and real-time supplements on an annual basis.

8. Reviewer Training

As resources permit, FDA will apply user fee revenues to support reviewer training that is related to the process for the review of devices, including training to enhance scientific expertise. We will provide summary information on an annual basis of the types of training provided to staff.

Third Party Inspection Program

FDA is proposing changes to the Third Party Accredited Persons (AP) inspection program in three major areas. These proposals are intended to: increase industry participation in the program, which to date has been minimal, and increase the quantity of information FDA has about the compliance status of medical devices marketed in the United States. The freeing-up of FDA's own inspectional resources from routine inspections will permit FDA to focus instead on firms and products posing the greatest risk to public health.

First, FDA is proposing to streamline the administrative processes associated with qualifying for the program. For example, rather than having to petition FDA for clearance to use an AP, the proposal would require only that a firm provide FDA with prior notice of intent to use an AP, along with information about the date of last FDA inspection, identity of AP selected, and certification that the firm markets, or intends to market, at least one device in a foreign country that recognizes the AP as a person authorized to conduct device inspections. If FDA does not require additional information from the firm within 30 days of that notice, the firm is deemed to have clearance to participate in the program.

Second, we are proposing to expand participation in the program. For example, the current AP program restricts qualified manufacturers of class II and class III medical devices to two consecutive AP inspections. FDA must conduct the next inspection unless the manufacturer petitions and receives a waiver from us. We propose to eliminate that restriction and permit eligible firms to use APs for an unlimited number of consecutive inspections without seeking a waiver. We would continue to conduct "for cause" or follow-up inspections when appropriate.

Third, we are also proposing to permit the medical device industry, on a voluntary basis, to submit to FDA AP reports assessing conformance with an appropriate international quality systems standard set by the International Organization for Standardization (ISO). We would consider the information in these reports when establishing our inspectional priorities.

CONCLUSION

As you know, MDUFMA will sunset on October 1, 2007. It is essential for us to work together to ensure that FDA does not lose this critical source of funding and to ensure that we can undertake the other important improvements to medical device review and safety we are recommending in this legislation. MDUFMA II is a priority for the American public, the medical device industry, and the many talented staff at FDA that we rely upon to conduct medical device reviews. Delay in the reauthorization of this program could trigger personnel disruptions in our workforce, particularly among expert reviewers whose skills are in very

high demand. The repercussions of such losses would undermine the efforts and resources we have put into hiring and retaining skilled scientists.

We have achieved much under MDUFMA, and we are ready to work with you in any way we can to ensure that FDA has the resources and tools we need to build on that success. We appreciate the support of you and your staffs, the assistance of other Members of the Committee, and that of the Appropriations Committees, in helping us move forward toward the re-authorization of this vital program.

Thank you for your commitment to the mission of FDA, and the continued success of our medical device program, which helps get safe and effective technology to patients and practitioners on a daily basis. We are happy to answer questions you may have.

Mr. PALLONE. Thank you, Dr. Shuren. I understand that Dr. Schultz is here to accompany you and answer questions, maybe, but not give an opening statement, so we will just move to questions and I will recognize myself. I only have 5 minutes and I want to get in something about post-market surveillance and these single-use devices, so I may ask you to answer yes or no or get back to me on some of these questions. I expressed concern that there did not appear to be any post-market surveillance provisions included in the MDUFMA II proposal before the subcommittee. Yet, in MDUFMA I, there was an authorization for appropriations for post-market surveillance activities at the FDA. Was that correct? Just yes or no.

Dr. SHUREN. Yes.

Mr. PALLONE. OK. And now that money, I understand, was never appropriated, but can you tell me if the agency ever requested that money in its submission to OMB during the past several years, when the administration was developing its fiscal year budget proposals? Again, yes or no.

Dr. SHUREN. Not to my knowledge.

Mr. PALLONE. OK. And you can get back to me, if you can find out more. Did the President ever include it in any of this year's budget proposals that he submitted, do you know?

Dr. SHUREN. Yes, fiscal year 2008, to my knowledge, had additional funding for device safety.

Mr. PALLONE. OK. Now, could you tell me—well, you said it was appropriated. What types of activities did that funding go for?

Dr. SHUREN. Well, the scope in MDUFMA is actually very broad. It encompasses a lot of post-market safety activities. It is very different from PDUFA, so we already had a broad scope. The second thing that we have and which MDUFMA is very different from PDUFA, from post-market safety, is that we have a trigger in place for protecting the appropriations for the entire device program. So the funding we get under MDUFMA goes for a lot of post-market safety activities and in addition, we have a little bit more protection on appropriations that will go to the rest of the program, which will cover the other remaining post-market safety activities.

Mr. PALLONE. OK. Now, as for the MDUFMA II proposal discussions, can you tell me whether the issue of post-market surveillance ever came up with industry representatives? Again, yes or no.

Dr. SHUREN. We did not go into any specific proposals for post-market safety. Our sense was that if we can ensure adequate funding for the agency, we will be in a fairly good place for post-market safety.

Mr. PALLONE. OK. And then finally on this issue, if the FDA and the industry agreed that some funding should be authorized for post-market surveillance in the first MDUFMA and to date, none of these funds—well, you said, actually, we have had some funds. So let me just ask you this. If Congress were to mandate that some percentage of the user fees were earmarked for post-market surveillance issues instead of pre-market activities, like we do with PDUFA, is that something you think that the administration would support?

Dr. SHUREN. Well, I think that the user fees already are directed at a lot of post-market safety activities. In addition, the funding we

have gotten to bring on board experts, those experts are used in post-market safety activities, so now we have greater expertise in a variety of fields. That is then integrated into post-market safety.

Mr. PALLONE. So then, you wouldn't necessarily have a problem if we actually said in the bill that a certain percentage of the user fees would have to be for post-market?

Dr. SHUREN. Well, what we would prefer, the better thing for us is that we have the funding and then we can apply it as we——

Mr. PALLONE. So you would rather have the discretion rather than have——

Dr. SHUREN. And we think we have that already built into the program.

Mr. PALLONE. OK. Let me get to the single-use devices. I know, in the first MDUFMA authorization, this issue was dealt with somewhat by requiring more data that validated the safety and the efficacy of reprocessed devices, yet the reprocessing of single-use devices still raises public health concerns for many of us, like Mr. Murphy mentioned as well, specifically in regards to infection and the malfunction of devices intended to be used only a single time. Can you tell me what steps have been taken by FDA since MDUFMA I was implemented to ensure the safety and efficacy of single-use devices, and whether you view those steps as adequate or would you support stronger regulation?

Dr. SHUREN. Well, first off, for single-use, reprocessing used medical devices, MDUFMA I, as you know, put in several provisions to ensure the safety of those products. So many of those devices that were exempt from submission of 510(k), they now have to submit data to us. Those that had to submit a 510(k) are now having to provide validation data regarding cleaning, sterility, functional performance. So we actually look at the fact of whether or not it is being adequately cleaned and there isn't bacteria present. We have also now put on our MedWatch form a box that if the product was actually a single-use device and it has been reprocessed, you think there was a problem with it, you can actually flag that for the agency. And we actually went back and we did a study. We looked at those reports that received through our medical device report regulation, through MedWatch, and from December 2005 to July 2006, we had about 434 reports in which people had said this was a reprocessed device. It turns out, out of that, only 65 were, in fact, reprocessed. In the other cases they were not reprocessed. And of the 65——

Mr. PALLONE. Well, go ahead, you finish. I have to ask you something else, but go ahead.

Dr. SHUREN. Well, of the 65, when we looked at it, we didn't see that any of the adverse events that were associated with those products were any different from the same things we were getting reports on from the original use of the product. There was no difference.

Mr. PALLONE. All right, I just want to quickly. In the Medical Device User Fee Stabilization Act of 2005, it implemented additional regulations that mandated that a reprocessed device include a removable label that identifies the manufacturer. How is that working?

Dr. SHUREN. What happens is you are supposed to actually either mark on the device itself, or on a detachable label, either the name or some symbol for the company and for the device, so that, when it is being reprocessed, people would actually know what that device, in fact——

Mr. PALLONE. Now, would you support any additional regulation, some kind of labeling or notification requirement that alerted patients to the fact that a reprocessed device would be used in a procedure on them? That is my last question.

Dr. SHUREN. At this point, we are not looking for additional changes in the oversight of single-use reprocessed devices. If there are any particular proposals or things you want to talk about, we would be happy to discuss further.

Mr. PALLONE. All right. Thanks a lot. Mr. Deal.

Mr. DEAL. Your guidance documents that explain to device companies the requirements and expectations for product submission, of course, as a key to reducing product development time and improving overall review processes, with the increased revenues that you expect with this reauthorization, do you plan to improve the rate at which you develop these guidance documents?

Dr. SHUREN. We will always try to, with the resources we have, put out as many as we can. I think what we wind up doing is we first identify where is there the greatest need for guidance and where is, particularly for the guidances you were talking about that may help in the development or the pre-market approval of particular guidances, a lot it depends upon the state of the science. So what you will see is a natural evolution where when we deal with a very innovative device and we don't know a lot about it, that is kind of our first rights of passage. With time, as we gain more experience and there is more science developed, that is when we will invest it into that kind of a particular guidance. So much of it depends upon where the needs are and the state of the science. We are always looking based on the resources we have available to invest in providing guidance, because we think it is not only good for the development of the devices, we have an invested interest ourselves, because it actually makes our work easier, too.

Mr. DEAL. Part of the user fees, you have indicated, will be used for further training of your employees. Obviously, I think we would all recognize that would be an important ingredient of the overall review process. What is your ability to retain employees? Once you have gone through this processes, what is your retention rate within the agency?

Dr. SHUREN. Well, our turnover rate, I guess, flip it the other way, our retention is about 92 percent. It depends which aspect of the program you look at and that is data from maybe about a year ago.

Mr. DEAL. That is pretty good.

Dr. SCHULTZ. And I think devices is actually higher.

Mr. DEAL. Mr. Pallone wants to know how that compares to Congress. I don't think we will get into that one.

Dr. SHUREN. We can discuss it off line.

Mr. DEAL. One of the complaints that we have heard is that FDA does not provide detailed explanation of how the user fees have actually been used in the process of reviewing the product. I am sure

you have heard the complaint. Do you intend to have more transparency in explaining where the fees have been used and how they have actually speeded up the process of approving a product?

Dr. SHUREN. Yes. Actually one of the qualitative goals that we are putting in our commitment letter actually goes to that kind of transparency, where twice a year we will sit down with industry. There will be other information that is made available to the public that will talk about, from a qualitative standpoint, how in fact we are investing the dollars that we are receiving.

Mr. DEAL. One of the criticisms that we have heard and probably will hear again today is that FDA did not meet with enough interested consumer and patient groups when negotiating the MDUFMA II agreement. Is that a fair criticism and what did you do in order to reach out to these other communities?

Dr. SHUREN. Well, actually before we started, before we engaged in the negotiation process, we had a public meeting to talk about where we are and where we may be headed with MDUFMA and sought public comment. I will say we got very little interest from the public on that. We just held a public meeting back on April 30 and we have opened up a public docket for comments and we had only about, I believe, eight organizations that came and wanted to give oral testimony. Most of those were actually—seven of the eight were fully supportive of the MDUFMA process. And right now we are getting comments submitted to our docket and we have only had a handful so far.

Mr. DEAL. Would you explain to us how the Office of Combination Products works and how there is coordination within the centers, and is it effective in terms of make sure there is not duplication or unnecessary red tape or delay with a product that is going through this Office of Combination Products?

Dr. SHUREN. Do you want to talk to that?

Dr. SCHULTZ. Yes. I think the Office of Combination Products has actually been one of the most important parts of MDUFMA and I think that, in the past, when we saw combination products involving drugs and devices or devices and biologics, it was really sort of looked upon as almost an overwhelming challenge to try to merge the different legislative review processes that we have and cultures that we have within the different centers. And while the Office of Combination Products does not actually perform its own review, what they do is something that is probably even more important. What they do is they monitor the process and make sure that the appropriate expertise from each of the individual centers is appropriately mobilized and focused to deal with the issues, the specific issues related to combination products. And I think one of the really sort of bright examples of that has been the review of the drug-eluting stents which, as you know, has been one of the real breakthroughs of the last few years, in terms of not only device technology but medical therapies. And obviously, we still have some challenges that we are continuing to work out, but part of the reason we were able to accomplish what we did was due to the efforts of the Office of Combination Products.

Mr. DEAL. Thank you.

Mr. PALLONE. Mr. Waxman.

Mr. WAXMAN. Thank you, Mr. Chairman. Dr. Shuren, there have been some well-publicized cases of safety problems with medical devices, for example, a faulty cardiac defibrillator, contact lens solutions associated with fungal eye disease infections, the dangers with cardiac stents. FDA's own budget documents indicate 1,550 medical device recalls were conducted last year and over 76 of those recalls involved dangerous or defective products that predictably could cause serious health problems or deaths, so we are talking about a serious matter. I want to focus on this question of user fees and how they have had an impact, if at all, on FDA's post-market safety of devices.

In 2002, when we adopted this user fee bill, we asked for a report so that we could take a look at how the law was impacting and we asked for that report no later than January 10 of this year. We wanted to look at several areas dealing with post-market safety; the impact of the user fee program on FDA's ability to conduct post-market surveillance of medical devices; the funding needed to conduct adequate post-market surveillance of these devices, in compliance with post-market surveillance requirements like the study commitments.

So this is an important document that we need. We expected to have it so it would be useful in this reauthorization. January 10 was the deadline. Now it is May 16. We could spend the rest of the hearing talking about your answers to these questions, but let me ask you the question. When could we get this report? What is holding it up?

Dr. SHUREN. It is in final clearance right now.

Mr. WAXMAN. What does that mean, final clearance? FDA has completed it or FDA is in the process of completing it?

Dr. SHUREN. FDA has completed it. It is now in final administration clearance.

Mr. WAXMAN. At the Office of Management and Budget, is that right?

Dr. SHUREN. No.

Mr. WAXMAN. It is not? Where is it?

Dr. SHUREN. It is with Health and Human Services and it went over there just a short time ago.

Mr. WAXMAN. I see. And who is holding it up?

Dr. SHUREN. I don't think anyone is holding it up.

Mr. WAXMAN. The report is completed and it is just waiting for the release?

Dr. SHUREN. Yes, but we also completed the report after the January time as well, so we are—FDA is a little late on the ball as well.

Mr. WAXMAN. I see. Now it seems to me obvious. I hope we can get this soon. Do you know when we could expect to get this report?

Dr. SHUREN. We are expecting to get it out soon.

Mr. WAXMAN. Well, I hope within the matter of a week or two, because we are going to reauthorize this program in this subcommittee and we ought to have the benefit of a report that Congress asked for and mandated in the legislation.

Dr. SHUREN. And I will also go back and convey those sentiments and push to have it put out.

Mr. WAXMAN. Please do. It is obvious that we need more resources for FDA's inspection program. Since 2003, FDA's own budget documents indicate that FDA was forced to reduce the number of medical device field staff, primarily inspectors, from 482 to 413. They are charged with conducting all types of inspections that FDA conducts, both pre-market and post-market, and FDA is required under the law to conduct these inspections every 2 years. How many U.S. facilities are there? How many staff are available to conduct post-market inspections of those domestic facilities?

Dr. SHUREN. Well, in terms of the inspections for domestic facilities, I know there has been a lot of talk about this, that you had raised as well, the statutory requirement for the biennial GMP or surveillance inspections. Domestically, there are about 5,500 facilities that would be subject to that statutory requirement. Those are the manufacturers of class II/class III devices. In 2006, we conducted about 1299 such inspections. That is about 23 percent. So right now, every 2 years we are probably covering just a little bit under 50 percent.

Mr. WAXMAN. Does that mean that some of them are going as long as 5 to 6 years before they are inspected?

Dr. SHUREN. Some of them are certainly going the 4 years. I don't know if any of them are going 5 to 6.

Mr. WAXMAN. And how many staff conduct foreign post-market inspections and how many foreign facilities are there?

Dr. SHUREN. Foreign facilities that are of the similar type, the class II/III, are about 4,500 facilities.

Mr. WAXMAN. I see my time is almost up and I have so many other questions. Mr. Chairman, I would like to request that I submit questions and get the responses to those questions so we can have them for the record.

Mr. PALLONE. Absolutely. And I would also ask, following up on what Mr. Waxman said, we really need this report by the end of next week, before the recess, in order for us to utilize it for the reauthorization. So we need to have it by next Friday if it is going to be useful.

Dr. SHUREN. It is the first thing I will follow up on when I leave here.

Mr. PALLONE. All right. Thank you. And thank you, Mr. Waxman. Mr. Ferguson.

Mr. FERGUSON. Thank you, Mr. Chairman. Just a courtesy heads-up, Mr. Chairman, and to our witnesses. You can see Mr. Shadegg is here today. He is a pretty high-energy guy to begin with. He has two cups of coffee in front of him, so we all may be in for it today. He was watching the debate last night, so you should have had the coffee during the debate, John. I am using all of my time. Thank you very much for being here. He is not laughing, either.

Dr. SHUREN. I am laughing on the inside.

Mr. FERGUSON. Not too many people are laughing when Mr. Waxman finishes with them, either, so join the club. Let us take a step back. Tell us where the U.S. stands in terms of approval of medical devices, compared to other countries. I am trying to get at what is the impact if we don't reauthorize this program?

Dr. SCHULTZ. Well, I think the impact would be pretty severe. We rely on MDUFMA for about 20 percent of our budget and a lot of the expertise that we now have in the Center, and more specifically the expertise that we have hired over the last few years, has been directly related to MDUFMA funding. And what that expertise is, a lot of the Members have made reference to the fact that medical devices are becoming more complicated, the technology is changing, our ability to keep up with that technology and to be able to hire the appropriate expertise and to be able to utilize outside expertise through contracts and our fellowship program, all of that is directly related to the funding that we have gotten from MDUFMA; in addition, giving those people the tools that they need in order to perform their jobs.

It is fine to have experts and it is fine to have appropriate expertise, but our IT infrastructure was woefully inadequate and becoming more woefully inadequate at the time when the first MDUFMA was authorized, and we have really been able to turn that around in the last 5 years and put systems into place that allow us to track documents so we actually know where they are, we can deliver reports on our performance in ways that we used to have to do by hand, and we have used those platforms.

One of the questions I think that has come up was how is MDUFMA influencing our post-market? And one of the things that we have really, really tried to do, consciously tried to do, is to make sure that the expertise that we have, as well as the infrastructure changes that we have made, can be adapted to use in a post-market as well as in the pre-market review process. So we certainly are sensitive to the fact that we take a lifecycle approach to medical device regulation and we need to do both.

Mr. FERGUSON. Now, we have been told that there has been kind of a slow up-tick for the Third-Party Inspection Program. As you had mentioned in your testimony, the Third-Party Inspection Program could help U.S. companies compete in the international markets by allowing a single inspection to satisfy both U.S. and foreign requirements. Does the MDUFMA II agreement, will it improve third-party inspection and how will it do that?

Dr. SHUREN. Well, our intent is that it would actually lead to greater participation by manufacturers in the program and the way we go about it is to make some very modest changes to sort of streamline the process. Right now, if you want to use an accredited person, this third party, you need to petition FDA and it is set up that FDA is supposed to receive this petition, review it and approve it. There is a default, that if we haven't responded within 30 days, it is supposed to be approved.

However, even manufacturers have felt that I really need to wait on the FDA for that approval. We would like to make that easier, because we have already reviewed these third parties. We know if they are in good standing or not. They have gone through rigorous training. So what we would replace that with is a notice that is sent to the agency and that the manufacturer can go ahead and use that accredited person, unless they have heard otherwise from us in 30 days.

Mr. FERGUSON. So if more companies used the Third-Party Inspection Program for routine inspections, will that allow you to con-

centrate more of your inspection resources on areas that pose, perhaps, greater risk?

Dr. SHUREN. That is exactly right. We are using a risk-based approach to begin with and the third party will help us address those companies where they may not be as big a concern and we can go ahead and focus on other companies. It would essentially expand our inspectional power.

Mr. FERGUSON. But just to be clear, a company could still be subject to a for-cause inspection even if it has participated in the Third-Party Inspection Program?

Dr. SHUREN. That is correct and we believe that is an essential piece to the Third-Party Inspection Program, that the agency retain that ability to go in and do an inspection if it needs to.

Mr. FERGUSON. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. I just wanted to entertain a unanimous request from Mr. Doyle.

Mr. DOYLE. Thank you for this courtesy, Mr. Chairman, and thanks for holding this important hearing on the reauthorization of MDUFMA. I just want to ask for two quick things, first, to insert a letter into the record of today's hearing that was sent by myself, Congressman Pete Sessions and two dozen other Representatives, including some of my colleagues here on this committee, asking the FDA to create a mandatory unique device identification system.

This is supported by the Advancing Patient Safety Coalition, which is comprised of prominent hospital, physician, nursing, research, quality and patient advocacy organizations such as AARP, the American Hospital Association, the American Nurses Association, the American Medical Association, National Rural Health Association, American Heart Association, American Association of Orthopedic Surgeons, and the Joint Commission. One of the members of the coalition, Premier, Incorporated, has prepared written testimony on this issue and I ask unanimous consent that it be made a part of the record of today's hearing.

Mr. PALLONE. Any objection? So ordered.

Mr. PALLONE. Thank you.

Mr. DOYLE. Thank you, Mr. Chairman.

Mr. PALLONE. Thank you. Next is Mrs. Capps.

Mrs. CAPPS. Thank you. And again, thank you for your testimony, Dr. Shuren. And we all know that medical devices range from simple tongue depressors to hip replacements. For more complicated devices like hip replacements, it is certainly true that one size fits all isn't going to work. I think this is particularly true for women, who tend to be smaller and have different body proportions than men. Now, it is my understanding that, within the FDA, class II and class III clinical studies contain the medical devices with the highest risk, such as hip replacements and heart defibrillators and others. May I ask you what percentages of devices in these two classes are tested in women?

Dr. SCHULTZ. I don't think we have a specific number that we can give you today, but we can certainly look at it.

Mrs. CAPPS. I would love to have an answer back, because my underlying question is how you stratify and report data. I mean how you choose your studies and do you give a balance of women and men and children. Increasingly, we are seeing a wide range of

our population wanting to use and being appropriately prescribed devices. And so I would like to have it, with permission of the chairman. You don't have any of that information with you, on how you choose subjects to be tested randomly or what percentages are different ethnic groups, different genders and so forth?

Dr. SCHULTZ. Let me try to answer that.

Mrs. CAPPS. Sure.

Dr. SCHULTZ. I think you have made reference to the fact that we regulate a number of different types of medical devices.

Mrs. CAPPS. Exactly.

Dr. SCHULTZ. We do have a branch within our Office of Device Evaluation that is specifically designated for the regulation of OB-GYN devices and specifically for women's health products. So we certainly pay attention to the fact that there are products that are specifically designed and need to be—OK. With regard to other devices, obviously there are certain devices that have use primarily in men and those devices obviously would be tested. And then there are the ones that are multi-use, whether they be adults or children. We have tried to encourage more and more diversity in terms of the types of populations that are being tested. Again, our success and our ability to do that in part has rested on the size of the studies and the ability to recruit subjects to some of these studies.

Mrs. CAPPS. Yes.

Dr. SCHULTZ. But it is certainly one of the things that we are becoming more and more focused on, recognizing exactly what you said, that there have been problems with gender, with race, with age and all of those things and we would like to get more diversity into those studies.

Mrs. CAPPS. All right. I guess I would like a written report back on how you do that. And to your last statement, you would like to get more diversity. Maybe you will give a response about the ways in which you intend to make sure that that happens, because it is not going to happen automatically or voluntarily, necessarily. So I think it is an area that really needs a concerted effort.

I do have one more question. As I understand it, device companies can pay a third party directly, Dr. Shuren, to inspect their manufacturing process. The device company then chooses the third-party inspector. I want to make sure I am correct in saying this, so I want to follow it through. Device companies can pay. They agree to pay a third party directly to inspect their process. They then choose, the device company itself chooses that third-party inspector and negotiates also the price that they are going to be paid for the inspection. I know that some critics believe that this creates an incentive for these third parties to please the device manufacturers if they want to stay in business.

I mean, it is hard for me not to think that that wouldn't weigh into this. So my question is, what is being done at the FDA to ensure that these inspectors are unbiased? I mean, what kind of controls do you have over them? And when conducting inspections, how do you make sure that they are going to give this the highest standard?

Dr. SHUREN. Well, first off, when the manufacturer—you are correct that the manufacturer will select, but they are selected from a very limited list.

Mrs. CAPPS. Who gives them the list?

Dr. SHUREN. Actually, we provide the list. We are the ones who accredit the individuals who can do the inspections and there are two parts to it. First, it is the firm. We would approve the firm and we go through a conflicts of interest check with that firm. The second is that——

Mrs. CAPPS. I don't have a lot of time, but what comprises a conflict of interest?

Dr. SHUREN. We are actually looking for the relationship between that organization and also we go to the individuals. So the next part is we then accredit the individual inspector. You can't say I just want to use this firm. You actually have to use a particular person who we have also done a check on, who we have done training on, classroom training, and then they actually go out and they do inspections with it and then we have an audit program on top of it and that is why I think you have seen we have invested a large amount of money into the program because it also has the training and it has got the checks.

Mrs. CAPPS. I am out of my time, but I can't help but say this is a pretty select group of people who would even be qualified to be inspectors.

Dr. SHUREN. That is absolutely correct.

Mrs. CAPPS. I mean, this is really tough. I am really concerned that specific provisions in MDUFMA II proposal might expand the role of third-party inspectors and leave the door open, wider open for conflicts of interest and I would hope, Mr. Chairman, that as we consider this bill in committee, we consider potential—well, I really want to understand who these players are and what their interest is and how the public is really going to be protected through this process and I hope we will have an opportunity to address some of these concerns. Thank you.

Mr. PALLONE. Thank you. And I will mention at the end that you may get questions like you did from Mrs. Capps. You know, we would like you to get back to us, obviously.

Dr. SHUREN. Of course.

Mr. PALLONE. Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman, and I thank the witnesses for your testimony. In the past, we have heard complaints that FDA has not provided detailed information on what it costs to review an application, nor has FDA provided detailed information on how it has used the revenues from user fees. How does the FDA plan to increase the transparency of how it is spending user fee revenues?

Dr. SHUREN. First off, we do provide information now. We do actually put out an annual report, our financial report that talks about how, in fact, we spent the dollars. On top of that, in MDUFMA II, as I mentioned, we have a qualitative goal where we will, in fact, twice a year report from a qualitative standpoint where we have actually used the dollars to make investments in the program. So our goal in MDUFMA II is greater transparency, on top of the information that we already put out there publicly.

Mr. PITTS. I understand that FDA has estimated the total revenues from fees to be collected each year and that the bill stipulates the revenues from fees the agency is authorized to collect each year. Could you please explain what happens if the agency's collections are higher than that authorized by the legislation? Will there be any fee reductions in future years? Would you explain how that would work?

Dr. SHUREN. There is an offset provision that we are proposing in this legislation, in which we would look at the revenues that we have collected over the first 4 years. It is not the full 4 years. We will estimate the last part. And if we have, in fact, it looks like we have collected more than we were supposed to for those first 4 years, we would make an appropriate reduction in the fees for the fifth year.

Mr. PITTS. OK. Guidance documents that explain to device companies the requirements and expectations for product submissions is a key factor in reducing product development time and improving the overall review process. With the increased revenues expected under MDUFMA II, does the FDA plan to improve the rate at which it develops guidance documents?

Dr. SHUREN. With the resources we have, we are always looking to put out appropriate guidance documents and when it is appropriate to do so and we have the ability to do so, we, in fact, do so. One of the things we are also putting into MDUFMA II, in one of our goals, is that we are giving an additional opportunity up front to provide some guidance to us as to the appropriate guidances in which we should invest our time. So we will put out once a year, here is a list of the guidances that we plan to work on over the next year or so, get feedback from the public as to this is the right set of guidances. Are there other ones we should work on? Are there particular things we should take in account or look at when we develop that guidance document, and feed that into the process before we actually put pen to paper.

Mr. PITTS. I understand that FDA has agreed to establish a more interactive review process so that FDA reviewers can communicate in a timely way with the device manufacturers, speed up the review process. What steps will FDA take to ensure that all reviewers will embrace this interactive review process so that it really does work?

Dr. SHUREN. Well, we are going to take two steps. First off, we will be putting out a guidance that lays out the basic principles for interactive review and that will come out in the next few months. We are under a very short timeframe to try to have that out around the time that MDUFMA II, in fact, would start. And the second is that we have a good integration with our staff and our management and we do a lot of training in terms of what are the expectations for the review and what are the expectations for oversight of that review, and that will be part of the training that we go into now for MDUFMA II. As we move over into this slightly modified regime for MDUFMA II, we are going to actually have to reprogram our systems and go through training with our staff as to what are the new goals and what are the steps we will take to achieve those goals and interactive review will be one of those components.

Mr. PITTS. Doctor?

Dr. SCHULTZ. And I think one of the key aspects is this legislation, as it has removed one of the impediments to interactive review. Interactive review has always been a key component of the device review process and I think one of the lessons learned from MDUFMA I was that when you impose specific cycle goals into the review process which require things to be done at certain times, that, in fact—and not unintentionally, but certainly did have a negative effect on our ability to have the kind of interactive review process that, quite frankly, has been a hallmark of device review for the last 30 years. So I think we are really getting back to our roots in terms of being able to do this interactive review and I think we will be able to do it even better than we did before.

Mr. PITTS. Thank you. My time is up. I yield back.

Mr. PALLONE. Thank you. Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. As I mentioned in my opening statement, I have a real interest in the whole area of pediatric medical devices. On the second panel we are going to be hearing from patient advocates about the need for children to be granted access to these medical technologies. It is a very special area and I think it is an area where we really need to give really solid direction from Congress and of course Mr. Markey. And as I said, Mr. Markey and Mr. Rogers have offered legislation in this area and I am pleased to be a co-sponsor of it. I often hear from the parents and from physicians at Lucile Packard Children's Hospital in my district about the need for devices that are appropriate for use in children.

We know that doctors have had to essentially jerry-rig devices to use on children on the operating table just to make sure that the device fits or works properly. So unfortunately, I don't see anything in your testimony and maybe it is because this is the reauthorization of MDUFMA, but I looked for it and there isn't anything in it emphasizing pediatric device safety. So can you tell me what, if anything, FDA is doing in this area to enhance pediatric medical device safety and obviously to incent innovation? And do you have anything that you want to share with us of what direction, what would be helpful to us as the subcommittee that is essentially setting the table in this area? Dr. Schultz?

Dr. SHUREN. First let me say you are quite right. We did not come here today to talk about pediatrics specifically, or you won't see it in the legislation we are talking about, because we have tried to focus on the four corners of MDUFMA here and leave what may be any other proposals pertaining to pediatrics.

Ms. ESHOO. Do you want to comment on that today or should we just wait?

Dr. SHUREN. We would certainly love to comment on things that the agency is doing currently. Let me talk about one thing and I will turn it to Dan.

Ms. ESHOO. I have another question, so keep it as concise as possible. Just give us a flavor of what you are doing.

Dr. SHUREN. Sure. We are actually doing a number of things in the area of enhancing post-market safety for children. Right now we have a program called MedSun, which is 350 satellite facilities, healthcare facilities, that do enhance monitoring for adverse

events. We are creating a subgroup under there, pediatric facilities that are focusing just on adverse events and problems that may occur with the use of the devices.

Ms. ESHOO. Is Lucile Packard one of these 300 places? Did you say 300?

Dr. SHUREN. Three hundred and fifty for the whole program. For pediatrics, it is a smaller subset. We have 24 pediatric hospitals right now signed up within our program.

Ms. ESHOO. Is Lucile Packard one of them?

Dr. SHUREN. I don't know but we can check.

Ms. ESHOO. OK. Yes. I wasn't aware of it, that is why I am asking.

Dr. SHUREN. Yes.

Ms. ESHOO. On the administration's PDUFA proposal this year, there is always—and I think you have heard this from Members on both sides of the aisle, probably more from our side, but you still heard this. There are tensions built into user fees and approval. From the outside looking in, people tend to look at this and say well, if a company is paying, then the agency is pressured to approve and where is the efficacy in this? Can you state for the record where the firewalls are in this?

Dr. SHUREN. Well, first off, the dollars that are sent to the agency, they are arms length from the reviewers.

Ms. ESHOO. I think I know what the answer is, but I think it is still important to raise, because there are creative tensions there.

Dr. SHUREN. The first thing, the dollars do not go—the reviewers are kept out of that process completely. The dollars actually go to the U.S. Bank in St. Louis and are kept separate, so they are not aware of fees being paid or amounts or anything like that. The second thing is that when we design our business process, we actually have focused it on meeting the goals but in a way that also ensures that we are not changing our standards. MDUFMA is not about changing the standards at FDA. It is merely enhancing the processes we have for review. One thing it has helped us do is to build up an expertise that also feeds back into all the safety aspects that we need to look at for devices. So in that respect, it has actually been very helpful to us.

Ms. ESHOO. On the reuse issue, how many actual inspections has FDA undertaken at these facilities? Is it robust?

Dr. SHUREN. To actually look at the facilities, we have been——

Ms. ESHOO. Not to look at, to inspect them.

Dr. SHUREN. Right, to inspect them. The answer is yes.

Ms. ESHOO. Because I think these reused devices, they terrify me, I have to tell you, and I did legislation in this area. People that are in the hospital don't know whether it is a device that is being reused and I think we need to drill down on this. I still think there is some work to be done, Mr. Chairman.

Mr. PALLONE. Thank you. I have to warn everybody that, apparently, the votes are already on. There are two votes and we have less than 10 minutes left, but our clock didn't work. So we are going to take a recess. You can wait for us to come back.

Ms. DEGETTE. Mr. Chairman?

Mr. PALLONE. Yes.

Ms. DEGETTE. I would like to ask unanimous consent before the recess, because I am not sure if I can come back and I just wanted—and what I was planning to do was just ask these gentlemen if they could submit a written response to the questions I asked in my opening statement. The first one is the recommendations that I listed, which my staff can provide to you, has the FDA adopted any of those recommendations with respect to pediatric populations? And the second question is, what has the impact been of those recommendations? Mr. Chairman, if we can just get written responses to those questions, then I won't have to ask this panel any questions.

Mr. PALLONE. That is fine.

Ms. DEGETTE. Thank you.

Mr. PALLONE. Thank you.

Ms. DEGETTE. Thank you.

Mr. PALLONE. But we still want you to wait because we have Mr. Shadegg and we may have others that come back about half an hour or so. So the subcommittee is in recess.

[Recess]

Mr. PALLONE. We obviously had a lot more votes than we expected, which, of course, happens around here. And I think when we left off, I was going to recognize Mr. Shadegg.

Mr. SHADEGG. Thank you, Mr. Chairman, and thank you for being here and pardon our long delay. I want to direct a couple questions to the Third Party Inspection Program. I would be correct in understanding that when companies use the Third Party Inspection Program, that produces both a savings in money and a savings in time for your agency and for the process of getting a device approved, correct?

Dr. SHUREN. That is correct.

Mr. SHADEGG. And therefore it is an overall benefit to you and to the process and to getting this equipment into the field to help patients who need care, correct?

Dr. SHUREN. That is correct. The whole gist of setting up the Third Party Inspection Program, I think, came out of a recognition that the agency did not have enough resources to do all the routine surveillance inspections and this was a way to sort of supplement so that we could actually increase our inspectual power.

Mr. SHADEGG. As a follow-on to that, my assumption would be that the more companies that use that process, the more you, as an agency, are able to focus your resources on areas where you feel there is a greater risk.

Dr. SHUREN. That is correct. That will allow us to actually better direct our resources at the higher risk products.

Mr. SHADEGG. Dr. Schultz, would you like to expand on that?

Dr. SCHULTZ. No, I think you got it exactly right. That is the plan, is that we could get more information. I mean, we are always looking for more information. We like to be able to get into companies as frequently as we need to. Obviously, we haven't been doing that. If we can use the Third Party Program successfully and understanding that there are some concerns and that we need to be cognizant of those concerns, but if we can get better information on routine inspections, using the Third Party Program, and focus

where we really need to focus our efforts, we think that that is the way to go.

Mr. SHADEGG. Thank you. It would be my observation that, at least from what I have seen and additionally, I have heard that you are handling the issue of conflict of interest fairly well and that this is a process that is working and serving the consuming public and patients who need care.

Dr. SHUREN. We agree and also, in MDUFMA II, we are not looking to make any changes to the conflict of interest. We are not looking to relax that, at all. We believe it is important to keep in that high level protection that is already built into the law.

Mr. SHADEGG. Let me ask you a question about reprocessed devices. As I understood your testimony earlier, you are watching complaints regarding reprocessed devices and at least, at this point, and doing inspections of reprocessing facilities and at this point, you do not see a disproportionate level of problems or infections or other concerns arising out of remanufactured devices as opposed to OEM devices, is that correct?

Dr. SHUREN. That is correct. And we also look at the facilities. There was a question before in terms of our looking at facilities. We will get the actual numbers, but we probably look at those facilities a lot more closely than we do for other device facilities more generally.

Mr. SHADEGG. Dr. Schultz, would you comment on that?

Dr. SCHULTZ. I think I would echo what Jeff said, but with the caveat that trying to tease some of this information out, especially some of this post-market adverse event data; looking at infections, looking at complications of complex procedures and trying to tease out the part of it related to a particular device is very difficult. In general, we have not seen any huge signals that say that there is a big difference.

Mr. SHADEGG. To follow up on that, do you believe the agency needs further authority to look at that issue to assure the consuming public that there are, in fact, no problems?

Dr. SCHULTZ. I am not sure that authority is going to give us better science. Sometimes the two do not necessarily go hand-in-hand. I think we are constantly looking at ways to develop better methods of looking at data that will allow us to make some of these distinctions, so I don't necessarily at this point see it as an authority issue.

Mr. SHADEGG. Well, if you do see a need for greater authority, please let us know. I think it is important to carefully watch that area. There was a comment earlier about a large number of complaints that believed the devices were reprocessed and you testified that only a fraction of them, in fact, were reprocessed devices. Is there a specific requirement that patients be advised that a reprocessed device is being used?

Dr. SCHULTZ. No, there is no requirement under our law for that.

Mr. SHADEGG. And do you think that is something that would be advisable?

Dr. SCHULTZ. It is something that we haven't considered in the past. It is something we can certainly think about and discuss with you in the future.

Mr. SHADEGG. Informed consumers, I mean, my view is if there is an economic use to reprocessing, that is a good thing, but I will also agree that informed consumers are an important part of a marketplace and if you do not know something about a device that is being used, perhaps that should be disclosed. Thank you, Mr. Chairman. I yield back.

Mr. PALLONE. Thank you, and thank you very much for bearing with us for the hour and a half or so. A half an hour that turned into an hour and a half. I just wanted to mention, I think I may have said before that Members may submit—some Members already asked questions that we would like you to get back to them. You may get additional ones within the next 10 days or so. And I know when Mr. Waxman talked about that report on the postmarket surveillance that I mentioned, we really would have to get it by a week from Friday in order for it to be useful for us in our reauthorization. Not this Friday, but the following. And then before he left, Mr. Waxman mentioned that there is another outstanding report in MDUFMA I where the FDA is supposed to report back to us no later than January 10, 2007 on FDA's experience with third party reviews of 510(k)'s. Can I ask you, is that something that is also in its final stages or——

Dr. SHUREN. Yes, and you will have that very soon, too.

Mr. PALLONE. Yes. I mean, that is the same thing, I mean, for us, to be useful to us, we would need it by a week from Friday before the break. So with that, thank you very much. I appreciate your being here. And we will move to the second panel. Thank you.

Dr. SHUREN. Thank you.

Mr. PALLONE. I am sorry. I would ask the second panel to come forward. Welcome to all of you again. Let me introduce this panel.

First we have Mr. Paul LaViolette, who is chief operating officer for Boston Scientific Corporation, and then we have Dr. Diana Zuckerman, who is president of the National Research Center for Women and Families here in DC.

And then third we have Mr. Kelvyn Cullimore, Jr., who is MDMA secretary, president and CEO of Dynatronics Corporation, Salt Lake City, Utah. I have to tell you that Mr. Matheson wanted to introduce you, but he might have gotten caught up in all these votes and everything, so I will introduce you for now. And then Mr. Steven A. Grossman, who is executive director of the FDA Alliance in Silver Spring. And last is Ms. Diane Dorman, who is vice president for public policy of the National Organization for Rare Disorders.

And again, we ask you to make 5 minute statements. If you want to add additional material, at our discretion, you can do that. And we will start with Mr. LaViolette.

STATEMENT OF PAUL LAVIOLETTE, CHIEF OPERATING OFFICER, BOSTON SCIENTIFIC CORPORATION

Mr. LAVIOLETTE. Thank you, Chairman Pallone and Congressman Deal. I am Paul LaViolette, chief operating officer of Boston Scientific and a major innovator in medical devices product area. I am here today in my capacity as a member of the AdvaMed Board of Directors and I am pleased to testify before the subcommittee today regarding the reauthorization of the Medical De-

vice User Fee and Modernization Act, obviously referred to as MDUFMA II.

The medical technology industry thanks you for convening this hearing about this important agreement. As a general matter, we believe this legislation is good for patients and for public health. It will facilitate the timely and effective review of new medical technologies and bring them to patients as soon as those products can be shown to meet FDA's rigorous requirements. I am pleased to report that FDA and industry support this agreement and look forward to its timely consideration.

The legislation builds on experience gained from the implementation of the original medical device user fee program which was enacted, of course, in 2002. The user fee program for medical devices has increased the availability of important new medical device technologies for patients and physicians faster and more efficiently than prior to the program's enactment. We are very encouraged that the Senate has recently passed, overwhelmingly, a MDUFMA II bill that incorporates all the essential elements we agree to with the FDA. We hope that you also see the value of the MDUFMA agreement and work toward a swift resolution in the House of Representatives. I hope today's hearing provides you with the necessary information to do just that.

Mr. Chairman, there are six key points about the MDUFMA agreement that I would like to highlight today.

First, the legislation would provide FDA with stable and predictable funding for the device program through a combination of appropriations and user fees. In fact, under MDUFMA II, the user fee collected over 5 years would increase approximately 90 percent over those collected during the previous 5 years under MDUFMA I. Importantly, the legislation continues a central provision of the original MDUFMA legislation whereby Congress is committed to providing FDA's device program with an annual inflationary increase. The user fee that is paid by industry would be an additive to the appropriated congressional base.

Under MDUFMA I, all of the FDA's revenues from user fees were derived from application fees. As a result, FDA's revenue was unpredictable and led to insufficient revenue in years in which fewer applications were submitted. To address this fluctuation in revenues, FDA and industry have agreed to a new fee structure that combines existing application fees with new facility registration and annual report fees. These fees will ensure that FDA has a more stable and predictable revenue stream.

The legislation contains significant improvements for small businesses, the lifeblood of so much innovation within our industry, by providing further reductions in fees for small businesses, as compared to what larger companies would be required to pay.

Quantitative performance goals for FDA's review of new medical device applications were an important component of MDUFMA I and we are pleased that FDA has agreed to continue performance goals under MDUFMA II. The agency is committed to review each application type within a specified time period. These performance goals have improved the overall efficiency and predictability of the review process that is essential to the industry. We are also pleased that FDA has agreed to revamp and simplify the perform-

ance goal structure to focus on the time for final decision goals rather than on intermediate cycle goals.

We are pleased that FDA has agreed to a number of qualitative goals, as well. Most important, as has been testified to previously today, is the agency's commitment to an interactive review process. The legislation would also make needed procedural adjustments to the Third Party Inspection Program, which was authorized under MDUFMA I. These procedural adjustments maintain the stringent conflict of interest requirements for third party inspectors and the stringent eligibility requirements for participating companies.

Last week, the Senate also passed legislation by Senator Dodd designed to address the challenges facing pediatric medical device development. As an industry, we support the goal of providing greater access to safe and effective medical devices for children. We look forward to working with Congressman Markey and Congressman Rogers on their bill, the Pediatric Medical Device Safety Improvement Act. We believe that creating incentives to encourage pediatric device development is critically important.

However, it also important that legislation intended to encourage pediatric device development does not create unintended consequences or adversely impact the availability of safe and effective medical devices for the broader population. Unlike drugs, the kinds of incentives that exist in the Best Pharmaceuticals for Children Act are not currently available for the device industry. We thank Congressman Markey and Rogers and Congresswoman Eshoo for their leadership on pediatric issues and we look forward to working with the committee on this important priority.

In conclusion, we believe the reauthorization of MDUFMA that incorporates all the essential elements industry and the FDA have agreed to, will enable FDA to further improve its performance, both in quantitative and qualitative ways, while creating a stable and predictable fee structure that benefits both FDA and the device industry. Most importantly, American patients will be the true beneficiaries. I want to thank both my industry colleagues and the FDA staff who worked so diligently over the past year to reach this point. Chairman Pallone, Mr. Deal and members of the subcommittee, I thank you for convening this hearing today and allowing me to share our perspective. We look forward to working with the committee as you consider the MDUFMA legislation. Thank you.

[The prepared statement of Mr. LaViolette follows:]

AdvaMed's Written Testimony for the Reauthorization of the Medical Device User Fee and Modernization Act

AdvaMed is pleased to submit this written testimony. AdvaMed, the Advanced Medical Technology Association, represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually.

Executive Summary

In summary, AdvaMed believes that the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA) is good for patients and for the public health. It will facilitate the timely and effective review of new medical technologies and bring them to patients as soon as those products can be shown to meet the necessary rigorous FDA requirements. It also ensures that FDA's medical device program will be on sound financial footing. FDA's device program needs sufficient funding to do its job in a timely way, and this bill will ensure that the agency has that funding for the next five years. We believe this legislation strikes a proper balance: stable and predictable funding for the FDA that is tied to continued incremental improvements in performance and important enhancements to the review process including more transparency and more interaction between FDA reviewers and applicants. This bill is the product of a year-long discussion between the agency and the device industry, and we are pleased that, today, the entire medical device industry and the FDA stand united, together, in support of this legislation.

Background

This legislation builds on experience gained from the implementation of the original medical device user fee program which was enacted in 2002. That program helped FDA bring important new technologies to patients sooner while maintaining the high standards needed to demonstrate safety and effectiveness. That is the bottom line. The medical device industry continues to be on the cutting edge of new technology development. We recognize the important statutory role the Food and Drug Administration (FDA) plays in reviewing the scientific basis for new device products prior to marketing. Therefore, we believe it is important that FDA have the necessary resources to fulfill that statutory function in a sound, effective, and efficient way.

We are pleased that MDUFMA made important strides towards accomplishing that goal. Over the past five years, FDA has received significant increases in funding for the device review program, including necessary funds for the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), and the Office of Regulatory Affairs (ORA). This funding came from a combination of user fees and increased appropriations. With these added funds, the agency has been able to hire and train additional staff as well as enhance its information technology systems. The result is that the agency has, to date, met the quantitative performance goals outlined in the "goals letter" accompanying MDUFMA. That is good news because it means patients are getting more rapid access to the newest, proven technologies.

To build on that successful start, over the past year, AdvaMed, together with our colleagues in the Medical Device Manufacturers Association (MDMA) and the Medical Imaging Technology Alliance (MITA, formerly NEMA), have been working with FDA over the past year to create a reauthorization package that would strengthen this program still further. AdvaMed

believes it is very important that we as an industry are united in support of this bill and that, together, we are united with the FDA on its contents, from start to finish.

We are very encouraged that the Senate has recently passed, overwhelmingly, a MDUFMA II bill that incorporates all the essential elements we agreed to with the FDA. We hope that the House acknowledges the value of the MDUFMA II agreement and works toward swift passage in the House of Representatives.

Key Provisions of User Fee Bill

Key elements of this legislation and the accompanying implementation commitments of the FDA include the following:

1. Increased Funding that is Stable and Predictable First, this legislation would provide FDA with a stable and predictable funding mechanism for the device program, through a combination of appropriations and user fees. In fact, under MDUFMA II, the user fee revenues to be collected over 5 years would increase approximately 90% over those collected during the previous 5 years under MDUFMA I. Importantly, the legislation continues a central provision of the original MDUFMA legislation whereby Congress is committed to providing FDA's device program with an annual inflationary increase. The user fees the industry pays will be additive to the appropriated Congressional base. Under MDUFMA I, all of FDA's revenue from user fees was derived from application fees. As a result, FDA's revenue was unpredictable and led to insufficient revenue in years in which fewer applications were submitted. To address this fluctuation in revenues, FDA and industry have agreed to a new fee structure that combines existing application fees with a new facility registration and annual report fees. These fees will ensure that FDA has a more stable and predictable revenue stream. The new fee structure also

includes limits on the amounts that application fees can increase from year to year. These limits are important to prevent the significant fluctuations in fee levels that industry experienced in the early years of MDUFMA I. Additional funding provided in MDUFMA II will also allow FDA to train its reviewers to enhance their scientific expertise.

2. Significant improvements for small businesses. This legislation contains significant improvements for small businesses, the lifeblood of so much innovation within our industry. The new fee structure provides further reductions in application fees for small businesses, as compared to what larger companies would be required to pay. This will provide an important incentive for innovation and will help ensure the viability of this vital sector of our industry. In addition, the process enhancements that FDA plans to implement such as a more interactive review process, will also provide greater benefits to those small businesses.

3. Quantitative Performance Goals. Quantitative performance goals for FDA's review of new medical device applications were an important component of MDUFMA I. We commend FDA for the modified goals included in MDUFMA II. The agency has committed to review each application type within a specified time period. These performance goals have improved the overall efficiency and predictability of the review process that is essential for industry. We are also pleased that the agency has agreed to continue making incremental improvements in the timeliness of its new product application reviews. For the first time, FDA will complete the review of the most sophisticated new devices in less than 300 days, under the premarket approval application (PMA) process, and FDA action on breakthrough devices (those device applications qualifying for "expedited review") will be completed even sooner. Finally, we are pleased that FDA has agreed to revamp and simplify the performance goal structure to focus on the time for final "decision goals" rather than on intermediate "cycle goals." Taken

together, we believe these goals will make the review process more predictable and more efficient, without compromising the high level of rigor necessary to ensure the safety and effectiveness of new medical devices.

4. Qualitative Goals. We are pleased that FDA has agreed to a number of qualitative goals as well. Most important is the agency's commitment to an interactive review process. An interactive review process will increase review efficiency and improve communication between reviewers and applicants. This will establish a more dynamic and efficient mechanism to obtain clarifications or readily available information needed to complete the review process. To facilitate this process, FDA has agreed to develop guidance to its reviewers and industry, based on the principles we have outlined. FDA has also agreed to take a number of steps to increase the clarity around a number of issues affecting the review of in vitro diagnostic products (IVDs) and combination products. Finally, we are pleased that FDA has agreed to work with industry to identify and develop priority guidance documents that provide companies with clearer insights into what the FDA expects to see in new applications for different categories of devices.

5. Third Party Inspection. This legislation would also make needed adjustments to the current third party inspection program authorized under MDUFMA I. These procedural adjustments will make it feasible and attractive for eligible companies to participate in the program while maintaining the stringent conflict of interest requirements for third party inspectors and the stringent eligibility requirements for participating companies. FDA's authority to inspect a facility at any time also remains unchanged. We are pleased that FDA is committed to making this program work. This program will allow FDA to focus its inspectional resources in a risk-based manner and better focus its limited inspectional resources. At a time

when everyone's resources are limited, it is important that FDA-accredited third parties are fully utilized.

6. Pediatric Device legislation. Last week, the Senate also passed legislation by Senator Dodd designed to address the challenges facing pediatric medical device development. We commend Senator Dodd and others who worked on the Senate legislation for their efforts and look forward to working with Congressman Markey and Congressman Rogers on their bill, the Pediatric Medical Device Safety and Improvement Act. Our industry is committed to the goal of providing children access to life-saving, life-enhancing medical devices. At the same time, it is equally critical that we prevent the unintended consequence of adversely impacting the availability of safe and effective medical devices for the broader population.

As we attack the problem of limited availability of pediatric devices for children, we need to address the root causes – lack of knowledge of pediatric needs and lack of incentives. The market for pediatric uses is often very limited, while the cost of development and regulatory clearance or approval can be comparable to the adult market. Unlike drugs, the kinds of incentives that exist in the Best Pharmaceuticals for Children Act are not available to the device industry. Creating incentives such as improvements in the pediatric HDE program, establishing a new compassionate use pediatric device provision, using existing regulatory mechanisms to facilitate device clearance and approval without reduced safety and efficacy standards for children, or creating tax credits or grant programs for companies developing pediatric devices could improve pediatric device access.

We thank Congressmen Markey and Rogers and Congresswoman Eshoo for their leadership on pediatric issues. We look forward to working with the Committee on this important priority.

Conclusion

We believe the reauthorization of MDUFMA that incorporates all the essential elements industry and the FDA have agreed to will enable FDA to further improve its performance—in both quantitative and qualitative ways—while creating a stable and predictable fee structure that benefits both FDA and the device industry. Most importantly, American patients will be the true beneficiaries because of their access to new and innovative medical technology. Advamed would like to thank both our industry colleagues and the FDA staff who worked so diligently over the past year to reach this point. AdvaMed again calls on the Committee work swiftly towards passage.

Mr. PALLONE. Thank you, but we have bad news. There are another two votes, and it appears that there is a pattern because the minority is upset. I don't know for good reason or not. So we will be gone about another 20 minutes or so. Hopefully no longer than that. Sorry. Committee is in recess.

[Recess]

Mr. PALLONE. OK, we will reconvene. And I think we listened to Mr. LaViolette and now we have Dr. Zuckerman.

STATEMENT OF DIANA ZUCKERMAN, PRESIDENT, NATIONAL RESEARCH CENTER FOR WOMEN AND FAMILIES

Ms. ZUCKERMAN. Thank you for inviting me to testify. MDUFMA is one of the most important bills to come before Congress this year and until today, it has received very little attention. So on behalf of medical researchers, patients and consumers, thank you very much for holding this hearing.

I am Dr. Diana Zuckerman, president of the National Research Center for Women and Families, which is an independent think tank that focuses on health and safety issues. Our center is an active member of the Patient and Consumer Coalition. I was trained as an epidemiologist at Yale Medical School. I conducted research at Harvard. I worked as congressional investigator on FDA issues in this building and I am the author of several books and book chapters, including a chapter in a new book on medical devices that just came out.

All of us use medical devices and baby boomers are increasingly relying on implanted medical devices, whether they are hips or heart valves or wrinkle fillers. And the bad news is that most of these medical devices have not been tested in clinical trials as part of the FDA review process. At the Center for Devices and Radiological Health, most devices are approved under an expedited process called the 510(k) process. This process is intended for products that are substantially equivalent to medical devices that are already on the market and sometimes that makes sense. For example, a device that has been modified very slightly to make it a little bit better, but it is still made by the same manufacturer.

But even small changes can affect safety and can be dangerous. So for example, when Bausch & Lomb added MoistureLoc to their contact lens solution. The new product was approved through the 510(k) process. No clinical trials were required and no inspections took place. The result was eye infections and blindness for some of the people who used this product. I am sure we can agree that nobody should become blind from contact lens solution when there is so many safe contact lens solutions available. And nobody should die from a stent or a heart valve that wasn't adequately tested.

I think FDA should always require clinical trials when potentially dangerous devices are modified. MDUFMA II should make sure that the approval process protects consumers. The performance goals of MDUFMA II would drastically speed up this 510(k) process. 90 percent of 510(k) reviews would have to be completed within 90 days, 90 percent/90 days. This is not safe. The PMA device approval process, which is more similar to the drug approval process, is also faster in MDUFMA II. 60 percent of PMA and PMA

supplements would need to be completed in just 6 months. This is considerably faster than what is expected of drugs.

So what would FDA get for speeding up the process? The user fees for these new reviews would actually decrease. For example, the user fee for a 510(k), which is already a bargain at about $4,000 in 2007, is reduced 18 percent to $3,400 in 2008. And it is my understanding that that is the maximum amount for a 510(k). It is the amount that even a multi-billion dollar company would pay for a 510(k).

FDA claims that the total user fees would increase, but that is only because the workload increases as each of these reviews is actually reimbursed—not reimbursed, has a user fee at a lower rate. So MDUFMA II is generous to medical device companies because it reduces those costs and gives faster reviews. What are the benefits to the American public? Sometimes the public benefits from faster reviews and innovations, but innovation is only good if a product is better; not if it is merely new and different. An innovative contact lens solution that causes blindness obviously is not progress.

Dr. Donald Ostergard, a nationally respected urologist, recently gave a speech at a national conference explaining that FDA's frequent use of 510(k) reviews and their failure to adequately test medical devices hurts doctors and hurts patients. He said with no data, doctors can only guess which products work and which ones don't. MDUFMA II has performance goals for speed, but it needs performance goals for public health, as well.

Instead, the FDA is making the approval process for devices even less cautious. So for example, in January of this year, the FDA held a public meeting on a new device called NeuroStar, which uses magnetic pulses to the brain to treat depression. The FDA says that NeuroStar can be approved as substantially equivalent to electroshock therapy, since both treat the same illness, which is depression, if the risk to benefit ratio is similar. So even though it is a completely different device using a completely different mechanism of treatment, they are saying it would be substantially equivalent if the risk to benefit ratio is similar.

But how can the FDA or anybody else determine if the risk to benefit ratio is similar if new devices don't necessarily require clinical trials? If Congress does not stop this regulatory loophole, almost any medical device can be eligible for the much less rigorous 510(k) process. This will certainly help speed up the process, but at the risk of flooding the market with medical devices that either don't work or are not safe.

MDUFMA II does not provide adequate user fees for the review of direct-to-consumer advertising to analyze adverse reaction reports or to make sure that post-market studies prove that the products are safe. So although FDA has the flexibility of spending the user fee money however they want, there is just not enough money for all of the things that they would need to do.

I want to mention that direct-to-consumer ads for potentially dangerous implanted devices, such as gastric LAP-BANDS, are featuring patients giving testimonials about how the product changed their lives and these testimonials are allowed to be paid for by the company in the form of free treatment.

My final criticism is third party inspections. MDUFMA would weaken the restrictions that limit third party inspections. That was already mentioned by Congresswoman Capps and others and I just wanted to reiterate that, that it is really important that something be done about that.

And I also just wanted to say that I share the concerns that were expressed by committee members about the reuse of single use devices and also to mention that one of the concerns about reuse of devices is that although they are relying on adverse reaction reports, we know that the adverse reaction report system isn't working very well and so therefore relying on that won't give us the information we need about whether single use devices are harmful.

Overall, we are very disappointed in FDA's proposed MDUFMA II. Substantial improvements are needed to this legislation to restore America's confidence in the FDA. With your leadership and revisions to MDUFMA II, you can make sure that CDRH has the resources, the regulatory responsibilities, the enforcement powers and the performance goals needed to protect our families, your constituents and the American public. Thank you.

[The prepared statement of Ms. Zuckerman follows:]

Statement of Diana Zuckerman, Ph.D.
President, National Research Center for Women & Families

Before the Subcommittee on Health
House Subcommittee on Energy and Commerce
May 16, 2007

Thank you for the opportunity to testify about the Medical Device User Fee and Modernization Act. MDUFMA II is one of the most important pieces of legislation to come before Congress this year, and so far it has received very little attention. On behalf of medical researchers, patients, and consumers, I thank you for giving it the attention it desperately needs.

I am Dr. Diana Zuckerman, president of the National Research Center for Women & Families, an independent think tank that analyzes and evaluates a wide range of health programs, policies, and agencies, and especially the FDA. We are the only think tank that is strongly focused on the safety of medical devices.

I am trained as an epidemiologist at Yale Medical School and for more than a dozen years I worked in Congress, the U.S. Department of Health and Human Services, and the White House, determining which health policies were working and which ones were not.

We are also active members of the Patient and Consumer Coalition, comprised of nonprofit organizations representing patients, consumers, public health researchers and advocates, and scientists. The Coalition is working to strengthen the FDA and to ensure that FDA approval once again represents the gold standard of safe and effective medical products.

While Vioxx and other drug safety issues have attracted most of the attention of Congress as well as patient and consumer groups, medical devices are increasingly important in our lives. All of us use medical devices, and many of us have a loved one with at least one medical device implanted in their bodies. The aging baby boomer population will increase our reliance on medical devices, whether replacement hips or

heart valves, and the safety of these devices is therefore becoming even more worrisome.

The vast majority of medical devices that the FDA considers for approval have not been required to prove safety and efficacy through double blind clinical trials. This may seem shocking, since double blind clinical trials are the gold standard to prove that a medical product is safe and that it actually works. But, at the Center for Devices and Radiological Health (CDRH), most devices are approved under an expedited process, the 510(k) process, rather than the Premarket Approval (PMA) device approval process.

The 510(k) process is intended for products that are "substantially equivalent" to medical devices already on the market. Sometimes that makes sense-- for example, a medical device that has been modified very slightly by the same manufacturer to improve it. But often, the medical devices approved through the 510(k) process are modified in ways that make them potentially very dangerous. For example, when Bausch & Lomb changed their contact lens solution, called ReNu, to ReNu with MoistureLoc, the resulting product caused eye infections and permanent blindness in numerous consumers. ReNu with MoistureLoc was allowed on the market through a 510(k) process, without *any* clinical trials submitted to the FDA.

As we have recently learned, changes in medical devices, such as heart valves or stents, can be deadly. Shouldn't FDA always require clinical trials when these **implanted** devices are modified? Shouldn't MDUFMA II make sure that the approval process protects consumers?

The performance goals of MDUFMA II would drastically speed up the 510(k) process. Instead of 80% of those applications being completed within 90 days, **90%** would be completed in **90 days**. That's just 3 months -- not long enough for anything resembling a careful review. At 80%, the performance goals were already dangerously fast for many products; 90% is worse, not better, for consumers. No wonder ReNu with MoistureLoc, and other devices, are harming consumers. MDUFMA II also requires that **98%** of 510(k)s be completed within **150 days**. So, you see there is truly no wiggle room for any concerns about more than 2% of these devices. This is not safe.

The PMA device approval process, which is more similar to the approval process for prescription drugs, is also faster in MDUFMA II. Instead of **half** the PMA and PMA supplements being completed in **180 days**, that would increase to **60%**. Instead of **90%** of panel track supplements and premarket reports in **320 days**, that would be shortened by almost a month to **295 days**.

At the same time that MDUFMA II would require speedier reviews, **the user fees are being reduced** for each product. For example, the user fee for a 510(k), already a bargain at $4,158 in 2007, is **reduced 18%** to $3,404 in 2008, even for multi-billion dollar companies. User fees should be much higher for 510(k) applications, to help

ensure that all the safety bases are covered before approval, and to ensure post-market safety standards. Under MDUFMA II, the user fees for a **full PMA review would be reduced more than one-third, from $281,000 in 2007 to $185,000 in 2008.**

The FDA claims that user fees would increase. However, that is only because the workload – the number of products under review – would increase. For each review, the FDA would receive less support from user fees.

The medical device companies must like MDUFMA II. It reduces their costs and gives them faster reviews.

Let me ask you to consider: What are the benefits to the American public?

We are told that the public benefits from faster reviews and innovations. That is sometimes true. But the truth is that contact lens solution choices have satisfied millions of consumers for many years. A new contact solution with MoistureLoc was not an urgent priority. Innovation is only good if a product is better, not if it is merely new and different.

A quick review with inadequate safeguards harms patients. It also harms companies, pressuring each into developing and marketing their own "new" products so that they can compete – even if their old products work wonderfully and need no improvement.

MDUFMA II has performance goals for speed, but none for public health. **Public health performance goals are urgently needed.**

In the last year or two, we learned that patients were harmed by FDA-approved stents, heart defibrillators, contact lens solution, and other products. What did the FDA learn from these terrible tragedies? How did it affect their MDUFMA II negotiations? You'd think that the FDA would respond to these and other medical device problems by being more cautious. You'd be wrong. Instead, FDA is making the approval process for devices even easier.

In January, the FDA held a public meeting on a new device called NeuroStar, which is intended to treat depression using magnetic pulses to the brain. For that product, clinical trials were conducted and the results indicated no significant difference whether the product was turned on or turned off.

Depression is a serious and debilitating disease. The use of ineffective treatments can contribute to feelings of hopelessness, which in turn can worsen the symptoms and even result in suicide. It is therefore especially important to make sure that medical products approved for the treatment of depression are proven safe and effective.

The FDA 510(k) process is intended to be for products that are substantially equivalent to other products already on the market. In this case, the company that makes NeuroStar is claiming that it is substantially equivalent to Electroconvulsive Therapy (ECT), even though it is a very different technology.

The FDA admits that NeuroStar is not really substantially equivalent to ECT because it is a *different kind of product using a different kind of mechanism* – magnetic pulses rather than electric shocks. It is also used on an outpatient basis, rather than inpatient. **But the FDA has apparently changed the definition of "substantially equivalent," which used to mean a very similar product used for the same purpose.** For the NeuroStar review, the FDA publicly stated that the product can be considered substantially equivalent as long as it treats the same illness (in this case, depression) and the *risk to benefit ratio is similar.* In this case, the product is not more effective than placebo, and is less effective than ECT, but it is also less risky than ECT. It can cause pain, muscle twitching, and several other serious adverse reactions, but it does not cause memory loss.

This very loose definition of "substantial equivalence" is also on the FDA web site. But, how can the FDA determine if the risks and benefits are similar for a new device if no clinical trials are required?

If Congress does not do stop this regulatory loophole, almost any medical device can be eligible for the much less rigorous 510(k) process. This could certainly help speed up the approval process, but at the risk of flooding the market with medical devices that either don't work or work but are not safe.

That kind of change will make MDUFMA II performance goals possible, but opens a Pandora's Box that is very dangerous for everyone in this room.

Who is minding the store at the FDA to make sure that medical devices are safe and effective before they can be sold in the United States?

The FDA claims that any medical product will have risks, and they promise that they will do a better job to figure out those risks **after** a product is approved by the FDA. Unfortunately, MDUFMA II does not provide adequate user fees for the review of direct-to-consumer (DTC) advertising or other post-market safety measures. The recently passed Senate drug safety bill does a better job, although not enough, on PDUFA user fees and enforcement of post-market drug safety issues, and those provisions should be expanded and improved upon as you consider much-needed improvements to MDUFMA II.

For example, please ask the FDA how many employees review medical device DTC ads to make sure they are accurate. I have been told that there is only one person in that role. However many reviewers there are, the result is not reassuring. The number of DTC ads for implanted medical devices, such as gastric lap bands and injections to the face to reduce wrinkles, is on the rise. DTC ads for breast implants are currently under review, according to implant manufacturers. Based on the DTC ads that I have personally seen for implanted medical devices on TV and on company Web sites, these ads often feature personal testimonials that present a rosy view of the product with no meaningful risk information. The patients giving the testimonial are paid by

the company, which often provides the treatment for free – a huge gift for just a few minutes of their time.

I have expressed my views on these ads and the lack of post-market surveillance to Dr. von Eschenbach when meeting with him face-to-face. He assures me that the FDA will enforce post-market study requirements. However, MDUFMA II clearly does not provide enough funding to make that possible. It would be an unfunded mandate, requiring FDA to do more with fewer resources to follow through on those promises.

There are other provisions in MDUFMA that concern us, but I will mention only one more: **third party inspections**. Rather than FDA conducting inspections of manufacturing facilities, device companies can directly pay a third party to do the inspection, and can negotiate the price of the inspection. This creates an incentive for these "third parties" to please their customers if they want to stay in business, and an incentive for "third parties" to be more positive about their findings when companies pay more generously.

Would we allow parents to select and pay a "third party" to make all grading decisions for their children in high school? Could different parents pay different amounts of money to these third parties? If we did that, do we think it would probably influence grades – even if school principals tried to monitor the situation?

Would we permit federal employees to select and pay a "third party" to evaluate them every year and make promotion recommendations? If we did, do we think it would probably influence those evaluations and recommendations?

Aren't unbiased reports by third party inspectors of medical products even more important and just as subject to bias?

MDUFMA currently has very modest restrictions on third party inspections of Class II and Class III medical devices, which are the most stringently regulated devices. The current law allows two consecutive third-party inspections, after which the FDA must conduct the next inspection (unless the FDA issues a waiver). These very modest restrictions are not adequate to ensure safety. However, MDUFMA II would weaken even these restrictions, allowing an unlimited number of consecutive inspections without requiring a waiver. This is a bad idea.

Overall, we are very disappointed in FDA's proposed MDUFMA II. Substantial improvements are needed to restore America's confidence in the FDA. With Congressional leadership and appropriate revisions to MDUFMA II, you can make sure that CDRH has the resources, the regulatory responsibilities, the enforcement powers, and the performance goals needed to protect our families, your constituents, and the American public.

Mr. PALLONE. Thank you. Mr. Cullimore.

STATEMENT OF KELVYN CULLIMORE, JR., MDMA SECRETARY, PRESIDENT AND CEO, DYNATRONICS CORPORATION

Mr. CULLIMORE. Thank you, Chairman Pallone and Ranking Member Deal. Appreciate the opportunity to be here today and make my testimony to talk a little bit about the reauthorization of the Medical Device User Fee and Modernization Act.

My name is Kelvyn Cullimore, Jr. I am the president and CEO of Dynatronics Corporation, a small publicly traded medical technology company headquartered in Cottonwood Heights, UT, just outside of Salt Lake City. And we also have manufacturing operations in Chattanooga, Tennessee. Today I am here to testify on behalf of the Medical Device Manufacturers Association, a national organization 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, many of which are developed by small research-driven medical device companies.

Before I discuss the specifics of the MDUFMA II proposal, I wish to emphasize that ideally, FDA's medical device pre-market review system would be funded solely by congressional appropriations. However, given growing budgetary constraints, that does seem unlikely. MDMA opposed device user fees for nearly a decade. However, we modified our position in 2002 when MDUFMA I incorporated specific protections for small companies.

It remains essential, however, that Congress continue to maintain its primary role in funding FDA. As mentioned, MDUFMA I included important provisions that granted smaller companies fee relief, including an initial PMA waiver and a two-tiered user fee structure. These provisions have proven critical given the entrepreneurial nature of the medical device industry. Unlike the pharmaceutical industry, innovation in the medical device industry is primarily driven by smaller companies working directly with doctors and engineers. Maintaining the safeguards for smaller companies under MDUFMA II is crucial to continuing this innovative environment.

The MDUFMA II proposal seeks to address a number of issues that arose under MDUFMA I. For example, under MDUFMA I, fee revenues were generated solely from application fees. As a result, in just a few years, some fees spiked as much as 60 percent. These types of increases cannot be sustained and MDMA was pleased when Congress acted, under MDUFSA, to cap annual fees increases at 8.5 percent. These same annual caps exist under the MDUFMA II proposal. MDMA views these caps as critical to the stability of the program.

MDUFMA II will expand the types of user fees that FDA collects; in addition to application fees established under MDUFMA I, MDUFMA II would add new annual report and registration fees, which would limit the fee variability encountered under MDUFMA I and reduce application fees for all companies.

MDMA also supports the interactive review principle established under MDUFMA II to improve communications and interaction between FDA and the industry. In light of continuing advancements

in medical technologies, it is increasingly important for FDA reviewers and sponsors to engage in open and regular dialog. MDMA believes that early and frequent communications with the agency will prevent unnecessary delays in the completion of the review, avoid surprises to FDA and the sponsor at the end of the review process, minimize the number of review cycles and ensure timely responses from the sponsors.

MDMA also supports efforts to simplify the MDUFMA performance goals to allow FDA to better manage the overall review process. FDA has stated that the current MDUFMA I cycle goals, created inefficiencies in the review process. Therefore FDA and industry have agreed, under MDUFMA II, to eliminate dozens of intermediate cycle goals. Instead, FDA would be measured on performance goals for overall time to final decision.

In addition to the user fee provisions, MDMA strongly supports modifications to the Third Party Inspection Program and provisions which encourage greater clarity on a variety of issues, including the development of additional guidance documents. MDMA understands that there are other issues beyond MDUFMA II that this committee will be considering in the coming weeks. Specifically, I would like to express MDMA's strong support for legislation that provides incentives to manufacturers to develop pediatric medical devices. However, MDMA wishes to emphasize that any legislation must be carefully crafted to avoid creating unintended disincentives. MDMA looks forward to working with the committee and other interested stakeholders to address these issues in a manner that encourages the development of pediatric products.

In closing, I would like to thank the committee for your efforts on behalf of the innovative entrepreneurial medical technology companies and patients. Both stand to significantly benefit with the reauthorization of MDUFMA II. I look forward to answering any questions that you might have.

[The prepared statement of Mr. Cullimore follows:]

Hearing Testimony

Kelvyn Cullimore Jr.
President and Chief Executive Officer
Dynatronics Incorporated

On Behalf Of
The Medical Device Manufacturers Association (MDMA)

Before the House Energy and Commerce
Subcommittee on Health

"Reauthorization of the Medical Device User Fee and Modernization Act"

May 16, 2007

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

Thank you for inviting me to testify before you today on the reauthorization of the Medical Device User Fee and Modernization Act ("MDUFMA").

My name is Kelvyn Cullimore and I am the President and Chief Executive Officer of Dynatronics Corporation.[1] 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 operations also

[1] I have included a copy of my curriculum vitae as Attachment I to this testimony.

located in Chattanooga, Tennessee. Between both operations, Dynatronics employs 140, with 90 employees in Utah and 50 employees in Tennessee.

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 $20,000,000 in annual sales.

Today, I am here to testify on behalf of the Medical Device Manufacturers Association ("MDMA"), a national organization 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 reauthorization of the Medical Device User Fee and Modernization Act of 2007 ("MDUFMA II").

Background of MDUFMA

Ideally, FDA's medical device premarket review system would be funded solely by congressional appropriations. As you may know, MDMA was founded in 1992 primarily to oppose attempts to institute a device user fee program. However, in 2002, with the country facing budgetary constraints and the need for FDA to enhance its capabilities, MDMA reconsidered its position on user fees. After long negotiations with FDA, industry and Congress, the Medical Device User Fee Modernization Act of 2002 ("MDUFMA I") was enacted which established a user fee program that provided FDA with the resources it needed from a combination of increased appropriations and industry fees. In addition, MDUFMA I included

important provisions to ensure that smaller companies received fee relief. These included 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.

Given the dramatic differences between the pharmaceutical industry and the medical device industry, the two-tiered fee structure has proven critical to ensure that smaller device companies continue to have the ability to innovate. Unlike the pharmaceutical industry, much of the innovation in the medical technology industry is driven by smaller companies working with doctors and engineers to improve the quality of care for patients.

The two-tiered structure was further enhanced in 2005 under the Medical Device User Fee Stabilization Act by increasing the small business threshold to $100 million in annual sales. This change was a direct result of companies with sales between $30 million -$100 million withholding PMA submissions because they did not have a half million dollars in their regulatory budget for the submissions. Therefore, changes were made to ensure that MDUFMA achieved its objective of providing patients with timely access to safe and effective products.

Other important provisions also were enacted under MDUFMA I including greater oversight of reprocessed single use devices ("SUDs") and the implementation of a third party inspection program.

MDMA supports reauthorization of MDUFMA and sees this as an opportunity to address some of the issues that arose under MDUFMA I. MDMA, other medical device industry representatives, and FDA have been collaborating since January 2006 on ways to improve the user fee structure, performance goals and premarket review of medical devices under MDUFMA II. In particular, MDMA supports the provisions that will simplify the MDUFMA performance

goals, improve communication between FDA and the industry, and create a more stable fee structure that provides greater fee relief for smaller companies.

User Fees

As an initial matter, I want to emphasize the importance of Congress maintaining its primary role in funding FDA. Under MDUFMA I, the device user fees represented approximately sixteen percent of FDA's overall device budget. Under MDUFMA II, that percentage is expected to increase to approximately twenty-three percent. As discussed in more detail below, MDMA strongly believes that moving forward, adequate congressional appropriations are necessary to ensure that industry's contribution in fees relative to the device budget does not increase in the future. Doing so would run the risk of the Center relying too heavily on the industry for resources and create an unsustainable program.

The FDA must have sufficient, stable resources to review and assess the safety and effectiveness of medical devices, and to provide physicians and patients with access to improved medical technologies as quickly as possible. MDMA supports user fees as a component of the funding necessary for FDA to achieve the improved performance goals. The user fee system established under MDUFMA II improves on the fee structure implemented under MDUFMA I. MDUFMA II will provide a fee structure that is more stable and provides greater fee relief for small companies. Instead of relying solely on application fees imposed under MDUFMA I, the reauthorization would expand the categories of fees to include new annual report and establishment fees.

Importantly, all companies will see significant reductions in their application fees under MDUFMA II's proposed fee structure. Over the five years of MDUFMA II, the application fees will be lower than those paid in 2007 in almost all application categories.

Indeed, for companies with annual revenue of less than $100 million, application fees will be reduced between fifty and seventy percent. For small and early-stage device companies, the significance of these fee reductions and the relief they provide can not be overstated.

Under MDUFMA II, application fees will account for approximately fifty percent of the user fees that are imposed. FDA would obtain additional user fee revenue from the new annual establishment fee and annual report fees. These fees, which will be spread across a larger number of device manufacturers, will supply the remaining fifty percent of the user fee revenues. Under MDUFMA I, fee revenues were generated from application fees alone. The revenues generated from application fees were unpredictable and fluctuated from year to year. The addition of the new establishment and annual report fees will provide necessary stability and predictability for FDA revenue and will reduce the link between the fees and the premarket review process.

Performance Goals

MDUFMA I tied the user fee provisions to performance goals for FDA's review of premarket submissions that were agreed to by industry representatives and the FDA in 2002. During the past four years under MDUFMA I, FDA has achieved many of its performance goals and has improved its review performance in many respects. However, some of the original performance goals created unnecessary inefficiencies in FDA's review process. In addition to performance goals for final decisions, MDUFMA I also included interim cycle performance goals, such as a requirement that FDA issue a first-action major deficiency letter within 150 days. FDA and industry found that these interim cycle goals artificially interrupted the review process and often delayed FDA's final decisions on premarket submissions. Therefore, the MDUFMA II reauthorization agreement has eliminated these cycle goals. Instead, the FDA will be measured

with respect to performance goals for overall time to final decisions. This will permit FDA to improve efficiency of the entire review process. For example, FDA has committed to reviewing sixty percent of PMAs in 180 FDA days. The elimination of inefficient and nonproductive cycle goals is expected to increase informal communications between FDA and industry and help get safe and effective devices to patients and healthcare professionals more quickly.

MDMA supports these efforts to improve communication and interaction between FDA and the industry. MDUFMA II encourages FDA to promote an interactive review process. It is increasingly important, in light of continuing advancements in medical technologies, for FDA reviewers and sponsors to engage in open and regular dialogue in order to enhance FDA's ability to make sound and timely premarket decisions on the safety and effectiveness of medical devices. MDMA believes that early and frequent communications with the agency will prevent unnecessary delays in the completion of the review; avoid surprises to FDA and the sponsor at the end of the review process; minimize the number of review cycles; and ensure timely responses from sponsors.

Pediatric Medical Devices

MDMA recognizes the significant challenges associated with the identification, development and testing of medical devices for pediatric patients. MDMA therefore strongly supports legislative efforts, such as provisions in the legislation recently passed by the Senate, increasing incentives to encourage manufacturers to develop medical devices specifically targeted to pediatric populations. In light of the additional challenges in developing and obtaining clearance or approval for pediatric devices intended for a small patient population, MDMA strongly supports the expansion of the Humanitarian Device Exemption ("HDE") to include devices that are intended for the treatment or diagnosis of a disease or condition that

occurs in small pediatric populations or subpopulations. This provision will improve access to pediatric devices required by these vulnerable patient populations. Indeed, we would encourage the Congress to grant broad flexibility to FDA to determine when and how to grant an HDE by, for example, permitting FDA to grant HDE status to a manufacturer even if the patient population exceeds 4,000 patients.

Legislation intended to provide incentives to develop pediatric medical device must not unintentionally create disincentives that would in fact discourage pediatric medical device development. We are concerned that the revisions proposed to Section 522 of the FFDCA in the legislation passed by the Senate, which would explicitly permit the FDA to order a postmarket surveillance study for a Class II or Class III device "that is expected to have significant use in pediatric populations," would provide just such disincentives. This proposed provision would permit FDA to order postmarket surveillance in pediatric patients as a condition of approval of a PMA application or clearance under section 510(k) of the FFDCA, regardless of whether the manufacturer is seeking approval or clearance to market the device for a pediatric subpopulation.

As an initial matter, we believe that the Senate's proposed revisions to Section 522 are unnecessary because FDA currently has ample authority under Section 522 to order postmarket surveillance for Class II or Class III devices the "failure of which would be reasonably likely to have serious adverse health consequence or which is intended to be implanted in the human body for more than one year, or a life sustaining or life supporting device used outside a device user facility." Thus, if FDA determines that a Class II or Class III medical device is likely to have serious adverse health consequences if used in a pediatric population, the FDA may, under existing Section 522, require postmarket surveillance. Furthermore, the proposed revision to

Section 522 could delay approval or clearance of devices for market. By permitting FDA to "condition" approval or clearance on postmarket surveillance, FDA could prevent a manufacturer from marketing a device, for its approved or cleared indications, until the manufacturer agreed to conduct potentially burdensome and expensive studies on unapproved pediatric uses of the device. As a result, the Senate's proposed revisions to Section 522 may deter manufacturers from developing medical devices that may have a potentially significant pediatric use. A manufacturer may decide during the initial approval or clearance process, to contraindicate its device for use in pediatric populations to avoid being subject to burdensome and costly postmarket surveillance.

MDMA is concerned that the Senate's proposed amendment to Section 522 will significantly increase burdens on manufacturers without resulting in any clear benefits. Use of a device in pediatric populations that does not have an approved or cleared pediatric indication may be considered off-label use. Collecting information regarding off-label uses of a device can be burdensome and costly since manufacturers typically have limited access to information regarding how physicians use the device. Data obtained from a manufacturer's postmarket surveillance of pediatric use of a medical device is therefore unlikely to produce meaningful information. Because manufacturers may not market their products for off-label pediatric uses, information regarding a device's off-label pediatric use will likely be incomplete and difficult to interpret. FDA should not be authorized to collect information that will not result in meaningful conclusions or changes.

Medical Device Clinical Trial Registry

MDMA strongly supports legislative efforts to improve patient and physician access to information regarding the safety and efficacy of medical devices. Such access is important to

permit physicians and patients to weigh the risks and benefits of a medical device as a treatment option. In developing measures to increase access to medical device information, it is critical to consider the nature of the medical device industry in order to avoid adopting requirements that will discourage innovation or that are prohibitively burdensome and expensive. As I have previously discussed, unlike the pharmaceutical industry, the highly competitive medical device industry is comprised mostly of small companies whose eventual success is dependent upon their ability to continually modify and improve their products and protect the trade secrets and intellectual property associated with their medical devices. Because of fundamental differences between drugs and medical devices, any requirements that are developed to increase access to information on medical devices should reflect their unique nature, use, development, and regulation.

MDMA believes that the legislation recently passed in the Senate provides patients, physicians and the public with useful information on medical devices that have been cleared or approved by FDA. The legislation recognizes that making this information public before FDA clearance or approval would stifle innovation because companies would be concerned about proprietary information being made available to competitors before the product was on the market. The medical device clinical trial registry and results database created under the Senate bill will provide beneficial information to patients and physicians while balancing medical device manufacturers' important need to protect their confidential trade secret and intellectual property of their medical devices.

Again, thank you for providing me with the opportunity to testify today before the Committee.

Mr. PALLONE. Thank you. We have another wonderful vote, but in the meantime I am going to try to keep going, so Mr. Grossman.

STATEMENT OF STEVEN A. GROSSMAN, EXECUTIVE DIRECTOR, THE FDA ALLIANCE

Mr. GROSSMAN. Chairman Pallone, Representative Deal, thank you for the opportunity to testify. I am Steven Grossman, the executive director of the FDA Alliance. We are a broad-based, nonpartisan coalition of consumers, patients, healthcare professionals and industry. Since our founding a year ago, we have grown to more than a hundred members, including seven former FDA commissioners.

Our core concern is that FDA is severely under-funded, relative to the vast responsibilities given it by Congress and the justifiable expectations of the American people. The FDA Alliance believes that the hardworking FDA staff cannot keep up with the increasingly complex and growing workload without additional staff, improved information technology and increased support for training, outreach and scientific standards.

Second, strengthening FDA must be a priority for this and subsequent Congresses. The funding shortfalls affect every aspect and every part of the agency.

Third, FDA should be fully funded through appropriations augmented by user fees. User fees cannot be allowed to substitute for sufficient levels of appropriated funds.

Since 2003, the FDA has lost about 20 percent of its buying power and has nearly a thousand fewer employees supported by appropriated dollars. There are consequences. It is harder to maintain our Nation's economically valuable position as the gold standard for food, drug and device regulation. Also, it is difficult for FDA to recruit and retain the best and the brightest when the resources are inadequate.

FDA spends more than 83 percent of its budget to support its workforce. It needs a 6 percent annual increase in appropriations just to maintain current services. CDRH, actually, is even needier. It needs about 7 percent. Yet annual appropriations to FDA never include the full costs of the agency of pay and benefit increases or rising non-pay costs.

FDA is the Nation's premier consumer health and safety agency. But in addition, it also is vital to the Nation's economy. Innovative companies need a cutting edge regulator to prepare the way for breakthroughs in medical science and products that combine drugs and devices. Companies are not helped when they are ahead of FDA on the science. That doesn't work and things slow down instead of speed up as they should.

FDA also must be strengthened to assess more sophisticated products and to monitor the increasingly complex safety parameters in drugs, food, medical devices and veterinary products. Congress should make a long-term commitment to upgrade FDA's appropriated funding. We recommend that Congress start providing FDA with $2 billion in appropriated budget authority for fiscal year 2008, an increase of about $450 million over the current appropriation. This would restore the 2003 agency operating capability, plus mandated programming. This is something of "Back to the Future."

Things were actually better 5 years ago and the agency has clearly lost ground.

Adding in user fee revenue would result in the total FDA budget of about $2.5 billion in fiscal year 2008. Of the proposed $450 million increase in appropriated funding, we recommend that the Centers for Medical Devices and Radiological Health and related field activities receive an increase of $72 million in fiscal year 2008. This would bring the Center from its current $230 million to $302 million, not including user fees.

Because devices are cutting edge science, CDRH needs these non-user fee monies for additional staff to perform product reviews, assure pre- and post-market safety, and facilitate innovative technology coming to market. An updated, modernized IT system is also essential to support the Center and its staff. Most of the praise that committee members have given to CDRH, which is justified, point at different activities and say MDUFMA did this and MDUFMA did that. Most of those activities were funded by appropriations and many of the expectations you have for CDRH and for medical devices in the future will not happen, user fees or no user fees, without an increased appropriation.

In closing, Congress appropriates $4.94 per American per year, excluding user fees, for the FDA. At our proposed level of $2 billion, we would be spending only $6.67 per American per year. For reference purposes, the difference is about the same as a package of 15 assorted Band-Aids. In closing, $2 billion in appropriated funds, sustained and increased over four subsequent fiscal years, will help FDA fulfill its mandate and be innovative in its approach to regulation, oversight, inspections and monitoring. Thank you.

[The prepared statement of Mr. Grossman follows:]

STATEMENT OF STEVEN A. GROSSMAN
EXECUTIVE DIRECTOR, THE FDA ALLIANCE
BEFORE THE
SUBCOMMITTEE ON HEALTH, HOUSE COMMITTEE ON ENERGY AND COMMERCE
WEDNESDAY, MAY 16, 2007

Chairman Pallone, Representative Deal and Members of the Subcommittee:

Thank you for this opportunity to testify on "Reauthorization of the Medical Device User Fee and Modernization Act" and related funding issues faced by the US Food and Drug Administration (FDA).

I am Steven Grossman, the Executive Director of The FDA Alliance. We are a broad-based, non-partisan coalition of consumers, patients, health care professionals, and industry. We have more than 100 members, including seven former FDA Commissioners. A list of members is at the end of my testimony.

FDA is America's premier consumer protection agency, yet the agency is **severely underfunded relative to the vast responsibilities given it by Congress and the justifiable expectations of the American people.** Appropriated funding (budget authority) is the agency's primary source of funds and needs to keep pace with the agency's mission and needs. Further, the FDA Alliance believes that:

- **The staff of the FDA are dedicated, hardworking and effective. They cannot keep up with the increasingly complex, growing workload without additional staff, improved information technology, and increased support for training, outreach, and scientific standards.** Over time, lack of support has made it difficult to recruit and retain the "best and brightest." It has eroded our nation's economically-valuable position as the "gold standard" for food, drug, and device regulation.

- **Strengthening FDA must be a priority for this Congress.** The funding shortfall affects every part of the agency, as well as its collective infrastructure. A five-year commitment is needed.

- **FDA should be fully funded through appropriations (budget authority) and augmented by the user fee programs that have become necessary to assure adequate funding for FDA.** Such fees cannot be allowed to substitute for sufficient levels of appropriated funds (budget authority).

Wholly apart from MDUFMA and other user fee revenue, **the FDA needs $2 billion in FY08 appropriated budget authority, an increase of about $450 million over this year's levels.** This higher level would restore FDA to the capabilities it had in FY03 and enable the agency to carry out the public health and safety program initiatives mandated by subsequent appropriations bills. **Of this $450 million increase, we recommend that the Center for Medical Devices and Radiological Health and its related field activities receive an increase of $72 million in appropriated funds (budget authority).**

Because devices are cutting-edge science, CDRH needs *these non-user fee monies* for additional staff to perform reviews, assure pre- and post-market safety, and facilitate innovative technology coming to market. An updated, modernized IT system is also essential to support the Center and its core and field staff.

Position of the FDA Alliance

The U.S. needs a strong FDA that is sized and modernized to carry out its responsibilities, now and in the future in a global economy with threats and opportunities that span the world. Instead, FDA is underfunded and understaffed despite responsibility for a quarter of all consumer spending. A weakened FDA undermines the agency's ability to carry out its dual roles: leading guardian of consumer health and safety and active leader in advancing global scientific and medical innovation.

FDA receives minimal new funds each year. Its ability to fulfill its mission is compromised by increasing costs, evolving missions, expanding science, and changing technologies. The American people and the Congress expect more from the FDA than it can deliver without additional funds.

User fees are an important component of the resources available to the FDA, but cannot substitute for significantly increased appropriations and a long-term commitment by Congress to assure that the FDA has the resources it needs.

The U.S. Food and Drug Administration needs $2 billion in FY08 appropriated budget authority in addition to any user fees. This increase would restore FDA to the capabilities it had in FY03 and would enable the agency to carry out the public health and safety program initiatives mandated by subsequent appropriations bills. Since FY03, FDA's budget has not kept up with inflation and has lost 20% of its buying power. An investment in FDA is imperative and long overdue. We need to preserve and sustain FDA's ability to protect Americans, advance innovation, and remain the regulatory "gold standard" worldwide. **Adding in user fee revenues, this would result in a total FDA budget of about $2.5 billion in FY 2008.**

Analysis done by FDA for stakeholder presentations last summer suggest that the agency appropriation is underfunded by $300 million to $800 million, compared to what is needed to accommodate its existing statutory program responsibilities and Congressional mandates. A version of this analysis is part of this testimony and demonstrates that $2 billion in FY 08 budget authority (with user fees additional) is an appropriate target for immediate reinforcement of FDA and its mission.

For example, $2 billion in FY08 appropriated funding (budget authority) is needed to sustain the public health and safety priorities given to FDA by Congress in such critical areas as:

- food safety
- counterterrorism/defense
- pandemic preparedness
- patient safety
- medical device reviews, as well as animal drug and generic drug reviews
- modernizing regulations to prepare for new technologies, such as nanotechnology.

Other key priorities include: improved and more capable information technology systems at FDA and restoring the field force that inspects foods, imports and manufacturing sites to post-9/11 staff levels.

Much of the historic underfunding of FDA can be attributed to a failure to fund the personnel costs required to fulfill the agency's mission. FDA spends more than 83% of its budget to support its workforce. The costs of maintaining and supporting staff have increased at a much faster rate than the agency's appropriated resources. By its own calculations, FDA needs inflation increases each year of at least 5.8% just to maintain its current service and staff level. Based on the MDUFMA proposal, this figure may actually be closer to 6.5%. Annual appropriations to FDA never include the full cost to the agency of pay and benefit increases or rising non-pay costs.

Currently, Congress appropriates just $4.94 per American per year (excluding user fees) to the FDA. At $2 billion in appropriated funds (budget authority) for FY08, this would still represent spending only $6.67 per American to help FDA keep pace with its vital missions and services. **Congress should make a long-term commitment to upgrade FDA's appropriated funding, so it can be more effective as the nation's premier consumer health and safety agency.**

A strong FDA is also vital to the nation's economy. Innovative companies need a cutting edge regulator to prepare the way for breakthroughs in medical devices and combination product regulation. As well, FDA must be strengthened to assess more sophisticated products and monitor the increasingly complex safety parameters in drugs, food, medical devices and veterinary products.

Providing $2 billion in appropriated funding in FY08 – and sustaining that level of budget authority and providing budget growth as needed for the next four fiscal years – will help the FDA fulfill its mandate and be innovative in its approach to regulation, oversight, inspections, approvals, and monitoring.

The following chart shows the FY 2006 appropriations, the FY 2007 final continuing resolution, the President's FY 2008 request and the FDA Alliance's request for FY 2008. The middle row—budget authority without user fees—is what sustains the bulk of the FDA's activities and is the focus of the FDA Alliance advocacy. A significant increase in budget authority appropriations is needed to strengthen FDA.

	FY 2006 Actual	FY 2007 CR	President's FY2008 Request	FDA ALLIANCE Request for FDA for FY 2008
Total program, incl. user fees	$1.876 billion	$1.965 billion	$2.085 billion	**$2.45 to $2.5 billion**
Budget authority (w/o user fees)	**$1.495 billion** includes $ 8 million For building and facilities	**$1.574 billion** Includes $ 5 million For building and facilities	**$1.641 billion** Includes $ 5 million For building and facilities	**$ 2.00 billion**
User fees	$ 382 million	$ 407.5 million	$ 444 million (FY07 plus inflation, not FDA user fee proposal of Feb. 2007) Includes proposed user fee: $ 16 million (generic drugs)	**$450 to $500 million (estimate)** **(assumes renewal of existing user fees at FDA's proposed higher levels)**

This table is subject to correction due to the nature of the sources used to compile the information. In addition, budget figures have been rounded for the purposes of this table.

Attachments:

1. Q&A: FDA Alliance Budget Recommendations for FY 2008
2. List of 108 FDA Alliance Members, as of May 11, 2007

The FDA Alliance

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Q & A: FDA ALLIANCE BUDGET RECOMMENDATIONS

What is the FDA Alliance Recommendation?

- ✓ $2 billion in FY 2008 budget authority/appropriations *(user fees would add about $500 million to this)*
- ✓ This is an increase of $450 million in BA appropriations compared to the FY 2007 CR level

How did the FDA Alliance derive its recommendation?

As shown in the chart on the next page, our $2 billion budget recommendation represents that amount of funding needed to bring FDA appropriations back up to its FY2003 funding level:

- ✓ FY 2003 appropriated funding, increased by 5.8% per year (the amount FDA's costs increase each year) for FY2004-FY2007; and
- ✓ Including program mandates as directed by the appropriations committee since 2003

Can FDA absorb $450 million in new budget authority/appropriations in one fiscal year?

Funding of this scale is necessary to assure the public health and support US economic growth. The FDA Alliance has consulted a variety of sources familiar with FDA's needs and capacity. They agree that:

- ✓ Upfront investment requirements are large (e.g. for adverse events data bases)
- ✓ A substantial number of new hires are needed (e.g. to restore personnel levels to at least FY03 levels)
- ✓ FDA has the ability to enter into contracts and hire personnel to use $450 million effectively

How would FDA Alliance allocate the $450 million among FDA's various missions?

- ✓ The FDA Alliance recommends that each center's percentage of a $430 million increase be equal to the center's percentage of non-rent budget authority appropriations over the last 5 years.
- ✓ The remaining $20 million is allocated to rent costs for increased staff at the proposed level

Recommended FY08 Budget Authority Increases by Center				
(based on 5-year historical FDA budget allocation of non-rent, non-user fee appropriations)				
Center/Major Function	FY 2007 Appropriations *(budget authority w/o user fees)*	*% of Non-Rent BA Approp.*	FDA Alliance : Recommendations for Budget Authority/Appropriations FY 2008	Increase Over FY 2007
Foods	$457,105,000	33%	$597,105,000	+$140,000,000
Drugs	$315,138,000	23%	$413,138,000	+$98,000,000
Biologics	$144,547,000	11%	$191,547,000	+$47,000,000
Animal Drugs& Feed	$94,749,000	7%	$124,749,000	+$30,000,000
Devices & Radiol. Health	$230,683,000	17%	$302,683,000	+$72,000,000
NCTR	$42,056,000	3%	$55,056,000	+$13,000,000
Other Activities	90,541,000	7%	$120,541,000	+$30,000,000
SUBTOTAL	**$1,374,819,000**		**$1,804,819,000**	**+$430,000,000**
Rent & Facility-Related Costs	$199,375,000		$219,375,000	+20,000,000
TOTAL	**$1,574,194,999**		**$2,024,194,000**	**+$450,000,000**

Note: FDA Alliance recommendations and allocations do not include any new authorities that may result from pending legislation and do not include user fee revenue.

Total FDA Appropriated S&E Budget Authority, If...

1. Appropriated Budget Authority had increased at 5.8% per year over FY 2003 level, and
2. All funds for program increases had really been added to the Appropriation

UNDER THESE ASSUMPTIONS,
THE FY 2008 BUDGET AUTHORITY SHOULD BE $2 Billion,
WITH USER FEES SEPARATE AND ADDITIONAL

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Amt if 2003 increased by 5.8% per year	**$ 1,373**	**$ 1,453**	**$ 1,537**	**$ 1,626**	**$ 1,720**	**$ 1,820**
Additions Shown in Budget, and then increased in Subsequent years at 5.8%						
1) Food Safety Counterterrorism/Defense		$ 20.5	$ 83.7	$ 94.4	*See Discussion Below Regarding FY 2007 Funding*	*See Discussion Below Regarding FY 2008 Funding*
2) Patient Safety		$ 3.0	$ 3.2	$ 3.4		
3) OTC Drugs		$ 0.7	$ 0.7	$ 0.7		
4) Generic Drugs		$ 8.0	$ 8.5	$ 9.0		
5) BPCA		$ 3.5	$ 3.7	$ 3.9		
6) Medical Device Review		$ 1.0	$ 26.6	$ 34.2		
7) Orphan Product Grants			$ 1.2	$ 1.3		
8) Influenza (transfer from OC)			$ 0.3	$ 0.3		
9) Medical Product Countermeasures			$ 5.0	$ 5.3		
10) BSE/Mad Cow Disease			$ 8.0	$ 8.5		
11) Drug Safety				$ 10.0		
12) Critical Path				$ 0.8		
13) DTC Advertising				$ 0.9		
14) Pandemic Preparedness				$ 20.0		
Total Additions		**$ 37**	**$ 141**	**$ 192**	**$ 203**	**$215**
What would have been:	**$ 1,373**	**$ 1,489**	**$ 1,678**	**$ 1,819**	**$ 1,924**	**$ 2,035**
Actual Appropriation: [1]	**$ 1,373**	**$ 1,379**	**$ 1,450**	**$ 1,487**	**$ 1,574**	
Difference (shortfall)		**$ (110)**	**$ (228)**	**$ (332)**	**$ (366)**	
Percent Difference (shortfall)		**-7%**	**-14%**	**-18%**	**-19%**	

[1] From S&E Budget Authority in All Purpose Tables in Congressional Budget Justifications

FY2007:

FY 2007 is calculated as a 5.8% increase over 2006, including prior year program additions

$1.819 billion X 1.058 = $1.924 billion

FY2008:

Using the above calculation as a baseline and assuming no further program additions, FY 2008 would be calculated as a 5.8% increase over 2007

$1.924 billion X 1.058 = $2.036 billion

Based on analysis done by Frank Claunts for FDA, with revisions, updates and annotations by the FDA Alliance March 13, 2007

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FDA ALLIANCE MEMBERS—as of 5/11/07: 108 members

HONORARY MEMBERS—Former FDA Commissioners

Charles C. Edwards, MD
Jere E. Goyan, PhD (deceased)
Frank E. Young, MD
Lester M. Crawford, DVM, PhD
Donald Kennedy, PhD
Arthur Hull Hayes, Jr., MD
Jane E. Henney, MD

NON-PROFITS

Academy of Managed Care Pharmacy
Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD)
Allergy and Asthma Network/Mothers Of Asthmatics
Alliance for Aging Research
American Celiac Disease Alliance
American Dietetic Association
American Porphyria Foundation
American Society for Clinical Pharmacology and Therapeutics
American Society for Pharmacology and Experimental Therapeutics
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
Aplastic Anemia and MDS International Foundation
Celiac Sprue Association
Center for Science in the Public Interest
Children's Tumor Foundation
The Critical Path Institute
Elizabeth Glaser Pediatric AIDS Foundation
FasterCures
Foundation for Allergy and Immunology Research
GBS/CIDP Foundation International
Hemophilia Federation of America
Hydrocephalus Association
Institute for African-American Health
Institute for Alternative Futures
International Foundation for Anticancer Drug Discovery
International Foundation for Functional Gastrointestinal Disorders
Jefferson County (AR) Industrial Foundation
Minority Physicians Research Alliance
National Alliance for Hispanic Health
National Consumers League

National Foundation for Celiac Awareness
National Hemophilia Foundation
National Kidney Foundation
National MPS Society
National Organization for Rare Disorders
National Research Center for Women & Families
Neurofibromatosis, Inc.
Parent Project Muscular Dystrophy
Patient Safety Institute
Prevent Blindness America
RetireSafe
Society for Women's Health Research
Sturge-Weber Foundation
TMJ Association
US Pharmacopeia
Wilson's Disease Association

TRADE ASSOCIATIONS
Consumer Healthcare Products Association
Cosmetic, Toiletry, and Fragrance Association
Massachusetts Medical Device Industry Council
Medical Device Manufacturers Association
National Association of Chain Drug Stores
Pharmaceutical Research and Manufacturers of America

COMPANIES
Allergan
Ligand Pharmaceuticals
Pfizer
Schering-Plough
AstraZeneca
Merck
ResVerlogix
UCB
Cephalon
Ovation Pharma
Sanofi Aventis

LAW FIRMS/CONSULTING FIRMS
Bedard & Associates Consulting
Chesapeake Research Review, Inc.
Engage Health
HealthPolCom Consulting
HPS Group
International Regulatory Affairs Group
Rx Development
Strategic Health Policy International
Webster Associates
Catalyst Healthcare Consulting
ECG, Inc.
Garvey Associates
HillCo Partners
Immel Resources
Resolute Regulatory Consulting
SciWords
TeleMedicine & Medical Informatics Webster and

INDIVIDUALS
Ronald Alexander
J. Richard Crout
Ron Hammerle
Bruce Mackler
Wayne Pines
Michael R. Taylor
Anthony Celeste
Donna R. Cryer
Pamela Jones
Gerry F. Meyer
Ted Roumel
Frank Claunts
James Dickinson
Sandra Kamisar
Art Norris
William Schultz
Richard Cooper
Mary H. Hager
John Kamp
Stuart Pape
Bert Spilker

Mr. PALLONE. Thank you, Mr. Grossman.

We have 5 minutes, so if you use your whole 5 minutes, we won't be able to stay. Thanks.

STATEMENT OF DIANE E. DORMAN, VICE PRESIDENT FOR PUBLIC POLICY, NATIONAL ORGANIZATION FOR RARE DISORDERS.

Ms. DORMAN. Mr. Chairman, Mr. Deal. Thank you for giving me the opportunity to testify before you today regarding the reauthorization of MDUFMA II. I will also share my views on the pediatric device bill, which is very important to NORD, that is sponsored by Mr. Markey and Mr. Rogers.

I am Diane Dorman, vice president of public policy for the National Organization for Rare Disorders. Because most patients with rare diseases have no or few treatments, our primary goal is to encourage research and development of new orphan drugs and biologics and humanitarian devices. I will speak only briefly about MDUFMA reauthorization.

NORD believes that the FDA, in a perfect world, should be fully funded through appropriations, but we recognize for now user fees are inevitable and crucial to ensure that safe and effective products reach the public as quickly as possible, therefore we do not oppose the concept of user fees for medical devices. I testify before you today to express NORD's strong support of the Pediatric Medical Device Safety Improvement Act. Children need medical devices that are safe, effective and made just for them. Devices must take into account the small size of children and accommodate their growing and changing bodies and active lifestyles.

Yet doctors continue to be frustrated by the lack of modern medical devices for children because today's devices are not made with these considerations in mind and some vital life saving devices are not made at all. Consequently, children are frequently denied access to the latest technologies that we have heard a lot about today. They don't have access to lifesaving devices, some that could save their lives. Doctors are left with only one untenable option and they are forced to jerry-rig existing devices in hopes of accommodating the needs of their young patients.

NORD supports all the provisions of H.R. 1494, including the FDA's ability to track the number and type of devices approved specifically for children, as well as the destination of a contact point or office within the NIH to help innovators. There are two provisions that are of particular interest to me. First is the 6-year demonstration grant provision supporting nonprofit consortium to provide critically needed support to help innovators with pediatric devises. Perhaps had this nonprofit consortium existed previously, it would have not taken Dr. Robert Campbell 14 years to invent, develop and then bring to market the Vertical Titanium Rib.

I would like to turn your attention to the screen. This is the titanium rib developed by Dr. Robert Campbell. He is a Professor of Orthopaedics and also a pediatric surgeon at the University of Texas Health Science Center in San Antonio. Next slide.

[Slide]

This is Devon prior to the surgery insertion of the titanium rib. Next one, please.

[Slide]

This is the surgery after.

Mr. PALLONE. Ms. Dorman, you know what I am going to do? I am just going to take a recess because I only have 2 minutes, all right?

Ms. ZUCKERMAN. OK.

Mr. PALLONE. And then we will come back and finish with your statement and then we will take questions.

Ms. ZUCKERMAN. OK.

Mr. PALLONE. Thank you. Sorry to do that to you, but I don't think we have enough time.

Ms. ZUCKERMAN. It is all right.

Mr. PALLONE. We will stand in recess.

[Recess]

Mr. PALLONE. OK, Ms. Dorman, what happened to the titanium rib? Wherever you left off.

Ms. ZUCKERMAN. Yes, I think I left off just showing these pictures. This is Devon, who was born without nine ribs and scoliosis. He was not expected to live at all.

[Slide]

And the next picture is after surgery. And the next picture.

[Slide]

And this is today. He is playing baseball. It is an incredible device. That is it. Thank you.

I would also like to talk about the Humanitarian Device Exemption to allow companies to make profit on HDE approved humanitarian devices. The HDE pathway is a tool used to approve devices intended to very small patient populations, which often include children, and those with very rare conditions. It was originally thought that the restriction on profit would force device manufacturers to conduct full clinical trials and seek pre-market approval from the FDA. That scenario never played out. Instead, the restriction on profits proved to be a barrier to innovation, especially for children.

Of the 39 humanitarian devices currently on the market, only seven are specifically intended for the use in the pediatric population. By eliminating the cap for children, the likelihood that companies will manufacture pediatric devices will increase, especially the small manufacturers, who are likely to embrace an affordable pediatric device development pathway.

I would now like to address an issue not specific to H.R. 1494, but of great importance to the rare disease community. FDA has been very sensitive to the value of humanitarian devices and has made clear that they are legally marketed products and not experimental. I have attached a page to my written testimony that illustrates the lengths the FDA has gone to to clearly establish that HUDs are legally marketed. Nonetheless, insurers and government programs often will not reimburse the use of humanitarian devices because they view them as experimental. In effect, they ignore FDA's regulations on the status of these devices.

We believe that the situation could be improved if the current FDA regulatory policy would be codified in statute. This would make it more difficult for reimbursement to be denied by making clear that FDA's position is backed by Congress. NORD would wel-

come the opportunity to accomplish this by working with committee staff and FDA to draft appropriate language to address this terrible problem.

I want to thank the committee for allowing me the opportunity to share my views on the reauthorization of MDUFMA and most importantly, the Pediatric Medical Device Safety Improvement Act. Thank you.

[The prepared statement of Ms. Dorman follows:]

TESTIMONY OF
DIANE EDQUIST DORMAN
VICE PRESIDENT
NATIONAL ORGANIZATION FOR RARE DISORDERS

before the

ENERGY AND COMMERCE COMMITTEE
HEALTH SUBCOMMITTEE

U.S. HOUSE OF REPRESENTATIVES

MAY 16, 2007

Department of Public Policy
1050 17th Street, NW
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Mr. Chairman and distinguished members of the Committee, thank you for allowing me this opportunity to testify today regarding the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA). I would also like to share my views of HR 1494, the Pediatric Medical Device Safety and Improvement Act of 2007.

I am Diane Dorman, Vice President of Public Policy for the National Organization for Rare Disorders (NORD). NORD is a non-profit voluntary health agency dedicated to the identification, treatment and cure of rare diseases through programs of education, research, advocacy and services to patients and families. Because most patients with rare diseases have no or few treatment options, our primary goal is to encourage research and development of new "orphan" drugs and biologics and "humanitarian use devices" (HUD).

NORD is also a member of the Alliance for Drug Safety and Access. ADSA members advocate on behalf of over 31 million patients, including those suffering from HIV/AIDS, Parkinson's disease, spinal cord injuries, paralysis, multiple sclerosis, leukodystrophies, Tourette syndrome, and over 6,000 known rare diseases. Our members also represent over 100,000 providers of care to pediatric patients and individuals with mental illnesses.

Reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA)

NORD believes that the Food and Drug Administration (FDA), in a perfect world, should be fully funded through appropriations, but we recognize that for now user fees are inevitable and crucial to ensure that safe and effective medicines reach the public as quickly as possible. As Vice President of the FDA Alliance Board, we support the concept of user fees for medical devices as one of several measures needed to assure adequate funding for FDA.

The Need for Safe and Effective Medical and Surgical Devices for Children

For the past several years, NORD has worked in concert with the American Academy of Pediatrics, the Elizabeth Glaser Pediatric AIDS Foundation, and other stakeholders, including the device industry, in the hopes of identifying a pathway by which medical device manufacturers would be encouraged to develop and then manufacturer devices for the pediatric population.

Simply put, children need medical devices that meet their unique needs. Devices must take into account the small size of children and accommodate their growing and changing bodies and active lifestyles. Yet, doctors continue to be frustrated by the lack of modern medical devices for children.

Children deserve access to devices that are safe, effective, and made just for them. But today's devices are not made with these considerations in mind, and some vital, life-saving devices are not made at all. Because pediatric disease is generally rare, there is a relatively small market for pediatric devices and there appears to be little incentive for device manufacturers to make them.

So today, I testify before you to express NORD's strong support for the Pediatric Medical Devices Safety and Improvement Act (HR 1494), and to express my deep gratitude to Mr. Markey, Mr. Mike Rogers, Mrs. Eshoo, Mrs. Capps, Mr.Grijalva, and Mr. Ramstad, for their commitment to achieve safe and effective medical devices for all children.

This legislation is the result of the extraordinary efforts of all stakeholders, including patient and medical provider groups, and device manufacturers. This bill will help children get the safe medical and surgical devices they need by strengthening safety requirements and encouraging research, development, and the manufacture of pediatric devices.

Device manufacturers face marketplace challenges not experienced by the pharmaceutical and biotechnology sectors because new medical surgical devices quickly become obsolete. Consequently, large markets are needed to justify the development and regulatory costs of devices. As a result, children are frequently denied access to the latest technologies in life-altering or life-saving devices. Doctors are left with only one option. They are forced to jury-rig existing devices in the hopes of accommodating the needs of their young patients.

Defining the Need

This bill streamlines federal agency processes by creating a "contact point" at the National Institutes of Health (NIH and requires FDA, NIH and the Agency for Health Quality and Research to work together to identify important gaps in knowledge, and to improve pediatric medical device development. An important component of this is the ability to survey the pediatric medical providers "rank and file" in order to learn the actual unmet pediatric device need.

Facilitating Pediatric Device Development and Manufacturer through Mentorship

The bill also establishes six-year demonstration grant(s) to support a nonprofit consortium to provide critically needed support in helping the innovators with pediatric device ideas to navigate the "system" successfully. The consortium will match inventors with appropriate manufacturing partners, provide mentoring for pediatric device projects with assistance ranging from prototype design to marketing, and connect innovators with available federal resources. The consortia will also coordinate with the NIH for pediatric device development and the FDA for facilitation of pediatric device approval.

Perhaps had this nonprofit consortium existed previously, it would not have taken Dr. Robert Campbell 14 years to invent, develop and then bring to market the Vertical Expandable Prosthetic Titanium Rib (VEPTR) (Exhibit I). Dr. Campbell is a pediatric orthopaedic surgeon, and Professor of Orthopaedics at the University of Texas Health Science Center at San Antonio, Texas. The Titanium Rib was invented in 1987 to save the life of a six-month-old with scoliosis and missing ribs who was full-time ventilator-dependent. It was not until August 2004 that Synthes' Humanitarian Device Exemption application was finally approved.

Improving the Humanitarian Device Exemption (HDE)

The Humanitarian Device Exemption was meant to be a tool for approving devices intended for small populations, which often included children and those with rare conditions. The specific criteria for the approval of a humanitarian use device (HUD) are:

- Expected to benefit fewer than 4,000 people in the U.S. per year;
- No comparable device is marketed;
- Patient will not be exposed to "unreasonable or significant risk of illness or injury; and,
- The potential benefits of the device outweigh its risk.

It was originally thought that the restriction on profit would force device manufacturers to conduct full clinical trials and seek pre-market approval from the FDA. That scenario never played out. Instead, the restriction on profits proved to be a barrier to innovation, especially for children.[1] Of the 39 HUDs approved by the FDA only seven are specifically intended for use in the pediatric population.[2]

[1] Currently, device manufacturers can only recoup the costs of research and development, fabrication, and the distribution of the device.
[2] There are 41 devices listed on the FDA web site. However, two HUDs have been withdrawn.

Device Name	Incidence	Device Description/Device Indications
Karl Storz Semi-Rigid TTS Fetoscopy Instrument	3,800	The Karl Storz TTS Fetoscopy Instruments Sets are indicated for selective laser photocoagulation in the treatment of twin-to-twin transfusion syndrome for fetuses whose gestation age is between16 and 26 weeks.
Vertical Expandable Prosthetic Titanium Rib	500	For the treatment of Thorasic Insufficiency Syndrome (TIS) in skeletally immature patients. Categories include: Flail Chest Syndrome, Rib fusion and scoliosis, hypoplastic thorax syndrome, including Jeune's syndrome, Achondroplasia, Jarcho-Levin syndrome, Ellis van Creveld syndrome
DeBakey VAD Child Left Ventricular Assist System	737	For use to provide temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are listed candidates for cardiac transplantation.
CONTEGRA Pulmonary Valved Conduit	3,756	The CONTEGRA Pulmonary Valved Conduit is indicated for correction or reconstruction of the Right Ventricular Outflow Tract in patients aged less than 18 years with any of the following congenital heart malformations: pulmonary stenosis, tetralogy of Fallot, Truncus arteriosus, transposition with ventricular septal defect, pulmonary atresia.
Shelhigh Pulmonic Valve Conduit Model NR-4000 with "No-React®" Treatment	3,275	For replacement of the diseases, damaged, or absent pulmonic artery in small children or infants to age 4 years.
Kings College Hospital Fetal Bladder Drainage Catheter	2,241	For urinary tract decompression following the diagnosis of post-vesicular obstructive uropathy in fetuses 18 to 32 weeks gestational age.
Harrison Fetal Bladder Stent Set	3,112	For fetal urinary tract decompression following the diagnosis of fetal post-vesicular obstructive uropathy in fetuses of 18 to 32 weeks gestational age.

By eliminating the profit prohibition for children, the bill increases the incentive for companies to manufacture pediatric devices, especially the small manufacturers who are likely to embrace an affordable pediatric device development pathway with definable, affordable regulatory requirements.

Tracking Pediatric Device Approvals and Streamlining Device Development

HR 1494 makes improvements in the way FDA tracks the number and type of devices approved for use in children or for conditions that occur in children. At present, FDA cannot satisfactorily produce data on the number and type of devices marketed for pediatric uses. The bill requires FDA to track new devices granted pre-market approval or approved under the humanitarian devices exemption and report on the number of pediatric devices approved in each category.

Strengthening Post-market Safety

In addition to the important incentives for pediatric device development proposed in HR 1494, the bill also ensures that medical devices used in children are safe. The Institute of Medicine conducted a thorough review of pediatric medical devices and found that FDA lacked significant capacity and authority for post-market monitoring and surveillance of devices in children (Exhibit II). The legislation provides the authority for FDA to order post-market surveillance of devices used in children, only when needed, and broadens the reach of the authority to the most commonly used pediatric devices. In addition, FDA is granted important flexibility to order longer post-market surveillance if necessary to ensure that the device remains safe in children's growing bodies. The new safety protections in HR 1494 are essential to keep children safe while the incentives provisions stimulate new devices that meet their medical needs.

Reimbursement for Humanitarian Use Devices (HUDs)

I would like to address an issue not contained in HR 1494, but of great concern to the rare disease community. Humanitarian Device Exemptions (HDEs) are a special type of marketing approval granted for humanitarian use devices intended to treat fewer than 4,000 people a year in the United States. Rare disease patients benefit greatly from HDEs and need their development to be encouraged in any appropriate way.

FDA has been very sensitive to the value of HUDs and has made clear that HUDs are legally marketed products and not experimental products. I have attached a page to my testimony that illustrates the lengths the FDA has gone to clearly establish that HUDs are legally marketed (Exhibit III). For this, the rare disease community is grateful.

Nonetheless, insurers and government programs often will not reimburse the use of HUDs on the basis that they are experimental. In effect, they ignore FDA's regulations on the status of these devices. This is disheartening to the rare disease community and frustrating because FDA policy is so clear: the agency stands behind these devices by treating them as legally marketed.

We believe that the situation could be improved if the current FDA regulatory policy were to be codified in statute. This will make it more difficult for reimbursement to be denied by making clear that FDA's position is backed by Congress. NORD would welcome the opportunity to accomplish this by working with committee staff and FDA to draft appropriate language for inclusion in HR 1494.

Conclusion

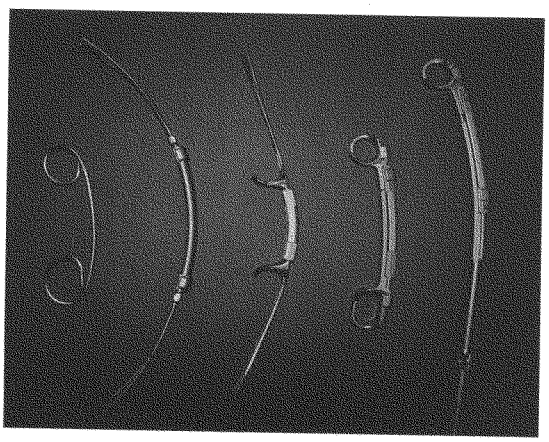
I want to thank the Committee for allowing me the opportunity to share my views on reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), and most importantly, the "Pediatric Medical Devices Safety and Improvement Act of 2007."

HR 1494 represents an historic step forward for children's medical and surgical devices similar to those steps taken on drugs. Children deserve access to devices that are safe, effective and made just for them. Children need medical devices that take into account their smaller size, growing bodies, and active lifestyles.

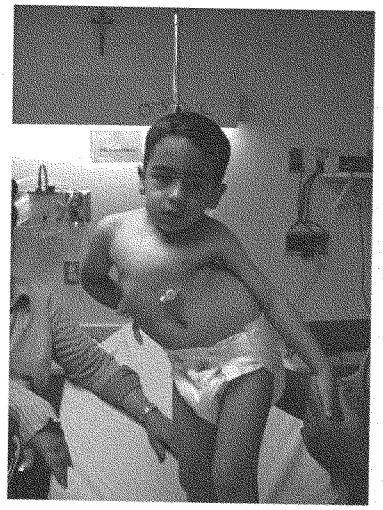
Thank you.

Exhibit I

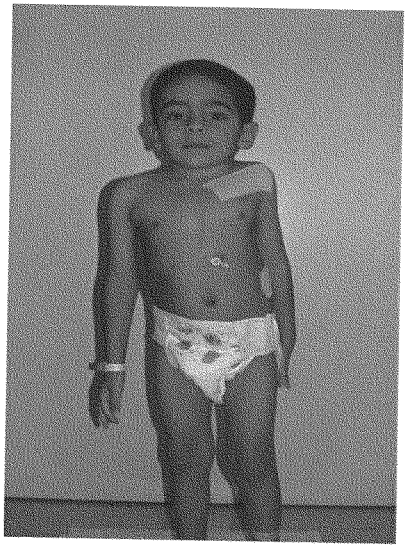
Vertical expandable Prosthetic Titanium Rib (VEPTR)



Before Surgery…



After Surgery…



Today…

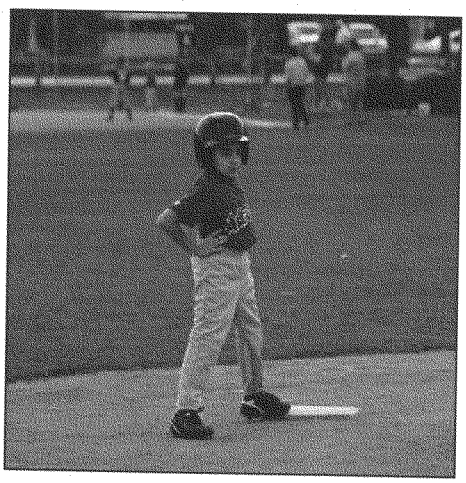


Exhibit II

Institute of Medicine
"Safe Medical Devices for Children"
Complete List of Recommendations
July 18, 2005

Adverse Event Reporting

Recommendation 4.1: FDA should collaborate with industry, health care professionals and organizations, and parent and patient advocates to:

- focus more attention on adverse device events, including events involving children;
- promote linkages between adverse event reporting systems, various FDA databases, and other safety programs;
- update product labeling, patient information, and other communications to promptly reflect safety-related findings from analyses of adverse event reports; and,
- issue yearly reports on results from adverse event analyses, including findings involving children.

Recommendation 4.2: FDA should continue educational and communication programs to promote recognition and useful reporting of serious adverse device events and device problems by hospitals and other user facilities. Such encouragement should continue whether or not requirements for mandatory reporting by user facilities are eventually eliminated with the effective implementation of the MedSun program. Reporting by user facilities of events possibly related to devices should continue to include deaths, serious injuries, and device malfunctions.

Recommendation 4.3: FDA's plan for evaluating MedSun's performance as a replacement for and improvement on mandatory user facility reporting should include, among other elements:

- assessment of ongoing program and participant facility success in educating facility personnel about identifying, evaluating, and reporting adverse device events and improving the quality, timeliness, and usefulness of event reports;
- determination of the extent to which the sample of MedSun participating hospitals-including children's hospitals-represents the relevant range of facility characteristics and experiences, including representation of both academic medical centers and community hospitals and sufficient representation of facilities with device-oriented specialties and procedures;
- comparison with the mandatory user facility reporting system, including the extent to which either program produced reports for FDA or manufacturers of emerging hazards, important close calls, or other significant events (including those involving children) that were missed or delayed by the other; and
- evaluation of the active surveillance components if the program is instrumental in reducing harm to patients, promoting constructive communication between facilities and FDA, and improving timely knowledge of the nature and extent of selected device problems, including errors in the use and design of devices.

Recommendation 4.4: Within the pilot MedSun program, FDA and participating children's hospitals should serve as a resource for the broader involvement of children's hospitals in patient safety programs to identify, evaluate, respond to, or prevent problems with the use and design of medical devices. In addition, FDA should promote efforts to link or otherwise employ event reporting, device recall, safety notification, and other databases within and outside FDA to better assess and report on device safety issues involving children.

Recommendation 4.5: When FDA mandates or agrees to device labeling that requires professionals to be trained in the safe and appropriate use of a medical device, the training should include information on the identification of adverse events, voluntary adverse event reporting under Med Watch, and user facility and manufacturer medical device reporting (MDR) requirements.

Recommendation 4.6: Medical, surgical, and other organizations or societies that include health professionals who care for children should:

- establish working groups to evaluate problems as well as benefits in the pediatric use of devices of particular importance to their practice;
- collaborate with existing public and private patient safety initiatives to add or expand attention to safe and appropriate use of medical devices with children;
- establish standards for professional education and competency in the use of these devices; and
- include as professional competencies the identification and appropriate reporting of device problems and the successful communication with patients and families about how to prevent, recognize, and respond to device problems.

Recommendation 4.7: Children's hospitals and other user facilities should establish a focal point of responsibility for medical device safety. Tasks include reviewing and monitoring the adequacy of institutional programs in areas such as tracking of safety alerts and recalls, responding to safety alerts and recalls training in adverse event evaluation and reporting, and factoring safety data or evaluations into device purchased decisions.

Recommendation 4.8: FDA should continue t o improve and expand its medical device safety resources for patients and families and its focus on devices used in the home and community by:

- working with patient, family, and consumer organizations, providers, and industry to make it easier for patients or their families to report device problems to manufacturers or FDA and to learn about resources to support the safe use of medical devices;
- making online reporting and information resources more accessible by using language and directions appropriate for lay users; and
- enlisting hospitals, home care agencies and vendors and other professional and provider groups to promote patient and family understanding of how to use devices safely, when and how to seek help, and when and how to report problems.

Monitoring Study Commitments

Recommendation 5.1: Congress should require FDA to establish a system for monitoring and publicly reporting the status of post-market study commitments involving medical devices. The system should also cover voluntary studies negotiated between FDA and manufacturers as part of the device approval or clearance process. The public database should, among other features, allow easy determination of the status of post-market studies that involve questions about device use with children.

Recommendations 5.2: FDA's system for monitoring and reporting post-market study commitments should include information about the disposition of study findings: for example, a change in the labeling of a device. It should also provide for the responsible and understandable reporting of the source, methods, and findings of monitored post-market studies.

Strengthening Post-market Studies

Recommendation 6.1: FDA should develop additional guidance for its own staff as well as for manufacturers and investigators on the identification and evaluation of pediatric questions at all stages in the design and evaluation of medical devices used with children.

Recommendation 6.2: As part of the government and private health informatics initiatives, such as those supporting the electronic medical record, FDA should promote the development and adoption of common device coding and other standards and approaches for capturing and linking use and outcomes data for medical devices. FDA should also work with agencies such as the Agency for Healthcare Research and Quality university- and industry-based methodologists to strengthen methods and tools for epidemiologic research on medical device safety.

Recommendation 6.3: As a resource for itself and others, FDA should create or collaborate with others to create a registry of relevant registries, that is, a database with information about registries that are either device specific or that have the potential to provide information useful in evaluating device safety and effectiveness.

Recommendation 6.4: As part of the public commitment to post-market surveillance of device safety, the Center for Devices and Radiological Health should have its own extramural research program to support studies using external data sources.

Recommendation 6.5: Congress should amend Section 522 of the Federal Food, and Cosmetic Act to:

- permit FDA to order post-market studies as a condition of clearance for the categories of devices for which Section 522 Post-market Surveillance studies are now allowed and;
- allow FDA to tailor the duration of Section 522 studies of devices likely to have significant pediatric use so that studies can take into account children's growth and development and, if appropriate, exceed the current 3-year limit on study length.

Recommendation 6.6: FDA should collaborate with the National Institutes of Health, the Agency for Healthcare Research and Quality, and other research funding agencies and interested parties to define a research agenda and priorities for the evaluation of the short- and long-term safety and effectiveness of medical devices used with growing and developing children.

Responsibilities for Medical Device Safety

Recommendation 7.1: FDA should establish a central point of responsibility for pediatric issues within the Center for Devices and Radiological Health to evaluate the adequacy of the Center's use of pediatric expertise and its attention to pediatric issues in all aspects of its work.

Recommendation 7.2: All those engaged in improving the quality of health care and protecting patients from harm should evaluate and sharpen, as appropriate, their attention to medical device safety, including safety issues that particularly affect children.

Exhibit III

FDA Views Humanitarian Use Devices as Legally Approved Products

In the preamble of the HUD final rule (FR vol. 61, No. 124, June 26, 1996) there was a discussion of why the provision was being placed in the market regulations (21 CFR 814), rather than the Investigational Device Exemption (IDE regulation 21 CFR 812). To make the point clear, it was decided by the agency to create a new subpart H Part 814 specifically addressing HUDs, thereby further establishing these devices as legally marketed products under the Act. I have appended to this testimony a page of references from FDA regulations that make clear FDA positions that these are legally marketed devices.

The first item below is very clear that FDA considers these to be legally marketed devices and that FDA chose not to put the provision into the investigational device exemption reg. to make that point clear.

1. In the preamble of the HUD final rule (FR vol. 61,No. 124, June 26, 1996) there is a discussion of why the provision was finally being placed in the marketing regulations 21 CFR 814, instead of the Investigational device exemption (IDE) regulation 21 CFR 812. It concludes **"Accordingly, the agency has chosen to create a new subpart H under part 814 specifically addressing HUD's, thereby establishing these devices as legally marketed products under the act".**

2. In the current HUD/HUD regulation 21 CFR 814.100 includes a few citations that "marketing approval" is mentioned.

   a. For example 814.100(a) states "The subpart provides procedures for obtaining (1) HUD designation of a medical device; and (2) **Marketing approval for the HUD** notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required under sections 514 and 515 of the act.

   b. 814.100(c) mentions **"Obtaining marketing approval for a HUD involves two steps**: (1) Obtaining designation [of the HUD from OOPD] and (2) Submitting and HDE [to CDRH}

   c. 814.126(b)(1)(iii) under Post-approval requirements and reports sates that requires that "The **number of devices that have been shipped or sold since initial market approval under this subpart H"** be submitted in periodic [annual] reports.

Exhibit IV

Humanitarian Use Devices
A brief guide for clinicians, investigators and IRB members

Dale E. Hammerschmidt, M.D.
University of Minnesota; October, 2001

Introduction

Regulations governing the use of medical devices cause a lot of confusion. In part, this is because several sets of statutes and regulations may apply — those involving patient care, those involving research with human subjects, those involving development of medical devices for marketing approval, those involving insurance billing. In part, too, it is because the grey zone is so large between activity that is unambiguously research and activity that is so small a variation on standard technique that it isn't subject to regulation or special scrutiny.

A special class of devices (and a special set of regulatory provisions) causes particularly much confusion: **Humanitarian Use Devices** (HUDs). These devices (and regs) are in the *Never-never Land* between research and ordinary practice – they will probably never make it as commercial products under ordinary licensing rules, but they may be recognized standard or even preferred devices for certain circumstances. In some respects, they may be thought of as a parallel to "orphan" drugs.

What the regs define as a Humanitarian Use Device

A HUD is a medical device that has been granted (by the FDA) a special exemption from some of the requirements for approval before marketing, because its expected market is so small that the studies needed for licensure would simply never be able to be carried out. The general criteria are:

- Expected to benefit fewer than 4,000 people in the US per year (in some FDA information sheets, worded more narrowly as "is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States.")
- No comparable device already available
- No exposure to "unreasonable or significant risk of illness or injury"
- Potential benefits of the device outweigh its risks.

Obviously, these criteria are a bit subjective, but that's not the *direct* worry of the local investigator or the IRB, as this determination is made by the FDA.

What's different about an HUD?

The main difference is a direct result of the small target group of patients. An HUD is expected never to be able to get the type of efficacy data required for an ordinary Pre-Market
Approval by the FDA, so it has its own special category of "approval," called a Humanitarian Device Exemption. This "approval" retains some of the flavor of the more usual clearance for research (the "IDE" or "Investigational Device Exemption"), including IRB oversight and limitations on the ability to charge for the device. The freedom of the clinician/investigator to use the device for other than its label indications is also restricted.

What this means in practical terms

• Before the first use of an HUD in an institution, the clinician intending to use the device must obtain IRB approval (stipulated in regs at 21 CFR 814.124(a), so not much "wiggle room" available). The applicant may request approval for several patients so that it is already in place the next time; case-by-case IRB oversight is not required unless the IRB for some special reason decides it to be necessary.
• IRB review has to be by a convened quorum; it cannot be by expedited review (even though this might at first blush seem to fit expedited review criterion 1[b][i] for those devices judged to pose no more than minimal risk).
• The informed consent requirements are the ordinary *clinical* requirements rather than the special requirements for research; most IRBs still require documentation that the patient has been told that the device has not been licensed in the ordinary manner (and/or that it has not been proven to be safe and effective by the usual criteria).
• IRB continuing review (annual or more frequent) is required, just as for other devices under development.
• Off-label uses require IRB scrutiny and notification of the manufacturer, and may require an amendment to the HDE.
• Off-label use that is an emergency, or first use that is an emergency that cannot wait for IRB action, is handled according to basically the same rules applied to the emergency use of an investigational drug or device of any other type:

- Life-and-limb-threatening emergency
- No other more standard (or already IRB-approved) intervention available with reasonable chance of success
- No preclusive regulatory barriers (*i.e.* within HDE provisions, or steps begun to obtain special approval) (usually handled by emergency communication with HDE sponsor)
- Urgency of situation does not allow time for IRB review
- (If consent must be waived) Physician uninvolved in patient's care concurs
- *Not in the regs* per se, *but both FDA policy and local policy provide that an attempt be made to screen the proposed use with an IRB officer, who can walk the applicant through the criteria and begin the required administrative process*
- Formal report to IRB within 5 working days; formal application if additional patients likely.

Conclusion

The use of Humanitarian Use Devices creates confusion, because they are in some ways regarded as not being research (consent requirements and some aspects of billing) and in other ways are regarded as research (IRB review). The simplest approach is just to treat them as though they were ordinary research devices under the usual sort of IDE, but be open to a lesser requirement for documentation of consent. Most of the other special features of HUDs pertain to aspects other than the on-site regulatory and oversight requirements faced by the IRB and the clinician/investigator.

See http://www.fda.gov/cdrh/ode/guidance/1381.pdf *for the most recent (July, 2001) FDA guidance document. An additional, more general FDA website addressing device issues is* http://www.fda.gov/cdrh/devadvice/dd_home.html

Exhibit V

POST-MARKET SURVEILLANCE

"SEC. 522. *7 [21 U.S.C. 360l] (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct post-market surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—*
(1) implanted in the human body for more than one year, or
(2) a life sustaining or life supporting device used outside a device user facility.
(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562."

Exhibit VI

Few medical devices exist for sick infants

Sunday, April 22, 2007
BY ROBERT COHEN
New Jersey Star-Ledger Staff

At the Bristol-Myers Squibb Children's Hospital in New Brunswick, pediatricians have had to scramble to deliver medicine to infants with life-threatening cardiac problems when the veins of the babies were too small to use IVs and infusion pumps.

"In such cases, you have to use needles to get into the bones and many times, they are not the right size for little babies. The needles are pretty big,' said Ernest Leva, director of pediatric emergency medicine at the hospital.

"You just keep trying. If you can't get the children the medicine they need, they could become impaired or die," he said. "These situations don't happen that often, but when they do, they can be tragedies." The dilemma described by Leva is common.

There is a big availability gap when it comes to external and implanted medical devices for children, with doctors often forced to jury-rig adult devices for diagnosis and treatment that weren't designed for small bodies.

Congress is seeking to address this problem with legislation that would offer incentives to manufacturers to create medical devices designed specifically for children. The bill also would establish grants for nonprofit groups to promote pediatric device development and help link inventors with manufacturers.

"While we all know children are not simply small adults and should not be treated as such, the pediatric market is so small and pediatric diseases relatively rare, there has been little incentive for medical-device manufacturers to focus their attention on children," said Sen. Chris Dodd (D-Conn.), sponsor of the Pediatric Medical Device Safety and Improvement Act.

The measure is included in a multifaceted Senate bill that gives the Food and Drug Administration added drug safety authority, renews the user fees paid by the pharmaceutical and device industries to the FDA, and re-authorizes a law to increase the number of drugs tested and labeled for children.

The sweeping legislation was approved by the Senate Health, Education, Labor and Pensions Committee last week. A similar measure is pending in the House, with lawmakers hoping for final passage by the summer.

Jay Berkelhamer, president of the American Academy of Pediatrics, said there is a critical need for medical devices manufactured for children.

"Although children and adults often suffer from similar diseases and conditions, their medical needs and physiology differ considerably," he said.

One example of the problem, Berkelhamer said, is advanced chemotherapy catheters that are too large for infants, requiring them to use less-advanced tubing that leaves children more vulnerable to infection. Another example: Devices that keep a failing heart beating while a patient waits for a transplant, known as left ventricular assist de vices, aren't available for children age 5 and younger.

In other cases, physicians have had to resort to invasive procedures when a baby needs assistance breathing because even the smallest nasal masks on the market aren't designed to fit infants.

Ed Rozynski, vice president of Stryker, a maker of orthopedics and other medical devices, said his company makes a bone-replacement implant for children with cancerous tumors that can be elongated to account for a child's growth. Stryker also makes plates and screws specially for children undergoing skull surgery.

But Rozynski, whose company has two manufacturing facilities in Bergen County, told a Senate committee last month the market is "very small" for pediatric devices and the hurdles of developing such products are high.

"The cost of developing a new medical device and performing the required pre-market clinical studies can be enormous, often steering some manufacturers to serve larger, more established and well- known adult medical device markets," Rozynski told lawmakers.

He said provisions in the pending legislation, including allowing a profit for companies marketing products under the so-called humanitarian device exemption, will "likely spur companies to develop pediatric products they otherwise might not have."

A humanitarian device exemption is special approval given by the FDA that allows the marketing of a device that is designed to treat or diagnose a condition that affects fewer than 4,000 individuals per year. The approval is granted even though the effectiveness of the de vice hasn't been tested or proven, because it isn't financially feasible to do the usual clinical testing when so few individuals are affected. While allowing companies to recover their costs, existing law prohibits them from making a profit.

The legislation by Dodd and Rep. Ed Markey (D-Mass.) would lift the profit restriction for sales of up to 4,000 a year.

In addition, the bill would:

- Require the National Institutes of Health to designate a contact point or office to help inventors and physicians access funding for pediatric medical device development.
- Grant authority to the FDA's Pediatric Advisory Committee to monitor pediatric devices and make recommendations for improving their availability and safety.
- Incorporate recommendations of the Institute of Medicine, including improving the post-market surveillance of medical devices used in children and expanding public access to post-market studies of pediatric devices.

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Mr. PALLONE. Thank you. And now we will take some questions and I will start with myself.

I was going to ask Mr. LaViolette, what is your view of the legal status of the performance goals mutually agreed upon by FDA and industry for the Medical Device Review Program? Specifically, do you believe these goals are binding or does FDA reserve the right to ignore or miss them?

Mr. LAVIOLETTE. The goals, as I understand it, are definitely not binding. They are attached, if you will, to the legislation. They are guidelines. They are intended to keep everyone focused on accountability and on process improvements, but they are absolutely not binding.

Mr. PALLONE. OK. And then I wanted to ask Ms. Dorman, you mentioned the need for additional incentives that would encourage manufacturers to develop and manufacture devices for the pediatric population. But specifically, what incentives not already in place would foster the development of additional lifesaving pediatric devices?

Ms. DORMAN. The one that I talked to you about is removing the cap on profits for humanitarian devices. I have spoken with FDA, with all the stakeholders, including industry, and they feel that this is a real roadblock when they are not able to make any type of profit at all. And we feel as if taking that cap would provide, hopefully, an incentive for companies, especially the smaller companies, to develop these devices for children.

Mr. PALLONE. And then Mr. Grossman, the President's budget for fiscal year 2008 requests for FDA's Medical Device Program, well, his budget request is $285 million. The FDA Alliance believes the agency will need $302 million for the fiscal year 2008 Medical Device Program. Why do you think there is such a discrepancy?

Mr. GROSSMAN. In general, the President's budget request for most of the agency is just barely above the level needed to continue the same staff. We feel that that is inadequate for the demands that are being placed on FDA and as I indicated, the fiscal year 2003 budget was better than the current one, so the agency has gone backwards. We believe that the additional money is needed for a variety of things; shorter application review times, more meetings and opportunities for interaction.

These are things you have heard. More guidance, development standards, more participation in industry workshops, maintain and expand combination products, international programs and most of all, information technology is something that has to be invested and you just can't throw a couple of million at it each year and expect that you are going to get the databases that actually add value.

Mr. PALLONE. OK. I was listening to Dr. Zuckerman's statement where she basically was very critical of the 510(k) process. She explained in some detail about why she thought it was kind of out of control. I just wondered if anybody wanted to respond to that because it seemed kind of—I mean, I hadn't heard it criticized so drastically, not to take away. I am glad you are here to say what you think is important. Did anybody else want to comment on what she said in that respect? Go ahead.

Mr. LAVIOLETTE. I will make at least one comment, which is that first of all, the number of 510(k)'s is probably in the 4,000 per year range in comparison to some limited hundreds of PMAs, so it is the majority of devices that obviously the resource intensity, if we were to apply the same standards to those, would swamp the system, No. 1. Number 2, by definition, they are lower risk devices. That is how they were categorized at the class 2 level to begin with. Despite their lower risk category, while many of them are not associated with clinical data, they are often associated with extensive mechanical bench testing data, so they are very highly tested, just not necessarily in randomized controlled trials. And despite that, at any point the FDA has the right to impose a clinical data generation requirement on the device.

Mr. PALLONE. They can do it; they can impose——

Mr. LAVIOLETTE. They absolutely can, any time they choose, and my company has clinical trials underway today on class 2 devices, so clinical data can be generated any time, as needed.

Mr. PALLONE. Mr. Cullimore, did you want to say something?

Mr. CULLIMORE. We are very pleased with the goals that are being set by the FDA under MDUFMA II, but I would point out that even if we achieve the goals that are being set, they still fall short of the statutory obligations under the original medical device amendment. And so without commenting on the adequacy of the original medical device amendment, I will just point out that the goals that are being set here, the acceleration, as minimal as it may seem, still does not return us to the statutory requirements set under the original medical device amendment.

Mr. PALLONE. OK. Anybody else? All right.

Ms. ZUCKERMAN. Mr. Chairman.

Mr. PALLONE. Yes, you can respond again, if you want. I will let you come back again.

Ms. ZUCKERMAN. I just wanted to mention that although the idea of a 510(k) was for less—well, for devices that were less potentially dangerous, it is not always clear what that would be and so contact lens solution, I think the perfect example where we take it for granted that contact lens solution is safe and who of us who uses it, who ever worries about it? But because this particular contact lens solution was changed, no clinical trials were done and no inspections were done, it ended up to have something in it that made it easier for bacteria to grow and to harm vision.

Mr. PALLONE. Well, would you advocate reclassifying what comes under 510(k) or I mean, it seemed like you were just saying scrap it altogether.

Ms. ZUCKERMAN. Oh, I didn't mean that, no.

Mr. PALLONE. Maybe I misunderstood.

Ms. ZUCKERMAN. No. I think there are plenty of devices that could be approved under a 510(k), but they are supposed to be, at least traditionally, they were substantially equivalent to something else on the market. That used to mean for the same purpose and a very similar device that had just been changed in some minor way. But that definition of substantially equivalent has changed so dramatically that now they are approving, sometimes, implanted devices and sometimes completely new technologies, and the

NeuroStar that I mentioned is a completely new technology, different from anything else.

Mr. PALLONE. Well, let me ask you this. Did you, either in your oral or written testimony, come up with a new definition or some way of redefining it? I mean, I tried to listen, but did you suggest that?

Ms. ZUCKERMAN. No, the FDA has redefined it. It used to be substantially equivalent meant similar materials, same purpose. But now it means similar purpose, which doesn't necessarily mean the same. It is like depression, which you are treating depression, but there is a lot of different ways to treat it. Similar purpose and it can be a completely different material, completely different technology, as long as the risks and benefits are similar, but that opens up Pandora's box, because you are not—assuming that this product is similar to something else that has already been through some kind of rigorous review.

You are just picking anything to try to figure out whether the risks and benefits are similar and without clinical trials, you can't determine if the risks and benefits are similar. So although it is correct that testing has been done, if the testing is not done on human beings with a particular treatment need, you don't necessarily know how it is going to affect them without those clinical trials.

Mr. PALLONE. OK. Thank you. Mr. Deal.

Mr. DEAL. Mr. Grossman, I understand that your alliance obviously supports additional budget funding for FDA. What is your take on the restructuring of the fee schedules? Are you satisfied with that restructuring, even though it may minimize or reduce the application fee, it makes up for it in other areas? Are you satisfied with that arrangement?

Mr. GROSSMAN. Our position goes to the aggregate resources and so we—I have 108 members. I would say we don't have a position on the specifics of whether it comes from facility fees or applications.

Mr. DEAL. OK. We heard the testimony of Ms. Dorman on the humanitarian device exemption. I suppose, from the two industry people, what is your position? I understand that the profit cap be removed and also that—what was the second part of your recommendation?

Ms. DORMAN. Initially, it was somewhat different. It was regarding the reimbursement for humanitarian devices, so it is outside the purview of this——

Mr. DEAL. And you were suggesting that the policy of FDA be put into statute so that the question of whether or not it is approved rather than experimental is removed, that was part of your suggestion?

Ms. DORMAN. That is correct.

Mr. DEAL. OK. What is the reaction of the two industry representatives to that?

Mr. LAVIOLETTE. Just speaking on our behalf, representing AdvaMed and Boston Scientific, I would favor that. I think that is a smart move. It is one small step. I think if we really want to encourage device development for pediatric applications, we have to take many more steps. We support the Markey-Rogers initiative

and it contains a number of efforts that begin to identify the needs and I think one of the issues with pediatric applications is that the needs are not clearly identified and then ultimately build some series of incentives to drive innovation in that direction. HDE is one route, but not by any means the sole route. Devices are very different than drugs. We need, I think, a different set of mechanisms to encourage innovation for pediatric patients.

Mr. CULLIMORE. Our position is not any different. We agree with that. We do have some concerns about how the bill is being crafted as far as language that has FDA, section 522 where FDA would have the option of requiring post-market surveillance as a condition of approval. We have concerns that that particular provision may actually have a contrary effect to what is intended because if someone views that as a potential additional cost, it could inhibit the interest in pursuing that course, so with that caveat, we also support this.

Mr. DEAL. Mr. Cullimore, while you are at the microphone, could I get you to address the issue of trying to down-class devices that may originally be classified in one area of classification, the process of down-classifying those. What, if anything, needs to be addressed in this legislation with regard to that?

Mr. CULLIMORE. I don't know that this particular legislation is the place for that, but the concept is not new. Back in the 1990s, when FDA was facing a very large backlog of applications, probably the worst in their history, one of the innovative approaches that was taken was to significantly down-classify devices that required applications and I think, like any business, you have to continue to innovate. You have to reevaluate and if there are products that can be down-classified, thus reducing the workload without jeopardizing the safety of products on the market, I would think that should certainly be considered.

Mr. DEAL. OK. Mr. LaViolette.

Mr. LAVIOLETTE. I agree fully. I think the FDA Modernization Act dealt with this. It is do-able within FDA auspices today. From my perspective, it is something that happens quite infrequently and should be done under careful review, but I am not sure that it needs to be changed that dramatically.

Mr. DEAL. OK. I believe that is all I have, Mr. Chairman.

Mr. PALLONE. I see the gentleman from Massachusetts has entered the room, but he didn't come alone. Would you like to tell us who accompanied you here today?

Mr. MARKEY. I would like to introduce St. Anthony's of Everett. And I would like you to know that when I was in the CYO and I played against St. Anthony's of Everett, that the star of their team scored 34 points against me and I think, as a result, was destined for a scholarship in college and that is how I have been helping kids from St. Anthony's to advance themselves ever since I became a defenseless opponent of them when I was a boy. So I wanted to have them here with us.

Mr. PALLONE. I would like to know if they speak like people from Medford?

Mr. MARKEY. Medford and Everett are arch rivals, actually.

Mr. PALLONE. The gentleman is recognized.

Mr. MARKEY. Thank you. I appreciate it. First, I want to welcome Mr. LaViolette, who is testifying on behalf of Boston Scientific, which is headquartered in my district in Natick, Massachusetts. And I would like to ask you to explain why it is important to increase access and encourage development of medical devices specifically for children and how you think the Markey-Rogers bill will help to do that?

Mr. LAVIOLETTE. Thank you for that question and it is a pleasure to address the issue. First of all, my company, as an example, makes 650 different families of medical technology and we are one of the largest companies in the industry. We do not address pediatric needs that specifically and I think that is actually somewhat of a shame. And we really do need to start with basic, a more basic understanding of pediatric requirements.

We have to assess precisely what the differences are in the device field as compared to the drug field because, indeed, in drug development a slightly lower dose or a slightly extended patent protection might act as an appropriate incentive for development for pediatric applications that is not sufficient in the device world. So we need to start with an identification of the way to fill those gaps. We need to integrate pediatric, the Academy of Pediatrics in that process and then ultimately stimulate investment in this area. It is a grossly underserved need. We support your legislation. We think it is a very strong move in that direction.

Mr. MARKEY. Thank you, sir, very much. Ms. Dorman, I thank you for your testimony, as well. Can you explain why the combination of incentives to industry for the development of devices specifically for kids and increased FDA authority that is in the legislation that I have introduced with Mr. Rogers is so important?

Ms. DORMAN. I think it is terribly important because children are not second class citizens. And this goes to the rare disease community with whom I have worked for, for many, many years, and they feel disenfranchised. They are denied treatments. They must wait years before they even are diagnosed, so this is kind of near and dear to my heart, since I do have two grandchildren, myself, and I would be loathe to think that if they became ill, there would not be a device that would be available to my grandchildren.

Mr. MARKEY. So the Institute of Medicine has recommended that Congress expand FDA's authority to monitor devices for kids after they are approved. Why is this expanded monitoring authority important?

Ms. DORMAN. I think it is very important because children grow, they change, they are active. And without very close monitoring of the devices after they have been inserted in the children, it could pose a real danger to the children, so we do very wholeheartedly agree with the IOM recommendation.

Mr. MARKEY. Thank you. And can you explain why, any of the other witnesses, why it is important to increase access and encourage development of these medical devices? Do any of the others of you wish to comment on that?

Ms. DORMAN. Mr. Markey, could I make one comment? Back in 1983, the nay sayers said why should we bother even passing an orphan drug act? What good is it going to do if we don't know what the problem is? And today the Orphan Drug Act is considered prob-

ably one of the most important healthcare pieces of legislation in the 20th century and I think that will probably most definitely apply to this, as well, for children.

Mr. MARKEY. OK, great. Thank you. Any of the other witnesses?

Ms. ZUCKERMAN. I would like to add something. I just wanted to say that of course what you have now is a situation where many physicians are trying to modify devices so that they work with kids and some are going to be more successful than others. If you have a rigorous program that encourages the development of devices that can be tested so you know which ones work best, that is just going to be so much better, for all of the health professionals involved and obviously, for all of the children because you have some kind of standards that you can compare to and you will have a much better idea of what is going to work.

Mr. MARKEY. OK, great. Thank you. Yes, sir.

Mr. LAVIOLETTE. Just, if I may, one closing comment. From my perspective, neither the typical device nor the typical regulatory approval process for devices is really designed for children. Children's needs are different and that relates both to the devices, but also to the approval process and what we have here is a marketplace and the marketplace is not focused on kids' needs because they are very hard to identify and very difficult to justify, so we really do need to encourage that development and I think your legislation heads very much in that right direction.

Mr. MARKEY. Thank you very much and Mr. Chairman, I thank you.

Mr. PALLONE. Thank you. And thank you all. We just made it, another vote, so we will conclude here. Thank you for bearing with us, really. I know this coming in and out has been tough. Let me just remind you that Members may submit additional questions within the next 10 days for you to respond to, so within the next 10 days we will notify you, if that is the case. And other than that——

Mr. GROSSMAN. Mr. Pallone?

Mr. PALLONE. Yes.

Mr. GROSSMAN. Could I take 10 seconds and clarify one thing that I had said? The number you quoted me for the administration request included user fees.

Mr. PALLONE. Right.

Mr. GROSSMAN. So that the comparable number that we are recommending is about $350 million. The $302 million, which would be budget authority and I think it is approximately $48 million or $49 million in user fees.

Mr. PALLONE. OK.

Mr. GROSSMAN. So there is a significant difference between the two figures.

Mr. PALLONE. In response to the question I asked, you mean? Right.

Mr. GROSSMAN. Right.

Mr. PALLONE. Right.

Mr. GROSSMAN. And the answer would still be the same, that we need a lot more of a lot of things that the money would buy.

Mr. PALLONE. OK. All right. Thank you very much, really. We appreciate it. This meeting is adjourned.

[Whereupon, at 3:06 p.m., the subcommittee was adjourned.]
[Material submitted for inclusion in the record follows:]

Statement for the Hearing Record
Submitted by Premier, Inc.

U.S. House of Representatives
House Committee on Energy and Commerce
Subcommittee on Health

"Reauthorization of the Medical Device User Fee and Modernization Act"

May 16, 2007

On behalf of its nearly 1,700 allied not-for-profit hospitals and health systems across the U.S., Premier, Inc. appreciates the opportunity to provide a statement for the record of the House Energy and Commerce Committee Subcommittee on Health hearing, entitled "Reauthorization of the Medical Device User Fee and Modernization Act." Premier is dedicated to facilitating its hospitals' and affiliated care sites' achievement of high clinical quality and financial performance. A mandatory, national unique device identification (UDI) system is an integral part of that goal because it will reduce medical errors, improve the accuracy and efficiency of device recalls and enhance adverse event reporting.

Serving 1,700 hospitals and almost 45,000 other healthcare sites, Premier Inc. is the largest healthcare alliance in the United States dedicated to improving patient outcomes while safely reducing the cost of care. Owned by not-for-profit hospitals, Premier operates the nation's largest healthcare purchasing network, the most comprehensive repository of hospital clinical and financial information and one of the largest policy-holder owned, hospital professional liability risk-retention groups in healthcare.

Unique identification of medical devices is paramount to improving patient safety, reducing medical errors and improving patient safety

The Food and Drug Administration (FDA) is currently exploring requiring a unique identification system for medical devices, similar to that already required for drugs and biologicals. Premier strongly supports a mandatory national UDI system to improve patient safety, reduce medical errors, facilitate recall processes and improve adverse event reporting and post market surveillance.

Patient Safety:

Clearly, a compelling patient safety interest lies in requiring a UDI system for medical devices, especially when a defective device is recalled. Today, the majority of hospitals must conduct recalls manually—a labor intensive and time consuming endeavor that does not guarantee a 100 percent success rate. Moreover, it is not possible to associate the use of a device with a particular patient. This greatly delays timely notification of patients if a particular device is recalled and can put patient safety at great risk.

For example, one large teaching hospital learned about a recall of potentially contaminated bronchoscopes after noticing a higher than expected patient infection rate. Hundreds of patients had to be contacted and evaluated for possible infections and two may have died as a result of the contamination. This can be a widespread problem. A study based on the FDA's records over the last 10 years found that 164,000 emergency defibrillators – about one out of every five sold – had been subject to an FDA recall or alert. Automatic, standardized identification would facilitate and improve upon the tracking of these devices in the event of a recall or other safety concern.

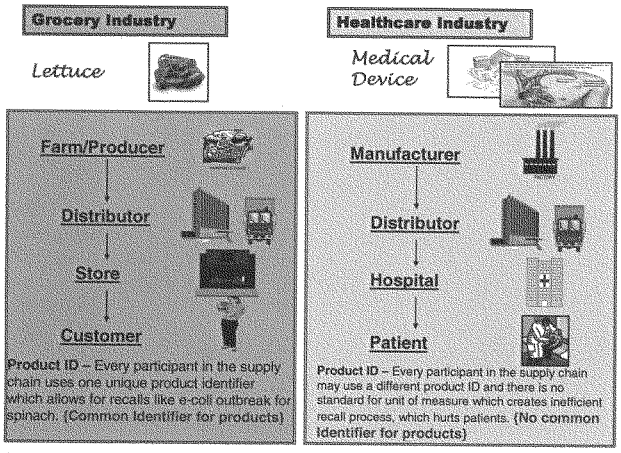
Manufacturers also issue many "device corrections" that can have serious consequences for patients if not handled correctly, which can be facilitated, tracked and undertaken more expeditiously with the use of UDI. They are not technically recalls because they can be corrected by the user, but can often be just as serious as a Class I recall. For example, the majority of problems over the last several years with IV pumps were device correction issues. These involved battery failures that could result in severe patient outcomes if all the equipment was not located and the corrections were not made by the users.

According to ECRI, a not-for-profit health services agency in Pennsylvania, some of the more serious device problems such as ventilator alarm failures, tracheal tube surgical fires and gas embolism deaths during use of argon beam coagulation were never classified as FDA recalls.

Reducing Medical Errors through Improved Recall Processes:

Being able to correctly identify devices, track them through the healthcare system and inform the proper practitioner about any potential dangers will reduce errors and improve patient care. According to a March 2006 report by the Eastern Research Group (ERG), UDI has the potential to facilitate the identification of device compatibility problems. Some implantable materials have turned out to be incompatible with magnetic resonance imaging (MRI) devices resulting in injuries and deaths. ERG concluded that UDI systems might help reduce such episodes by facilitating communication of more information about implants and implant accessories and by helping to get the additional information into patients' medical records. Additionally, UDI systems could improve methods for ensuring patients with allergies are not treated with or touched by medical devices to which they are allergic (i.e., latex gloves).

We can simply and quickly identify each and every jar of peanut butter that might have salmonella and remove them from store shelves in hours. We can also identify where contaminated spinach was grown, but we cannot do that reliably today with potentially life threatening defective medical devices.



Improving Adverse Event Reporting/Post Market Surveillance:

Accurate and reliable device tracking would also enable data mining so that FDA and manufacturers could better identify potential problems or device defects. Because of the increasing complexity and variety of devices, the potential for problems is escalating. Implementation of a UDI would be a valuable step in improving processes for monitoring adverse events related to medical devices, something that is currently being done by the FDA related to drug safety because of clarity in identifying drugs.

Current systems such as MedSun – a collaborative pilot project launched by the FDA and a group of 350 healthcare facilities to share information about the use of medical devices – only focus on providing information on safety issues with devices and do not address the user issue of tracking the use of the device and locating it easily if there is a recall because of an identified safety problem.

Health professionals say mandatory unique device identification system would improve patient safety

Premier's Safety Institute conducted a survey of nearly 1,000 healthcare professionals and more than 80 percent of survey respondents believe an industry-wide unique device identification (UDI) system can enhance patient safety.

According to the survey, a manual system is the most common method used to record medical device implant information in the patient record. Sixty percent of healthcare professionals surveyed transfer a label from the device packaging to the patient's paper record and/or 51 percent insert a handwritten note. When recalls occur, the majority of hospitals are conducting *manual* searches of records or log listings to identify patients who received a recalled device or product.

Although many device manufacturers bar code their products, there is no industry-wide device identification system with a common vocabulary, which results in many manufacturers using the same number. This prevents hospitals from reliably tracking devices. Without an industry-wide identification and tracking system, healthcare providers can't identify device incompatibilities – such as pace makers that negatively interact with an MRI machine's magnetic fields – in time to avoid devastating patient safety errors.

The Problem:

Same Product – Different Numbers Assigned *

Nearly every hospital has a different Product ID for 3M 8630! Makes ordering, recalls, and proper identification to the patient difficult.

Industry Distributor Numbers for 3M Product # 8630:

Allegiance	- M8630
Owens & Minor	- 4509008630
BBMC-Colonial	- 045098630
BBMC-Durr	- 081048
Kreisers	- MINN8630
Midwest	- TM-8630
Pacific	- 3/M8630
UnitedUMS	- 001880

* Source: Department of Defense Data Synchronization Study

The Problem:

Same Number – Different Product*

Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.

Part Number: 10313 refers to:

Medtronic's - "**NEEDLE** CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"
Hantover's - "**CARTRIDGE REPLACEMENT** STUNNER YELLOW F/CALVES/HEAVY HOGS"
Chattanooga Group's - "ACCESSORY TRACTION **REPLACEMENT STRAP** XL FOR HALTER THORACIC RESTRAINT"
HF Scientific's - "**TEST KIT** WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

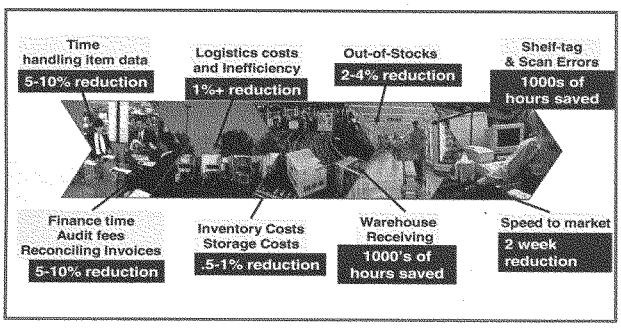
Part Number: 1050 refers to:

3M Company's - "**DRAPE INCISE** 35 3/8X 17 5/8IN"
Tyco's - "**PAD TELFA** 3 X 4IN STER"

* Source: Premier Inc. Product Item Master

The counterfeiting of medical devices is on the rise, threatening to compromise the safety of patients. An example was an October 2006 FDA warning about counterfeit blood glucose strips that were identified in the market. Another and more potentially detrimental example was when counterfeit surgical mesh entered the healthcare supply chain and was implanted in multiple patients. A consistent and unique method of identifying medical devices could have helped in the detection and prevention of these counterfeit items before they passed into the supply chain.

In addition to the patient safety implications, implementing a national unique device identification system would enable more efficient device identification processes such as bar coding, product identification and billing which could **save the U.S. healthcare system $16 billion**, according to an Arizona State University study.



* Source: ATKearney Study 1/12/03 on behalf of FMI/GMA/UCC

Healthcare industry leaders support a mandatory, national UDI system to improve patient safety

Healthcare industry leaders have united to create the "Advancing Patient Safety Coalition" to provide supporting evidence and rally support for the adoption of a national UDI system. Premier is proud to be part of this broad based coalition which is comprised of 35 prominent hospital, physician, nursing, research, quality and patient advocacy organizations. The "Advancing Patient Safety Coalition" is committed to improving safety processes for our nation's hospitals and the patients they serve.

Premier appreciates the opportunity to provide testimony to the Subcommittee on Health on this important patient safety issue. If you have any questions or need additional information please contact Blair Childs, senior vice president of public affairs at 202.393.0860.

About Premier, 2006 Malcolm Baldrige National Quality Award recipient, www.premierbaldrige.com
Serving 1,700 hospitals and 45,000 other healthcare sites, Premier Inc. is the largest healthcare alliance in the United States dedicated to improving patient outcomes while safely reducing the cost of care. Owned by not-for-profit hospitals, Premier operates the nation's largest healthcare purchasing network, the most comprehensive repository of hospital clinical and financial information and one of the largest policy-holder owned, hospital professional liability risk-retention groups in healthcare. Premier's Safety Institute provides publicly available safety resources and tools to promote a safe healthcare delivery environment for patients, workers, and their communities. Headquartered in San Diego, Premier has offices in Charlotte, N.C. and Washington. For more information, visit www.premierinc.com.

Congress of the United States

Washington, DC 20515

May 7, 2007

Commissioner Andrew C. Von Eschenbach
Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Buidling, Room 14-7
Rockville, Maryland 20857-0002

Dear Commissioner von Eschenbach:

We are writing to express our strong interest in seeing the U.S. Food and Drug Administration (FDA) require a national unique device identification (UDI) system for medical devices as soon as possible. We have witnessed first-hand the multiple and varied product numbering and coding systems by visiting hospitals and other health care facilities in our districts. The officials who run these facilities have expressed to us their concern about the negative impact that these multiple coding systems have on our health care system. Our provider constituents overwhelmingly believe that a national UDI would improve patient safety, reduce medical errors, enhance device recall processes, and improve device adverse event reporting. We believe that our nation's health care system will benefit by having a defined UDI with a global nomenclature that complements the FDA National Drug Code system.

In May of 2005, several of us wrote the FDA to inquire about its intentions for plans to require the bar coding of medical devices. Since that letter was sent, the FDA and the Agency for Healthcare Research and Quality (AHRQ) have commented that an urgent need exists for a unique identifier for medical devices. At the FDA's recent public meeting on October 25, 2006 the Centers for Medicare and Medicaid Services (CMS) and the Department of Defense (DoD) also voiced support for UDI.

A national UDI standard has great potential for our entire health care system. It will benefit manufacturers and improve patient safety by reducing the potential for counterfeit products being used on a patient. Also, several of us have been working with health care organizations in our districts to promote electronic health records (EHRs) and Regional Health Information Organizations (RHIOs). A UDI standard would help contribute to the success of those electronic systems and improve patient care by providing appropriate health care providers with accurate information.

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We appreciate the great effort that the FDA has put into the national UDI standard issue under your leadership. As technology continues to evolve, we believe that our health care system must have the appropriate standards to help facilitate that technology and enhance patient safety and improve health care efficiency.

Sincerely,

Mike Doyle
Member of Congress

Pete Sessions
Member of Congress

Bart Gordon
Member of Congress

Lee Terry
Member of Congress

Robert Brady
Member of Congress

Tom Price
Member of Congress

Michael C. Burgess, M.D.
Member of Congress

Thaddeus McCotter
Member of Congress

Bob Etheridge
Member of Congress

Jason Altmire
Member of Congress

Todd Platts
Member of Congress

John Carter
Member of Congress

David Price
Member of Congress

Ralph Hall
Member of Congress

David Davis
Member of Congress

Stephanie Herseth
Member of Congress

Linda Sanchez
Member of Congress

Jim Moran
Member of Congress

Mike Conaway
Member of Congress

Maurice Hinchey
Member of Congress

Silvestre Reyes
Member of Congress

David Hobson
Member of Congress

Chip Pickering
Member of Congress

Diane Watson
Member of Congress

Brian Bilbray
Member of Congress

Michael Turner
Member of Congress

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A consumer advocate's perspective on medical device epidemiology and surveillance

Diana M. Zuckerman, PhD

National Research Center for Women & Families, Washington, DC, USA

Consumers show their confidence in the safety of medical devices when they spend the equivalent of more than $200 billion worldwide annually [1]. Nevertheless, consumers are not necessarily familiar with the term 'medical device' and might not be able to name any if asked. Virtually every consumer uses medical devices, and many have friends and family members with implanted medical devices. In recent years, the number of men, women, and even children with implanted medical devices has increased dramatically, as artificial knees, hips, heart valves, and shunts have become increasingly common [2,3]. Medical implants come in a very wide range of shapes, sizes, and substances, including the increasingly popular oils and gels that are injected into millions of faces every year to fill wrinkles and scars [4]. The use of implanted devices, either to replace aging body parts or to help people look younger, will certainly continue to increase as the baby boomers age. Lasers are also widely used medical devices, with more than 2 million eye laser surgeries performed in the USA in 2004, more than 1 million laser hair removal procedures, and numerous other laser procedures [5].

Medical devices received relatively little public attention throughout most of the twentieth century, with a few exceptions, such as: the excitement followed by disappointment about lives prolonged with an artificial heart; widespread media attention about infertility and deaths caused the Dalkon Shield in the mid-1970s; serious illness and death from toxic shock syndrome caused by tampons in 1980; and the growing popularity of replacement knees and hips in the last two decades. It was especially difficult to obtain

Medical Device Epidemiology and Surveillance Edited by S. Lori Brown, Roselie A. Bright and Dale R. Tavris
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useful safety data about devices prior to 1976, when the Food, Drug and Cosmetic Act was amended to give the US Food and Drug Administration (FDA) substantial authority to regulate medical devices. At that point, there were thousands of medical devices already on the market, most of which were 'grandfathered' so that they could continue to be sold until the FDA determined whether studies of safety and effectiveness would be required.

In the 1990s, very few consumer advocates or nonprofit organizations focused any attention on medical devices. Even so, the few groups that were concerned about medical devices generated considerable public attention regarding the questionable safety of specific devices, such as breast implants, jaw implants, and fetal monitors, especially in the USA, Canada, and the UK. Organizations such as the National Women's Health Network, Canadian Women's Health Network, Public Citizen Health Research Group, and the TMJ (temporamandibular joint) Association were vocal critics of specific implants, and they were joined by the National Research Center (NRC) for Women & Families when that research and advocacy organization was founded in 1999. In the last few years, increased attention has been given to the benefits of medical devices for life-saving procedures as well as common age-defying cosmetic solutions, and the risks have also come under greater scrutiny. In 2001, while working with an informal coalition of approximately a dozen organizations called the Patient & Consumer Coalition, NRC for Women and Families and the National Women's Health Network brought the issue of improving legislation regarding medical devices to the Coalition for the first time. As a result, broad-based consumer organizations in the USA, such as National Consumers League, Consumer Federation of America, Center for Medical Consumers, Gray Panthers, International Union of UAW, and The Title II Community AIDS National Network, have become knowledgeable about medical devices and started to raise questions about safety data and surveillance. Although consumer groups in or outside the government have been less vocal in other countries, medical devices have attracted the attention and concerns of organizations such as the Canadian Women's Health Network, Health Canada's Women and Health Protection, Women's Implant Information Network New Zealand, and Silicone Support UK.

Until 1993, medical device regulation within Europe was the responsibility of the health ministries of each country. Although few countries required clinical trials to determine safety, the regulatory process was nevertheless considered burdensome because different countries posed different requirements for inspecting and authorizing the sale of medical devices [6,7]. These variations made it difficult for European manufacturers to obtain approval to market their products in other countries. When the European Union (EU) established a harmonization program in 1993, however, the program mandated only general requirements for medical devices, and although the criteria include product safety and protection of health, clinical trials are not required to establish either [6]. Manufacturers need only demonstrate compliance in one EU country in order to sell a medical device throughout Europe. Conformity assessment bodies (CABs) are hired by the companies to determine and certify whether a company's product meets the minimum technical requirements. Few consumers are knowledgeable about the specific safety requirements or approval process for medical devices in their

[1]at which time it was called the National Center for Policy Research (CPR) for Women and Families; the name was changed in 2004.

country. From the consumer perspective, the main concern is one's health: do the benefits of a medical device outweigh the risks? Consumers want medical devices that can save their lives or improve their quality of life, and that means that the device should work, last as long as possible, and not have dangerous side effects. However, for many medical devices sold around the world, there is often limited clinical and epidemiological research to determine the risks and benefits. A brief history of the medical devices receiving the greatest public attention in recent years is instructive in illustrating the concerns expressed by consumers and the organizations that advocate on their behalf.

Examples of widely publicized problems with selected medical devices

Dalkon Shield

Medical devices were not systematically regulated in the USA and most other countries when the Dalkon Shield intrauterine contraceptive device (IUD) was studied in 1970 (see Figure 14.1). The inventor, Dr Hugh Davis, published a study claiming exceptional effectiveness with no serious risks [8]. The study's shortcomings were overlooked: only 700 women participated in the study, they were followed for less than 6 months, the researchers did not report that the women used additional contraceptive foam for the first several months, and efficacy statistics were compiled within a week after the study was completed, so that later pregnancies were not reported.

After the study was completed and publicized, Davis revised the IUD, adding copper and using a smaller size; the revised product was not tested for safety or efficacy. Approximately 2 million Dalkon Shields were inserted in women in the USA and Puerto Rico [8].

By 1974, pelvic inflammatory disease, ectopic pregnancies, septic abortions, sterility, and 12 deaths had been reported among women who used the Dalkon Shield, and the FDA requested that the manufacturer of the Dalkon Shield, A. H. Robins, remove the IUD from the US market. The company complied, but continued selling it in other countries. It was not until 1980 that the company advised doctors to remove the Dalkon Shield from women who still had them in their bodies, and the IUD was not recalled until 1985. By then, about 9500 cases had been litigated or settled, 6000 more cases were pending, and 16 new cases were being filed each day. Robins filed for Chapter 11 (bankruptcy) protection in 1985, and the settlement included a $2.5 billion trust fund for compensation of more than 100 000 women who sought damages [8].

In response to the Dalkon Shield disaster, and the increased recognition of the risks of medical products, Congress passed the 1976 Medical Device Amendments, which gave the FDA authority to systematically regulate all medical devices [9].

Tampons

A few years later, in May 1980, investigators reported to the US Centers for Disease Control and Prevention (CDC; at that time the agency was called the Center for Disease

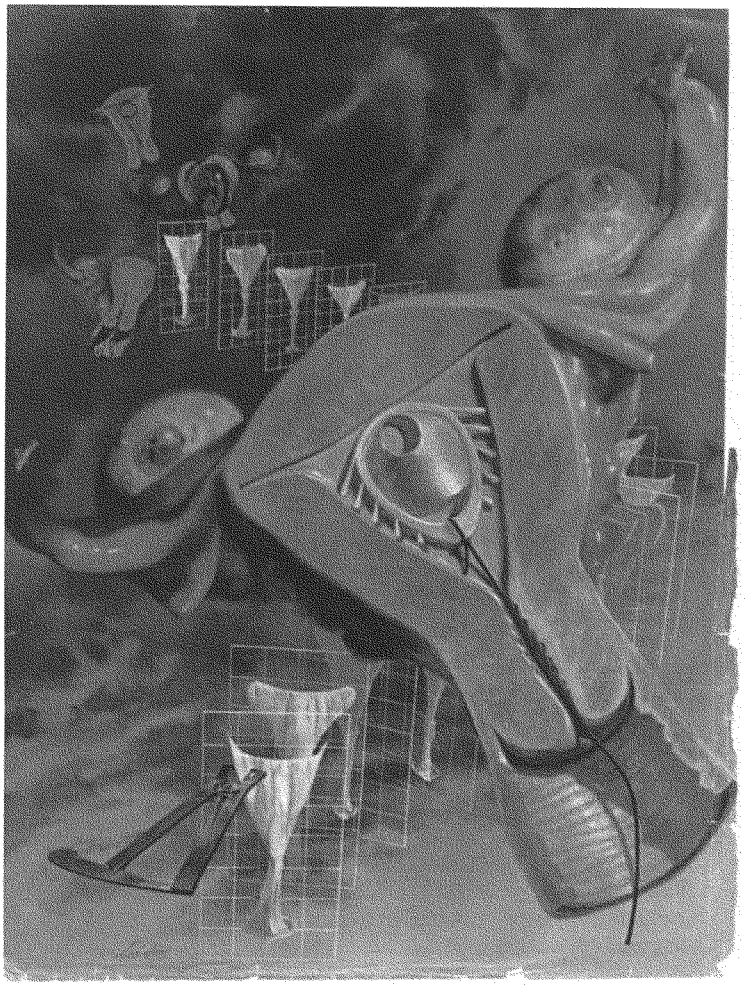

Figure 14.1 Dalkon Shield poster from the 1970s. Courtesy of the FDA History Office

Control) 55 cases of toxic shock syndrome (TSS), a newly recognized illness characterized by high fever, sunburn-like rash, desquamation, hypotension, and abnormalities in multiple organ systems [10]. Fifty-two (95%) of the reported cases occurred in women, and the onset of illness occurred during menstruation in 38 (95%) of the 40 women from whom menstrual history was obtained. In June 1980, a follow-up report described three studies that found that women with toxic shock syndrome were more likely to have used tampons: case-control studies in Wisconsin and Utah and a national study by CDC.

Subsequent studies established that toxic shock syndrome was more likely among women who used a new, highly absorbent tampon called Rely™. By September, Rely tampons were voluntarily withdrawn from the market by the manufacturer. During 1980, 890 cases of toxic shock syndrome were reported, 91% of which were associated with menstruation; there were 28 deaths. In response, tampon makers reduced the absorbency of tampons and the FDA began to require that all tampon packages include package inserts explaining the risks of toxic shock syndrome.

Silicone gel breast implants

In the late 1970s and early 1980s, following the addition of medical device regulation to the FDA's responsibilities, the agency was overwhelmed with an enormous number of devices that had previously been on the market and now needed to be classified and possibly evaluated. Breast implants were among the many devices that were allowed to stay on the market until those reviews were completed. Silicone breast implants had been sold since the 1960s and remained on the market while decisions were made about what kind of safety and efficacy studies might be required. Meanwhile, numerous other silicone implants were considered under the law to be 'substantially equivalent' to breast implants, and therefore allowed to be sold without any clinical trials to prove safety Scientists and physicians started expressing strong concerns about the safety of silicone breast implants, and by the early 1980s, the suspected risks were officially described in the US government Federal Register [11]. However, it was not until 1988 that the FDA held a public meeting that focused on these risks, and an advisory committee recommended that the FDA establish a national registry of women who have breast implants. The US registry was never established. By 1990, approximately one million women in the USA and Canada, and unknown numbers in other countries, had breast implants, and a scientist at Health Canada had lost his job after publicly urging the agency to remove them from the market. Meanwhile, no government regulatory agencies had yet required the manufacturers to evaluate their safety and no empirical studies had been published regarding their effects on human health.

In 1991, pressured by Congressional hearings and enormous news media attention in Canada and the USA regarding non-medical grade polyurethane coverings and reports of implant patients' illnesses and complications, the FDA finally required the manufacturers to submit safety studies on silicone gel breast implants [11]. The company that made polyurethane-covered breast implants removed their product from the market amid studies indicating that the foam broke down to a known carcinogen, 2,4-toluene diamine (TDA), which was found in the breast milk of women with breast implants. Other implant companies, including Dow Corning, submitted safety data, which FDA scientists reviewed and found to be inadequate [11].

Despite being on the market for almost 30 years, the studies submitted by the breast implant makers were deficient in many respects: they included small sample size and all the women were studied for less than 1 year. However, silicone gel breast implants had been widely available for more than two decades and had become increasingly popular,

providing considerable income for implant manufacturers and plastic surgeons; both groups lobbied heavily to keep them on the market. That pressure, however, was counterbalanced by implant company documents, made public in the course of several lawsuits, indicating that company scientists had expressed concern about the lack of safety data, and the leaking of silicone from intact silicone implants [11,12].

In 1992, as a compromise, silicone gel breast implants were allowed to remain available as a 'public health need', with the FDA limiting their availability to clinical trials, primarily for women who have mastectomies, breast deformities, or to replace a broken gel implant. A similar compromise was instituted in Canada. At the same time, other countries considered similar restrictions. In most countries, these restrictions were lifted several years ago and silicone gel breast implants are available to virtually any patients who want them, but the restrictions were not lifted in the USA and Canada until Fall 2006, and even then extensive long-term post-market safety studies were required. In 2001, after years of consumer advocacy pressure by Silicone Support UK, using information published in medical journals and compiled by consumer organizations, the European Commission adopted plans to improve informed consent for women considering breast implants, and urged member countries to establish minimum age limits and to establish registries in all 15 EU Member States [13]. The UK had previously established the first registry of breast implant patients in 1993. Several countries, including Australia and Denmark, have followed suit. All registries are voluntary, which limits the number of patients.

Meanwhile, patients won multimillion dollar law suits against implant companies in the early 1990s, so the manufacturers entered into an international legal settlement with patients totaling more than $3 billion dollars, all the while claiming that their implants were safe and not responsible for the health problems that the settlement compensated.

TMJ Implants

In 1992, Congressional hearings brought attention to even more obvious health problems caused by jaw implants used to treat temporamandibular joint (TMJ) disorder. Several companies sold TMJ implants made of silicone or other materials, and Dow Corning sold silicone sheeting that could be used for custom-made TMJ implants. Another company, Vitek, made TMJ implants with Teflon and proplast. Most adverse reactions that were reported to the FDA were for implants made from silicone or Teflon; the friction of the joint caused the jaw implant to flake or break, and the body reacted to the particles with an immune reaction that could cause debilitating pain, bone loss, and in some cases with the Vitek implants, bone degeneration in the joint and skull [14,15]. Like breast implant patients, TMJ implant patients reported systemic autoimmune symptoms and reported that their physicians often assumed that the symptoms were unrelated to their implants. However, patients with TMJ implants reported many symptoms in the jaw joint area, so that at least some of the risks of the implants were identified relatively quickly.

In response to law suits from patients with permanent jaw damage, Vitek declared bankruptcy, but their implants continued to be sold under the names Novamed, Inc., and Oral Surgery Marketing, Inc. When the FDA required them to stop selling their implants, the head of the companies, Dr Charles Homsey, left the USA and sold the TMJ implants in other countries [14]. In 1993, the FDA notified the World Health Organization of its concerns about the proplast implants, and in 1994 the FDA wrote to regulatory agencies in Japan, Italy, Switzerland, Canada, Mexico, Australia, and New Zealand, and the Director General of the European Union, to describe the serious and debilitating complications of proplast implants among TMJ patients in the USA [14].

The examples of the Dalkon Shield, tampons, silicone gel breast implants, and TMJ implants all indicate that there can be substantial risks for medical devices used within the body. The latter three examples also indicate how, even in a country that regulates medical devices, pre-1976 'grandfathered' devices have been allowed to be sold that can have devastating effects on human health. Also, when regulators in one country demand that a product be removed from the market, companies can continue to sell their products in other countries with less stringent regulations for medical devices. Particularly in small countries, where the number of patients using the products is modest, or in products that work well at first but fail over time, the risks of a defective or poorly designed device may not be noticed for many years.

Consumer concerns

Consumer concerns about device manufacturers and their research

As these examples illustrate, consumers or their physicians were the first to complain about the adverse reactions to these medical devices, and in most cases the manufacturers defended their products and challenged consumers in court. In some examples, such as tampons, healthcare professionals were instrumental in bringing attention to the problem; in others, physicians tended to assume that the medical devices were safe and unrelated to the problems being reported. In the case of breast implants, it was only when it became clear that there were no safety data to back up company claims, and internal corporate documents indicated the possibility of a cover-up, that the products were withdrawn from the market or restricted, usually with belated pressure from the regulatory agencies of countries such as the USA and Canada. In recent years, the European Commission has applied pressure on EU countries to institute safeguards that implant manufacturers and plastic surgeons were not providing, such as informed consent that provides information about specific risks.

All these examples have a fundamental scientific problem in common: the lack of meaningful short-term or long-term safety research. It was only when unexpected adverse reactions were reported – by the CDC, as part of law suits, or by physicians – that there was pressure on government regulatory agencies to require that research be conducted. In the case of breast implants, this was initiated by a Health Canada engineer who served as a whistleblower, generating media attention in Canada that spread to the USA [11].

Manufacturers defend the lack of research for medical devices, stating that, unlike pharmaceutical companies, devices tend to be modified frequently in response to the requests and recommendations of physicians. For example, AdvaMed, the largest medical technology trade association in the world, claims that:

> 'Medical device innovation development differs significantly from pharmaceutical innovation in that most devices on the market today result from a series of incremental improvements to preexisting devices. These improvements result from continued vigilance by the manufacturer and substantial input from the provider community. Although well-designed research plays a significant role, formal research projects cannot substitute for the one-to-one interaction between the researchers tasked with developing and improving a technology and the clinical personnel who use it in their therapeutic and diagnostic interactions with patients' [16].

AdvaMed represents 800 companies selling more than half of the healthcare technology products purchased worldwide [16]. Based on their view, a study of an implant made 10 years ago or even 2 years ago might be irrelevant to the product being sold today. However, in some cases described in this chapter, there was evidence that research indicating risks was not published or made public.

Consumer concerns about regulatory safeguards for medical devices

Concerns about insufficient regulatory safeguards for medical devices reflect the differences between these devices and prescription drugs. Historically, most devices were used outside the body (such as scalpels and band-aids), and there was a perception that 'what you see is what you get', making research seem less important. As implanted medical devices have become more common, long-term research has become more important, but the safeguards and resources for regulatory agencies, in the USA and other countries, has not kept up with the increased importance of those devices.

In most countries, medical devices are routinely approved for marketing on the basis of short-term studies. This is also true in the USA, although manufacturers of high-risk devices are often required to do longer-term postmarket studies as a condition of device approval. Postmarket studies that are required because of concerns that arise after product approval, rather than as a condition of approval, are limited by FDA regulations. For example, 3 years is the maximum time that the FDA can impose for postmarket research requirements on medical devices ordered after approval without the agreement of the manufacturer; that is not sufficient to examine long-term safety [17]. Moreover, recent reports by the Institute of Medicine and the FDA indicate that postmarket studies, imposed as a condition of approval, have been inadequately monitored, and that the studies were often not performed or finished [18,19]. Add to that the corporate rationale that devices are constantly being improved and therefore regulatory flexibility is necessary, and there is a clear conflict between consumer demand that products be proven safe and corporate demands that products be approved quickly and be allowed to change without the need for new approval applications. These issues are raised in countries all over the world, and there is not one country that has insisted on or

consistently enforced long-term postmarket surveillance of medical devices, not even of those implanted for very long-term use.

FDA regulations differ in the safety criteria for medical devices compared to new drug approvals, and these differences are similar in other countries as well. Drugs must be safe for the uses recommended in labeling, which is interpreted as meaning that the benefits outweigh the risks. In contrast, a medical device must have a 'reasonable assurance of safety', which is more ambiguous; the law requires that the 'probable benefits to health' should outweigh 'any probable risks' (21CFR860.7). This has been interpreted as a less stringent criterion for safety and effectiveness, where scientific proof that the benefits outweigh the risks is not necessarily required.

In racially and ethnically diverse countries such as the USA, the potential for racial and ethnic differences in responses to implanted medical devices has become an issue of concern among consumer groups. The NRC for Women & Families, the National Medical Association, and the Congressional Black Caucus of the US Congress have all expressed their concern that implant makers rarely include racial and ethnic minorities in their studies. Since individuals of African or Asian ancestry are more likely to have keloid scarring, and since individuals of African ancestry are more susceptible to autoimmune diseases, medical implants may be more risky for those groups. However, it is impossible to know whether this is the case if no studies have been done.

Consumer groups have the opportunity to influence regulatory decisions in countries using independent advisory panels, such as is the case in the USA and Canada. Consumers are represented on the advisory panels and also have the opportunity to speak during the open public comment periods. However, whatever the roles consumers play, there is reason to be concerned that advisory panels tend to be a rubber stamp for approval. In a study released in 2006, NRC for Women & Families compared recommendations from FDA advisory panels for medical devices with advisory panels for prescription drugs. Votes between 1998 and 2005 were compared for five randomly selected device advisory panels and six randomly selected drug advisory panels. During those 8 years, the advisory panels recommended approval for 82% of medical devices that they reviewed, compared to 76% of prescription drugs under review. Some panel members always voted for approval for any product during their entire tenure on the advisory panel. NRC for Women & Families concluded that the less stringent criteria for approval for medical devices created an expectation that most medical devices were 'reasonably safe' and therefore suitable for FDA approval. Although panel members often expressed concern about the lack of safety information, they apparently assuaged those concerns by recommending postmarket studies and other conditions of approval. Unfortunately, as discussed later in this chapter, postmarket studies and surveillance are often not enforced [18].

Consumer concerns about long-term safety of implants

Of all the concerns that consumers have about medical devices, the long-term safety of implanted devices has attracted the most attention. There is widespread agreement

among consumer advocates that in most countries the current statutes regulating medical devices are inadequate for ensuring adequate safety studies, especially for life-saving and implanted devices. In the USA, the Patient and Consumer Coalition has participated in meetings with individual FDA officials, FDA forums, meetings with Members of Congress and their staff, and Congressional briefings to urge policy makers to require better research, including long-term safety studies, and better postmarket surveillance to improve the safeguards for implanted medical devices. These concerns are similar to those expressed by consumer advocates in Canada, the UK, and other countries.

The lack of long-term safety studies is a particular problem for implanted devices. Medical devices are allowed to be sold without proof of long-term safety. Solutions that have been suggested by consumer groups include the following:

- Government regulatory agencies must devote more resources to postmarket surveillance that focuses on long-term efficacy, reliability, and safety.

- Government regulatory agencies should be required to closely monitor, document, and audit all medical device Phase IV trials. The studies should be monitored for the adequacy of informed consent and human subject protection, the quality of study design, and the accuracy of results. Registries should be used more often to keep track of adverse reactions to devices and as a mechanism to inform patients of recalls or other problems.

- Adverse event reporting must be improved for medical devices, especially implanted devices. All hospitals, Health Maintenance Organizations (HMOs), nursing homes, and other healthcare providers should be required to immediately submit all adverse event reports to government regulatory agencies, and this should be stringently enforced. Information technology must be employed to facilitate the submission of adverse event reports.

- Government regulatory agencies or health agencies should be required to write and distribute consumer guides that provide unbiased, clearly-worded research-based information about the risks and benefits of medical devices used by consumers, such as implanted medical devices. This need is exemplified by the fact that, although US health experts have focused increasing efforts to provide understandable materials for consumers, there is little effort to develop consumer-oriented written materials for medical devices, since devices are often 'used' by medical professionals (sometimes by surgically implanting them in patients) rather than by patients.

In the rare instances when postmarket studies or surveillance are required (which is more likely in the USA than in other countries) consumer advocates are concerned that such studies and surveillance are not monitored adequately to ensure that they are conducted appropriately, or to ensure that companies or physicians provide information relevant to adverse reaction reports. Whether this is due to inadequate resources or inadequate

regulatory authority, it has become increasingly obvious in recent years that patients can not be assured they have the information they need to avoid medical disasters resulting from insufficiently safe medical devices, particularly those implanted in their bodies.

For example, a study by the FDA of all 127 premarket agreements (PMAs) approved during 1998–2000 found that 45 required postapproval studies. Although the law requires manufacturers to include information about these studies in their annual reports, only 19 of the 45 legally required studies (42%) were mentioned in annual reports. For the 11 PMAs where the results were due, final results had not been submitted in six (54%) cases [19]. This would make it impossible for consumers to obtain the information they need about the long-term safety of these devices. In 2006, the FDA announced initiatives to improve the enforcement of postmarket requirements; future reports will evaluate the results of those FDA initiatives [20].

Given the failure of device companies to submit required data, government regulatory agencies would benefit from subpoena power to compel manufacturers and healthcare providers to deliver documents relevant to all mandated regulatory functions regarding medical devices. Since premarket studies for medical devices are often small and of short duration, these postmarket studies take on even greater significance. That manufacturers agree to these studies as a condition of approval for their medical device and then do not finish them should be adequate reason for withdrawal of the product from the market, until such a time as adequate studies are completed.

Regulatory mechanism recommendations

Recalls

Several well-publicized recalls have brought attention to shortcomings in removing defective products from the market. For example, in 2002, a defect in a bronchoscope manufactured by Olympus led to persistent bacterial contamination of the instruments (see Chapter 17, 'Medical device-related outbreaks'). A recall was delayed for two months, and problems continued even after the recall. As reported in newspapers across the country, the recall notice to Johns Hopkins Hospital was sent by Olympus to a loading dock instead of the department using the bronchoscope. As a result, Johns Hopkins continued using the defective instruments for several months after the recall was initiated [21]. Apparently, other medical centers also were unaware of the recall, which was not widely publicized and which we found was posted on neither the company's nor the FDA's websites.

As a result of this and other examples, consumers and their advocates have become increasing concerned about medical device recalls. In the USA, an article in a mainstream women's magazine, *Good Housekeeping*, in March 2004, explained that neither device companies nor physicians are required to send patients a notification that a medical device implanted in their body has been recalled. The magazine encouraged readers to respond, resulting in more than 10 000 consumers joining a campaign to

change these policies – the largest response the magazine has ever received [22]. Similarly, consumer organizations agree that government regulatory agencies need to have a more active role in the oversight of medical device recalls, for example:

- Government regulatory agencies need a clear and explicit legal mandate to assume primary responsibility for the supervision, monitoring, and enforcement of all medical device recalls, rather than requesting that the companies provide recall information to the public. The agencies should be required to quickly and efficiently disseminate accurate and pertinent information regarding the recall of medical devices to patients and healthcare providers.

- An office or agency independent of the health regulatory agency is needed to investigate the circumstances surrounding the withdrawal of any approved medical device from the market.

Legislative and regulatory changes requested

As a result of the EU's streamlined process, which rarely requires clinical trials to examine the safety of medical devices, the USA came under pressure to ease their approval process for medical devices. In 2002, the US Congress passed the Medical Device User Fee and Modernization Act (MDUFMA), and this law was amended in 2004 [23]. Consumer groups opposed many aspects of these bills, which weakened rather than strengthened FDA's regulatory muscle. In their opposition, consumer groups pointed out three general concerns:

- The law favors rapid medical device approval over medical device safety.

- The law ignores the need for improved postmarket surveillance.

- The law sets time limits on reviews of medical device safety, which could divert resources from other important FDA functions.

Consumer groups were especially concerned that the bill supports privatization of several essential regulatory functions of the FDA, by allowing for third-party reviews and inspections. The bill extended a previous law implementing 510(k) review by third parties of most Class II devices. In addition, the law initiated/expanded the use of non-FDA 'accredited persons' to conduct inspections of medical device facilities, including Class II and Class III devices that are permanently implantable, life-sustaining, or life-supporting. The third parties must be selected from a list of accredited persons compiled by the FDA; however, the specific accredited third party can be chosen by medical device manufacturers. Compensation for accredited persons is determined by medical device manufacturers in agreement with the third parties, and is paid by the manufacturer. Consumer groups point out that this arrangement creates a clear financial conflict of

interest; if a company wants to be hired for these tasks, it is in their financial interest to please their customers.

Consumer concerns about the need for legislative and regulatory changes have increased during the early years of the twenty-first century, in response to several well-publicized failures of medical devices. Although consumer groups have been concerned about how recalls are handled, recalls also bring attention to issues with the approval process, not just the recall process. For example, recent recalls of heart valves and defibrillators have brought public attention to life-threatening problems that can result from defective medical devices [24–28]. Thus far, however, consumer groups have been unsuccessful in their efforts to strengthen the regulation of medical devices. On the contrary, medical device companies can get new products approved in an expedited process that does not necessarily require clinical trials if the new product is considered 'substantially equivalent' to another product on the market. The definition of 'substantial equivalence' is very vague, and has included products made of different materials and/or for very different intended uses – differences that could substantially affect safety and effectiveness.

Consumer group accomplishments: mixed results

As a reflection of the growing clout of consumer organizations, in September 2005, Health Canada held its first-ever public meeting of an advisory panel, for the review of a controversial medical device: silicone gel breast implants. The public meeting was in response to consumer complaints about a secret meeting that took place in March 2005, with an 'independent' advisory panel. The controversy arose when it became known that the 'expert advisors' who participated in the panel meeting included two men who were paid consultants to one of the breast implant manufacturers, Inamed, whose products were being reviewed by Health Canada. In fact, both 'expert advisors' had testified on behalf of the safety of Inamed silicone gel breast implants at an FDA advisory panel in April of the same year. When consumer groups pointed out that paid consultants were unlikely to make unbiased judgments about the product, Members of Parliament joined them in demanding a more open, balanced process. As a result, Health Canada officials held a public advisory panel meeting, modeled after the FDA public meetings. However, consumer groups were shocked to learn that the same industry-paid consultants who were on the panel for the secret meeting would remain on the panel for the public meeting, as well as other consultants to one or both implant manufacturers. Only one consumer advocate was on the panel, and patients and advocates were given only 3 minutes each to testify during the public comment period. The expense and inconvenience of traveling to Ottawa, and concerns that the panel vote for approval was preordained, apparently outweighed patients' desire to publicly testify for 3 minutes, and few consumer representatives or patients testified.

Recent consumer efforts in the USA indicate similarly mixed results. In response to consumer and Congressional pressure about inadequate postmarket surveillance of medical devices, the FDA announced its intention to address shortcomings in 2006,

and held the first in a series of 'workshops' on this topic in early February 2006. The first workshop was described afterwards in the FDA's press release as a meeting 'between the FDA and AdvaMed', the organization that represents device manufacturers. Consumer groups were not included in the planning or agenda of the workshop, and were not notified that it was held until after the meeting was over. Moreover, the meeting was organized by AdvaMed rather than the FDA, and participants were charged several hundred dollars each to attend, which likely reduced the participation of government employees and representatives of nonprofit organizations. Presumably consumer groups will be invited to a later workshop organized by the FDA, but the question arises as to why they were not included as an integral part of all FDA meetings on the topic.

These examples indicate that consumer organizations are actively pushing for better regulatory processes and safeguards for medical devices, but are meeting with limited success to even 'be at the table' and have their voices heard. As device manufacturers savor their victories in streamlining the approval process, consumer advocates complain that they are tilting at windmills in the face of regulatory agencies that seem oblivious to conflicts of interest, unconcerned about long-term safety data, and indifferent to the shortcomings of postmarket surveillance. Nevertheless, consumer advocates continue to make their voices heard, and partly as a result of those efforts the news media are focusing more attention on dangerous defects and numerous recalls of specific medical devices. In the USA, Canada, and the UK, legislators have joined consumer advocates in their demands for greater safeguards, and the combined forces of consumer groups, Members of Congress, Members of Parliament, and the attention of the news media may eventually influence government regulatory agencies and device manufacturers, resulting in improved safety studies and postmarket surveillance.

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28. FDA issues nationwide notification of recall of certain Guidant implantable defibrillators and cardiac resynchronization therapy defibrillators: http://www.fda.gov/bbs/topics/NEWS/2005/NEW01185.html

June 1, 2007

Jeffrey Shuren, M.D., J.D.
Assistant Commissioner for Policy
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Shuren:

Thank you for appearing before the Subcommittee on Health on Wednesday, May 16, 2007, at the hearing entitled "Reauthorization of the Medical Device and User Fee Act." We appreciate the time and effort you gave as a witness before the Subcommittee or Health.

Under the Rules of the Committee on Energy and Commerce, the hearing record remains open to permit Members to submit additional questions to the witnesses. Attached are questions directed to you from a certain Member of the Committee. In preparing your answers to these questions, please address your response to the Member who has submitted the questions and include the text of the Member's question along with your response.

To facilitate the printing of the hearing record, your responses to these questions should be received no later than the close of business **Friday, June 15, 2007**. Your written responses should be delivered to **316 Ford House Office Building** and faxed to **202-225-5288** to the attention of Melissa Sidman, Legislative Clerk/Public Health. An electronic version of your response should also be sent by e-mail to Ms. Melissa Sidman at **melissa.sidman@mail.house.gov** in a single Word formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Melissa Sidman at (202) 226-2424.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Frank Pallone, Jr., Chairman
Subcommittee on Health

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health

The Honorable Diana DeGette, Member
Subcommittee on Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUL 9 2007

Dear Mr. Chairman:

Thank you for the opportunity to testify at the May 16, 2007, hearing entitled, "Reauthorization of the Medical Device User Fee and Modernization Act," before the Subcommittee on Health, Committee on Energy and Commerce. Jeffrey E. Shuren, M.D., J.D., Assistant Commissioner for Policy, testified on behalf of the Food and Drug Administration (FDA or the Agency). FDA is responding to the June 5, 2007, letter you sent containing follow-up questions for the record. Below we have re-printed the questions in bold followed by our response.

The Honorable Diana DeGette

Question 1: The Institute of Medicine (IOM) conducted a study to determine whether FDA's system for post-market surveillance of medical devices provides adequate safe guards for their use in pediatric populations. That study included a number of recommendations for FDA, including:

- **Collaboration with the National Institutes of Health and the Agency for Health Care Research and Quality "to define a research agenda and priorities for the evaluation of the short-and long-term safety and effectiveness of medical device use with growing and developing children;"**
- **Promotion of the development and use of standards and approaches for capturing and linking use and outcomes data for medical devices;**
- **Collaboration with industry, health care professionals and organizations, and parent and patient advocates to improve adverse event reporting;**
- **Oversight of the management of high-profile medical device safety issues, similar to the independent drug safety oversight board within FDA; and**

- **Establishment of a central point of responsibility for pediatric issues within the Center for Devices and Radiological Health to evaluate the adequacy of the Center's use of pediatric expertise and its attention to pediatric issues in all aspects of its work.**

Has FDA adopted any of these recommendations: What has been the impact of those recommendations that have been adopted by FDA?

Answer: In general, FDA concurs with all of IOM's main recommendations to improve FDA's post-market surveillance activities. FDA believes that many initiatives to address the IOM concerns have already begun at the Agency.

Although MDUFMA directed IOM to examine FDA's post-market surveillance program for devices used for pediatric indications, IOM's findings note shortcomings in FDA's post-market surveillance program for medical devices in general. IOM notes, "an effective regulatory program for evaluating and monitoring the safety of medical devices in general is a necessary foundation for efforts to safeguard children in particular." Thus, the majority of IOM's recommendations were directed to improvements in FDA's overall device post-market safety program. Recognizing this, FDA has already made efforts to improve its program and understands that further enhancements are necessary.

In January 2006, FDA issued the report entitled, "Ensuring the Safety of Marketed Medical Devices: the Center for Devices and Radiological Health's (CDRH's) Medical Device Postmarket Safety Program," and in November of 2006, FDA issued the companion report entitled, "Postmarket Transformation Leadership Team Report,"[1] which lays out an implementation strategy for improvements recommended in the first report. FDA believes these efforts to transform its post-market safety program will go a long way toward addressing IOM's concerns.

The following is a list of IOM recommendations we've already adopted or addressed. The first set of recommendations prominently addresses FDA's Medical Product Safety Network (MedSun).

- IOM Recommendation 4.1: Focus more attention on adverse device events, including those involving children.

  MedSun continues to recruit pediatric hospitals and now has 24 agreements in place. This is in addition to many other institutions with significant pediatric services. A subset of these hospitals will form KidNet, a network that will initially focus on devices used in the pediatric and neonatal intensive care unit settings. Another major new initiative within another subset of MedSun facilities, also involving children's hospitals and known as HeartNet, will target active reporting by specialists from electrophysiology labs on the devices they use (e.g., pacemakers).

[1] These reports may be found at: *www.fda.gov/cdrh/post-market/mdpi.html*

- IOM Recommendation 4.2: FDA should continue educational and communication programs...

  MedSun has vigorous educational and communication efforts underway.

- IOM Recommendation 4.3: FDA's plans for evaluating MedSun's performance...

  MedSun assures continuous quality improvement, provides many avenues of routine feedback to user facilities, and routinely documents actions taken based on reports. MedSun assures representation of the user facility universe, and most user facility reports now come only through MedSun.

- IOM Recommendation 4.7: Children's hospitals and other user facilities should establish a focal point of responsibility for medical device safety...

  MedSun staff work with hospital focal points (usually risk managers or biomedical engineers) to develop best practices in establishing the effective flow of safety information through their institutions. MedSun provides the network routine feedback on reports submitted as well as FDA actions (e.g., public health notifications and recalls). Periodic audio conferences are held among network members to find best solutions to safety issues affecting all of them (e.g., electromagnetic interference). In addition, special studies are undertaken.

  The impact of these MedSun-related activities has been to: 1) expand the universe of hospitals (particularly children's hospitals) committed to improving device safety and the culture of safety within their institutions; 2) create plans for more active surveillance targeting specific clinical areas (e.g., devices used in neonatal and pediatric ICUs and devices used to treat heart rhythm disturbances); and 3) further identify safety concerns and take appropriate measures.

Other non-MedSun efforts which are of importance and have been adopted or addressed:

- IOM Recommendation 4.6: Medical...and other organizations or societies that include health professionals who care for children should establish working groups...collaborate...establish standards...

  FDA agrees that these are important issues. Where and when appropriate, FDA facilitates these efforts and collaborates with professional societies.

- IOM Recommendation 4.8: FDA should continue to improve and expand its medical device safety resources for patients and families...

  FDA recognizes the importance of these issues and strives to make safety information readily available.

- IOM Recommendation 5.1: Congress should require FDA to establish a system for monitoring and publicly reporting the status of post-market study commitments...

  FDA has significantly revamped the post-approval study (PAS) program, issued guidance on report format and content, set up an Implementation Working Group, established an electronic tracking system, and is posting the status of reports and studies on its website.

- IOM Recommendation 6.1: FDA should develop additional guidance for its own staff as well as for manufacturers...on the identification and evaluation of pediatric questions...at all stages in the design...of medical devices used with children.

  FDA has issued pediatric guidance to address these issues in general (Premarket Assessment of Pediatric Medical Devices and Pediatric Expertise for Advisory Panels). These can be viewed on CDRH's Pediatric Home Page at http://www.fda.gov/cdrh/pediatricdevices. More specific guidances can be issued as the need arises.

- IOM Recommendation 6.2: ...FDA should also work with agencies such as AHRQ and university- and industry-based methodologists...to strengthen...epidemiologic research...

  As part of the Agency's strategic planning, FDA has identified a number of areas where increasing its collaborative efforts with other Federal agencies will help develop the methods and tools needed to foster epidemiologic research on device safety. For example, FDA continues to explore the use of registries as an important tool in the ongoing post-market evaluation of the safety and effectiveness of medical devices. In addition, FDA has projects underway with a variety of institutions and agencies to further explore relevant databases.

- IOM Recommendation 6.3: ...FDA should ... create a registry of relevant registries...

  FDA currently has a Fellow working full time on this project.

- IOM Recommendation 7.1: FDA should establish a central point of responsibility for pediatric issues within CDRH...

  FDA has already established a central point of responsibility for pediatric issues within CDRH. In July 2005, CDRH created a Pediatric Steering Committee that consists of representatives from each of the six offices within CDRH, as well as representatives from each division within the major pre-market review office (Office of Device Evaluation). The primary function of this group is to ensure that appropriate pediatric expertise is obtained, when needed, to assess pre-market and post-market issues. This may include the use of expertise within the Center, within other FDA Centers or outside the Agency (e.g., through the use of members of our Medical Device Advisory Panels). The steering committee also works with FDA's Office of Pediatric Therapeutics to coordinate the development of policies related to pediatric issues with other FDA Centers.

- IOM Recommendation 7.2: All those engaged in improving the quality of health care...should evaluate and sharpen...their attention to medical device safety...

  FDA's report entitled, "Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program," notes the need to partner with public and private enterprises throughout the medical device community to ensure ongoing effective communication and to leverage FDA's limited resources. MedSun is a great example of partnering with health care institutions on the front line to enhance the nation's ability to address device safety issues. Also, FDA continues outreach efforts to industry via guidance development and workshops to enhance product design and trials and ultimately product safety. Finally, FDA also heightens awareness of the clinical community and the general public to medical device safety via its educational outreach efforts.

The impact of these activities has been as varied as the recommendations themselves. FDA's PAS program has been significantly revamped and enhanced, and our ability to track and assure that post-market commitments are being honored has improved significantly (IOM Recommendation 5.1). FDA has worked internally and with other agencies and professional societies to enhance the development and use of post-market tools, particularly registries, to fill the database gap and to enhance our collective capability to address important safety issues (IOM Recommendations 6.2, 6.3, 6.4). FDA has established a central point of responsibility for pediatric issues within CDRH to ensure, among other things, that appropriate expertise is obtained to assess pediatric pre- and post-market issues (IOM Recommendation 7.1).

Question 2: The IOM's report also cited a number of recommendations for Congress, including:

- **Requiring FDA to establish a system for monitoring and publicly reporting the status of post-market study commitments involving medical devices;**

- **Permitting FDA to order post-market studies as a condition of clearance for the categories of devices for which Section 522 Post-market Surveillance studies are not allowed; and**

- **Allowing FDA to extend those studies for devices with expected high pediatric use beyond the current three-year limit.**

Do you believe that Congress should follow these recommendations and make the necessary statutory changes?

As stated above in reference to IOM recommendation 5.1, FDA has significantly revamped the post-approval study program, issued guidance on report format and content, set up an Implementation Working Group, established an electronic tracking system, and is posting the status of reports and studies on its website.

Under current section 522, FDA has the authority to require a study at any time, including at the time of approval or clearance. The IOM's suggested change to section 522 would not add to FDA's current authority and could delay getting devices to market while the details of post-market surveillance are worked out.

FDA agrees that there are situations in which having more than three years of post-approval surveillance would be useful. Currently, FDA must obtain the agreement of the manufacturer in order to require a longer surveillance period.

In addition, during the hearing, FDA's witness, Dr. Jeffrey Shuren, Assistant Commissioner for Policy, offered to provide written responses to the following questions.

The Honorable Henry A. Waxman

Request: Deliver to the Committee by May 25, 2007, two MDUFMA-mandated reports: Section 104 Post-Market Surveillance and Third Party 510(k) Review.

Answer: These reports were delivered to the Committee on Friday, May 25, 2007, as requested.

The Honorable Mike Ferguson

Question: What's the impact of not reauthorizing MDUFMA?

Answer: The authority to collect medical device user fees sunsets on October 1, 2007.

- If Congress does not reauthorize fees for "MDUFMA II," FDA will lose a critical source of funds that has made possible many improvements to the medical device program over the past five years.
- FDA will be forced to make significant personnel reductions of nearly 200 FTEs paid for by device user fees.
- The loss of experienced device reviewers will cause review performance to fall and significantly delay critical work that supports the President's vision of a healthier America.
- Medical device user fees also support pre-approval inspections conducted by FDA's Field staff in the Office of Regulatory Affairs (ORA). Without user fees, ORA would have to cut approximately 100 pre-approval device inspections per year.
- The loss of user fees will dramatically slow the flow of new potentially life saving medical devices for patients who need them.
- In addition to this public health impact, the U.S. medical device industry will suffer significant economic disruption.

The Honorable Lois Capps

Question: What percentage of Class II and III devices are tested in women? How do we ensure that women and children are included in studies?

Answer: FDA approved 276 Class III devices through the pre-market approval (PMA) program from fiscal year (FY) 00 – FY 06. Ninety-five percent of the clinical studies supporting these approvals (262/276) included women. This is what we would expect, since most devices can be used on men and women in the same manner (e.g., contact lenses, orthopedic implants, heart valves). Some studies did not include both men and women because device use is limited to a particular gender (e.g., penile implants, prostate specific antigen, breast implants). Between FY 03 and FY 06, FDA cleared 1,022 pre-market notification submissions [510(k)s] containing clinical data (data are not readily available before FY 03). We would expect approximately the same percentages of these trials to include women as did the PMA studies.

Many devices can be used safely and effectively across all demographics and, consequently, have "general labeling" that applies to all populations. However, there are some devices that present unique issues based on gender, age, or race/ethnicity of the patients. CDRH looks at the clinical data presented in the marketing application and determines if the data adequately address the special risks that may be presented by a particular subpopulation for which the device is to be indicated. In reviewing the PMA marketing applications from the last seven years (above), we determined that the majority of the trials included the appropriate patient population, including women and different ethnic groups.

In cases where special issues may not have been addressed in the clinical trial, these issues can be addressed through the labeling for the device. For example, the labeling for a device to treat dermal defects that was not studied in African-Americans would have a warning or precaution to notify health care practitioners that there may be additional risks, such as keloid formation, in these patients. In some cases, we have required companies to conduct a study to obtain this data as a condition of approving the PMA so that the risks could be specifically addressed in the labeling.

Recently CDRH formed a working group that is exploring ways to ensure that the clinical data submitted to FDA in support of marketing approval are representative of patients in the U.S. with the disease or condition. One objective is to improve our ability to identify special issues for these populations. Potential measures include developing guidance and revising our internal Standard Operating Procedures to ensure that staff and sponsors have reviewed inclusion/exclusion criteria for a proposed study in light of diversity issues.

The Honorable Anna G. Eshoo

Question: Is Lucile Packard Children's Hospital at Stanford University participating in the MEDSUN program?

Page 8 - The Honorable John D. Dingell

Answer: Lucile Packard participates in FDA's MEDSUN program, a national network of health care facilities that constitutes a representative profile of user reports for device related deaths and serious illnesses or injuries. Participating hospital personnel are trained to recognize and report problems in real time, providing critically important data on medical devices to FDA.

Thank you again for the opportunity to testify. If you need additional information or have other questions, please let us know.

Sincerely,

Stephen R. Mason
Acting Assistant Commissioner
for Legislation

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