

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

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

Overview

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

all the rigorous quality system requirements established by the FDA.

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

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

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

Summary of Concerns

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

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

There has been no demonstrated public health need for pre-marketing inspection of facilities making Class II products. Implementation of such a system would actually harm the public health, by drastically slowing the introduction and availability of improved medical devices. FDA currently conducts pre-approval inspection of approximately 50 class III devices a year, and pre-approval inspection is appropriate for these high risk devices. Requiring FDA to conduct pre-approval inspections of the 3,600 plus class II devices that are approved every year would bring the approval process to a grinding halt. Appropriately, FDA inspects facilities that make class II products on a risk-based schedule.

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

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

1. The costs of inspection would certainly vary significantly for a domestic facility versus a foreign facility in a developed country versus the cost of

inspection in a less developed country. Is it fair to charge one price for these different facilities and potentially have domestic companies subsidizing the costs of inspections for foreign facilities?

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

Additional Comments

The proposed pre-inspection requirement for all class II devices.

Section 202 of the discussion draft calls for a new FDA inspection requirement for all class II medical devices. FDA already conducts such inspections for class III products. Under this proposal, an FDA inspection would be required prior to the distribution of all new products, and FDA would have just 2 years

to inspect all facilities marketing such products today. This new requirement is not justified on public health and safety grounds, would be impractical to implement, and is premature, given the potential benefits of the third-party inspection program just streamlined through the FDAAA.

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

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

Should more inspections of domestic medical device facilities be needed, one approach would be for FDA to fully

implement the third-party inspection provisions of the FDAAA. Although Congress first authorized FDA accredited third parties to conduct inspections of medical device establishments in the original MDUFMA legislation in 2002, legislative changes were needed and instituted in 2007 to make that process more attractive and feasible from both an agency and industry standpoint. We are hopeful that this program will free up significant FDA resources.

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

Importer fees.

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

"Country-of-Manufacture" labeling requirement

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

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

Unique facility identifier.

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

Conclusion

AdvaMed appreciates the opportunity to share its views with the Committee on the discussion draft of the FDA Globalization Act of 2008. We share your goal of an effective, risk-based inspection system that applies to both foreign and domestic manufacturers and is adequately funded. As I have outlined in my testimony, we have a number of concerns about

specific provisions of the bill, and serious questions about the concept of a broad-based user fee to fund inspection activities. However, we share the overarching goals of the Committee as it pertains to safety in the global supply chain, and look forward to working with the Committee to achieve them.