

Testimony Summary of Joseph A. Levitt
Partner, Hogan Lovells US LLP
On behalf of the Advanced Medical Technology Association
House Energy & Commerce Health Subcommittee -- April 18, 2012

- The U.S. medical technology industry is an American success story, directly employing more than 400,000 workers nationwide.
- Success in our industry comes only from innovation. We are very proud of our contributions to the U.S. economy and are even more proud of our contributions to improving patient care.
- FDA is a critical partner in our companies' efforts to bring safe and effective medical devices to patients. Without a strong, effective and efficient FDA, we cannot have a strong and competitive industry.
- While the FDA has consistently maintained a strong record of assuring safety and effectiveness of the products it reviews, delays in product approval, inconsistency in the review process, and the resulting downstream effects on investment and innovation have undermined the competitiveness of our industry and harmed patient access to new treatments, diagnostics, and cures.
- We are pleased that after extensive negotiations, FDA and industry reached a user fee agreement that has the potential to help achieve meaningful change in FDA performance through groundbreaking accountability and transparency measures and enhanced FDA resources.
- This user fee agreement establishes average total time goals for FDA product review. Total time is the best indicator of whether FDA is consistent and efficient in its review and is providing sponsors with adequate information in advance of what data is needed for different types of products. These total time goals are shared performance goals, because industry also has an obligation to submit good applications to FDA.
- The agreement also establishes improved goals for time on the FDA clock and the improved FDA goals and the total time goals work together to encourage FDA to focus on a thorough but efficient review of all product submissions.
- The agreement includes process standards that we anticipate will improve the consistency and timeliness of the review process, including meaningful presubmission interactions, midway review interactions, and a new process for submissions that are outside the FDA time target.
- The agreement provides greater accountability to industry, patients and to Congress and the Administration, through regular reporting on key metrics and an outside analysis of FDA's management of the review process, coupled with an FDA corrective action plan to address opportunities for improvement.
- Lastly, to give FDA additional tools to meet the new goals, the agreement provides \$595 million in user fees for 2013-2017.
- Each of the provisions of this agreement has the potential to make a difference in improving FDA performance, but the whole is truly greater than the sum of its parts.
- We urge the Committee to act promptly to reauthorize the MDUFA program and enact this agreement into law. Failure to act would not only jeopardize the critical improvements made by the new agreement but would have a devastating impact on our industry's ability to bring improved treatments and cures to patients.

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Thank you Chairman Pitts, Ranking Member Pallone and members of the Committee for the opportunity to testify today.

My name is Joe Levitt, and I am a partner with the firm of Hogan Lovells US LLP. I am here today on behalf of the Advanced Medical Technology Association (AdvaMed), although my testimony today on the MDUFA agreement is submitted on behalf of three of the medical technology industry associations who participated in the MDUFA negotiations—AdvaMed, the Medical Device Manufacturers Association (MDMA), and the Medical Imaging Technology Association (MITA).

I want to thank you for convening today's hearing, and for your interest in improving medical device regulation for patients and industry. Over the course of the last year, members of this committee have demonstrated their focus on improving the efficiency and effectiveness of FDA regulation, and your outreach to the agency and the policy proposals that have been introduced show your commitment to this important issue.

The U.S. Medical Technology Industry

The medical technology industry is an American success story. Our industry directly employs more than 400,000 workers nationwide. Typically, for every worker our industry directly

employs, another four workers are employed by businesses supplying components and services to our industry so that the total number of employees generated by our industry exceeds two million.

The jobs our industry provides are good jobs—the kinds of jobs that allow employees to live the American dream. Industry pay levels are 38 percent higher than average pay for all U.S. employment and 22 percent higher than other manufacturing employment. While the number of manufacturing jobs was plummeting across the larger economy, even before the recent economic downturn, employment in our industry was expanding. Between 2005 and 2007, medical technology employment grew 20.4%, adding 73,000 jobs. During the recession, between 2007 and 2008, MedTech employment dropped 1.1 percent, compared to 4.4% for manufacturing as a whole.

Our industry is heavily skewed toward small companies—the kind of companies that begin with a doctor, an engineer, and an idea to improve patient care. Almost two-thirds of the 7,000 medical technology firms in the U.S. have fewer than 20 employees. A high proportion of the breakthrough products in our industry come from these small, often venture-capital funded companies.

And whether the firm is large or small, success in our industry comes only from innovation—the creation of diagnostics, treatments and cures that extend and enhance lives. Our industry's investment in research and development is more than twice the national average. Our product life-cycle is only 18-24 months.

Our industry is so competitive that price increases have averaged only one-quarter the rate of other medical goods and services and just one-half the general CPI for almost 20 years.

With \$33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports. Notably, unlike virtually every other sector of U.S. manufacturing, medical technology has consistently enjoyed a favorable balance of trade. With the aging of both U.S. and foreign populations, the projected explosive growth of large middle class populations demanding modern health care in developing countries like China and India, and the accelerating pace of biomedical discovery, the potential for growth of our industry is great.

While we are very proud of our contributions to the U.S. economy, we are even more proud of our contributions to improving patient care. For patients, medical progress has been remarkable. Between 1980 and 2000, medical progress added more than three years to life expectancy. The death rate from heart disease was cut in half; the death rate from stroke was cut by one-third, and the death rate from breast cancer was cut 20%. Medical technology has been a major driver of this progress.

FDA Regulation of Medical Devices – MDUFA III

While we are making progress in improving patient care and see immense future opportunities to provide jobs and contribute to long-term economic growth, we are also worried. Today, America is the world leader in medical technology. But there are warning signs. As a recent

PriceWaterhouse Coopers report showed, our lead is slipping on a number of dimensions of competitiveness. And a key factor in our loss of competitiveness has been the decline in FDA's performance in ensuring timely patient access to safe and effective medical devices.

Put simply, FDA is a critical partner in our companies' efforts to bring safe and effective medical devices to patients. Without a strong, effective, and efficient FDA, we cannot have a strong and competitive industry. The predictability, consistency and efficiency of FDA decision-making, as well as reasonable, risk-based standards of evidence to assure the safety and effectiveness of medical technology products, is essential to drive new innovations for patients and for the long-term success of the medical device industry.

As a former FDA veteran of 25 years who served in a variety of capacities, including as Deputy Director for Regulations and Policy at the FDA's device center in the 1990's, I can tell you that FDA has consistently maintained a strong record of assuring the safety and effectiveness of the products it reviews. The hard working staff at FDA has always focused on patient safety as a top priority, and the data bear out their dedication to protecting the end users of medical devices.

At the same time, there has been slippage in FDA's track record of reviewing products in a timely and consistent manner. FDA has recognized this as well. Taken together, longer FDA review periods, inconsistency in the review process, and the resulting downstream effects on investment and innovation have lessened the competitiveness of our industry and harmed patient access to new treatments, diagnostics, and cures.

The user fee agreement reached between FDA and industry after extensive negotiations has the potential to help achieve meaningful improvement in FDA performance through groundbreaking accountability and transparency measures and enhanced FDA resources.

The FDA leadership and Dr. Shuren have recognized the need to vigorously address the issues affecting the device center and are already taking a number of steps that we believe have the potential to bring significant improvements. The user fee agreement has the potential to be an additional step in the right direction. It is good for industry. It is good for FDA. And most of all, it is good for patients.

We urge this Committee and the Congress as a whole to act promptly to reauthorize the user fee program and enact this agreement into law. Failure to act would not only jeopardize the critical improvements made by the new agreement but would have a devastating impact on our industry's ability to bring improved treatments and cures to patients.

The user fee agreement builds the conditions for success in a number major ways:

Total Time to Decision Goal

For the first time ever, this user fee agreement establishes the shared outcome goal of average total time to decision for FDA product review. All previous agreements have set goals in terms of time on the FDA clock. When the FDA asks sponsors for additional information or data, the FDA clock stops. The result was that, while FDA may have been technically meeting the goals

for 510(k) submissions in terms of FDA review times, the total average time from submission to final decision increased 43% when comparing the 2003 through 2007 timeframe with comparable data from 2010. Of course, what matters to companies and patients is not an artificial construct like time on the FDA clock, but rather the total time (including any necessary time spent by the device sponsor in answering FDA's questions) it actually takes to get a final decision from FDA.

We refer to this new performance metric as a shared performance goal. Under the agreement, industry has an obligation to submit good applications and to respond expeditiously to legitimate questions from FDA about an application, and FDA will have authority to decline to begin review of an application that is obviously deficient when it is submitted. We recognize that FDA cannot control the amount of time it takes for a sponsor to respond to questions about any individual application. What FDA can and should do better at, however, is communicating to device sponsors, in advance, what the data requirements are for a given device, so sponsors have maximum likelihood of getting it right the first time. This would, in turn, reduce the total time from submission to final decision. All sponsors want to submit applications that meet FDA standards, so transparency of data expectation is key to their success. We believe total time is the best indicator of whether FDA is consistent and efficient in its review and is providing sponsors with adequate information in advance of what data are needed for different types of products.

By setting in place this new goal, efforts will be focused on the metric that is truly most important to all concerned.

Improved FDA Day Goals

Second, the agreement also establishes significantly improved goals for time on the FDA clock. For example, in the case of PMAs receiving advisory panel reviews—which tend to be the most innovative products—90% of those PMA products will be receiving a decision within 320 days by the end of this agreement. The improved FDA day goals and the total time goals work together to encourage FDA to focus on a thorough but efficient review of all product submissions.

Process Improvements

Third, the agreement includes process improvements that we anticipate will improve the consistency and timeliness of the review process independent of the specific time goals.

The agreement provides for meaningful presubmission interactions between FDA and companies where agreements reached will not change, so that companies know what FDA expects and FDA is bound by its commitments, unless, of course, new information arises that requires a change to protect public health. As noted earlier, this is a key element for improving the efficiency of the device review program—communicating data requirements in advance so sponsors have maximum chance of getting it right the first time.

Additionally, there will be a substantive interaction between FDA and the company midway through the review process. This will assure that both companies and FDA identify any deficiencies in the application early, so that they can be corrected promptly.

Also, a new procedure that we call “no submission left behind” will be instituted, so that if the FDA time target is missed for 510(k) and PMA submissions, the company and the FDA will meet to work out a schedule for resolving remaining issues, so that the submission doesn’t go to fall off the radar screen.

Greater Accountability

Fourth, the agreement provides for greater accountability. Greater accountability means that FDA’s success under this agreement will be transparent to FDA management, to industry, to patients, and to Congress and the Administration, so that any problems that arise can be corrected promptly. Under the agreement, there will be quarterly and annual reporting on key metrics, providing reliable and consistent tracking of new performance indicators that both FDA and industry have agreed are important.

In addition, the agreement requires an analysis of FDA’s management of the review process by an independent consulting organization, coupled with an FDA corrective action plan to address any identified inefficiencies and provide opportunities for improvement. We were gratified during the negotiations with FDA that the agency welcomed this independent review as a way to

bring fresh eyes to the issues and work constructively towards meaningful process improvements.

Appropriate Resources

Finally, to give FDA additional tools to meet the new goals, the agreement provides \$595 million in user fees for 2013-2017. Additional reviewers, lower manager-to-reviewer ratios, enhanced training, and other resources provided by the agreement will give FDA what it needs to improve performance. Overall, the agreement will allow FDA to hire approximately 200 additional FTEs, the vast majority of which will be put into place where needed most – additional reviewers. This, coupled with additional supervisors who are being hired this year, should lead to improved consistency in the review process.

Each of the provisions of this agreement has the potential to make a difference in improving FDA performance. But the whole is truly greater than the sum of its parts. Each of the elements of the agreement reinforces the others. For example, as I noted earlier, the combination of total time goals and faster FDA time goals should result in greater improvements than either one would achieve separately.

And, of course, no agreement, no matter how good on paper, is self-executing. Making it work as intended will require the full efforts of FDA's dedicated staff and managers. Our industry is

committed to work with FDA in any way we can to make it a success. Continued oversight and interest from the Congress will also be important. Patients are depending on all of us.

Legislative Package

In addition to the underlying user fee agreement, a number of legislative proposals have been introduced with the goal of improving the FDA's operations. We are appreciative of efforts by all Members who seek to give the FDA the tools and structure it needs to succeed, and are encouraged by the package of legislative reforms released by the committee. Legislative reforms that do not alter the substance of the negotiated agreement between FDA and industry and seek to improve consistency and predictability in the FDA device review process hold the potential to create a legislative reauthorization package that maximizes the opportunity for success at the agency, which should be the shared goal of all involved.

For example, legislation has been proposed to streamline the de novo process by eliminating the statutory requirement that a sponsor receive a finding of "not substantially equivalent" before even beginning the de novo process. FDA itself has recognized that the current process is cumbersome, and FDA is looking at using its regulatory discretion to improve that process. However, statutory change may be the most effective way to address the problem, which will help FDA, industry, and ultimately patients.

There is also a proposal to address the confusion created by FDA's draft guidance regarding when, under the FDCA, a modification to a cleared device requires the submission of a new

510(k) application. Left in its current form, this draft guidance could be interpreted as establishing a standard that requires a new 510(k) submission for almost every modification. This has the potential to dramatically increase the number of 510(k) applications required, with no related public health benefit. According to a survey of AdvaMed members, this has the potential to increase submissions by 300 to 500%. This could serve to seriously impact patient access to medical devices, increase FDA's workload and put pressure on agency resources. We believe Congress should provide clarity and certainty that the existing approach to device modifications is appropriate.

In addition, the committee's legislative package seeks to address FDA's new approach to the investigational device exemption, or IDE. In the preamble to the IDE final rule, an IDE is described as "conditions under which investigations of medical devices involving human subjects may be exempt from certain requirements of the Federal Food, Drug, and Cosmetic Act . . . to permit devices to be shipped for clinical investigations to determine their safety and effectiveness." We believe the IDE review and approval process therefore should focus on the determination of whether the anticipated benefits of the device outweigh risks to human subjects, the importance of the knowledge to be gained and whether the investigation is scientifically sound. This new FDA policy is not only inconsistent with the regulation but is counterproductive from a public health point of view. It has been a major factor in slowing down the clinical trial process and extending the time it takes a product to get to market. It requires FDA to make early stage judgments that should appropriately be reserved for product clearance or approval. It has encouraged reviewers to try to resolve every possible trial design question in advance, making the trials themselves more cumbersome and costly than may be

necessary. FDA's apparent expansion of authority to include the additional determination of whether an investigation is sufficient to support product approval or clearance is not appropriate, and goes beyond what is contained in the statute and in the regulation. IDE approval should not be tied to product approval, but rather, should be based on what the clinical study is intended to do.

These are but a few examples of areas that we believe are appropriate to consider as legislative reforms to accompany the user fee agreement. At the same time, I want to emphasize that we are strongly committed to the user fee agreement as negotiated and do not support any proposals that would change the terms of the agreement or undermine its goals. Further, any legislative reforms should strike the appropriate balance between giving FDA the appropriate tools while preserving companies' due process rights so that innovative, life-improving and life-saving products can receive proper consideration.

I thank the Committee for the opportunity to testify and urge you to act promptly to reauthorize the user fee program, which is so critical to patients, to the FDA and to our industry.