EXECUTIVE SUMMARY

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President and Chief Executive Officer
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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

My name is Kelvyn Cullimore and I am the President and Chief Executive Officer of Dynatronics Corporation, an advanced-technology medical device manufacturer. I am testifying today on behalf of the Medical Device Manufacturers Association ("MDMA"), a national organization representing the innovative, entrepreneurial sector of the medical technology industry, on the reauthorization of the Medical Device User Fee and Modernization Act ("MDUFMA").

In 2002, Congress enacted MDUFMA which established a user fee program that provided FDA with resources necessary for the efficient and effective review of medical devices from a combination of increased appropriations and industry fees ("MDUFMA I"). MDMA supports reauthorization of MDUFMA ("MDUFMA II") and sees this as an opportunity to address some of the issues that arose under MDUFMA I. In particular, MDMA supports the provisions that will simplify the MDUFMA performance goals, improve communications between FDA and the industry, and create a more stable fee structure that provides greater fee relief for smaller companies.

Congress should maintain its primary role in funding FDA. MDMA supports user fees as a component of the funding necessary for FDA to achieve improved performance goals. However, 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 FDA relying too heavily on the industry for resources and create an unsustainable program.

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. These changes will result in greater fee stability and predictability and will significantly reduce application fees for all companies.

FDA has achieved many of its performance goals under MDUFMA I. However, some of the original performance goals, such as interim cycle goals, created unnecessary inefficiencies in FDA's review process. The MDUFMA II reauthorization agreement has eliminated these cycle goals in order to improve the efficiency of the entire review process and to reduce the overall review time, getting safe and effective devices to patients more quickly.

There are 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. However, such legislation must not unintentionally create disincentives that might have the effect of discouraging the development of pediatric medical devices.

MDMA strongly supports legislative efforts to improve patient and physician access to information regarding the safety and efficacy of cleared or approved medical devices. 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.

Hearing Testimony

Kelvyn Cullimore Jr.
President and Chief Executive Officer
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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.