



Hearing Testimony

Kelvyn Cullimore Jr.
President and Chief Executive Officer
Dynatronics Corporation

On Behalf Of
The Medical Device Manufacturers Association (MDMA)

Before the House Energy and Commerce
Subcommittee on Health

“Food and Drug Administration Globalization Act”

May 14, 2008

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

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

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

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

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

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

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

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

Background of User Fees

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

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

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

Proposed New User Fees

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

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

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

FDA Inspections

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

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

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

Penalties

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

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

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

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

Attachment I

User Fees

- While MDMA recognizes the appropriate role of government regulation of the industry, the association believes that any additional resources from FDA must come from Congressional appropriations and not from industry user fees.
- The device industry has seen its user fee totals jump from approximately \$150M from 2002-2007 to nearly \$300M from 2008-2012.
- The device industry is composed primarily of small companies (80% less than 50 employees and 98% less than 500 employees) who cannot afford to pay additional user fees.

Inspections

- Section 202 of the legislation ignores the risk-based classification system for medical devices, and would require FDA to reallocate its resources from life-supporting or life-sustaining devices to those that pose fewer risks.
- Congress and FDA have historically recognized the importance of allocating FDA's review of and regulatory control over medical devices according to the device's intended use, indications for use, and significantly, the risk the device poses to the patient. Instead of subjecting every medical device to the same pre-market and post-market regulatory review and oversight, Congress and FDA have recognized the importance of establishing risk-based classifications for medical devices based upon the level of FDA control necessary to establish and assure the safety and effectiveness of the medical device.
- Adding an additional waiting period for an FDA pre-clearance inspection would result in unacceptable and unnecessary delays for both patients and manufacturers.

Penalties

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

Conclusion

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