What’s Ahead for Medical Device Companies

While prospects look promising, tough issues must be resolved to ensure that patients and caregivers have access to innovative technologies. Failure to address the anticompetitive practices of certain GPOs or to modify MDUFMA will result in long-term problems for the industry.

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Mark B. Leahey, Esq. is the executive director of the Medical Device Manufacturers Association, 1900 K St., NW, Ste. 100, Washington, D.C., 20006. He can be reached at (202) 496-7124 or mleahey@medicaldevices.org [1]. The Medical Device Manufacturers Association (MDMA) is a national trade association that represents more than 200 manufacturers of medical devices, diagnostic products, and healthcare information systems. Its mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology. Leahey’s responsibilities include advocating on behalf of the entrepreneurial sector of the medical device industry to the U.S. Congress, FDA, Centers for Medicare and Medicaid Services, and other federal agencies. He is a member of the Massachusetts Bar and is a graduate of Georgetown University and the Georgetown Law Center.

By Mark B. Leahey, Esq.
Whether it is getting a device cleared or approved by the FDA, receiving adequate reimbursement by Medicare and private payers, or gaining access to the hospital marketplace through hospital buying groups known as group purchasing organizations (GPOs), companies will face a host of challenges in 2005. While the Bush administration and Congress have indicated no plans to take up Medicare legislation in 2005, Congress may address two other areas of critical importance to the device industry. These are reviewed below.

Group Purchasing Organizations

Over the past decade, small businesses and entrepreneurs in the U.S. medical device industry have shared a growing concern that the relaxation of antitrust laws, the promulgation of safe harbors in Medicare’s anti-kickback provisions for GPOs, and the concomitant concentration of market power in two dominant GPOs have

combined to significantly reduce competition, stifle innovation, and create unforeseen barriers to market entry for small to medium-sized manufacturers in the healthcare industry. The unintended impact of these policy changes and unchecked consolidation in GPO market concentration have led to the competitive harm of small business entrepreneurs and compromises on the safety and health of the nation’s healthcare workers and their patients.
The opportunity to compete for GPO contracts has become more difficult for small- and middle-sized manufacturers, especially if they compete with established product lines of incumbent manufacturers. Given the exclusionary and often anti-competitive behavior of certain GPOs and others, in concert with certain large manufacturers, small to medium-sized manufacturing firms are effectively denied the opportunity to market or sell their products to the vast majority of hospitals. As a result, small manufacturers&#151the primary catalyst for innovation in medical technology&#151are faced with the unappealing option of either selling their company to a larger manufacturer with GPO ties or facing near certain financial ruin.

In September 2004, the Senate Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights conducted its third hearing in as many years to explore the continued problems that innovative manufacturers were having accessing the hospital marketplace. Manufacturers with clinically preferred products at greater savings were still being denied access to doctors and patients.

The GPOs attempted to reform their practices through a voluntary industry code following the first Senate hearing in April of 2002. However, the information gathered at the most recent Senate hearing indicated that the codes were not working as quickly or as effectively as Congress had intended. As a result, Chairman of the Senate Judiciary Antitrust Subcommittee Mike DeWine (R-OH) and ranking member Senator Herb Kohl (D-WI) introduced bi-partisan legislation on October 1, 2004.

The Medical Device Competition Act of 2004 (S 2880) will help ensure that physicians and patients have access to the best, safest, and most cost-effective life-saving medical devices. The bill would authorize the Department of Health and Human Services to oversee the hospital purchasing industry to prevent GPOs from engaging in anticompetitive or unethical practices. Industry has hailed the bill as a critical step in addressing the anticompetitive and other questionable practices by certain GPOs that have long prevented cost-effective medical technologies from reaching the market.

While action on this bill had not occurred at the time of publication of January’s *Medical Design Technology,* the medical technology industry hopes that passage will occur in 2005. In addition to enhancing the quality and cost of current care in the U.S., this legislation will open the marketplace and drive investment from the venture capital community, resulting in greater advancements in the future.

Food and Drug Administration

The other major issue impacting medical technology companies that will likely be

addressed in 2005 will be modifications to the Medical Device User Fee and Modernization Act (MDUFMA). Often the first major hurdle that companies face in the U.S. is navigating the regulatory process at the FDA. The amount of time, energy, and resources a company expends on this process can be staggering. However, medical device user fees established in October 2002 by MDUFMA were designed to provide the FDA’s Center for Devices and Radiological Health (CDRH) with additional funds to improve the quality and timeliness of its review process.

In a number of ways, however, MDUFMA has not played out as expected. Fee increases, Congressional appropriation shortfalls, and unimpressive decision goals threaten to undermine the program’s effectiveness. Moving forward, the industry remains committed to ensuring that the FDA receives the stable and predictable funding it needs to regulate the industry. On the other hand, device manufacturers cannot continue to shoulder steeply increasing setup user fee rates. Reconciling these concerns collaboratively will allow MDUFMA to continue.

Funds for the FDA

The lack of Congressional appropriations for device reviews has been a major disappointment of MDUFMA. During the first three years of the program, Congress failed to meet its appropriations obligations twice. While Congress did appropriate the required funding for FY 2005, it failed to make up the shortfalls from previous years, totaling $30 million. Since the original appropriations targets were not met and the MDUFMA program received less than half of the committed government funds in its first three years, modifications will be needed for the program to continue. It is worth pointing out that during those same three years, the industry will have contributed approximately $80 million to the program, carrying a disproportionate share of the load. Since user fees have failed to work as intended, the industry supports modifications to the program or else letting the program sunset.

The “sunset provision” of MDUFMA calls for the program to end without $60 million in new, inflation-adjusted funds for the CDRH. It is now clear that the funds will not be there, and thus, the MDUFMA trigger will force Congress to either modify the program through legislative action or allow it to end. This is an opportunity to strengthen the user fee program in an effort to benefit the FDA and industry and&#151more important&#151to promote patient access to new technologies.

Modifying MDUFMA

In 2005, Congress has some important work to do to strengthen this program. Of primary concern are the skyrocketing user fee rates themselves. Rapidly escalating rates cannot be sustained. In the program’s first two years alone, Premarket Approval (PMA) application fees increased nearly 60 percent. In 2005, a PMA applicant will pay $239,237 for a review. At this rate, the PMA will exceed $300,000 by FY 2007. This is a startling trend, and one that cannot continue.

During the MDUFMA negotiations, the FDA promised a 25 percent improvement in 510(k)s and PMA review times. However, the Office of Device and Evaluation’s 2003

Annual Report shows that for 99 percent of the submissions, the FDA was already meeting or exceeding the decision goals under MDUFMA before the law was even enacted.

The $150 million investment the industry will pay over the first five years merits more than the status quo. The original expectations of the MDUFMA legislation obviously were unrealistic. For future years, the industry and FDA need assurances that a certain level of appropriations will be in place. Otherwise, the program cannot continue.

Looking Ahead

While the prospects for medical technology companies look promising in 2005, important issues must be resolved to ensure that patients and caregivers have access to innovative technologies. Failure to address the anticompetitive practices of certain GPOs and failure to modify MDUFMA to address the skyrocketing costs for FDA reviews will result in long-term problems for this industry, but ultimately, it will be the patient who loses.

ONLINE
For additional information, see *Medical Design Technology* online at www.mdtmag.com [2] or MDMA’s website at www.medicaldevices.org [3].

Outsourcing Outlook: Medical Electronics
According to data compiled for *Medical Design Technology* by Sweely InfoQuest, a research firm based in Rose Valley, PA, outsourcing will continue its impressive rise among OEMs in the medical electronics market.

&#149 Frost & Sullivan says the main processes outsourced will continue to be peripheral manufacturing, device manufacturing, product development, and R&D. Although the manufacturing process will be the most often outsourced activity, the outsourcing of R&D and product development is gaining momentum.

&#149 According to a survey by Technology Forecasters Inc., four main factors are driving the outsourcing surge. They are increased competition resulting from the commoditization of products, price pressure and cost cutting in the supply chain, greater focus on core competencies, and the globalization of medical products, which leads to globalization of manufacturing strategies.

&#149 New Venture Research Corp. predicts the market for medical device contract manufacturing to reach $9.5 billion by 2007&#151a growth of more than 40 percent from the end of last year. And, it is the assembly of medical equipment by qualified contract manufacturers that is considered to be one of the bright spots in the contract electronic manufacturing services market.

Medical electronics includes monitoring, diagnostic, imaging, invasive, and non-invasive devices such as CT scanners, hearing aids, electrocardiographs, pacemakers, ultrasound equipment, and MRI systems.

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