MDMA
MEDICAL DEVICE
MANUFACTURERS
ASSOCIATION

November 15, 2004

Submitted electronically

The Honorable Tommy G. Thompson
Secretary
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Solicitation of Comments on Stimulating Innovation in Medical Technologies [Docket No. 2004S-0233]

Dear Secretary Thompson:

I am filing these comments on behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative and entrepreneurial sector of the medical device industry. Hundreds of device manufacturers comprise our membership, including makers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of innovative products in the marketplace.

Encouraging innovation in healthcare and speeding the development of effective new technologies is critical to the overall wellbeing of the public. Most of the comments submitted to the docket and presented at the November 8, 2004 meeting focused on pre-market issues related to NIH, FDA or CMS. However, MDMA strongly believes that the greatest improvement in promoting innovation would result from actions taken by the HHS Office of Inspector General (OIG).

HHS OIG

Today, innovative medical technologies are currently being withheld from patients who need them because of the anticompetitive practices of certain hospital group purchasing organizations (GPOs). If the goal of this task force is to promote innovation, it must not only review pre-market issues facing companies, it must also examine certain post-market conditions to ensure that innovative products reach the patients who need them. HHS OIG currently has oversight authority over GPOs and must take steps to ensure and open and competitive marketplace.

MDMA members represent the future of medical technology in America. The vast majority of technological advancements in medical devices and ancillary equipment and diagnostic products are driven by small, innovative, entrepreneurial manufacturers (as is the case in many sectors of the economy). Unlike other industries, medical devices see constant updating and improvements. At any given time, 60 percent of the medical products sold are less than 12 months old. The life cycle of a typical medical device is only 18 months. This continuous innovation has traditionally been the hallmark of the entrepreneurial medical device industry.

The large manufacturers are important to the continuity of supply of quality products. They themselves were once small operations begun in a garage or a converted lab. Their own histories thus urge them to look in the direction of small entrepreneurial companies for innovation. Today, moreover, these leaders find it economically logical and strategically advantageous to look to us – the next generation – for the innovation that will keep the industry moving in a dynamic and positive way toward the future.
But we are profoundly concerned about the future of medical technology in this country. For years, many of us in the innovative sector have watched with alarm as our new products have cleared the multitude of

research and development hurdles. To gain regulatory approval, manufacturers must gather a vast array of laboratory, animal and human test results, as well as secure adequate funding to endure the long process. Next, a manufacturer must navigate the Medicare and private pay reimbursement mazes. Yet, once a device has cleared these hurdles, significant barriers exist that limit the ability for many manufacturers to compete in an open, fair marketplace.

Over the past three years, the Senate Judiciary Antirust Subcommittee has investigated the issue of hospital GPOs and has held three hearings addressing the problem of patient access to innovative technologies. Witnesses have testified about receiving NIH grants, successfully navigating the FDA regulatory process and in many cases receiving adequate reimbursement from CMS and private payers. However, these innovative technologies have been blocked from patients due to the practices of certain GPOs. Unless and until this issue is addressed, innovative products will not gain access to the marketplace and the quality and cost of healthcare will not improve at a sufficient rate.

While looking at ways to improve the pre-market conditions for innovation are important, the fastest and most efficient way to promote innovation would be to ensure that the post market conditions are fair and open. As a result, MDMA requests that the HHS OIG provide greater oversight of the GPO marketplace. Currently, the Senate has introduced bi-partisan legislation, "The Medical Device Competition Act of 2004" (S2880), which directs HHS OIG to provide greater oversight of GPOs contracting and business practices. Given the time left in the legislative calendar, it is unlikely to pass this Congress. However, HHS should move forward and provide the oversight as part of this task force's initiative. Of all the suggestions made to the task force to promote innovation, MDMA strongly believes that greater GPO oversight from HHS will produce tangible results in a relatively short period of time.

FDA

Ensuring that medical innovations are translated into advancements in patient care is a key part of MDMA's mandate. We constantly see small device companies struggling to clear the many hurdles along the path from idea to market. In looking for areas to promote innovation, we encourage HHS to ensure that device review processes in FDA, including imposition of user fees, do not harm innovation or discourage investors from supporting visionary device research.

MDMA has submitted comments to FDA on various draft guidance documents and most recently on the Critical Path initiative restating the need to down classifying devices and utilizing the least burdensome approach to in an attempt to better utilize FDA's resources.
We refer you to comments already submitted to FDA.

CMS

MDMA has also submitted numerous comments to CMS regarding specific changes necessary to ensure that innovative technologies are reimbursed at adequate levels in a variety of settings. Adequate payment is a critical element to ensure that patients have access to innovative products.

We also look forward to working with CMS's new Council for Technology and Innovation. MDMA hopes this group will not only bolster internal communications at the agency, but also serve as important entry point for medical device innovators to communicate with CMS officials. As the Council is formed, we encourage CMS to design it in a way that is open to the public and allows reception of comments, concerns, issues, and ideas from the device industry. We share the same goal of promoting medical technology innovation and look forward to working with the new Council.

NIH

MDMA has also commented on the need for adequate funding for innovative technology. Specifically, we are concerned that a new policy adopted by the NIH will interpret the eligibility rules for SBIR grants in such

a way as to exclude manufacturers backed by venture capital (VC) funding. This new interpretation is at odds with the program's intent to benefit U.S. small businesses. Making VC-backed companies ineligible for SBIR grants will hinder innovation, especially among smaller companies that are performing much of the industry's research and development of new products. Furthermore, the most promising small manufacturers also are the ones most likely to win VC support. They should not be penalized by the government and denied SBIR grants. This new policy could affect the SBIR programs of all federal agencies.

In closing, MDMA would like to highlight the important differences between the medical device and the pharmaceutical industries. The device innovation and development process includes a different set of hurdles than drugs. Device innovation, for example, tends to be evolutionary rather than revolutionary. As evidenced by the frequency of 510(k) reviews as opposed to PMAs, devices are improved gradually and incrementally. This causes devices to enjoy little or no revenue security in patent protection as new models are constantly being developed. As a result, the average 18-month life cycle ensures that no single device has the same revenue potential of a blockbuster drug. Yet the device development process is just as costly and time-consuming. And small companies are the ones bearing a disproportionate amount of the research and risk of finding novel treatments. Additional steps are needed to develop and promote innovative technologies and MDMA thanks you for your attention to this pressing matter. We look forward to working with the task force to improve the quality and cost of care in this country and around the world.

Sincerely,

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Executive Director
Medical Device Manufacturers Association