Statement Submitted for the Record
Consumers Union
to the Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
May 16, 2007

"Medical Device User Fee and Modernization Act (MDUFA)"

Mr. Chairman, Members of the Committee:

Consumers Union, the independent, non-profit publisher of *Consumer Reports*, is greatly concerned by the FDA's "hands-off" approach toward regulating medical devices. The high volume of injuries, and even deaths, caused by unsafe medical devices remains a serious problem requiring careful consideration by the FDA and its Board of Directors, the U.S. Congress. Every year, 1.3 million Americans are injured in medical product related adverse events.[i] In 2006, 452,000 emergency room visits resulted from injuries related to medical devices. 58,000 of these patients either died at the hospital, or were hospitalized.[ii] Consumers Union strongly agrees with the importance of ensuring access to life-saving medical devices and technology, but these tragic numbers demonstrate that rapid access must be balanced with reliable evidence of safety and effectiveness and increased attention to post-market safety monitoring.

Unless there is increased attention to post-market safety, Consumers Union does not support the FDA's proposed MDUFA II application processing goals, which would increase the number of applications to be processed by the FDA within a predetermined amount of time. The MDUFMA II processing goals do not appear to be supplemented with additional safety measures and these goals may substitute patient safety for industry speed. Consumers Union also disagrees with the FDA's recommendation that would allow accredited third parties to conduct facility inspections indefinitely with little interference and oversight by the FDA.

Furthermore, we request the FDA to consider patient and consumer needs for a more publicly accessible and usable adverse event reporting system. Currently, patients and consumers who wish to understand the risks associated with FDA-approved medical devices are limited to hard-to-use and complex online search functions.

Our Recommendations

I. LESS EMPHASIS SHOULD BE PLACED ON APPLICATION PROCESSING DEADLINES

We are concerned that the FDA's enormous pressure to meet MDUFMA I application processing deadlines may already have resulted in a number of unsubstantiated device approvals. The proposed goals, however, establish even more stringent deadlines for FDA device approvals. MDUFMA II increases the percentage of premarket approval applications and panel track supplements to be completed within 180 days from 50 percent to 60 percent. The new goal for processing 510(k) applications within 90 days has increased from 80 percent of the applications to 90 percent of the applications. Expedited premarket approval application times would be decreased by 20 days, from 300 days to 280 days. A push for faster application processing times, while they may be helpful for consumers and are certainly highly profitable for the medical device industry, needs to be balanced with more attention to post-market safety and efficacy monitoring.

We hope that the FDA will learn from the lessons of PDUFA, which are cited in internal staff polls as creating pressures and problems in drug approvals. A February 2007 study by Harvard Professor Daniel Carpenter and others entitled, "Deadline Effects in Regulatory Drug Review: A Methodological and Empirical Analysis," found that

> The rate at which drugs experience most-marketing regulatory events is appreciably higher for drugs approved in the months before the PDUFA clock deadlines, compared to other drugs, especially those approved in the months just following the elapsing of the deadline. For non-priority molecules, pre-deadline approvals are associated with three to five times the rate of safety-based withdrawal from the global market and Canadian markets. Pre-deadline approvals have two to three times …labeling changes per year of marketing and, for drugs approved since FDAMA, over five times the rate of product discontinuations per year.

The same problem we have seen on the drug side, we may see on the device side. To avoid distortions, user fees need to have limited strings attached or be accompanied by greater staff freedom to dissent from approvals and raise questions about decisions rushed to meet deadlines.

A one-dimensional emphasis on meeting application processing deadlines with no additional assurances of device safety and efficacy may contribute to device-related deaths and serious injuries. In 2003, the FDA expedited the application process for Cordis Corporation's CYPHER Sirolimus-Eluting Coronary Stent, approving the device in less than one year.[iii] The FDA approved this drug-eluting stent based on a 9 month short-term study sponsored by interested parties[iv] while simultaneously acknowledging that a "long term outcome for this *permanent* implant is unknown at present." [v] By the end of 2004, drug-eluting stents were used in more than 80 percent of all percutaneous coronary interventions, and several million drug-eluting stents have been implanted worldwide since then.[vi]

Unfortunately for the patients now implanted with drug-eluting stents, long-term post-market studies featured in the March 2007 New England Journal of Medicine reveal a darker side of drug-eluting stents. At best, one study concluded that no significant

differences in death rates could be observed between users and non-users of drug-eluting stents after four years.[vii] A less neutral finding from a Swedish study concluded that drug-eluting stents increased the rate of death by 0.5 percent after six months.[viii] Quick approval of drug-eluting stents seemed to make sense at the time, but given the importance of these devices, could post-market safety activities have been quicker to have detected problems in older patients, thus preventing millions of unnecessary and even detrimental invasive surgeries?

II. 510(k) APPROVAL PROCESS LOOPHOLE MUST BE FIXED

The current 510(k) application process must be corrected to close the loophole that has been used to market products without having to demonstrate safety or efficacy. Device manufacturers applying to market their products typically must submit either a 510(k) clearance or a pre-market approval application (PMA). PMA applications are more detailed and require a showing of scientific evidence assuring that the device is safe and effective for its intended use.[ix] The 510(k) application merely requires a showing of substantial equivalence to a legally marketed device.

Manufacturers wishing to opt out of providing safety and efficacy data can avoid a PMA application by self-labeling their product as "substantially equivalent" to marketed devices. Meanwhile, dangerous new devices could be mass marketed while the manufacturer waits for the FDA to contradict their finding of substantial equivalence. Such was the case for Bausch & Lomb, who filed a 510(k) application for a product called "ReNu with MoistureLoc." In its application, Bausch & Lomb likened "ReNu with MoistureLoc" to the previously marketed "Multi-Plus Multi-Purpose Solution," despite preservative differences in the two contact lens formulas.

"ReNu with MoistureLoc" was approved by the FDA without any showing of safety or efficacy and ultimately contributed to 122 cases of fungal infection, 15 possible infections, and 60 pending investigations in 33 states and territories.[x] Hong Kong health officials first observed a link between increased Fusarium fungi outbreaks and the new lens formula in July 2005. Notices to Bausch & Lomb were subsequently issued by Hong Kong, Malaysian, and Singaporean health officials in October 2005.

Remarkably, Bausch & Lomb's 510(k) application for "ReNu with MoistureLoc" was still approved by the FDA after the Asian fungi outbreaks. The application did not require any safety or efficacy data, and the FDA did not challenge Bausch & Lomb's finding of substantial equivalence for its "ReNu with MoistureLoc" solution. Bausch & Lomb knew about the problems with its new formula, but failed to disclose this knowledge on the company's 510(k) application. It took the FDA another five months to link American outbreaks to "ReNu with MoistureLoc" and finally begin an investigation of the facility site.[xi]

CU believes that serious injuries like the eye infections caused by Bausch & Lomb's lens formula could be avoided in the future by limiting the scope of 510(k) applications, and creating a stricter set of requirements before a new device can be

regarded as "substantially equivalent" to a marketed device. Devices that do not meet the 510(k) standard would then be evaluated for device safety and efficacy.

III. ACCREDITED THIRD PARTY INSPECTIONS SHOULD NOT BE ALLOWED TO REPLACE FDA FACILITY OVERSIGHT

MDUFMA II empowers manufacturers to avoid direct government oversight by replacing regulators with funded third party inspectors. CU believes the resulting conflict of interest may ultimately weaken the oversight of medical device manufacturing facilities. MDUFMA I allows accredited third parties to conduct facility inspections for manufacturers who market devices internationally. To maintain objectivity in the inspection process, MDUFMA I requires the FDA to conduct, at a minimum, every third facility inspection unless a waiver request is granted. MDUFMA II dissolves the requirement for even an occasional FDA-conducted facility inspection and would allow accredited third parties to conduct facility inspections indefinitely.

Accredited third party inspectors are businesses, driven by maximizing revenue and profit from inspection fees. Without a minimum level of government oversight over all manufacturing facilities, the American public is left to rely on the profit motives of third party inspectors to ensure that manufacturing facilities are FDA-compliant. Allowing inspections funded by the inspected has proven problematic in the health care arena.

As just one example, in 1999 and 2002, the Joint Commission on Accreditation of Healthcare Organization (JCAHO) accredited the hugely profitable Redding Medical Center, owned by Tenet Healthcare Corporation. Despite allegations of fraud and doctors performing medically unnecessary heart surgeries, Redding Medical Center continued to receive high scores from the Joint Commission. In fact, no systemic problems were identified by the Joint Commission until a *state surveyor* highlighted the lack of a physician review of heart surgery patients who experienced complications or died. It was later revealed that two out of the six Joint Commission directors also held leadership positions at Tenet Healthcare Corporation.[xii] At least one other Congressional hearing has pointed to the type of cozy relationship that can develop between an inspecting or accrediting agency and the people who pay for the services of the organization.

Similarly, the proposed third party provision in MDUFMA II would allow a corporation to fund its own facility inspection with no threat of FDA oversight until a "for cause" determination. The JCAHO example underscores a constant need for objective, interest-free oversight. Without FDA conducted inspections, third-party accrediting agencies hungry for clients, business, and profits, would be motivated to engage in a race to the bottom.

Instead of indiscriminately allowing third parties to conduct inspections, the FDA must take additional steps to ensure that good manufacturing practice violations are effectively handled. Simply warning about unsanitary manufacturing facilities and compromised device safety will not deter manufacturers from continuing to engage in

these poor practices. Manufacturing facilities have been notorious for ignoring FDA warnings of non-compliance, jeopardizing the health and lives of patients who rely on these devices.

Shelhigh Inc., manufacturer of pediatric heart valves and conduits, surgical patches, arterial grafts, and annuloplasty rings, knew about its serious site sterility problems in 2000. [xiii] Yet it took the FDA six years, one negative inspection, two FDA warning letters, and one FDA seizure to finally halt the estimated 1 million tainted device parts and finished products from entering the stream of commerce. This is already too weak a record, but allowing outside parties to conduct facility inspections may only lengthen the amount of time before dangerous products can be stopped.

IV. POST-MARKET DEVICE SAFETY DATA SHOULD BE MADE ACCESSIBLE TO THE PUBLIC

The proposed recommendations do not address the need for a publicly accessible adverse event reporting system. Once a device has been approved by the FDA, consumers are forced to rely on medical device manufacturers to report adverse events. Health care facilities are only required to report device-related adverse events where a serious death or injury has occurred, and facilities often do not associate adverse events with a particular medical device. In 1998, manufacturers reported 980 device-related deaths, while doctors and hospitals reported only 277 deaths.[xiv] According to Dr. Larry Kessler, senior scientist and manager within the CRDH, when devices are reported by health care facilities, "often the product is poorly identified, or not identified at all, and it's very limited information."[xv]

Consumers who wish to understand the risks associated with FDA approved medical devices have a difficult path to search. They can look through CDRH's database on devices causing serious injury or death but are limited to events occurring from1984 through 1996. MAUDE, the current CDRH database, only represents adverse events voluntarily reported since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since 1996. The database is also difficult to use. Consumers must know the exact manufacturer name of a device they are interested in because the MAUDE search engine does not retrieve any closely misspelled manufacturer names. The MAUDE website even notes that "MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices." [xvi]

Empowering consumers and patients to follow-up on their own medical device concerns requires a database that allows for easy searches that yield useful results. Not only should a database report factual information about device incidents, Consumers Union supports some type of analysis feature that evaluates adverse event rates across devices.

Conclusion

We appreciate the opportunity to share our views on the medical device approval process and proposed recommendations for MDUFMA II. The FDA device approval process plays such a vital safety role that we strongly encourage the agency to focus on the safety of medical devices rather than the speed at which applications are processed. We urge the FDA to facilitate the transparency of medical device incidents through a consumer-friendly device database. Ensuring patient and consumer access to new technology is important to Consumers Union, not only with medical devices, but also with a user-friendly device database.

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[i] Carol Rados, *Summary of FDA's Medical Device Reporting Requirements; FDA Works to Reduce Preventable Medical Device Injuries*, FDA CONSUMER, July 7, 2003.

[ii] The report did not indicate percentages of those who died, and percentages of those who were hospitalized. Don Long, *Device adverse event rates comparable to those of drugs*, DIAGNOSTIC UPDATE, Jan. 26, 2006.

[iii] To view a copy of the FDA approval letter, see http://www.fda.gov/cdrh/PDF2/P020026A.PDF (last accessed April 26, 2007).

[iv] To view a copy of Cordis Corporation's safety and effectiveness data for CYPHER Sirolimus-Eluting Coronary Stents, see http://www.fda.gov/cdrh/PDF2/P020026b.PDF (last accessed April 26, 2007).

[v] The FDA approval letter may be viewed at http://www.fda.gov/cdrh/PDF2/P020026A.PDF (last accessed April 26, 2007).

[vi] Dr. William H. Maisel, *Unanswered Questions – Drug-Eluting Stents and the Risk of Late Thrombosis*, 356 NEW ENGLAND JOURNAL OF MEDICINE 981 (2007).

[vii] Gregg W. Stone, Jeffrey W. Moses, Stephen G. Ellis, et al., *Safety and Efficacy of Sirolimus and Paclitaxel-Eluting Coronary Stents*, 356 NEW ENGLAND JOURNAL OF MEDICINE 998 (2007).

[viii] Bo Lqgerqvist, Stefan K. James, Ulf Stenestrand, et al., *Long-Term Outcomes with Drug-Eluting Stents versus Bare-Metal Stents in Sweden*, 356 NEW ENGLAND JOURNAL OF MEDICINE 1009 (2007).

[ix] FDA'S DEVICE ADVICE, OVERVIEW (PMA APPLICATION), *available at* http://www.fda.gov/cdrh/devadvice/pma/# (last visited January 23, 2007).

[x] Barnaby J. Feder, From Asia to America, How Bausch's Crisis Grew, NY TIMES, May 18, 2006, at Section C, Col. 2.

[xi] Barnaby J. Feder, From Asia to America, How Bausch's Crisis Grew, NY TIMES, May 18, 2006, at Section C, Col. 2.

[xii] Statement of Sen. Chuck Grassley, July 20, 2004.

[xiii] Associated Press, Devices Seized Amid Sterility Concerns, WASH. POST, April 17, 2007, *available at* http://www.washingtonpost.com/wpdyn/content/article/2007/04/17/AR2007041701399.html (last accessed April 26, 2007).

[xiv] Marc Kaufman, Cardiac Devices May Need Replacing; Guidant Confirms Defects in Up to 28,000 Pacemakers, WASH. POST, July 19, 2005, at D1.

[xv] Janet Moore, Keeping heart devices in reach, KNIGHT-RIDDER TRIBUNE BUSINESS NEWS, Aug. 10, 2006.

[xvi] MAUDE database may be accessed at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm (last accessed on April 20, 2007).