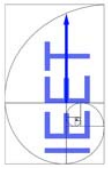

Jacobs Institute of Women's Health

October 27, 2010

The Honorable Joe Barton
Ranking Member
Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Dear Ranking Member Barton:

As members of the Patient, Consumer, and Public Health Coalition, we are very concerned about the millions of recalled medical devices that have put your constituents at risk in recent years. We urge you to support the Food and Drug Administration (FDA) Working Group's recommended changes to the 510(k) medical device clearance process regarding rescission authority, split and multiple predicates, intended use, premarket inspections and proprietary information. In addition, we ask you to support more careful reviews of 510(k) cleared devices to ensure they are safe and effective.

We are disappointed in the October 12, 2010 letter you and your colleagues sent to FDA Commissioner Margaret Hamburg because it will likely slow down FDA's efforts to improve the safety of medical devices. We appreciate your mentioning patient safety, and hope you will clarify the importance of those issues, since that is the mandate of the FDA. We want to assure you that many of the changes the Working Group proposed would address serious safety shortfalls in the 510(k) process, which have led to injuries and deaths. According to the FDA's Center for Devices and Radiological Health (CDRH), in fiscal year 2006, the FDA received reports of 116,086 potential device-related injuries, 2,830 potential device-related deaths, and more than 200,000 adverse event reports concerning medical devices.[1] These reports are considered the tip of the iceberg, since most adverse reactions are not reported to the FDA.

CDRH's mission is to protect and promote the public health. Congress gave the FDA the authority to regulate medical devices in 1976 in response to deaths and infertility caused by the Dalkon Shield and other contraceptive intrauterine devices. Unfortunately, the history of the FDA is one of strengthening patient safeguards after tragedies and then loosening those safeguards a few years later.

According to the FDA's own statistics, most "high-risk recalls" – recalls of devices that could cause death or serious injury, are of 510(k) devices. This is disturbing because devices are not supposed to be cleared through the FDA's 510(k) process if they are considered "high risk." AdvaMed, the device manufacturers' association, admits that most high-risk recalls are 510(k) devices but says this is acceptable because most devices cleared through the 510(k) process are not recalled. However, the 510(k) process was intended for **low and moderate risk devices, not high-risk devices.** No 510(k) devices should result in death or serious harm if they are defective. The standard for a high risk device should be based on the risks if it works well and also the risks if it fails. Moreover, even one recalled device can result in the recall of millions of products used by millions of Americans. For example, according the FDA data, more than 28 million insulin infusion sets were recalled on June 29, 2009, and more than 3.4 million pediatric-sized tracheal tubes were recalled on August 25, 2009. Another example is the recall of hundreds of thousands of automated external defibrillators that are intended to save the lives of people who have had a heart attack. All of these medical devices were Class I recalls, which the FDA defines as recalls where "there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."[2]

Another example of the impact of these recalls is the FDA's recently issued warning that it had received more than 900 serious adverse reports associated with cardiac devices called "inferior vena cava filters" that were cleared via 510(k) without any clinical data.[3] In an article in the well-respected *Archives of Internal Medicine*, Dr. William Nicholson and his colleagues at York Hospital and Penn State Medical School reported that 25% of these devices fractured and embolized within an average of four years and 12% of an "improved version" had fractured within an average of two years. As previously noted, adverse events are underreported and, therefore, represent a tiny proportion of people who were harmed. Hundreds of thousands of Americans with these difficult-to-remove implanted devices are now at risk for these life-

threatening events.

In your letter, you state that several proposed recommendations are "controversial." Below are the reasons why we support these recommendations and do not believe they are controversial.

Rescission Authority

Currently, the FDA does not have clear authority to rescind clearance once a 510(k) device is cleared except under very limited circumstances, such as to correct a mistake. According to FDA's Director of the Office of Device Evaluation, "it is difficult to fix/modify or remove a cleared 510(k)."[4] Devices cleared through the 510(k) process are not subject to clinical trials, so safety information is very limited when they are first put on the market. When they are used by the general public, it is often the case that a medical device is found to have safety problems that were not expected. CDRH should be able to act on that scientific evidence and rescind the 510(k) clearance, just as they can withdraw approval of medical devices that were approved by the FDA using the more stringent Premarket Approval (PMA) process. This authority is not controversial, it is common sense.

Split and Multiple Predicates

We agree with the FDA that the use of split predicates to establish substantial equivalency compromises patient safety. The FDA's Working Group stated, "The use of a 'split predicate' is akin to combining different attributes of more than one device into a single, nonexistent predicate device, whose risks and benefits are unknown." The Working Group further stated that CDRH should "explore the possibility of explicitly disallowing the use of 'split predicates."[5] We agree.

The FDA Working Group found that 510(k) applications that cite more than five predicates are significantly more likely to have substantially more adverse event reports. While the FDA is reviewing these data in greater detail, the safety of our families should be protected by the FDA. The agency should not allow applicants to cite more than five predicates.

Clarifying Intended Use and Indications for Use

We agree with the FDA that they should clarify these terms. The interpretation has been so flexible that it is unpredictable for companies and for patients who rely on FDA safety decisions. We are very concerned that the CDRH's own survey found confusion among reviewers, many of whom did not realize "that a device with a new 'intended use' cannot be found substantially equivalent."[5] There has also been a problem of reviewers confusing the term "indication for use" with "intended use." The FDA Working Group has recommended that the two terms be consolidated as "intended use" in order "to provide greater clarity and simplicity, not necessarily to make the concept of "intended use" more restrictive."[5] Instead of getting bogged down in semantics, we strongly urge the FDA to use established public health (safety and effectiveness standards) and scientific standards to determine if a product is substantially equivalent.

Mandatory Premarket Inspections

The FDA has stated that the "majority of recalls are due to manufacturing and design control problems,"[6] but the FDA does not inspect the manufacturing plants of 510(k) products prior to clearance. The agency therefore misses an opportunity to spot contamination, manufacturing flaws, and changes in device design or materials. In addition, key manufacturing information such as engineering specifications about the device design and assurances of on-going quality, may not be included in the 510(k) review process.[7] In contrast, the agency does inspect manufacturing establishments as part of its review of original PMA submission.[8] As previously stated, it makes no sense for devices cleared through the much less stringent 510(k) process to also be sold without first inspecting the manufacturer of those devices. We believe that if premarket inspections find that device makers do not comply with good manufacturing requirements, then their devices should not receive clearance, regardless of whether it is Class I, Class II, or Class III.

Proprietary Information

We support the FDA Working Group's recommendation to revise regulations "to explicitly require 510(k) submitters to provide a list and brief description of all scientific information regarding the safety and/or effectiveness of a new device known to or that should be reasonably known to the submitter."5

In its efforts to be more transparent, FDA should ensure that its 510(k) database provides complete and up-to-date device information. This information should be publicly available in an easily searchable database that includes a verified 510(k) summary. CDRH should develop a standardized electronic template for 510(k) summaries, which will help to make the database more accurate and complete.

Proprietary information must be precisely defined, so that CDRH will be able to ensure that it is not included in the summary or database. Device makers have an obligation to provide CDRH with all pertinent data about their devices, not just the studies that show the benefits of the device. Industry cannot be allowed to hide unflattering information by claiming that it is proprietary information.

Conclusion

The medical device industry has argued that an unintended consequence of strong safety regulations for the 510(k) process is that it will restrict innovation. What kind of innovation do they have in mind? As patients, consumers, and public health experts, we care about innovation to the extent that innovative medical products are safe and effective -- preferably safer and more effective (or otherwise superior) compared to other products already on the market. Innovation is just a flashy marketing term if the innovation makes the product less beneficial to patients. There is clear scientific evidence that the unintended consequences of some innovative devices have resulted in thousands of injuries and deaths. We agree with you that innovation needs to be balanced by safety, and are very concerned that your letter to Commissioner Hamburg may be interpreted as embracing the concerns of industry more than the concerns of consumer advocates, public health experts, and the hundreds of thousands of your constituents who rely on the FDA to safeguard their health.

Sincerely,

American Medical Women's Association
Annie Appleseed Project
Breast Cancer Action
Center for Medical Consumers
Community Access National Network
Consumers Union
GAP (Government Accountability Project)
Institute for Ethics and Emerging Technologies
Jacobs Institute of Women's Health
National Research Center for Women & Families / Cancer Prevention and Treatment Fund
National Women's Health Network
Our Bodies Ourselves
THE TMJ Association
Truth in Medicine
Union of Concerned Scientists
U.S. PIRG (Public Interest Research Group)
WoodyMatters

---

[1] [1] U.S. Food and Drug Administration, Center for Devices and Radiological Health. CDRH FY 2006 Highlights. Retrieved October 22, 2010 from www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm129258.pdf

[2] U.S. Food and Drug Administration (2010). Safety, Background and Definitions. Retrieved October 19, 2010 from http://www.fda.gov/Safety/Recalls/ucm165546.htm

[3] U.S. Food and Drug Administration (August 2010). Removing Retrievable Inferior Vena Cava Filters: Initial Communication. Retrieved October 25, 2010 from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm221676.htm

[4] U.S. Food and Drug Administration, Center for Devices and Radiological Health (March 2010). Understanding the Premarket Notification (510(k)) Process. FDA's 510(k) Working Group. Presentation to the Institute of Medicine by Donna-Bea Tillman, Ph.D., Director, Office of Device Evaluation.

[5] U.S. Food and Drug Administration, Center for Devices and Radiological Health (August 2010). CDRH Preliminary Internal Evaluations – Volume I: 510(k) Working Group, Preliminary Report and Recommendations.

[6] Food and Drug Administration, Center for Devices and Radiological Health (February 2010). FDA's 510(k) Workshop: Issues Related to New Technologies and Scientific Evidence presentation by Arleen Pinkos, Scientific Reviewer, Office of In Vitro Diagnostic Device Evaluation and Safety.

[7] U.S. Food and Drug Administration, Center for Devices and Radiological Health (February 2010). FDA's 510(k) Workshop: Issues Related to the Following Types of Submissions: Bundled, 3rd Party, and Submissions which Contain Standards presentation by Barbara Zimmerman, Deputy Director for Premarket Program Management, Office of Device Evaluation.

[8] Government Accountability Office (January 2009). Medical Devices: FDA Should Take Steps to Ensure that High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process.