Congress of the United States
Washington, DC 20515

August 15, 2012

Jeffrey Shuren, MD, JD
Director, Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Shuren:

As Members of Congress concerned about weaknesses in the premarket review process used to evaluate most medical devices, we write to ask the Food and Drug Administration (FDA) to overhaul and streamline its Recalls and 510(k) Premarket Notification databases to provide publically available and easily searchable information regarding the safety of devices that rarely undergo clinical trials in humans prior to being sold on the market.

Over the past several years, reports have surfaced of patients being seriously harmed or even killed by medical devices such as artificial hips or mesh implants used to treat urinary incontinence in women. These devices are among the thousands of products FDA clears each year through the 510(k) process, which permits devices to be sold as long as the sponsor demonstrates that the product is similar – or "substantially equivalent" – to a legally marketed device, known as the "predicate" device. Though 95% of all devices that undergo premarket review are reviewed through the 510(k) process, this process requires clinical testing in humans in only a small percent of submissions. As long as the sponsor shows that the new device is substantially equivalent in design, technology, and intended use to the predicate, FDA is generally required to "clear" the device.

However, a flaw in the 510(k) process opens the door for defective devices to make their way onto the market and jeopardize patient safety. Current law requires FDA to clear a device shown to be substantially equivalent to a predicate, even in cases where the new product contains the same flaws as an earlier model that had to be recalled by the manufacturer due to a fundamental design flaw.

Already, thousands of patients have been harmed – in some cases grievously and irrevocably – by medical devices that were modeled after recalled devices. Among the most prominent example is the transvaginal mesh implant, used to treat urinary incontinence and pelvic organ prolapse. Despite the original mesh's recall in 1999, a number of subsequent meshes – some still on the market and being implanted in patients today – trace their FDA clearance back to that defective product. Patients with complications from the implants have experienced bleeding, severe pain, life-threatening infections, and even death.

Ultimately we believe the solution to this problem requires an expansion of FDA's authority to enable it to reject clearance if a device repeats design flaws that have led to the voluntary recall of earlier products, as proposed in H.R. 3847, The Safety Of Untested and New Devices (SOUND Devices) Act. However, we also believe that providing device manufacturers, the public, and medical professionals with better information about devices recalled for serious design flaws could help avoid future injuries.

This greater transparency could be accomplished by FDA updating its 510(k) database to reflect: (1) if the device itself was the subject of a recall because of a serious design flaw that negatively affected safety of effectiveness, and (2) whether the device itself was cleared on the basis of a predicate recalled for a serious design flaw that negatively affected safety or effectiveness. In these cases, the database entry for such a device should provide a link to information about the predicate's adverse event reports and recall, so that consumers and doctors can determine the nature of the earlier problem.

These database improvements would enhance the transparency of the 510(k) process and help manufacturers avoid using recalled devices as predicates that may put their own devices at risk for future enforcement action. These changes would also enhance awareness among the public and medical professionals of the potential dangers of medical devices that are based on flawed predicates.

- **Sponsors need better information about which devices could pose problems should they be named as predicates in a 510(k) submission. To provide better clarity for sponsors, is FDA willing to update its 510(k) database so that it clearly indicates devices that have been recalled for serious design flaws that could adversely affect safety or effectiveness? Please explain why or why not.**

    - **Will FDA update the database within 30 days after completing its review of a manufacturer's root-cause analysis which concludes that a flaw triggering the recall was a serious one that could adversely affect safety or effectiveness? If not, why not?**

The 510(k) database should be updated retrospectively to reflect previous recalls due to serious design flaws, to the extent that reliable information about older recalls is available. If the database does not include serious recalls going back at least several years, its usefulness to companies attempting to ascertain which predicates to avoid will be severely limited.

- **Will FDA include in the database past recalls clearly marked for serious design flaws that could adversely affect safety or effectiveness, so device manufacturers and the public have comprehensive information about problematic predicates? If not, why not? If so, how many years back does FDA plan to update its database?**

It is conceivable that there may be certain instances where it is appropriate and safe for a manufacturer to use a device recalled for a serious design flaw as a predicate. This could be the case if the manufacturer demonstrates to FDA that its new 510(k) device has addressed the

design flaw of the predicate or if the new device relies on an aspect of the predicate that is unrelated to the aspect that triggered the recall.

However, if the new device repeats the same serious design flaw that caused the predicate to be recalled, the public should be aware that a potentially dangerous device is being sold on the market.

- **If a company fails to show that their proposed 510(k) device either avoids or adequately mitigates the design flaw that caused a predicate's recall, is FDA willing to notify the sponsor in writing that this omission puts the device at risk of being deemed misbranded or adulterated? Please explain why or why not.**
    - **Will FDA include such notification in the 510(k) clearance letter issued to the sponsor? Please explain why or why not.**
    - **If so, will FDA include the 510(k) clearance letter it the 510(k) database within 30 days after the issuance of the letter, so that the public is aware that such devices may pose a health risk? Please explain why or why not.**

It is important that, when possible, the changes to the 510(k) Premarket Notification database are made for previously cleared devices to the extent reliable information can be provided. We understand the resource challenges associated with making such changes retrospectively, as well as the fact that it is not possible to modify past 510(k) clearance letters to issue warnings about the increased risk of enforcement action to manufacturers that have already received 510(k) clearance for the device. However, to the greatest extent possible, FDA should select certain high-profile, high-risk devices based on recalled predicates and, if reliable information is available, make the appropriate database updates to notify patients and doctors about the possible risks.

- **Is FDA willing to revise its 510(k) Premarket Notification database to notify the public that a certain product repeats the same design flaw that caused a predicate's recall?**

Some devices currently being used in patients, such as transvaginal mesh implants, trace their clearance back to a product that had to be recalled by its manufacturer for a serious design flaw adversely impacting its safety. In the case of mesh, the immediate predicate remains on the market but earlier versions have caused major injuries and even death.

- **To the extent feasible, can FDA develop a mechanism for identifying certain 510(k) entries to reflect instances where a device's clearance traces back to a predicate recalled for a serious design flaw adversely impacting its safety, even if the original problematic device is not the immediate predicate?**

We ask for a response to these questions no later than September 19, 2012. We appreciate the FDA's commitment to safe medical devices and look forward to working with the agency to ensure that 510(k) devices do not repeat the flaws of earlier models, jeopardizing patient health

because of defects that were known and avoidable. Should you have any questions, please contact Sara Schaumburg in Rep. Markey's office at 202-225-2836 or sara.schaumburg@mail.house.gov or Susan Lexer in Sen. Merkley's office at 202-224-3753 or susan_lexer@merkley.senate.gov.

Sincerely,

Edward J. Markey
Member of Congress

Jeff Merkley
U.S. Senator

cc: The Honorable Kathleen Sebelius, Secretary of the Department of HHS