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Review and Analysis of the April 23, 2012 *Food and Drug Administration Safety and Innovation Act* Manager's Amendment

Provisions strongly opposed by Public Citizen

- **Sec. 608. Clarification of least burdensome standards:** Would weaken the safety of medical devices approved or cleared by the Food and Drug Administration (FDA) by applying standards least burdensome to industry, further constraining the agency's authority to ask for important information relevant to the safety and effectiveness of devices, and pressuring the agency to take short cuts to meet the demands of an accelerated review process.
- **Sec. 609. Custom devices:** Would expand a dangerous loophole in the medical device regulations allowing health care providers to manufacture and use medical devices to treat their own patients without meeting any standards for safety, effectiveness, or good manufacturing practices.
- **Sec. 613. Humanitarian use device exemptions:** Would substantially weaken medical device safety by broadly extending a provision that eliminates an important financial incentive for manufacturers of devices approved under a humanitarian device exemption (HDE) to conduct appropriate clinical studies following HDE approval to establish that their devices are actually, not just tentatively, safe and effective.
- **Sec. 614. Reauthorization of third-party review and inspections:** Would perpetuate a flawed process that fails to ensure medical device safety because third parties have an inherent conflict of interest favoring the manufacturer of the device under review. Device manufacturers can shop around for the accredited third party that will render the determination most favorable to them and are unlikely to use a third party who has previously rendered an unfavorable review.
- **Title VIII. Generating antibiotic incentives now:** Would increase health care costs to patients, due to the delayed entry of generic drugs into the market, and shift resources within the FDA away from the review of other drugs. More importantly, these provisions have the potential to promote the development of antibiotics that are ineffective and unsafe.
- **Sec. 901. Enhancement of accelerated patient access to new medical treatments** and **Sec. 902. Breakthrough therapies:** Would weaken the safety of prescription drugs by expanding the use of the accelerated approval process — which relies on surrogate (as opposed to disease-improving) efficacy end points and much smaller clinical trials for approval — to a wide range of drugs. This will likely increase the number of unsafe and ineffective drugs marketed in the U.S.
- **Sec. 1121. Advisory committee conflicts of interest:** Would eliminate all limits on the number of FDA-granted waivers of the prohibition against individuals serving as

members of an FDA advisory committee who have (or whose immediate family members have) financial interests that could be affected by the advice provided by the committee. This will result in more individuals with substantial conflicts of interest serving on the FDA's advisory committee, undermining the integrity and credibility of these committees in the eyes of the public.

Additional, common-sense provisions needed to improve medical device safety

- **Predicate nullification:** Include the provisions — such as those proposed in H.R. 3847, the SOUND Devices Act of 2012 — that would close a dangerous loophole in the 510(k) process that allows the FDA to clear a new device for marketing even though its predicate device has been removed from the market because of hazardous safety defects.
- **Conditional 510(k) clearances:** Include the new section 510A proposed in S. 1995 — the Medical Device Patient Safety Act, introduced by Senators Grassley, Kohl, and Blumenthal — that would authorize the FDA to conditionally clear medical devices under the 510(k) process.
- **Address *Riegel v. Medtronic* (2008):** Restore patients' ability to seek compensation under state law for injuries caused by defective devices approved under the PMA process.
- **Prohibit class III devices from being cleared under the 510(k) process:** Amend section 510(k) of the FDCA (21 U.S.C. 360(k)) to prohibit any new class III device from being cleared under the 510(k) process. All such devices should be reviewed under the PMA process.
- **Classification of devices:** Classify all devices which are permanently implanted, life-supporting, or life-sustaining in class III.

Provisions that do not go far enough to improve medical device safety

- **Sec. 603. Postmarket surveillance:** The proposed required time frame for a manufacturer to commence postmarket surveillance after the FDA determines that the manufacturer's plan for conducting such surveillance is appropriate and adequate should be reduced from 15 months to no more than six months after approval. Also, the 36-month limitation on the duration of postmarket surveillance studies for medical devices intended for use in adults under subsection (b)(1) of Section 522 should be removed because studies limited to 36 months are insufficient for assessing medical devices that are intended to be permanently implanted in adults and that provide medical benefits for much longer than three years.
- **Sec. 605. Recalls:** Expand the data elements on recalls that must be collected by the FDA to include those elements listed in S. 1995. Such data would provide critical information for the FDA, health professionals, and patients. Also, add a provision requiring the FDA to make available to the public detailed reports on the agency's assessment of medical device recall information. Publicly available reports will greatly

improve patient and health care provider awareness of important safety information regarding medical device recalls.

- **Sec. 607. Unique device identifier**: The proposed timeline for the effective date of the final unique device identifier regulations with respect to devices that are implantable, life-saving, or life-sustaining should be reduced to not later than one year after these pending regulations are finalized.

Provisions supported by Public Citizen as proposed

- **Sec. 601. Reclassification procedures:** Would enhance the oversight of medical devices by requiring that the FDA convene a meeting of a device classification panel prior to the agency reclassifying a device.
- **Sec. 602. Condition of approval studies**: Would improve the safety of medical devices by granting the FDA explicit authority to require, as a condition of approval of any PMA device, that the sponsor conduct a postmarket study regarding the device.
- **Sec. 604. Sentinel:** Would enhance safety of medical devices by expanding the FDA's postmarket risk-identification system, known as the Sentinel System, to include medical devices cleared under the 510(k) process or approved under the PMA process.
- **Sec. 606. Clinical holds on investigational device exemptions:** Would enhance the protection of human subjects who volunteer to participate in clinical studies testing investigational medical devices by granting the FDA authority to place a clinical hold on such trials, as it can now do for studies of investigational new drugs.