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Review and Analysis of the May 8, 2012 House Committee Print of Legislation Proposing to Renew and Extend the Food and Drug Administration's User Fee Program and to Make Other Amendments to the Federal Food, Drug, and Cosmetic Act

Provisions Strongly Opposed by Public Citizen

- **Section 602. Conflicts of interest:** Eliminates the general prohibition against individuals serving as members of a Food and Drug Administration (FDA) advisory committee who have (or whose family members have) significant 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.
- **Section 701. Investigational device exemptions.** Places inappropriate constraints on FDA regarding the review of investigational device exemptions (IDEs), thereby endangering human subjects. This provision is not found in the counterpart Senate legislation.
- **Section 702. Clarification of least burdensome standard:** Would weaken the safety of medical devices approved or cleared by the 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.
- **Section 741. Persons accredited to review reports under section 510(k) and make recommendations for initial classification:** Would perpetuate a flawed process that fails to ensure medical device safety because private 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. However, this section was improved in comparison to the discussion draft by eliminating sections that would have weakened medical device safety by (a) placing inappropriate time constraints on the FDA's review of third-party recommendations; (b) expanding the use of third-party reviews of 510(k) submissions to high-risk devices intended to be permanently implanted, life-sustaining, or life-supporting, and (c) eliminating the conflict of interest provisions related to accredited persons conducting such reviews.
- **Section 751. Expanded access to humanitarian use devices:** Substantially weakens medical device safety by eliminating an important financial incentive for manufacturers of such devices to conduct appropriate clinical studies following HDE approval to establish that their devices are safe and effective. However, this section was improved by eliminating the provision that would have dangerously expanded the number and types of high-risk devices granted humanitarian device exemptions by the FDA.

- **Section 771. Custom devices.** Expands 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.
- **Title VIII—Drug Regulatory Improvements, Subtitle C—Generating Antibiotic Incentives Now:** Increases health care costs to patients from the delayed entry of generic drugs into the market and shifts 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. This part of the House bill is worse than counterpart legislation in the Senate, which narrows the definition of "qualifying pathogens" to those that pose a serious threat to public health.
- **Title VIII—Drug Regulatory Improvements, Subtitle D—Accelerated Approval:** Weakens the safety of prescription drugs by expanding the use of the accelerated approval process, which relies on surrogate (as opposed to disease-improving) efficacy endpoints and much smaller clinical trials for approval. This will likely increase the number of unsafe and ineffective drugs marketed in the U.S.

<u>Provisions that do not go far enough to improve medical device safety</u>

- **Section 711. Establishment of schedule and promulgation of regulations:** We recommend adding a prohibition against clearing, under the 510(k) process, any new devices from any category of class III devices for which final rulemaking requiring a premarket approval (PMA) application or reclassification into class I or II has not occurred.
- **Section 712. Program to improve the device recall system:** Expand the data elements on recalls that must be collected by the FDA to include those elements listed in S. 1995 — the Medical Device Patient Safety Act, introduced by Senators Grassley, Kohl, and Blumenthal. 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.

<u>Additional provisions needed to improve medical device safety</u>

- **Predicate nullification:** Include the provisions of H.R. 3847, the SOUND Devices Act of 2012.
- **Conditional 510(k) clearances:** Provide the FDA with the authority to require post-market studies as a condition of clearance 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.
- **Classification of devices:** Classify all devices which are permanently implanted, life-supporting, or life-sustaining in class III.

- **Third-party reviews:** Eliminate section 523 from the FDCA and provide the FDA with sufficient resources to internally conduct all regulatory functions required for 510(k) submissions.
- **Clinical Holds on IDEs:** Grant the FDA the authority to place IDE studies on clinical hold, as is the case with investigational new drug studies. The counterpart Senate legislation includes such a provision.
- **Reclassification:** Require that the FDA convene an advisory panel prior to the agency reclassifying a device. The counterpart Senate legislation includes such a provision.
- **Condition of approval studies**: Grant 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. The counterpart Senate legislation includes such a provision.

Provisions supported by Public Citizen as proposed

- **Section 761. Unique device identification system regulations.** Imposes deadline (120 days after enactment) for promulgation of regulations implementing the unique device identification system regulations.
- **Section 762. Effective device sentinel program.** Expands sentinel program to include medical devices.