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April 2, 2012

Senator Tom Harkin
Chairman
U.S. Senate Committee on Health, Education, Labor, and Pensions
731 Hart Senate Office Building
Washington, DC 20510

Senator Michael B. Enzi
Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions
379A Russell Senate Office Building
Washington, DC 20510

Re: Senate HELP Committee discussion draft medical device policy

Dear Senators Harkin and Enzi:

Public Citizen, representing more than 250,000 members and supporters nationwide, appreciates the opportunity to comment on the March 16 discussion draft of medical device policy legislation prepared by the Senate Committee on Health, Education, Labor, and Pensions (the HELP Committee).

We are concerned about a number of provisions in the discussion draft legislation to amend the Federal Food, Drug, and Cosmetic Act (FDCA) — particularly those related to the Food and Drug Administration's (FDA's) implementation of least burdensome review requirements, third-party reviews, humanitarian device exemptions, and FDA advisory committee member conflicts of interest. These provisions would weaken the regulatory requirements for medical devices and endanger patients.

On the other hand, we support several other provisions that would strengthen medical device oversight, including those related to reclassification procedures, condition of approval studies, the Sentinel System, and clinical holds on investigational device exemptions. In addition, some provisions could be clarified or improved, such as the proposals for postmarket surveillance, recalls, the unique device identification (UDI) system, and performance standards.

We are concerned about the potential adverse impact of the following provisions on medical device safety:

(1) Section 10. Clarification of Least Burdensome Standard: proposed amendments to Sections 513(a)(3)(D) and 513(i)(1)(D) of the FDCA (21 U.S.C. 360c(a)(3)(D) and 360c(i)(1)(D))

The least burdensome standards for approving a device under a premarket approval application (PMA) or clearing a device under the 510(k) process have long been a hindrance for ensuring the safety of medical devices. They prevent the FDA from requesting information that may be critical to the assessment of the safety and effectiveness of medical devices being reviewed under the PMA and 510(k) processes. The provisions of Section 10 would further constrain the agency's authority to consider important information relevant to the safety and effectiveness of medical devices. Section 10 would also pressure the agency to take shortcuts to meet the demands of an accelerated review process for increasingly complex medical devices.

We strongly urge the HELP Committee to eliminate Section 10 from the proposed legislation. Alternatively, we recommend the following addition:

> Amend 21 U.S.C. § 360c to require moderate- to high-risk devices — particularly those that are intended to be life-sustaining, life-supporting, or permanently implanted — to meet the same standards as those required for drugs and include language such as the following:
>
> (a) The application for the device must include substantial evidence that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; substantial evidence means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the device involved; and
> (b) The application for the device must include adequate tests by all methods reasonably applicable to show that such device is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof.

(2) Section 15. Humanitarian Use Device Exemption (HDE): proposed amendment to Section 520(m) of the FDCA (21 U.S.C 360j(m))

The proposed language in the new subsection 520(m)(6) — in particular: "is intended for treatment or diagnosis of a disease or condition that does not occur in pediatric patients" — would broadly extend the exception to the prohibition against a manufacturer selling a device approved under an HDE for an amount exceeding the costs of research and development, fabrication, and distribution of the device to any HDE device intended for the treatment of a disease or condition affecting only adult patients.

This extension of the exception to this prohibition is overly broad. It would eliminate the financial incentive for manufacturers to conduct the clinical trials necessary to determine the actual safety and effectiveness of HDE devices intended for use in adults and to seek approval under a PMA, if the data supports such approval. Failure to conduct such trials ultimately would be a disservice to the patients who are being treated with these inadequately tested devices, some of which will have risks that outweigh their benefits,

resulting in significant harms to patients, as was recently demonstrated for the Wingspan Stent System.[1]

The FDA approved the Wingspan Stent System in 2005 under an HDE application for the treatment of patients at high risk of stroke due to intracranial atherosclerotic disease. A subsequent well-designed clinical study demonstrated that the Wingspan Stent System plus aggressive medical therapy causes significantly more harm (i.e., a 2.5-fold higher risk of stroke or death at 30 days post-intervention) and is no more effective in comparison to aggressive medical treatment alone.[2] The proposed amendments in Section 15 would likely lead to similar occurrences in which unsafe and ineffective devices are brought to market under an HDE and cause substantial harm to patients.

Therefore, we strongly urge the HELP Committee to eliminate Section 15 from the proposed legislation.

(3) Section 16. Reauthorization of Third-Party Review: proposed amendment to Section 523(c) of the FDCA (21 U.S.C. 360m(c))

Extending the FDA's authority to use third-party reviews for review of devices under the 510(k) process and for making recommendations on the initial classification of devices under Section 513(f)(1) of the FDCA would perpetuate a flawed process that fails to ensure medical device safety. In particular, 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. Internal FDA professional staff are best positioned to make the independent, unbiased, science-based determinations required under the medical device regulations. Therefore, we recommend that Congress not renew the FDA's authority to use third-party reviewers.

(4) Section 17. Advisory Committee Conflicts of Interest: proposed amendments to Section 712 of the FDCA (21 U.S.C. 379d-1))

Section 17 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. Recent data provided by the FDA indicate that the current statutory limits on such waivers have not prevented the agency from finding sufficient numbers of experts to serve on its advisory committees. FDA Commissioner Margaret Hamburg recently indicated that eliminating these waiver limits is *not* necessary for the advisory committees to operate effectively. Passage of this

[1] Carome MA, Sorscher S, Wolfe SM. Petition to the FDA to withdraw approval for the HDE for the Wingspan Stent System. December 21, 2011. Available at http://www.citizen.org/documents/petition-to-fda-to-withdraw-approval-of-wingspan-stent-system-122111.pdf/ Accessed April 2, 2012.
[2] Chimowitz MI, Lynn MJ, Derdeyn CP, et al. Stenting versus aggressive medical therapy for intracranial arterial stenosis. N Engl J Med. 2011;365:993-1003.

provision 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.

We strongly urge the HELP Committee to eliminate Section 17 from the proposed legislation.

We recommend amendments to the following provisions of the draft legislation:

(1) Section 5. Postmarket Surveillance: proposed amendment to Section 522 of the FDCA (21 U.S.C. 360l))

We support the proposal to grant the FDA the explicit authority to require postmarket surveillance studies either at the time of approval or clearance of a device covered by this provision or at any time after approval or clearance. We also recommend the following amendment to strengthen this provision:

(a) Regarding the proposed amendment to subsection (b)(1) of Section 522, 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 one year to no more than six months, and perhaps no more than three months, after the FDA's determination. A one-year interval would unnecessarily delay the collection of critical information needed to protect the public health and potentially expose potentially large numbers of subjects to harm from dangerous, inadequately tested devices.

(b) We recommend removing 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. Studies limited to 36 months are insufficient for medical devices that are intended to be permanently implanted in adults and to provide medical benefits for much longer than three years, such as implantable cardiac pacemakers, implantable cardioverter-defibrillators, cardiac stents, endovascular grafts, surgical mesh, and artificial joint implants, to name a few.

(2) Section 7. Recalls

We support the proposal to require that the FDA routinely and systematically assess information regarding medical device recalls and improve procedures for conducting device recall audit checks by agency investigators. However, we recommend that the section be amended to enhance the quality of recall data collected and analyzed by the FDA, and to routinely make such data available to the public:

(a) Subsection (a)(2) of Section 7 should require that the proposed device recall assessment program identify the following additional data:

- The causes of device audits;

- The length of time needed for a person subject to a device recall to complete the recall;
- The length of time needed for the Secretary to terminate a device recall; and
- The number of recalls per device manufacturer.

The required collection of these data elements was included in S. 1995, the Medical Device Patient Safety Act, which was introduced by Senators Charles Grassley, Herbert Kohl, and Richard Blumenthal. The data would provide critical information for the FDA, health professionals, and patients.

(b) Expand subsection (a) of Section 7 to include 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.

(c) Amend subsection (d) (Termination of Recalls) of Section 7 to include a provision requiring the Secretary to publish the documentation for the basis of any termination by the FDA of (i) an individual device recall ordered by the agency, or (ii) the requirement on a manufacturer or importer of a device to report any correction or removal action for which a report is required to be submitted to the Secretary under section 519(g) of the FDCA.

The proposal to include publication of such documentation was included in S. 1995.

(3) Section 9. Unique Device Identifier: proposed amendment to section 519(f) of the FDCA (21 U.S.C. 360i(f))

We strongly support the long-overdue implementation of the UDI system that was required by Congress in legislation passed in 2007. We recommend that Section 9 of the draft legislation specify a date by which a final rule implementing a UDI system must be published by the FDA, preferably no more than one year after passage of the legislation. Without a statutorily mandated deadline, more years may pass without this essential system for enhancing patient safety being implemented.

(4) Section 13. Performance Standard: proposed amendments to Sections 514(c)(1)(A) and 513(f)(1)(A)(ii) of the FDCA (21 U.S.C. 360d(c)(1)(A) and 360c(f)(1)(A)(ii))

We recommend that the proposed amendment to Section 513(f)(1)(A)(ii) be clarified because the FDA can only compare a proposed device to another device. A device cannot be held substantially equivalent to a performance standard.

<u>We support the following sections in the draft legislation</u>:

(1) Section 3. Reclassification Procedures: proposed amendments to Section 513(e)(1) of the FDCA (21 U.S.C. 360c(e)(1)) and other technical and conforming amendment

We applaud, in particular, the requirement that any reclassification of a medical device would in all cases require that the FDA convene a meeting of a device classification panel prior to the agency issuing a reclassification order.

(2) Section 4. Condition of Approval Studies: proposed amendments to Section 515(d)(1)(B)(ii) of the FDCA (21 U.S.C. 3360e(d)(1)(B)(ii))

We support this provision, which would grant the FDA explicit authority to require, as a condition of approval of any medical device reviewed under a PMA, that the sponsor conduct a postmarket study regarding the device.

(3) Section 6. Sentinel: proposed amendments to Sections 519 and 505(k)(3)(C)(i) of the FDCA (21 U.S.C. 360i and 355(k)(3)(C)(i))

We support this provision, which would expand 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.

(4) Section 8. Clinical Holds on Investigational Device Exemptions: proposed amendments to Section 520(g) of the FDCA (21 U.S.C. 360j(g))

We strongly endorse this provision, which would grant the FDA authority to place a clinical hold on an investigational device exemption, as it can now do for an investigational new drug application. This provision would enhance the protections for human subjects who volunteer to participate in clinical trials testing investigational medical devices.

<u>We recommend including the following provisions in the proposed legislation</u>:

(1) Amend Section 521 of the FDCA (21 U.S.C. 360k) by adding at the end the following:

> "(c) No Effect on Liability Under State Law– Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State."

Furthermore, this amendment should (a) take effect as if included in the enactment of the Medical Device Amendments of 1976 (Public Law 94-295), and (b) apply to any civil action pending or filed on or after the date of enactment of the legislation.

This language is needed to provide patients harmed by dangerous or defective medical devices approved under the PMA process with the right to seek compensation under state tort law. In 2008, in *Riegel v. Medtronic*, the U.S. Supreme Court held the 1976 Medical Device Amendments preempt most tort claims arising from allegedly defective devices if the device in question was approved under the PMA process.[3] The Court's ruling gave

[3] Riegel v. Medtronic Inc., 552 U.S. 312 (2008), http://bit.ly/wv1xrN.

device makers immunity from most product liability claims. That is, if the FDA approves a dangerous or defective device through the PMA process, federal law generally bars consumers harmed by the device from seeking redress in court. Given the weakness of medical device oversight, patients harmed by dangerous or defective devices approved under a PMA should be able to seek such redress.

(2) Chapter V of the FDCA (21 U.S.C. 351 et seq.) should be amended to include the new section 510A proposed in S. 1995 introduced by Senators Grassley, Kohl, and Blumenthal that would authorize the FDA to conditionally clear medical devices under the 510(k) process. Such conditions could include, among others:

(a) Restrictions on the sale, distribution, or use of the device;
(b) Requirements for continued evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended uses;
(c) Requirements for a prominent display in the labeling of the device and in the advertising of warnings, hazards, or precautions important for the device's safe and effective use; and
(d) Requirements for maintenance of records for specified periods of time and organization and indexing of records into identifiable files to enable the FDA to determine whether there is a reasonable assurance of the continued safety and effectiveness of the device.

(3) Sections 513(i) and 519 of the FDCA (21 U.S.C. 360c(i) and 360i) should be amended to include the changes proposed in H.R. 3847, the Safety of Untested and New Devices Act of 2012, introduced by Representatives Edward Markey, Henry Waxman, Jan Schakowsky, and Rosa DeLauro. These provisions would close the dangerous loophole in current medical device regulations that allows a new medical device to be cleared under the 510(k) process based upon a determination of substantial equivalence to a predicate device that was recalled or withdrawn from the market by the manufacturer because of serious safety problems related to the design of that predicate device.

(4) Section 510(k) of the FDCA (21 U.S.C. 360(k)) should be amended 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.

Conclusions

Ensuring that the medical devices used to treat patients in the U.S. are safe and effective should be the paramount goal of any new medical device legislation. U.S. patients deserve legislation that improves the review and oversight of the safety and efficacy of these devices.

Thank you for your consideration of our comments regarding this important issue. We would welcome the opportunity to meet with your committee to further discuss our recommendations.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group