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May 9, 2012

The Honorable Fred Upton
Chairman
U.S. House of Representatives Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
U.S. House of Representatives Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, DC 20515

Re: Food and Drug Administration User Fee Legislation

Dear Representatives Upton and Waxman:

Public Citizen, representing more than 250,000 members and supporters nationwide, offers the following comments regarding the May 8 Committee Print version of legislation to amend the Federal Food, Drug, and Cosmetic Act to revise and expand the Food and Drug Administration's (FDA's) user-fee programs for prescription drugs and medical device and for other purposes, which will be considered by the House of Representatives Energy and Commerce Committee when it convenes in executive session tomorrow.

The revised legislation contains several important improvements in comparison to the earlier discussion draft — which we strongly opposed — including the following:

(1) The Section 601 (**FDA's mission**) of the discussion draft, which would have inappropriately made promotion of medical innovation and job creation a primary focus of the agency's mission, has been eliminated.
(2) The revised bill restores the section related to conflicts of interest for FDA advisory committee members, which had been completely eliminated from the earlier discussion draft (see enclosure for details). However, as discussed below, the revised bill still threatens to undermine the integrity of the agency's advisory committee review process.
(3) The discussion draft version 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. These provisions have been eliminated.
(4) The revised bill would (a) impose a deadline for the promulgation of unique device identifier system regulations; and (b) expand the FDA's sentinel program to include medical devices.

However, despite these incremental improvements, the beneficial provisions in the revised bill are still offset by:

(1) The inclusion of multiple provisions that would weaken the oversight system of medical devices and drugs and pose a risk to the health and lives of patients; and

(2) The continued exclusion of several other simple, common-sense proposals for strengthening medical device safety, some of which are found in the counterpart legislation recently passed by the Senate Committee on Health, Education, Labor, and Pensions (HELP Committee).

Therefore, in balance, this bill would have an overall negative impact on medical device and drug safety.

Enclosed is a brief summary of our review of the revised legislation. Among the provisions that would negatively affect medical device and drug safety are those that:

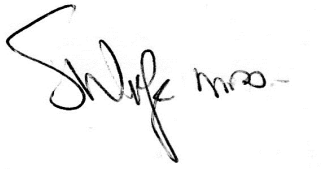
- Further weaken medical device oversight by placing undue emphasis on the implementation of least burdensome (to industry) standards during the review of 510(k) submissions and premarket approval applications for medical devices;
- Promote the development of antibiotics that are ineffective and unsafe;
- Allow more drugs to come to market without adequate testing for safety and effectiveness by expanding the use of the accelerated approval process; and
- Damage the integrity of the FDA's advisory committee review process by eliminating the general prohibition against individuals with substantial financial conflicts of interest from serving on FDA advisory committees.

Ensuring that the medical devices and drugs used to treat patients in the U.S. are safe and effective should be the paramount goal of any new medical device and prescription drug legislation. Patients in the U.S. deserve legislation that strengthens the FDA's review and oversight of these medical products to ensure their safety and effectiveness, not legislation that seeks to promote the corporate interests and profits of industry by weakening such review and oversight.

As the Energy and Commerce Committee deliberates on legislation to renew and expand the FDA's user fees, we urge you to stand up for the interests of patients and make amendments that would enhance the safety of medical devices and drugs.

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

Enclosure

cc: House Energy and Commerce Committee