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April 23, 2012

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

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

Re: The PATIENTS's FDA Act Drafted by Senators Burr and Coburn

Dear Senators Harkin and Enzi:

Public Citizen, representing more than 250,000 members and supporters nationwide, strongly opposes the *Promoting Accountability, Transparency, Innovation, Efficiency, and Timeliness at the FDA Act of 2012* (the PATIENTS' FDA Act), drafted by Senators Richard Burr and Tom Coburn, because the bill would substantially weaken the Food and Drug Administration's (FDA's) regulatory oversight of medical products — particularly those related to medical devices — and thus poses a significant threat to the health and lives of patients.

Enclosed is a brief summary of our most serious concerns regarding the draft legislation. Among the most egregious provisions in the PATIENTS' FDA Act opposed by Public Citizen are those that would:

- Dramatically lower the safety and efficacy standards for FDA clearance or approval of medical devices;
- Endanger patients by exempting moderate- and high-risk devices — including devices that are permanently implanted, life-sustaining, or life-supporting — from undergoing critically important clinical testing before being sold in the U.S. if the devices meet foreign standards that are much less stringent than the FDA's already inadequate standards for approving medical devices;
- 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;
- Endanger human subjects participating in clinical trials of medical devices by placing inappropriate constraints on the FDA regarding the review of investigational device exemptions; and

- Damage the integrity of the FDA's advisory committee review process by weakening provisions that limit participation to individuals who have financial conflicts of interest.

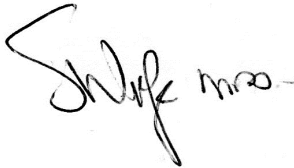
Ensuring that the medical devices and drugs used to treat patients in the U.S. are safe and effective should be the paramount goal of any new medical device and prescription drug legislation. Patients in the U.S. deserve legislation that strengthens the FDA's review and oversight of these medical products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

As the Senate Committee on Health, Education, Labor, and Pensions deliberates on legislation to renew and expand the FDA's user fees, we urge you to stand up for the interests of patients and reject the many dangerous provision of the PATIENTS's FDA Act.

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: Senate HELP Committee