ORGANIZATIONS OPPOSED TO UNDERCUTTING FOIA IN FDA BILLS

May 22, 2012

Chairman Tom Harkin
Senate Committee on Health, Education, Labor & Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Michael Enzi
Senate Committee on Health, Education, Labor & Pensions
835 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

The undersigned organizations concerned with openness and accountability are writing to urge you to remove or substantially narrow a provision of S. 3187, the Food and Drug Administration Safety and Innovation Act, that needlessly prevents the public from having access to potentially important health and safety information and that could greatly diminish the public's access to information about the work of the U.S. Food and Drug Administration (FDA).

Section 708 of S.3187 allows the FDA to deny the public access to information relating to drugs obtained from a federal, state, local, or foreign government agency, if the agency has requested that the information be kept confidential. Section 812 of H.R. 5651, the Food and Drug Administration Reform Act of 2012, contains similar language.

We understand that Congress intends the language to promote the sharing of drug inspection information by foreign governments with the FDA. However, the FDA does not need this authority because the Freedom of Information Act (FOIA) already provides exemptions to protect against the release of many law enforcement records; confidential, commercial information; and trade secrets.

At the very least, section 708 should be narrowly tailored to avoid unintentionally or unnecessarily increasing secrecy at the FDA. The provision currently covers information obtained from other federal agencies, which are themselves subject to FOIA, and information obtained from state and local agencies, despite an FDA regulation that specifically protects from disclosure many records submitted to FDA by those agencies. Furthermore, the provision is written so broadly that it could include information that now is required to be disclosed to the FDA, restricting the public's right to know about potential health and safety risks.

We urge you to address this problem before S.3187 is brought to the floor for a vote and to work with the conference committee to ensure that section 708 is either removed or, at a minimum, substantially narrowed to protect the public's right to critical health and safety information. Representatives from the

undersigned organizations are willing to discuss possible ways to address these issues. If you would like to discuss these issues further, please contact Patrice McDermott, Executive Director of OpenTheGovernment.org, at 202-332-6736 or pmcdermott@openthegovernment.org.

Sincerely,

American Library Association

Citizens for Responsibility and Ethics in Washington – CREW

Freedom of Information Center at the Missouri School of Journalism

National Freedom of Information Coalition

OMB Watch

OpenTheGovernment.org

Project On Government Oversight – POGO

Public Citizen

Sunlight Foundation

cc: Chairman Patrick Leahy, Senate Judiciary Committee