

May 29, 2012

Chairman Fred Upton  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

Ranking Member Henry Waxman  
House Energy and Commerce Committee  
2322A Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

The undersigned organizations concerned with openness and accountability are writing to urge you to remove or substantially narrow a provision of H.R. 5651, the Food and Drug Administration Reform Act of 2012, 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 812 of H.R. 5651 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. As introduced, Section 708 of S. 3187, the Food and Drug Administration Safety and Innovation Act, contained similar language. The Senate accepted an amendment to the provision offered by Senator Leahy (D-VT) that limits the scope to information voluntarily provided by foreign governments, requires that the request to keep the information confidential be in writing, and, unless otherwise agreed upon, specifies a time frame after which the information will no longer be treated as confidential.

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 812 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 H.R. 5651 is brought to the floor for a vote and to work with the conference committee to ensure that section 812 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](mailto:pmcdermott@openthegovernment.org).

Sincerely,

American Booksellers Foundation for Free Expression

American Library Association

American Society of News Editors

Association of Research Libraries

Center for Media and Democracy

Citizens for Responsibility and Ethics in Washington – CREW

Essential Information

Freedom of Information Center at the Missouri School of Journalism

iSolon.org

Mississippi Center for Freedom of Information

National Coalition Against Censorship

National Freedom of Information Coalition

National Priorities Project

OMB Watch

OpenTheGovernment.org

Progressive Librarians Guild

Project On Government Oversight – POGO

Public Citizen

Sunlight Foundation

Tully Center for Free Speech at Syracuse University

Washington Coalition for Open Government

cc: Food and Drug Administration Commissioner Margaret Hamburg

Chairman Tom Harkin, Senate Committee on Health, Education, Labor & Pensions

Ranking Member Michael Enzi, Senate Committee on Health, Education, Labor & Pensions

Chairman Joe Pitts, House Energy and Commerce Subcommittee on Health

Ranking Member Frank Pallone, House Energy and Commerce Subcommittee on Health

Senator Patrick Leahy

Representative John Dingell