I

112TH CONGRESS
2D SESSION

H. R. 4056

To amend the Federal Food, Drug, and Cosmetic Act to prevent a State or political subdivision thereof from conducting or requiring duplicative inspections of establishments in which a drug or device is manufactured, processed, packed, or held by a manufacturer or wholesale distributor of the drug or device.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2012

Mr. BILBRAY (for himself, Mrs. DAVIS of California, Mr. LEWIS of California, Mr. ROYCE, Mr. CALVERT, Mrs. BONO MACK, and Mr. HUNTER) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prevent a State or political subdivision thereof from conducting or requiring duplicative inspections of establishments in which a drug or device is manufactured, processed, packed, or held by a manufacturer or wholesale distributor of the drug or device.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Science and Technology Regulatory Relief Act of 2012''.

SEC. 2. LIMITATION OF STATE AUTHORITY TO INSPECT.

Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following:

''(h) LIMITATION OF STATE AUTHORITY TO INSPECT.—

''(1) IN GENERAL.—Except as provided in paragraph (2), no State or political subdivision of a State may conduct or require an inspection of a factory, warehouse, or establishment in which a drug or device is manufactured, processed, packed, or held by a manufacturer or wholesale distributor of the drug or device, for introduction into interstate commerce or after such introduction, for purposes of verifying compliance with—

''(A) the requirements of—

''(i) section 351 of the Public Health Service Act; or

''(ii) this Act; or

''(B) any similar requirements established pursuant to State law.

''(2) EXCEPTIONS.—Paragraph (1) does not apply to an inspection of such a factory, warehouse, or establishment by a State or a political subdivision of a State in any of the following circumstances:

"(A) The State or political subdivision (or a department or agency thereof) makes a determination, based on receipt of a complaint or otherwise, that a drug or device presents a threat of serious adverse health consequences or death, and the inspection relates to such risk.

"(B) The Secretary orders a recall of a drug, biological product, or device manufactured, processed, packed, or held at the factory, warehouse, or establishment, and the inspection relates to such recall.

"(C) The Secretary requests or authorizes the State to conduct or require the inspection.".

○