## 111TH CONGRESS 1ST SESSION

## S. 613

To prohibit the use of Federal funds to approve certain biologics license applications by the Food and Drug Administration.

## IN THE SENATE OF THE UNITED STATES

March 17, 2009

Mr. Brownback introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

## A BILL

To prohibit the use of Federal funds to approve certain biologics license applications by the Food and Drug Administration.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. PROHIBITION ON USE OF FEDERAL FUNDS TO
- 4 APPROVAL CERTAIN BIOLOGICS LICENSE AP-
- 5 PLICATIONS.
- 6 Notwithstanding any other provision of law, no funds
- 7 provided by any Appropriations Act enacted before the
- 8 date of enactment of this Act that remain unobligated as
- 9 of such date of enactment shall be used by the Food and
- 10 Drug Administration to process a biologics license applica-

1	tion under section 351 of the Public Health Service Act
2	(42 U.S.C. 262) for any such product for which—
3	(1) information submitted in such application,
4	or any other information available to the Secretary
5	of Health and Human Services, shows that the bio-
6	logic product is, bears, or contains a listed select
7	agent or toxin within the meaning of part 331 of
8	title 7, Code of Federal Regulations, part 121 of
9	title 9, Code of Federal Regulations, and part 73 of
10	title 42, Code of Federal Regulations; and
11	(2) the entity filing such application has, during
12	the 2-year period before the date of submission of
13	such application to the Secretary—
14	(A) marketed, sold, or distributed that
15	product in the Islamic Republic of Iran;
16	(B) provided select agents or toxins to in-
17	stitutions in the Islamic Republic of Iran, in-
18	cluding to the Pasteur Institute in Tehran and
19	Tehran University;
20	(C) submitted patient safety or efficacy
21	data produced through experiments or trials
22	that would violate the laws of the United States
23	governing the proper handling of select agents
24	or toxins: or

1 (D) been the subject of an investigation by
2 the Office of Foreign Assets Control of the De3 partment of Treasury, the Bureau of Industry
4 and Security of the Department of Commerce,
5 or the Department of Justice for potential vio6 lations of the Iran Sanctions Act of 1996 (Pub7 lie Law 104–172; 50 U.S.C. 1701 note).

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