107TH CONGRESS
2D SESSION

S. 2049

To amend the Federal Food, Drug and Cosmetic Act to include a 12 month notification period before discontinuing a biological product, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 21, 2002

Mr. DEWINE (for himself, Mrs. CLINTON, and Mr. DODD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug and Cosmetic Act to include a 12 month notification period before discontinuing a biological product, and for other purposes.

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 ''Childhood Vaccine Supply Act of 2002''.

SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) INCLUSION OF BIOLOGICAL PRODUCTS.—Section 506C(a) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 356c(a)) is amended—

(1) in the matter preceding paragraph (1) by striking ''that is the sole manufacturer of a drug'' and inserting ''of a product regulated by the Food and Drug Administration'';

(2) in subparagraph (C) of paragraph (1), by striking ''of a debilitating disease or condition;'' and inserting ''or treatment of a serious disease or condition; and'';

(3) in paragraph (2), by striking ''; and'' and inserting '', or for which a biologics license application has been approved under section 351 of the Public Health Service Act;'';

(4) by striking paragraph (3); and

(5) in the flush matter at the end, by striking ''of the drug at least 6 months'' and inserting '', in the case of a product approved under section 505(b) or 505(j), at least 6 months, or in the case of a product approved under section 351 of the Public Health Service Act, at least 12 months''.

(b) REDUCTION IN NOTIFICATION PERIOD.—Section 506C(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(b)) is amended—

(1) in paragraph (1), by striking ''6-month period'' and inserting ''notification period prescribed in subsection (a)'';

(2) in paragraph (2), by striking ''6-month period'' and inserting ''notification period prescribed in subsection (a)'';

(3) in paragraph (3), by striking ''6-month period'' and inserting ''notification period prescribed in subsection (a)'';

(4) in paragraph (4), by striking ''6-month period'' and inserting ''notification period prescribed in subsection (a)''; and

(5) in paragraph (6), by striking ''of the drug involved for 6 months'' and inserting ''of the product approved under section 505(b) or 506(j), for 6 months, or the product approved under section 351 of the Public Health Service Act, for 12 months''.

(c) DISTRIBUTION.—Section 506C(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(c)) is amended by inserting '', hospital,'' after ''physician''.

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended by adding at the end the following:

''(3) The Secretary may purchase pediatric and adult vaccines for national stockpiles utilizing a portion of the funds made available under this subsection.''.

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