

underlying FDA's decision to treat noncorrective lenses as cosmetics. For that reason, the bill includes a rule of construction stating that the bill should not be construed as having any effect on any product regulated by the FDA other than the specific contact lenses at issue here. I thank the gentleman from Ohio and the distinguished chairman of the Subcommittee on Health, and I join with every Member who has spoken on this bill in urging support for it.

Mr. BILIRAKIS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. OSE). The question is on the motion offered by the gentleman from Florida (Mr. BILIRAKIS) that the House suspend the rules and pass the bill, H.R. 2218, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

The title of the bill was amended so as to read: "A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of all contact lenses as medical devices, and for other purposes."

A motion to reconsider was laid on the table.

FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Monahan, one of its clerks, announced that the Senate has passed with an amendment in which the concurrence of the House is requested, a bill of the House of the following title:

H.R. 2297. An act to amend title 38, United States Code, to improve benefits under laws administered by the Secretary of Veterans Affairs, and for other purposes.

The message also announced that the Senate has passed a bill of the following title in which the concurrence of the House is requested:

S. 1156. An act to amend title 38, United States Code, to improve and enhance provision of health care for veterans, to authorize major construction projects and other facilities matters for the Department of Veterans Affairs, to enhance and improve authorities relating to the administration of personnel of the Department of Veterans Affairs, and for other purposes.

PEDIATRIC RESEARCH EQUITY ACT OF 2003

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 650) to amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration to require certain research into drugs used in pediatric patients.

The Clerk read as follows:

S. 650

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 "Pediatric Research Equity Act of 2003".

SEC. 2. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 505A the following:

"SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

"(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—A person that submits an application (or supplement to an application)—

"(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

"(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration;

shall submit with the application the assessments described in paragraph (2).

"(2) ASSESSMENTS.—

"(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

"(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

"(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

"(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

"(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

"(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from 1 age group can be extrapolated to another age group.

"(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(A) the Secretary finds that—

"(i) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

"(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

"(iii) there is another appropriate reason for deferral; and

"(B) the applicant submits to the Secretary—

"(i) certification of the grounds for deferring the assessments;

"(ii) a description of the planned or ongoing studies; and

"(iii) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time.

"(4) WAIVERS.—

"(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver,

as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used in a substantial number of pediatric patients.

"(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

"(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

"(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

"(iii) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

"(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

"(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

"(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation.

"(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—After providing notice in the form of a letter and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may (by order in the form of a letter) require the holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the assessments described in subsection (a)(2) if the Secretary finds that—

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

"(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

"(2) WAIVERS.—

"(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to