108TH CONGRESS
2D SESSION

S. 2445

To amend the Federal Food, Drug, and Cosmetic Act relating to direct-to-consumer prescription drug advertising.

IN THE SENATE OF THE UNITED STATES

MAY 19, 2004

Mr. EDWARDS 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 relating to direct-to-consumer prescription drug advertising.

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 ''Direct to Consumer Prescription Drug Advertising Act of 2004''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) The pharmaceutical industry spent $2,700,000,000 on direct to consumer advertising in 2001, nearly a 60 percent increase since 1997.

(2) Direct to consumer prescription drug advertisements can significantly increase the number of sales. In 2000, almost $2,500,000,000 was spent on direct to consumer advertising to promote 50 different drugs. The following year, retail sales for these drugs skyrocketed by 21.4 percent.

(3) According to the Government Accounting Office, pharmaceutical companies have increased spending on direct to consumer advertising more rapidly than they have increased spending on research and development.

(4) New prescription drugs that are introduced into the market are generally more expensive than older drugs in the same class. Consequently, direct to consumer advertising may lead consumers to spend more money on new prescription drugs than those of similar quality.

(5) Although direct to consumer prescription drug advertisements aid consumer awareness, they are often misleading as the benefits are more accessible than the risks.

(6) There has been a sharp increase in sales for direct to consumer advertised prescription drugs, which is disproportionate to the growth in the market.

(7) Due to a revision of procedure within the Department of Health and Human Services, the Food and Drug Administration is often too late to act on misleading direct to consumer advertisements by the pharmaceutical industry. By the time they revoke an advertisement, many consumers have already viewed the misleading information.

SEC. 3. PRESCRIPTION DRUG COMPARATIVE EFFECTIVENESS.

(a) IN GENERAL.—With respect to each prescription drug that is covered under a plan offered under the Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code, the Director of the National Institutes of Health shall conduct research that compares the effectiveness and safety of such prescription drug relative to other prescription drugs used to treat the same condition or disease.

(b) RULE OF CONSTRUCTION.—The results of the research conducted under subsection (a) shall not be construed to be a condition of approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

SEC. 4. DIRECT-TO-CONSUMER ADVERTISING.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and

Human Services shall promulgate amended regulations governing prescription drug advertisements.

(b) CONTENTS.—In addition to any other requirements, the regulations under subsection (a) shall require that—

(1) any advertisement present a fair balance, comparable in depth and detail, between—

(A) information relating to effectiveness of the drug (including, if available, effectiveness in comparison to other drugs for substantially the same condition or conditions); and

(B) information relating to side effects and contraindications;

(2) any advertisement present a fair balance, comparable in depth, between—

(A) aural and visual presentations relating to effectiveness of the drug; and

(B) aural and visual presentations relating to side effects and contraindications, except that nothing in this section shall require explicit images or sounds depicting side effects and contraindications;

(3) prohibit false or misleading advertising that would encourage a consumer to take the prescription drug for a use other than a use for which the pre-

scription drug is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(4) require that any prescription drug that is the subject of a direct-to-consumer advertisement include in the package in which the prescription drug is sold to consumers a medication guide explaining the benefits and risks of use of the prescription drug in terms designed to be understandable to the general public.

SEC. 5. CIVIL PENALTY.

Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

''(g) DIRECT-TO-CONSUMER PRESCRIPTION DRUG ADVERTISING.—

''(1) IN GENERAL.—A person that commits a violation of section 301 involving the misbranding of a prescription drug (within the meaning of section 502(n)) in a direct-to-consumer advertisement shall be assessed a civil penalty if—

''(A) the Secretary provides the person written notice of the violation; and

''(B) the person fails to correct or cease the advertisement so as to eliminate the viola-

tion not later than 180 days after the date of the notice.

''(2) AMOUNT.—The amount of a civil penalty under paragraph (1)—

''(A) shall not exceed $500,000 in the case of an individual and $5,000,000 in the case of any other person; and

''(B) shall not exceed $10,000,000 for all such violations adjudicated in a single proceeding.

''(3) PROCEDURE.—Paragraphs (3) through (5) of subsection (f) shall apply with respect to a civil penalty under paragraph (1) of this subsection to the same extent and in the same manner as those paragraphs apply with respect to a civil penalty under paragraph (1) or (2) of subsection (f).''.

SEC. 6. REPORTS.

The Secretary of Health and Human Services shall annually submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that, for the most recent 1-year period for which data are available—

(1) provides the total number of direct-to-consumer prescription drug advertisements made by tel-

evision, radio, the Internet, written publication, or other media;

(2) identifies, for each such advertisement—

(A) the dates on which, the times at which, and the markets in which the advertisement was made; and

(B) the type of advertisement (reminder, help-seeking, or product-claim); and

(3)(A) identifies the advertisements that violated or appeared to violate section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)); and

(B) describes the actions taken by the Secretary in response to the violations.

SEC. 7. REVIEW OF DIRECT-TO-CONSUMER DRUG ADVERTISEMENTS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall expedite, to the maximum extent practicable, reviews of the legality of direct-to-consumer drug advertisements.

(b) POLICY.—The Secretary of Health and Human Services shall not adopt or follow any policy that would have the purpose or effect of delaying reviews of the legality of direct-to-consumer drug advertisements except—

(1) as a result of notice-and-comment rule-making; or

(2) as the Secretary determines to be necessary to protect public health and safety.

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