AMENDMENT TO COMMITTEE PRINT OFFERED BY MR. TOWNS OF NEW YORK ANDMR. BUYER OF INDIANA

[The Towns-Buyer Direct-To-Consumer Advertising Amendment to REMS_001, June 11, 2007]

Page 9, strike lines 11 through 18 (relating to inclusion of a unique symbol) (and make such technical and conforming changes as may be necessary).

Strike page 15, line 23, through page 16, line 14 (relating to preclearance).

Strike page 16, line 15, through page 17, line 13 (relating to specific disclosures).

Strike page 17, line 14, through page 18, line 14 (relating to 3-year moratorium).

Page 25, strike lines 3 though 5 (and make such technical and conforming changes as may be necessary).

Page 26, strike lines 7 through 15 (relating to marketing plan) (and make such technical and conforming changes as may be necessary).

Page 37, strike lines 13 through 19 (and make such technical and conforming changes as may be necessary).

Page 40, strike lines 1 to 6 and insert the following:

(d) PREREVIEW OF ADVERTISEMENTS.—

(1) SENSE OF CONGRESS.—It is the sense of the Congress that—

(A) ''Guidance for Industry Consumer-Directed Broadcast Advertisements'' issued by the FDA in August, 1999, represents generally good guidance for direct-to-consumer (DTC) advertising of prescription medicines and other treatments;

(B) direct-to-consumer advertising as an accurate source of health information for all populations, specifically including the elderly populations, children, chronically ill and racial and ethnic minority populations, should be made more reliable by ensuring the truth and credibility of information provided through such advertising; and

(C) the Congress will work with the Food and Drug Administration to ensure that information provided through direct-to-consumer advertising of prescription medicines and other treatments is not false or misleading and communicates clearly and sensitively to all communities.

(2) PREREVIEW.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amending—

(A) in section 301 (21 U.S.C. 331), by adding at the end the following:

''(____) The dissemination of a television advertisement in violation of section 503B.''; and

(B) by inserting after section 503A the following:

''SEC. 503B. PREREVIEW OF TELEVISION ADVERTISEMENTS.

''(a) IN GENERAL.—The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

''(b) REVIEW.—In conducting a review of a television advertisement under this section, the Secretary may make recommendations—

''(1) on changes that are—

''(A) necessary to protect the consumer good and well-being; or

''(B) consistent with prescribing information for the product under review; and

''(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to a specific population group, including elderly populations, children, and racially and ethnically diverse populations.

''(c) NO AUTHORITY TO REQUIRE CHANGES.—This section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

''(d) ELDERLY POPULATIONS, CHILDREN, RACIALLY AND ETHNICALLY DIVERSE COMMUNITIES.—In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

''(e) SPECIFIC DISCLOSURES.—

''(1) SERIOUS RISK; SAFETY PROTOCOL.—In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

''(2) DATE OF APPROVAL.—In conducting a review of a television advertisement under this section, the Secretary may require the advertisement to include, for a period not to exceed 2 years from the date of the approval of the drug under section 505, a specific disclosure of such date of approval if the Secretary determines that the advertisement would otherwise be false or misleading.''.

(3) DIRECT-TO-CONSUMER ADVERTISEMENTS.—

(A) IN GENERAL.—Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) is amended by adding at the end the following: ''In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear and conspicuous manner.''.

(B) REGULATIONS TO DETERMINE CLEAR AND CONSPICUOUS MANNER.—The Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and

contraindications of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (as amended by subparagraph (A)) is presented in the manner required under such section.

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

''(____)(1) Any person who disseminates a direct-to-consumer advertisement for a prescription drug that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period. For the purposes of this paragraph, repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered as one violation. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(3)) shall apply to a violation regarding direct-to-consumer advertising.

''(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed

a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

''(3) Upon the request of the person to be assessed a civil penalty under paragraph (1), the Secretary, in determining the amount of the civil penalty, shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

''(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A.

''(B) Whether the person submitted the advertisement for review if required under section 503B.

''(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated the advertisement before the end of the 45-day comment period.

''(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

''(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

''(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

''(G) Whether the violations were material.

''(H) Whether the person who created the advertisement acted in good faith.

''(I) Whether the person who created the advertisement has been assessed a civil penalty under this provision within the previous 1-year period.

''(J) The scope and extent of any voluntary, subsequent remedial action by the person.

''(K) Such other matters, as justice may require.

''(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated such advertisement after incorporating

any comment received from the Secretary other than a recommendation subject to subsection 503B(c).

''(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

''(5) The Secretary may compromise, modify, remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

''(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period

beginning on the date the order making such assessments was issued.

''(7) On an annual basis, the Secretary shall report to the Congress on direct-to-consumer advertising and its ability to communicate to subsets of the general population, including elderly populations, children, and racial and ethnic minority communities. The Secretary shall establish a permanent advisory committee to advise the Secretary with respect to such report. The membership of the advisory committee shall consist of nationally recognized medical, advertising, and communications experts, including experts representing subsets of the general population. The members of the advisory committee shall serve without pay, but may receive travel expenses, including per diem in lieu of subsistence in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code. The advisory committee shall study direct-to-consumer advertising as it relates to increased access to health information and decreased health disparities for these populations. The annual report required by this paragraph shall recommend effective ways to present and disseminate information to these populations. Such report shall also make recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities, and medically

underserved populations in clinical drug trials and shall recommend best practice approaches for increasing the inclusion of such subsets of the general population. The Secretary shall submit the first annual report under this paragraph to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives not later than 18 months after the advisory committee has been convened by the Secretary.

''(8) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

''(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

''(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such

an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.''.