

making ourselves easily seduced by arguments of drill, drill, drill, with oil companies having record profits and with, of course, the people, our folks, all of us, having to endure \$3 a gallon gasoline.

In an ideal world, you could say that you could do both—yes, in an ideal world. But this isn't an ideal world. This is a world in which the policy has always been drill, drill, drill. We have to break that policy. We have to start on things just like this proposal which is another part of the drill strategy of this administration. Only then are we going to protect our national security and only then are we going to protect our national economy by shifting to other fuels and to vehicles of which we easily have the technology now to get 40 miles per gallon on the fleet average instead of 27 miles per gallon on the fleet average.

You can imagine, if we can do that, instead of relying on a plan to drill for more oil that is not going to become available for another 10 years—if we will change the policy right now, which will have an immediate effect, starting tomorrow, on our consumption of oil—then, only then, will America start to move on a path truly toward energy independence.

Madam President, I yield the floor.

#### CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is now closed.

#### PRESCRIPTION DRUG USER FEE AMENDMENTS OF 2007

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to the consideration of S. 1082, which the clerk will report by title.

The assistant legislative clerk read as follows:

A bill (S. 1082) to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes.

The Senate proceeded to consider the bill, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment to strike all after the enacting clause and insert in lieu thereof the following:

##### SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Administration Revitalization Act".

##### TITLE I—PRESCRIPTION DRUG USER FEES

##### SEC. 101. SHORT TITLE; REFERENCES IN TITLE.

(a) SHORT TITLE.—This title may be cited as the "Prescription Drug User Fee Amendments of 2007".

(b) REFERENCES IN TITLE.—Except as otherwise specified, whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

##### SEC. 102. DRUG FEES.

Section 735 (21 U.S.C. 379g) is amended—

(1) by striking the section designation and all that follows through "For purposes of this subchapter:" and inserting the following:

##### "SEC. 735. DRUG FEES.

"(a) PURPOSE.—It is the purpose of this part that the fees authorized under this part be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety, as set forth in the goals identified for purposes of this part in the letters from the Secretary to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

##### "(b) REPORTS.—

"(1) PERFORMANCE REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in subsection (a) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

"(2) FISCAL REPORT.—For fiscal years 2008 through 2012, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and 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 on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

"(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet website of the Food and Drug Administration.

##### "(c) REAUTHORIZATION.—

"(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year 2012, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

"(A) the Committee on Energy and Commerce of the House of Representatives;

"(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

"(C) scientific and academic experts;

"(D) health care professionals;

"(E) representatives of patient and consumer advocacy groups; and

"(F) the regulated industry.

"(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

"(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

"(B) publish such recommendations in the Federal Register;

"(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

"(D) hold a meeting at which the public may present its views on such recommendations; and

"(E) after consideration of such public views and comments, revise such recommendations as necessary.

"(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

"(d) DEFINITIONS.—For purposes of this part:—

(2) in subsection (d)—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking "505(b)(1)," and inserting "505(b), or";

(ii) by striking subparagraph (B);

(iii) by redesignating subparagraph (C) as subparagraph (B); and

(iv) in the matter following subparagraph (B), as so redesignated, by striking "subparagraph (C)" and inserting "subparagraph (B)";

(B) in paragraph (3)(C), by—

(i) striking "the list" and inserting "the list (not including the discontinued section of such list)"; and

(ii) striking "a list" and inserting "a list (not including the discontinued section of such a list)";

(C) in paragraph (4), by inserting before the period at the end the following: "(such as capsules, tablets, and lyophilized products before reconstitution)";

(D) by amending paragraph (6)(F) to read as follows:

"(F) In the case of drugs approved under human drug applications or supplements, postmarket safety activities, including—

"(i) collecting, developing, and reviewing safety information on approved drugs (including adverse event reports);

"(ii) developing and using improved adverse event data collection systems (including information technology systems); and

"(iii) developing and using improved analytical tools to assess potential safety problems (including by accessing external data bases).";

(E) in paragraph (8)—

(i) by striking "April of the preceding fiscal year" and inserting "October of the preceding fiscal year"; and

(ii) by striking "April 1997" and inserting "October 1996";

(F) by redesignating paragraph (9) as paragraph (10); and

(G) by inserting after paragraph (8) the following:

"(9) The term 'person' includes an affiliate of such person."

##### SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) in the matter preceding paragraph (1), by striking "2003" and inserting "2008";

(2) in paragraph (1)—

(A) in subparagraph (D)—

(i) in the heading, by inserting "OR WITHDRAWN BEFORE FILING" after "REFUND OF FEE IF APPLICATION REFUSED FOR FILING"; and

(ii) by inserting before the period at the end the following: "or withdrawn without a waiver before filing";

(B) by redesignating subparagraphs (E) and (F) as subparagraphs (F) and (G), respectively; and

(C) by inserting after subparagraph (D) the following:

"(E) FEE FOR APPLICATION PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—An application or supplement that has been refused for filing or that was withdrawn before filing, if filed under protest or resubmitted, shall be subject to the fee under subparagraph (A) (unless an exception under subparagraph (C) or (F) applies or the fee is waived or reduced under subsection (d)), without regard to previous payment of such a fee and the refund of 75 percent of that fee under subparagraph (D)."; and