something important to keep us safe. We have to take that information just that seriously.

In the lead-up to the war in Iraq, we were given these briefings by members of the Bush administration about why they were going to invade. I was not in that room and listen day after day to hours and hours of testimony. What I heard then has now been declassified, so we can speak of it openly, but at the time, we couldn’t. It was classified information and cannot be disclosed. As I listened to the administration debating one another about whether there was a potential for nuclear weapons or whether there were weapons of mass destruction, it became obvious to me that even within the administration there were serious doubts about some of the things which were being told to the American people. It troubled me. I said as much on the floor last week and say it again this week.

It is interesting, after having said that, one of the more ultraconservative publications, the Washington Times, has been critical of me for not disclosing classified information. Senator Nelson knows what I am talking about. He made a speech out to the newspapers and said: The Bush administration is in a battle within its own ranks as to whether this is true, you can imagine the next morning’s headline: “Durbin Discloses Classified Information.” I couldn’t do it. None of us could from that committee.

I accept the challenge from these ultraconservative publications and some of their blogs. I think I did the only thing I could do. With my conscience and with my own knowledge, I voted against this war, feeling at the time that it was a mistake for us to go forward. I still feel it was a mistake. Now we have to do something to turn that around. We have to start bringing our soldiers home.

I hope that when the President has a chance to veto this bill or sign it tomorrow, he will stop and think for a moment. If he fails to sign this bill, he will, unfortunately, endanger the lives of American soldiers who are wedded to his failed policy in Iraq. These fine men and women in uniform are the very best in America. They are doing their duty. They didn’t write this policy. It was written by the Commander in Chief and those who work for him. They will go into battle as instructed and risk their lives day in and day out. But we know, with 3,351 dead and no end in sight, we have to move forward.

When the President vetoes this bill, if he chooses to make that decision, he will be vetoing billions of dollars for National Guard equipment that we added to his request. He will be vetoing billions of dollars for military hospitals so we don’t have the scandal we had at Walter Reed a few weeks ago. He will be vetoing billions of dollars for us to put into veterans hospitals to take care of returning wounded soldiers. He will be vetoing billions of dollars for Hurricane Katrina relief that is long overdue. The President has a chance in signing this bill to not only move us in an orderly manner to bringing American troops home but serving so many other important needs for this country. I hope he won’t just instinctively and reflexively veto the bill. I hope he will consider that it is time for change and it is time for a new direction.

Mr. Nelson of Florida. Madam President, I commend my colleague from Illinois for the very cogent and heartfelt plea he has made that this Government function as it should between the three branches and that the appropriations process is one which is joined between the executive branch and the legislative branch. It was never intended to be all one way or not. Yet that is what publicly has been insisted on by the White House on this Iraq funding bill. It is expected that the President is going to veto this legislation. Then the question is, Are we going to be able to have a meeting of the minds? Can we have a little bit less partisanship, with the help of this Senator and others, come let us reason together? It is my hope that we will see more of that.

EXPANSION OF DRILLING

Mr. Nelson of Florida. Madam President, I rise to speak to the Senate because there is another thing the executive branch of Government has done today; that is, the Secretary of the Interior has announced a vast new expansion of drilling off of the continental United States. The area proposed for lease sale for oil and gas production and drilling that is acceptable is the area we negotiated in the legislation we passed last year, which is lease sale 181 in the Gulf of Mexico and part of the eastern Gulf of Mexico. Members will recall that this has been a 6-year struggle, of which this Senator from Florida actually had to engage in a filibuster in 2006 to protect the interests of my State, as well as the interests of the U.S. military, and finally prevailed in that protection in 2006, when we agreed to an area that could be drilled, but it was kept far from the coast of Florida and away from the major drilling area, which is the largest testing and training area in the world for our military. Why that? Because where we are testing sophisticated new weapons systems and where there is live ordnance involved covering a vast array of space, you simply cannot have oil rigs on the surface of the water below where all of this testing utilizing new ordnance is going on.

So what the Secretary of the Interior has proposed is some exploration in those areas which was approved last year, which was approved with this Senator’s consent because we protected the financial, economic interests of Florida, keeping the oil drilling away from our precious, sugary, white-sand beaches, which spawn a $52 billion-a-year tourism industry, keeping it away from the bays and estuaries that are so necessary to the ongoing marine life, and at the same time protecting the U.S. military which needs live ordnance to test its weapons tested so they are ready to go in case they are needed.

The proposal today also includes other areas off the continental United States, namely, the waters off of Virginia, 50 miles off the shore of Virginia. I would think the States of South Carolina and North Carolina ought to have something to say about that. I would think the State of Delaware or the State of New Jersey ought to have something to say about that because the wind and wave action doesn’t just keep a potential oil spill right off of Virginia, even if Virginia wanted that drilling 50 miles off of its coast. There is a major tourism industry built on the beauty of those beaches in North Carolina as well as the beaches of Delaware and New Jersey, not to even speak of the beaches of South Carolina.

The other part the Secretary of the Interior is proposing is four different areas off the coast of Alaska. We certainly remember the concerns, which were valid concerns, as a result of the Exxon Valdez disaster decades ago. But my argument against this proposal by the Secretary of the Interior goes far beyond those valid concerns I have just mentioned. It goes to the heart of the matter of national security and protection of the national economy; that is, we have an economy and a defense posture that puts us in the position today of being reliant on foreign oil to the tune of 60 percent of our daily consumption of oil coming from foreign shores in places such as the Persian Gulf region, Nigeria, and Venezuela, three parts of the world that are not necessarily stable and of which Venezuela— you have had some difficulty we have had with the President of Venezuela, who continues to threaten us in the areas of oil. We have an oil demand crisis today. The United States has 3 percent of the world’s oil reserves, but the United States consumes 25 percent of the world’s oil production. It doesn’t take a mathematical genius to figure out that you can’t drill your way out of the problem. Valid concerns I have is the problem of dependence on foreign oil, all the time...
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 is the bill that we 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 assessed under this part be dedicated toward expediting the drug development process, the process for the review of human drug applications, and postmarket drug safety, and to achieve 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 subparagraph (A) of subsection (a) of section 735 (21 U.S.C. 379g(a)) and the Federal Register;

(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) address all public views and comments, revise such recommendations as necessary.

“(2) 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:

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking “505(b)(1),” and inserting “505(b)(1), or”;

(ii) by striking subparagraph (B); and

(B) in paragraph (2), 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)”;

(2) in subsection (d)—

(A) in paragraph (1)—

(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”;

(B) by redesigning paragraph (9) as paragraph (10); and

(C) by inserting after paragraph (6) the following:

“(9) The term ‘person’ includes an affiliate of such person.”.

SEC. 103. AUTHORITY TO AUTHORIZE 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), by redesigning paragraph (D) as subparagraph (E); and

(B) in the heading, by inserting “OR WITHDRAWN BEFORE FILING” after “REFUND OF FEE IF APPLICATION REFUSED FOR FILING”;

(3) by inserting before the period at the end of subparagraph (E) the following:

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

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

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

(E) by redesigning paragraphs (9) and (10) as paragraphs (9) and (10); and

(F) by redesigning paragraphs (E) and (F) as paragraphs (E) and (F), respectively; and

(G) by inserting after paragraph (6) the following:

“(9) The term ‘person’ includes an affiliate of such person.”.

SEC. 104. REPORTS.

SEC. 105. AUTHORITY TO USE DRUG FEES.

SEC. 106. AUTHORITY TO REauthorize DRUG FEES.

SEC. 107. AUTHORITY TO USE DRUG FEES.

SEC. 108. AUTHORITY TO USE DRUG FEES.

SEC. 109. AUTHORITY TO USE DRUG FEES.

SEC. 110. AUTHORITY TO USE DRUG FEES.

SEC. 111. AUTHORITY TO USE DRUG FEES.

SEC. 112. AUTHORITY TO USE DRUG FEES.

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CONGRESSIONAL RECORD—SENATE

April 30, 2007