

Working with President Bush, we have strived to make our homeland more secure and fight the global war against terror. In addition to the funds approved in the budget, the \$80 billion supplemental appropriations bill, passed in April, not only helped pay for the cost of the Iraq campaign, but it provided funds to protect our own borders as well.

In what may someday, I believe, be considered our most far-reaching initiative, Congress has approved—and the President, next Tuesday, will sign—a 5-year, \$15 billion commitment to combat the global spread of that deadly HIV/AIDS virus—a virus we knew nothing about 25 years ago, a virus that represents, in the pandemic that has ensued, the greatest public health challenge of our time, killing more than 23 million people, infecting more than 40 million people alive today, ultimately killing, in all likelihood—even if we discovered a vaccine today—another 60 million people over the next 20 to 30 years.

But now, because of the action of this body, following the leadership of the President of the United States, working hand in hand with the House of Representatives, America is now—and proudly so—the global leader in HIV/AIDS funding and has brought the lamp of hope to millions of people threatened by this devastating disease.

I have been privileged, as a physician, to be able to perform medical mission work in various places around the world, but specifically in Africa, and I can tell you how desperately—how desperately—needed is this leadership, is this funding. This legislation is a manifestation of the caring spirit—that spirit of compassion—that spirit of caring and compassion on behalf of the United States of America. It shows our commitment to the less fortunate in the world and that we are, indeed, a nation of moral courage.

In foreign policy, we supported the Moscow Treaty, which calls for the most dramatic reduction of nuclear weapons between Russia and America in history. Under the terms of this treaty, the number of nuclear weapons will be lower than at any point since 1954.

Also in foreign policy, we supported the expansion of NATO, bringing seven new democracies into the alliance: Bulgaria, Estonia, Latvia, Lithuania, Romania, Slovakia, and Slovenia.

At home, we have not only acted to spur the economy to create jobs but we have looked after those who do not have a job but who are looking for a job. Today, again, just a few hours ago, we once again extended the unemployment insurance to ensure that families will have the economic support they need while they continue to look for a job.

On issues here at home, we voted to end that abhorrent practice of partial-birth abortion. We approved the CARE Act to encourage charitable giving to charitable and nonprofit organizations.

These are just a few of the many accomplishments of this Congress. I could go on: AMBER Alert, air cargo security, a national "Do Not Call" list to stymie unwanted phone solicitors, military tax relief—and the list continues.

I mention all this because as we focus on our day-to-day activities, it is rare that we look at that large picture from 30,000 feet as to what we have accomplished. And, indeed, we have done much. It has been a productive 5 months. It has not always been a smooth road, but in a closely divided Senate few paths are easy. It takes working in a bipartisan way.

Before I close, I do want to say, as part of a new leadership team on the Republican side of the aisle, it has been extremely important for me to have developed a positive working relationship with the other side of the aisle, both in terms of leadership and really throughout the Senate. I do want to thank the corresponding leaders on the other side of the aisle for working with me in a bipartisan way as we have set out this agenda and as, indeed, we have completed the agenda that has been set out.

I do hope my colleagues on both sides of the aisle enjoy the break and come back from their time refreshed because we have a lot of work to do. On the top of that list will be to bring our Medicare Program up to date so we can include prescription drugs as part of the armamentarium for health care delivery and health care security for our seniors. That is going to require bipartisan cooperation if we are truly to accomplish what I know we will accomplish, what we can accomplish, and what our seniors deserve; that is, a strengthening and improvement of our Medicare Program.

We will do that the month we come back. It will be hard work, but in the end I know we can approve a plan to improve the current system, to strengthen it, to guarantee all seniors access to prescription drugs in a plan that can best meet their health care needs.

I do want to thank my own Republican leadership team. We heard a few moments ago from my colleague, the assistant majority leader, our whip, Senator MCCONNELL. Our working relationship has been such that it excites me, as we look to the future, again, having worked hand in hand to address these many issues in the past.

As our colleagues go home, I know they will all be paying tribute to the men and women who have returned to their own communities after representing the best that we have in the United States of America, as they have fought for freedom and democracy—those freedoms that we are able to enjoy each and every day.

We have done much, but we have much to do.

EXECUTIVE SESSION

EXECUTIVE CALENDAR

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate immediately proceed to executive session to consider the following nominations on today's Executive Calendar: Calendar Nos. 134, 176, 177, 206 through 217, and nominations on the Secretary's desk in the Army, Foreign Service, Marine Corps, and Navy.

I further ask unanimous consent that the nominations be confirmed en bloc, the motions to reconsider be laid upon the table, and the President be immediately notified of the Senate's action.

The PRESIDENT pro tempore. Without objection, it is so ordered.

The nominations considered and confirmed are as follows:

DEPARTMENT OF EDUCATION

Karen Johnson, of Virginia, to be Assistant Secretary for Legislation and Congressional Affairs, Department of Education.

RAILROAD RETIREMENT BOARD

Michael Schwartz, of Illinois, to be a Member of the Railroad Retirement Board for a term expiring August 28, 2007.

NATIONAL MUSEUM SERVICES BOARD

John E. Buchanan, Jr., of Oregon, to be a Member of the National Museum Services Board for a term expiring December 6, 2006.

ARMY

The following named officer for appointment in the United States Army to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Maj. Gen. Jerry L. Sinn, 7044

The following named officer for appointment in the United States Army to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Maj. Gen. Steven W. Boutelle, 1030

The following named officer for appointment in the United States Army to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Maj. Gen. Ricardo S. Sanchez, 9260

The following named officer for appointment in the United States Army to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Maj. Gen. Anthony R. Jones, 7571

The following named officer for appointment in the United States Army to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be lieutenant general

Maj. Gen. John R. Vines, 5345

The following named officer for appointment in the Reserve of the Army to the grade indicated under title 10, U.S.C., section 12203:

To be major general

Brig. Gen. Emile P. Bataille, 3318

The following named officer for appointment as the Chief of Chaplains, United

States Army and for appointment to the grade indicated under title 10, U.S.C., section 3036:

To be major general

Brig. Gen. David H. Hicks, 1012

The following Army National Guard of the United States officer for appointment in the Reserve of the Army to the grade indicated under title 10, U.S.C., section 12203:

To be major general

Brig. Gen. Brian L. Tarbet, 0965

The following named officer for appointment in the United States Army to the grade indicated under title 10, U.S.C., section 624:

To be brigadier general

Chaplain (Col.) Jerome A. Haberek, 0306

NAVY

The following named officer for appointment in the United States Navy to the grade indicated while assigned to a position of importance and responsibility under title 10, U.S.C., section 601:

To be vice admiral

Rear Adm. Michael J. McCabe, 0987

The following named officer for appointment in the United States Naval Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be rear admiral

Rear Adm. (lh) John P. Debbout, 9101

The following named officer for appointment in the United States Naval Reserve to the grade indicated under title 10, U.S.C., section 12203:

To be rear admiral (lower half)

Capt. Craig O. McDonald, 8124

ARMY

PN283 Army nominations (13) beginning CHARLES R BAILEY, and ending DAVID W SMARTT, which nominations were received by the Senate and appeared in the Congressional Record of January 29, 2003

FOREIGN SERVICE

PN356-1 Foreign Service nominations (23) beginning Anne H. Aarnes, and ending Edward W. Birgells, which nominations were received by the Senate and appeared in the Congressional Record of February 25, 2003

MARINE CORPS

PN637 Marine Corps nominations (871) beginning BENJAMIN T ACKISON, and ending ROBERT B. ZWAYER, which nominations were received by the Senate and appeared in the Congressional Record of May 14, 2003

NAVY

PN588 Navy nominations (39) beginning AMADO F. ABAYA, and ending SHANNON J. WELLS, which nominations were received by the Senate and appeared in the Congressional Record of May 1, 2003

NOMINATIONS DISCHARGED

Mr. FRIST. Mr. President, in executive session, I ask unanimous consent that the HELP Committee be discharged from further consideration of the following nominations for the National Science Board: Steven Beering, PN44; Ray Bowen, PN46; Elizabeth Hoffman, PN50. I further ask unanimous consent that the Senate proceed to their consideration, the nominations be confirmed, the motions to reconsider be laid upon the table, the President be immediately notified of the Senate's action, and the Senate resume legislative session.

The PRESIDENT pro tempore. Without objection, it is so ordered.

The nominations considered and confirmed are as follows:

NATIONAL SCIENCE BOARD

Steven C. Beering, of Indiana, to be a Member of the National Science Board, National Science Foundation, for the remainder of the term expiring May 10, 2004.

Ray M. Bowen, of Texas, to be a Member of the National Science Board, National Science Foundation, for a term expiring May 10, 2008.

Elizabeth Hoffman, of Colorado, to be a Member of the National Science Board, National Science Foundation, for a term expiring May 10, 2008.

LEGISLATIVE SESSION

The PRESIDENT pro tempore. Under the previous order, the Senate will return to legislative session.

ANIMAL DRUG USER FEE ACT OF 2003

Mr. FRIST. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 104, S. 313.

The PRESIDENT pro tempore. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 313) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Health, Education, Labor, and Pensions, with amendments, as follows:

[Strike the parts shown in black brackets and insert the parts shown in italic.]

S. 313

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 "Animal Drug User Fee Act of 2003".

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of new animal drug applications.

(3) The fees authorized by this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 3. FEES RELATING TO ANIMAL DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following part:

["PART 3—FEES RELATING TO ANIMAL DRUGS]

["PART 4—FEES RELATING TO ANIMAL DRUGS]

["SEC. 738. DEFINITIONS.

["For purposes of this subchapter:"]

["SEC. 739. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) DEFINITIONS.—For purposes of this subchapter:

"(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

"(2) The term 'supplemental animal drug application' means—

"(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

"(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

"(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

"(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

"(5) The term 'investigational animal drug submission' means—

"(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

"(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

"(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under Section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

"(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

"(8) The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

"(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

"(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational