

There was no objection.

MESSAGE FROM THE SENATE

A message from the Senate by Ms. Curtis, one of its clerks, announced that the Senate has passed without amendment bills of the House of the following titles:

H.R. 38. An act to designate a portion of the White Salmon River as a component of the National Wild and Scenic Rivers System.

H.R. 481. An act to further the purposes of the Sand Creek Massacre National Historic Site Establishment Act of 2000.

H.R. 541. An act to direct the Secretary of Agriculture to convey certain land to Lander County, Nevada, and the Secretary of the Interior to convey certain land to Eureka County, Nevada, for continued use as cemeteries.

H.R. 794. An act to correct the south boundary of the Colorado River Indian Reservation in Arizona, and for other purposes.

H.R. 1046. An act to authorize the Secretary of the Interior to contract with the city of Cheyenne, Wyoming, for the storage of the city's water in the Kendrick Project, Wyoming.

The message also announced that pursuant to Public Law 105-292, as amended by Public Law 106-55, and as further amended by Public Law 107-228, the Chair, on behalf of the President pro tempore, upon the recommendation of the Majority Leader, appoints the following individual to the United States Commission on International Religious Freedom:

Dr. Richard D. Land of Tennessee, for a term of two years (July 25, 2005–July 24, 2007).

MEDICAL DEVICE USER FEE STABILIZATION ACT OF 2005

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that the Committee on Energy and Commerce be discharged from further consideration of the bill (H.R. 3423) to amend the Federal Food, Drug, and Cosmetic Act with respect to medical device user fees, and ask for its immediate consideration in the House.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Georgia?

Ms. ESHOO. Mr. Speaker, reserving the right to object, and I do not intend to object, I yield to the gentleman from Georgia to explain his unanimous consent request.

Mr. DEAL of Georgia. Mr. Speaker, I thank the gentlewoman from California for yielding.

In 2002, Congress passed the Medical Device User Fee and Modernization Act, and it allowed the Food and Drug Administration to collect user fees from manufacturers who would submit applications for medical devices. This legislation was in response to the fact that there were many applications for new devices, and we were falling behind in the approval process.

With the passage of this legislation, the FDA was authorized to add addi-

tional personnel, and have done so and have speeded up the approval time for these new devices.

However, the legislation provided that Congress had to set and reach certain marks of appropriations for fiscal year 2003 and through 2005 for this program to continue; and in the event we did not reach those targeted appropriation levels, then the program would expire at the end of this September. Unfortunately, Congress did not meet those targeted appropriation levels.

□ 1845

Since Congress did not reach the targeted appropriations required to keep the program in place, this user fee program will cease at the end of September, and the FDA will be required to start sending out notices of termination.

So this legislation is essential to keep this very successful program in place, and it will allow us to retain the medical personnel who are working and approving device applications in a much more speedy and rapid fashion than they would have been able to do without the user fee being in place.

Mr. Speaker, that is the purpose of this legislation is to extend the program.

Ms. ESHOO. Further reserving the right to object, Mr. Speaker, I would like to make a few comments about H.R. 3423, the Medical Device User Fee Stabilization Act, which is being considered today. I am the lead Democrat, along with my colleague, on the committee, the gentleman from Pennsylvania (Mr. PITTS), who is also my neighbor across the hall from me in the Cannon House Office Building.

In 2002, former Representative GREENWOOD and myself introduced the Medical Devices User Fee Modernization Act. It passed the House unanimously, and it was signed into law by the President. The goal of the bill was to eliminate FDA's backlog in approving new medical devices so that doctors and patients could more quickly benefit from them.

While the law required device manufacturers to contribute toward FDA's cost in evaluating and approving new devices, the program was contingent on the Federal Government paying its fair share. If Federal funding did not reach the trigger level, the program would be eliminated. This legislation fixes the trigger so that the user fee program can continue.

Specifically the bill will reduce the rate of user fee increases to the single-digit range for the remaining 2 years of the program. It will help small medical device companies, which is very important, because the small companies operate differently under different circumstances than the larger ones. The small device companies, it helps them to afford the cost to submit new medical devices for FDA review and approval. And finally, the bill will enhance labeling and tracking of reprocessed single-use devices. So this legis-

lation before us only authorizes the program for 2 more years.

It really is a significant accomplishment, and it allows us to now concentrate on making the device approval process even better in 2007. And I know that both of my colleagues, both the gentleman from Georgia (Mr. DEAL), the subcommittee chairman, as well as my colleague, the gentleman from Pennsylvania (Mr. PITTS), are committed to that.

I want to thank Ryan Long with Chairman BARTON's staff; John Ford, who is seated here to my left, with Ranking Member DINGELL's staff; and for Vanessa Kramer of my staff who has worked so hard on this. And it is because of all of them and their hard work that this bill has successfully reached the floor today.

Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER pro tempore (Mr. HAYES) Is there objection to the request of the gentleman from Georgia?

There was no objection.

The Clerk read the bill, as follows:

H.R. 3423

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 "Medical Device User Fee Stabilization Act of 2005".

SEC. 2. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) DEVICE USER FEES.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in subsection (b)—
(A) after "2004;" , by inserting "and"; and
(B) by striking "2005;" and all that follows through "2007" and inserting "2005";

(2) in subsection (c)—
(A) by striking the heading and inserting "Annual Fee Setting.—";

(B) by striking paragraphs (1), (2), (3), and (4);

(C) by redesignating paragraphs (5) and (6) as paragraphs (1) and (2), respectively;

(D) in paragraph (1), as so redesignated, by—

(i) striking the heading and inserting "**IN GENERAL.**—";

(ii) striking "establish, for the next fiscal year, and" and all that follows through "the fees" and inserting "publish in the Federal Register fees under subsection (a). The fees";

(iii) striking "2003" and inserting "2006"; and

(iv) striking "\$154,000." and inserting "\$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of \$281,600."; and

(E) by adding at the end the following:

“(3) SUPPLEMENT.—

“(A) IN GENERAL.—For fiscal years 2006 and 2007, the Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of fiscal year 2008.

“(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on

Energy and Commerce and the Committee on Appropriations of the House of Representatives.”;

(3) in subsection (d)—

(A) in paragraph (1), by inserting after the first sentence the following: “For the purposes of this paragraph, the term ‘small business’ means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.”; and

(B) in paragraph (2)(A), by—

(i) striking “(i) **IN GENERAL.**—”;

(ii) striking “subsection,” and inserting “paragraph.”;

(iii) striking “\$30,000,000” and inserting “\$100,000,000”; and

(iv) striking clause (ii);

(4) in subsection (e)(2)(A), by striking “\$30,000,000” and inserting “\$100,000,000”;

(5) in subsection (g)(1)—

(A) in subparagraph (B)—

(i) by striking clause (i) and inserting the following:

“(i) For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is equal to or greater than \$205,720,000 multiplied by the adjustment factor applicable to the fiscal year.”; and

(ii) in clause (ii), by striking the matter preceding subclause (I) and inserting the following:

“(ii) For fiscal year 2005, if the amount so appropriated for such fiscal year, excluding the amount of fees appropriated for such fiscal year, is more than 1 percent less than the amount that applies under clause (i), the following applies:”;

(B) in subparagraph (C)—

(i) in the matter preceding clause (i), by—

(I) striking “2003 through” and inserting “2005 and”; and

(II) inserting “more than 1 percent” after “years, is”; and

(ii) in clause (ii), by striking “sum” and inserting “amount”; and

(C) in subparagraph (D)(i), by inserting “more than 1 percent” after “year, is”;

(6) in subsection (h)(3)—

(A) in subparagraph (C), by striking the semicolon and inserting “; and”; and

(B) by striking subparagraphs (D) and (E) and inserting the following:

“(D) such sums as may be necessary for each of fiscal years 2006 and 2007.”; and

(7) by striking “subsection (c)(5)” each place it appears and inserting “subsection (c)(1)”.

(b) **ANNUAL REPORTS.**—Section 103 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250 (116 Stat. 1600)) is amended—

(1) by striking “Beginning with” and inserting “(a) In General.—Beginning with”; and

(2) by adding at the end the following:

“(b) **ADDITIONAL INFORMATION.**—For fiscal years 2006 and 2007, the report described under subsection (a)(2) shall include—

“(1) information on the number of different types of applications and notifications, and the total amount of fees paid for each such type of application or notification, from businesses with gross receipts or sales from \$0 to \$100,000,000, with such businesses categorized in \$10,000,000 intervals; and

“(2) a certification by the Secretary that the amounts appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year and obligated by the Secretary for the performance of any function relating to devices that is not for the

process for the review of device applications, as defined in paragraph (5) of section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i), are not less than such amounts for fiscal year 2002 multiplied by the adjustment factor, as defined in paragraph (7) of such section 737.”.

(c) **MISBRANDED DEVICES.**—

(1) **IN GENERAL.**—Section 502(u) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(u)) is amended to read as follows:

“(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

“(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.”.

(2) **GUIDANCE.**—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance to identify circumstances in which the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, is not “prominent and conspicuous”, as used in section 502(u) of Federal Food, Drug, and Cosmetic Act (as amended by paragraph (1)).

(d) **EFFECTIVE DATE.**—Section 301(b) of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250 (116 Stat. 1616)), as amended by section 2(c) of Public Law 108-214 (118 Stat. 575), is amended to read as follows:

“(b) **EFFECTIVE DATE.**—Section 502(u) of the Federal Food, Drug, and Cosmetic Act (as amended by section 2(c) of the Medical Device User Fee Stabilization Act of 2005)—

“(1) shall be effective—

“(A) with respect to devices described under paragraph (1) of such section, 12 months after the date of enactment of the Medical Device User Fee Stabilization Act of 2005, or the date on which the original device first bears the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, whichever is later; and

“(B) with respect to devices described under paragraph (2) of such section 502(u), 12 months after such date of enactment; and

“(2) shall apply only to devices reprocessed and introduced or delivered for introduction in interstate commerce after such applicable effective date.”.

The bill was ordered to be engrossed and read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

GENERAL LEAVE

Mr. DEAL of Georgia. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks on H.R. 3423, the bill just passed.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Georgia?

There was no objection.

GENERAL LEAVE

Mr. TOM DAVIS of Virginia. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks, and include extraneous material on H.R. 22.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Virginia?

There was no objection.

POSTAL ACCOUNTABILITY AND ENHANCEMENT ACT

The SPEAKER pro tempore. Pursuant to House Resolution 380 and rule XVIII, the Chair declares the House in the Committee of the Whole House on the State of the Union for the consideration of the bill, H.R. 22.

□ 1850

IN THE COMMITTEE OF THE WHOLE

Accordingly, the House resolved itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 22) to reform the postal laws of the United States, with Mr. SIMPSON in the chair.

The Clerk read the title of the bill.

The CHAIRMAN. Pursuant to the rule, the bill is considered as having been read the first time.

Under the rule, the gentleman from Virginia (Mr. TOM DAVIS) and the gentleman from California (Mr. WAXMAN) each will control 30 minutes.

The Chair recognizes the gentleman from Virginia (Mr. TOM DAVIS).

Mr. TOM DAVIS of Virginia. Mr. Chairman, I yield 2 minutes to the gentleman from Indiana (Mr. BURTON), the former chairman of the Government Reform and Oversight Committee, who has played a lead role in moving this bill to where it is today, and spent 6 long years in the vineyards laboring on this when he was chairman of the committee.

Mr. BURTON of Indiana. Mr. Chairman, first of all, I want to congratulate the gentleman from New York (Mr. MCHUGH), who has done yeoman's service to the committee and to this government in fighting for a postal reform measure. He has just done a great job. I want to congratulate him on all of the hard work in bringing this thing to the floor.

I want to congratulate our chairman, the gentleman from Virginia (Mr. TOM DAVIS). We fought for, I think, 6 years when I was chairman to bring this bill to the floor and pass it, and, Mr. Chairman, I want to congratulate you on being able to get this thing to the floor.

I hope that we are successful in getting it not only through here, but through the Senate as well.

I want to congratulate the gentleman from Illinois (Mr. DAVIS), my good buddy, who has one of the best voices in the Congress. If I could talk like