Mr. Speaker, I ask the U.S. House of Representatives to join me in thanking Sheriff Lawrence "Lumpy" Leveille for his nearly 40 years of service to the people of St. Ignace, Mackinac County and to the State of Michigan and wish him well in his new position. Lawrence "Lumpy" Leveille's commitment to community and to justice has been a model of public service.

A TRIBUTE TO ELMER HAMILTON

HON. DAVID SCOTT

OF GEORGIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mr. SCOTT of Georgia. Mr. Speaker, I rise today in recognition of Mr. Elmer Hamilton, a civil-rights activist, a crusader for labor rights, a loving husband, and a caring father and grandfather. On August 20, 2005, Elmer will retire from a 45-year career in community and public relations and the organized labor movement.

Mr. Hamilton's life of service began in 1953 when he enlisted in the Navy, eventually serving as a machinist mate. After his military service, Elmer's commitment to civil rights led him to work on voter registration drives in Alabama and Mississippi and organize against racial discrimination in Georgia. He also served as a special assistant to Southern Christian Leadership Conference leader Ralph David Abernathy during his congressional bid.

Elmer's served in various community relations capacities in New York and South Carolina providing educational and job placement services to community members. At one point he served as a community organizer for the Brooklyn, NY, Borough President.

After moving to Georgia, Elmer worked in public transportation as a bus operator for MARTA, the Metro Atlanta Rapid Transit Authority. He became the president of the Amalgamated Transit Union, Local 732 where he negotiated contracts for over 3,000 transit employees from MARTA, Cobb County Transit, and Gwinnett County Transit. When he retires, he will also leave his post as a board member of the AFL–CIO representing the Coalition of Black Trade Unionists.

Mr. Speaker and colleagues, please join me, Elmer's wife, Peggy, his six children and two grandchildren in congratulating Elmer on a fulfilling career. Best wishes, Elmer, and enjoy your retirement.

MEDICAL DEVICE USER FEE STABILIZATION ACT OF 2005

SPEECH OF

HON. JOE BARTON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 26, 2005

Mr. BARTON of Texas. Mr. Speaker, on October 26, 2002, the Medical Device User Fee and Modernization Act, MDUFMA, was signed into law.

I. BACKGROUND AND NEED FOR LEGISLATION

MDUFMA amended the Federal Food Drug and Cosmetic Act, FFDCA, to authorize the Food and Drug Administration, FDA, to collect user fees from manufacturers who submit certain applications to market medical devices. The premise behind initiating a user fee program for medical devices was to provide for more timely and predictable review of medical device applications, as well as to make the necessary infrastructure investments required to conduct the review of increasingly complex medical device applications in the future in a timely and predictable fashion.

The FFDCA as amended by MDUFMA, authorizes FDA to collect user fees for certain medical device applications in FY 2006 and FY 2007 only if certain conditions are met. MDUFMA specifies that for FY 2006 fees may not be assessed if the total amounts appropriated for FY 2003 through FY 2005 for FDA's device and radiological health program did not meet certain targets. Appropriations for FY 2003 through FY 2005 for FDA's device and radiological health program were below the amount specified in MDUFMA. This legislation modifies those conditions, minimum appropriation levels for FY 2003 through FY 2005, to allow FDA to continue to collect user fees until October 1, 2007.

User fees make possible investments in information technology infrastructure and human capital, more comprehensive training for reviewers, greater use of experts in academia and the private sector, enhanced project management, increased guidance development, expanded participation in globalization and standards setting activities, and increased interaction with industry both before and during the application review process. As medical device applications become progressively more complex, this investment will become ever more necessary to keep up with performance standards that FDA has thus far been successful in meeting. Keeping the device review program on sound financial footing is essential to ensure timely and predictable review of medical device applications. Providing the device review program with sufficient resources to fulfill its mission is critical to ensure that patients have access to the latest and most effective technology.

The Committee also believes it is important to provide industry with predictable annual increases in application fees. Since the inception of MDUFMA, user fees for certain application types have increased dramatically from year to year. To address these concerns, H.R. 3423 will limit fee increases in FY 2006 and FY 2007 until MDUFMA sunsets on October 1, 2007. This legislation is designed to provide a transition until Congress reauthorizes the program in 2007. During deliberations on the reauthorization of the program the Committee on Energy and Commerce recognizes the need to consider comprehensive changes to the structure of the program to provide for stability and predictability in both application fees and fee revenues for companies that pay user fees and for the FDA.

II. ANALYSIS OF THE LEGISLATION

H.R. 3423 removes the requirement that the total amounts appropriated for FY 2003 through FY 2005 for FDA's device and radiological health program must meet levels specified in MDUFMA before FDA can collect user fees in FY 2006 and FY 2007. As a result, FDA will be able to collect user fees in FY 2006. To avoid similar problems in FY 2007, FDA may continue to collect user fees as long as appropriations are not more than 1 percent below the target amount.

This legislation also provides industry with greater predictability as to the amount by which fees will increase over the next two fiscal years. The fee rate for a premarket approval application (PMA) will increase by 8.5 percent in FY 2006 to $259,600 and by 8.5 percent in FY 2007 to $281,600. Small businesses will receive additional financial relief by expanding the definition of a small business to include entities that reported $100,000,000 or less of gross receipts or sales in their most recent Federal income tax return for a taxable year, except that the small business threshold for an entity to be eligible for a first time, full-fee waiver for a PMA application will remain at $30,000,000. For FY 2006 and FY 2007, FDA will report to Congress on the number of different applications and notifications, and the total amount of fees paid for each type, from businesses with gross receipts or sales at or below $100,000,000.

To provide FDA with a measure of financial security should fee revenues fall short of current projections, the agency may use unobligated carryover balances from fees collected in previous fiscal years if the following conditions are met: (1) Insufficient fee revenues are available in that fiscal year, (2) the agency maintains unobligated carryover balances of not less than one month of operating reserves for the first month of FY 2008, and (3) the agency sends a notice to the Committee on Health, Education, Labor, and Pensions, the Committee on Energy and Commerce, and the Committee on Appropriations of the United States Senate and the United States House of Representatives at least 14 days prior to using these funds. To ensure that funds are not directed away from device safety activities, FDA must certify that the amounts spent by the agency for salaries and expenses to perform device-related activities not pertaining to the review of applications are no less than the amounts spent on those functions in FY 2002 multiplied by the rate of inflation.

Section 301 of MDUFMA added a new subsection (u) to section 502 of the FFDCA that required devices or attachments to a device prominently and conspicuously to bear the name of the manufacturer of the original device or of the reprocessed device, if it was reprocessed, a generally recognized abbreviation of that entity, or a unique and generally recognized symbol identifying the manufacturer. This provision was intended to ensure that the manufacturer of the device, whether the original manufacturer or reprocessor, could be properly identified. In developing the original provisions of Section 301, the Committee believed it was important for device user facilities and the agency to have the ability to correctly identify the responsible party for a device when there is an adverse event associated with a device.

However, under the current language of Section 301, the FDA could waive the branding requirement if compliance is not feasible or compromises the reasonable assurance of safety or effectiveness of the device. For some devices it may be difficult to comply with the marking requirement due to their physical characteristics, such as size and composition. Even if the physical characteristics make it difficult to mark a device, the Committee believes it is important that every device have a mechanism to identify the manufacturer of the product when there is an adverse event.

Reporting of adverse events of medical devices by manufacturers and device user facilities is fundamental to the FDA's post-market

regulation of medical devices. Concerns have been raised that once a medical device is removed from its packaging and placed on a tray ready for use on a patient, physicians and nurses are likely to identify the device with the OEM. While medical device user facilities are required to report manufacturer information beyond the product labeling, the lack of specific labeling to identify devices has led to claims of underreporting of patient injuries and product malfunctions involving reprocessed devices. It is important to the Committee that device facilities are properly reporting the manufacturer responsible for the device. The Committee believes the effectiveness of the FDA's medical device reporting system is undermined when the agency does not receive proper information regarding the party responsible for the safety of the device, and that FDA should take steps to ensure it is in fact receiving such information.

The Committee has carefully considered the concerns about section 502(u) as originally adopted and has amended it to provide for a more comprehensive provision that does not allow waivers to branding requirements. Section 502(u) now focuses on reprocessed single-use devices. Any single-use device reprocessed from an original device that the original manufacturer has prominently and conspicuously marked (which may be accomplished through marking an attachment to the device) with its name, a generally recognized abbreviation of its name, or a unique and a generally recognized symbol for it, must be prominently and conspicuously marked (which may be accomplished through marking an attachment to the device) with the reprocessor's name, a generally recognized abbreviation of its name, or a unique and a generally recognized symbol for it.

H.R. 3423, while limiting compliance to reprocessed devices, allows such a device to satisfy this labeling requirement by using a detachable label that identifies the reprocessor if the original device did not prominently and conspicuously bear the name of, abbreviation of, or symbol for the manufacturer. Under this new provision, there will be no possibility of a waiver of the branding requirements, and every device should be traceable back to the responsible party. The Committee recognizes the benefits of the detachable label can only be recognized if the labels are used as intended by being affixed to a patient's medical records. The Committee believes the amended provision will strengthen the medical device reporting system. However, the Committee will continue to closely monitor the use of detachable labels by device user facilities to ensure that the intent of the provision is realized.

Although the Committee encourages the use of these detachable labels on all reprocessed devices, the use of such a detachable label on a reprocessed single-use device that is prominently and conspicuously marked by the original manufacturer is not a legitimate substitute for the requirement of section 502(u)(l) that the reprocessor directly mark the reprocessed device or an attachment to it. In order to avoid erroneous identification of the original manufacturer as the source of a reprocessed device and to ensure that the MDR system provides FDA with the information it needs with respect to reprocessed devices to adequately protect patients, the identification of the reprocessor by means of a detachable package label is strictly limited to those circumstances where the device itself, or an attachment thereto, does not prominently and conspicuously reflect the identity of the original manufacturer.

The effective date of this provision is 12 months from the date of enactment. In the interim, the FDA is charged with developing guidance to identify circumstances where the original equipment manufacturer's marking is not prominent and conspicuous. Section 519 of the FFDCA, and FDA's Medical Device Reporting (MDR) regulations, require manufacturers to report patient injuries and product malfunctions to FDA, and device user facilities to report these adverse events to FDA and manufacturers. The Committee believes that the requirements of section 502(u), as amended, will operate to improve this post-market surveillance system, and thus patient safety. It is the intention of the Committee that upon the effective date of this provision device user facilities should in every instance be able to determine the proper party responsible for this device.

For those devices that already contain a marking by the original equipment manufacturer the Committee believes that companies currently reprocessing devices should begin to place identifiable markings as soon as possible. The Committee also believes the 12-month effective date should give ample opportunity for the regulated companies to comply with this provision, and the Committee expects the FDA will enforce this provision on the date it becomes effective.

Section 1. Short title.

This section provides the short title of the bill, the ''Medical Device User Fee Stabilization Act of 2005.''

Section 2. Amendments to the Federal Food, Drug and Cosmetic Act.

This section amends Section 738 of the FFDCA (Authority to Assess and Use Device Fees), Section 103 of MDUFMA, Section 502(u) of the FFDCA (Misbranded Devices), and Section 301(b) of MDUFMA.

Subsection (a) addresses amendments to the device user fee program authorized in Section 738 of the FFDCA. Subsection (a)(1) eliminates the statutory fee revenue targets for device user fees in fiscal years 2006 and 2007 in section 738(b).

Subsection (a)(2) eliminates the inflationary, workload, compensating, and final year adjustments previously used in annual fee-setting calculations, as provided for in Section 738(c). Subsection (a)(2) also sets the pre-market application user fee at $259,600 for fiscal year 2006 and $281,600 for fiscal year 2007, which is an 8.5 percent increase each year (fees for other device submissions are then determined as a percentage of the pre-market application fee, as provided generally in section 738(a)(2)(A)). Finally, subsection (a)(2) also amends Section 738(c) to permit FDA to use up to two-thirds of fees carried over from previous years to supplement fee revenues in fiscal years 2006 and 2007. FDA must notify Congress if it intends to use these carryover balances.

Subsection (a)(3) amends section 738(d) to clarify that the small business threshold for the purposes of a first-time waiver of the fee on a pre-market approval application or a pre-market report remains at $30 million, as under current law. It raises the small business threshold from $30 million to $100 million for the purposes of fee reductions on all other applications, reports, and supplements. Subsection (a)(3) also eliminates the ability of the FDA to reset this new small business threshold if user fee revenues are reduced by 16 percent because of the small business fee reduction. Subsection (a)(4) amends section 738(e) to raise the small business threshold from $30 million to $100 million for the purposes of fee reductions on pre-market notifications.

Subsection (a)(5) amends section 738(g) to eliminate the ''trigger'' requirement of additional appropriations in the FY 2003 and FY 2004 for FDA to be able to collect user fees in FY 2006 and FY 2007. It also builds in a 1 percent tolerance on the appropriations trigger for FY 2006 and FY 2007, to cushion against possible across-the-board rescission in the appropriations process for those years, which would lead to accidental termination of the program.

Subsection (a)(6) eliminates the statutory authorization targets for FY 2006 and FY 2007, and subsection (a)(7) makes a conforming amendment throughout Section 738.

Subsection (b) amends section 103 of MDUFMA to require additional information in FDA's medical device user fee program annual reports for FY 2006 and FY 2007 on the number and types of applications received by the size of small business up to the new small business threshold of $100 million, and to require a certification by the Secretary of Health and Human Services in the annual report that appropriated funds obligated for other purposes relating to medical devices are not diverted for device review.

Subsection (c)(1) amends section 502(u) of the FFDCA to address the marking and tracking of reprocessed medical devices intended for single-use by the original manufacturer. Section 502(u) as amended requires reprocessors to mark a reprocessed device if the original manufacturer has marked the device. If the original manufacturer does not mark the device, the reprocessor must still mark the device, but has more flexibility in how to mark the device, such as by using a detachable label on the package of the device that is intended to be placed in the medical record of the patient on whom the device is used.

Subsection (c)(2) requires FDA to issue a guidance document no later than 180 days after the act becomes effective to address compliance with section 502(u) in circumstances where an original manufacturer has not marked the original device prominently and conspicuously.

Subsection (d) amends section 301(b) of MDUFMA to make the amendment made by subsection (c)(1) to section 502(u) of the FFDCA effective 12 months after the date of enactment of the act, or 12 months after the original manufacturer has first marked its device, if that is later.

CONGRATULATIONS DR. MARC LIEBERMAN ON TEN YEARS OF TIBET VISION PROJECT

TOM LANTOS
OF CALIFORNIA
IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mr. LANTOS. Mr. Speaker, I rise today to celebrate with Dr. Marc F. Lieberman the tenth