

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)(1) 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 cir-

cumstances 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 FFDCFA, 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 FFDCFA (Authority to Assess and Use Device Fees), Section 103 of MDUFMA, Section 502(u) of the FFDCFA (Misbranded Devices), and Section 301(b) of MDUFMA.

Subsection (a) addresses amendments to the device user fee program authorized in Section 738 of the FFDCFA. 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 FFDCFA to address the marking and tracking of reprocessed medical devices intended for single-use by the original manufacturer. Section 502(u) as amended requires reproprocessors 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 FFDCFA 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

anniversary of his humanitarian work in Tibet. Since 1995, Dr. Lieberman, an ophthalmologist and clinical professor at University of California at San Francisco, has traveled back and forth from Tibet as the founder of the non-profit, non-governmental organization called Tibet Vision Project.

Dr. Lieberman was truly inspired after meeting His Holiness the Dalai Lama in 1990 and discussing the high occurrence of preventable blindness plaguing the people of Tibet. Due to the high altitudes of Tibet and the harmful UV radiation that permeates the "roof of the world," cataracts progressively erode the sight of many Tibetans.

Tibet Vision Project's primary goals are twofold. First, the Project seeks to provide state-of-the-art eye treatment to a population suffering from cataract blindness. Second, Tibet Vision Project aims to assist Tibetans in developing their own medical resources to eliminate cataract blindness throughout Tibet by the year 2020.

Mr. Speaker, Dr. Lieberman spends almost two months in Tibet each year, traveling by Land Cruisers to remote and underserved rural areas, an eye camp comprised of 6–8 Tibetan nurses and technicians, and an entire mobile hospital unit complete with microscopes, lens implants, sutures and medicines, provides free eye care to everyone who visits. During the first three out of five days of eye camp, 250 to 400 patients—who travel by yak or on foot—are evaluated. Eyeglasses are disbursed as appropriate and children receive corrective lenses. As many as 150 patients are provided free, sight-restoring lens implant surgery—all performed by Tibetan surgical teams.

Along with the 2000 people whose vision has been restored by the Tibet Vision Project, 20 Tibetan surgeons provide great hope to the people of Tibet. Dr. Lieberman and his colleague Dr. Melvyn Bert work with an extension of the Tibet Vision Project at the School for Blind Children in Lhasa, Tibet, supervising medical and referral needs to ensure the well-being of the children.

In conjunction with the Swiss Red Cross, Tibet Red Cross and Tilganga Eye Centre of Kathmandu, Nepal, Dr. Lieberman gains greater access to remote underserved populations in Tibet, meanwhile creating infrastructure for long term solutions to eye problems in Tibet.

Mr. Speaker, in the next ten years, Tibet Vision Project aspires to help Tibetans become completely self-sufficient in eye care, providing competent and compassionate care to their own people. Dr. Lieberman and his crew are developing pilot projects for primary eye care such as accessibility to reading glasses, treating simple eye infections, and referring cataract cases to larger towns for surgery.

Originally from Baltimore, Maryland, Dr. Lieberman was trained at Johns Hopkins University before coming to the West Coast. While in the United States, he divides his time treating glaucoma in his offices in San Francisco, San Mateo and Santa Cruz. He is currently considering spending more time in Tibet, expanding his visits from two to four a year.

Despite the struggle to work with a budget of \$50,000 a year and the obstacles of setting up remote eye camps, on rough terrain with poor roads, and dealing with the Chinese medical system, Lieberman and his teams continue their much needed work. Dr.

Lieberman's visits to Tibet are nothing of miraculous. I admire his incredible, indefatigable work and his leadership in organizing so many others to help him on this quest. I am delighted that Tibet Vision Project has been so successful in its tireless work to help the people of Tibet.

I would like to recognize Dr. Lieberman with some words from His Holiness the Dalai Lama, which summarizes the recognized need and gratitude for Dr. Lieberman, his colleagues, and his trainees' efforts.

"In Tibetan Buddhist culture numerous positive references equate clear sight with wisdom and knowledge and obstructions to it with ignorance and negativity. The quest for the clear-sightedness of wisdom is priced on par with developing the kind heart of compassion. But these largely concern cultivating the mind.

By voluntarily training Tibetan doctors and nurses in modern eye care he and his colleagues have contributed to restoring the sight of thousands of the rural poor in Tibet. What a great act of kindness!"

Mr. Speaker, it is my belief that Dr. Lieberman's generosity stems from his faith and practice of Judaism and Buddhism. In the spirit of gratitude and continued support for his humanitarian work, I ask my colleagues to join me in congratulating Dr. Marc Lieberman in the tenth year of Tibet Vision Project.

DOMINICAN REPUBLIC-CENTRAL AMERICA-UNITED STATES FREE TRADE AGREEMENT IMPLEMENTATION ACT

SPEECH OF

HON. LINCOLN DAVIS

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Wednesday, July 27, 2005

Mr. DAVIS of Tennessee. Mr. Speaker, I am a Conservative Democrat representing a rural area of Tennessee, and I rise today in opposition to the Dominican Republic-Central America Free Trade Agreement.

Mr. Speaker, I will support any trade agreement that results in American job growth and allows our manufacturers and farmers to export their products to new, fair, and competitive markets in other countries. In fact, I have supported previous trade agreements with Chile, Singapore, Australia, and Morocco. But my constituents and I are fearful of this particular agreement.

Our fear is that the only export we will see in this country because of CAFTA is American jobs. This fear is based on our real life experience with a similar agreement that sounds much like this one. That agreement, of course, was NAFTA. My congressional district has been devastated by the loss of jobs since NAFTA's passage.

You know, I've been told a lot of different things by a lot of different folks about why I should support this agreement. One argument was that supporting CAFTA is the Christian thing to do. Well, I am a devout Christian, and I for one do not think exploiting cheap labor for corporate profits is particularly Christian. So, I have a message for corporate America: the real Christian thing for you to do is provide wages to your new Central American employees that are equivalent to wages of the employees in my district who will lose their jobs

as a result of this Central American Free Trade Agreement.

I strongly urge all my colleagues who truly care about the American working man and woman to reject this trade agreement, and let's work on creating new jobs in this country instead of outsourcing the ones we currently have.

INTRODUCTION OF THE NORTH MAUI COASTAL PRESERVATION ACT OF 2005

HON. ED CASE

OF HAWAII

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mr. CASE. Mr. Speaker, I rise today to introduce the proposed North Maui Coastal Preservation Act of 2005, a bill directing the National Park Service to assess the feasibility of designating certain coastal lands on the north shore of the Island of Maui between the towns of Pa'ia and Sprecklesville as a unit of the National Park Service. This area is fully worthy of designation as a National Seashore, National Historic Park, or National Recreation Area.

Since assuming office as the representative for Hawaii's Second Congressional District, I have heard loud and clear from the people of Maui, in person during countless times on the island and through petitions and postcards from some 2,000 constituents, about their deep concern for preserving this beautiful, historically significant and resources-rich coastline. Although the 128 acres identified in the bill are currently zoned as open space or parkland, they lie directly in the path of development in Maui's hot real estate market.

The desire of the people of Maui is to have the natural, scenic, and cultural resources of this unique area preserved and protected from development, and ultimately designated as the Patsy Takemoto Mink North Shore Heritage Park. As many of my colleagues know, my predecessor in this body, the late Congresswoman Patsy T. Mink, was born and grew up in Hamakua Poko, a small village near Pa'ia on just this coastline. If the Park Service finds that the area merits inclusion in the National Park System, I will introduce legislation authorizing establishment of a park and directing that it be named after Congresswoman Mink.

I want to take this opportunity to acknowledge the contribution of the Maui Sierra Club and especially of Lance Holter, a dedicated community activist, for inspiring the introduction of this bill. I can tell by the hundreds of cards I continue to receive from Maui residents in support of establishing such a park that there are many more people who have dedicated enormous energy and time in the hopes of preserving our precious natural and cultural heritage for future generations.

I urge my colleagues to join me in supporting this bill, and invite you to come to the Island of Maui to visit this special area. I know that if you do so, you will be convinced as I am of the vital importance of protecting these lands.