and overall embracing of non-Finns to the culture and heritage of the community. Aside from the encouragement of Finnish people to understand more about their own history and traditions, those involved with this festival hope that all people are able to enjoy and learn more about the Finns' unique ethnicity that has evolved in the American and Canadian societies throughout the years.

Mr. Speaker, it has been due to the incredible insight, dedication, passion and innovation of the planning boards from the U.S. and Canada that have made this four-day joint festival possible. I am pleased Marquette has been chosen for the second time to host the U.S. festival and as the first American location for the joint festival—it is because Marquette is ''Sisu''. I applaud the Finnish communities in both the United States and Canada for preserving their sense of identity into the next generation and, based on the theme ''Heritage Powers the Future'', I applaud them for utilizing their past to power the direction of their culture for years to come. I wish the Finn Grand Fest 2005 the greatest success and look forward to participating in the event this August.

TRIBUTE TO VICE ADMIRAL JAMES B. STOCKDALE

HON. SUSAN A. DAVIS

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mrs. DAVIS of California. Mr. Speaker, I rise today to honor the life of Vice Admiral James Bond Stockdale, a true American patriot and a great military veteran. Vice Admiral Stockdale passed away on July 5, 2005 at the age of 81 after a life of public service and sacrifice. He is survived by his beloved wife Mrs. Sybil B. Stockdale of Coronado, Calif., and his four sons.

I believe Gordon R. England, the Secretary of the Navy, eloquently described the legacy Mr. Stockdale has left behind: ''Admiral Stockdale's courage and life stand as timeless examples of the power of faith and the strength of the human spirit.''

I could not agree more and would like to share a few details of his extraordinary life. Vice Admiral Stockdale was born on Dec 23, 1923 in Abingdon, Ill. At the age of 24 he graduated from the U.S. Naval Academy in the Class of 1947 and began his unmatched naval career. Among his many distinctions, Vice Admiral Stockdale is remembered for his remarkable leadership as the senior naval officer held in captivity during the Vietnam War.

On September 9, 1965, after flying more than 200 missions over Vietnam, he ejected over a small village after his plane was struck by anti-aircraft fire. He broke his left knee during the landing and it was broken a second time during his captivity.

During his 7½ year imprisonment, Vice Admiral Stockdale was tortured numerous times, was forced to wear heavy leg irons for over two years and spent four years in solitary confinement.

But his spirit and determination to survive never wavered. Despite the torture and abuse, he refused to participate in enemy propaganda films. Vice Admiral Stockdale's extraordinary heroism became widely known when he was awarded the Medal of Honor in 1976, only three years after his release.

His 26 combat awards included two Distinguished Flying Crosses, the Distinguished Service Medals, two Purple Hearts and four Silver Stars. He is a member of the Navy's Carrier Hall of Fame, the National Aviation Hall of Fame and an Honorary Fellow of the Society of Experimental Test Pilots. Stockdale received several honorary doctoral degrees.

He is the highest-ranking naval officer to wear both aviator wings and the Medal of Honor. His other accomplishments include earning a master's degree from Stanford University and serving at the prestigious institution's Hoover Institute for 15 years. He was also President of the Citadel for two years.

In 1992, he was a candidate for Vice President of the United States winning nearly 20 percent of the popular vote.

Mr. Speaker, I introduce this resolution today to recognize the great sacrifices Vice Admiral made protecting the freedoms of the United States and to recognize his commitment to public service. I would also like to extend my deepest sympathies to the family Mr. Stockdale left behind, including his wife and four sons.

His life serves as an inspiration to the many servicemen and women protecting our country at home and abroad. Vice Admiral Stockdale was admired and respected for his courage and unfaltering determination.

A TRIBUTE TO JOHN KERFOOT

HON. ROBERT E. ANDREWS

OF NEW JERSEY

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mr. ANDREWS. Mr. Speaker, I rise today to celebrate the 90th birthday of one of New Jersey's finest citizens, John Kerfoot, and to honor all that he has done for his fellow Americans.

John is a model citizen who devoted his life to serving his country and community. He fought bravely in the European Theater in World War Two, and was rightly honored with a Combat Infantry Badge and a Bronze Star for his service.

Upon his return, John Kerfoot committed himself to helping the great state of New Jersey. He has devoted time and energy to the Camden County Democratic Committee, the Office of the Aging, and the Camden County Municipal Utilities Authority. He has served as a Sergeant at Arms for the New Jersey State Senate, a Camden County Freeholder, and a Labor Compliance Inspector for the Camden County Community Development Program. Over the past fifty years, John has helped his hometown of Audubon by serving honorably with the Audubon Park Fire Company, the Audubon Board of Education, and the Audubon Park Borough Council.

Although John is an extremely busy man, he still finds time to bowl with his wife Anne. His skills are certainly not limited to bowling, however. He successfully boxed in the Golden Gloves Tournament in the early 1930's, and even won the boxing championship at Fort Dix in 1932 at the age of seventeen.

Mr. Speaker, it is a great privilege to honor John Kerfoot today. He has certainly accomplished much in the past 90 years, and his exemplary life of service is one to be admired. Moreover, it is a pleasure to call John a friend, and I wish him a very happy birthday, with the hope of many more to come.

SHERIFF LAWRENCE ''LUMPY'' LEVEILLE

HON. BART STUPAK

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Thursday, July 28, 2005

Mr. STUPAK. Mr. Speaker, I rise today to pay tribute to an outstanding law enforcement officer who 40 years ago began his dedicated career in St. Ignace, Michigan as a police officer and rose through the ranks to head the Mackinac County Sheriff's Department. Sheriff Lawrence ''Lumpy'' Leveille retired this past winter with eight service stars upon his epaulets, each representing five years on the force. Sheriff Leveille's nearly 40 years as a law enforcement officer and leader stand as a shining example to us all.

Sheriff Leveille graduated from LaSalle High School in St. Ignace in 1965 where in the 10th grade he was given the nickname ''Lumpy''. Being native of the first city across the Mackinac Bridge from Michigan's Lower Peninsula, it seemed fitting for Leveille to return to St. Ignace when he began his career as a police officer on May 25th, 1965. That same year on September 11, he married Ara Jean Litzner. Through the years, they have grown their family with five children and eleven grandchildren. After nine years of patrolling and protecting St. Ignace along the shores of the Straights of Mackinac, Leveille was promoted to Sergeant of the local police department.

Among his long list of accomplishments, Sheriff Leveille has decreased the number of drunk driving arrests thanks to new technology and better training for his officers, despite the increase in Mackinac County's population. He has improved safety for residents and his officers because of new cameras installed on patrol cars and in booking rooms which have lead to a reduction in criminal trials. He was also able to achieve fast finger print and background searches to help officers as well as the Straits Area Narcotics Enforcement Team. Sheriff Leveille's staff of 22 and budget of about $1.5 million made his department the largest in the county.

Although Sheriff Leveille's career with the Mackinac County Sheriff's Department has come to an end, he has continued to serve the public as a Mackinac County Commissioner. There he has and will continue to have an influence on local policy with the best interests of County residents in mind. Having worked with many of the people involved in the county's administration, ''Lumpy'' Leveille's transition to the Board has been smooth as he works to bring a better harmony to the system.

On a personal note, Mr. Speaker, as a former State Trooper myself, I have had the pleasure of knowing Sheriff Leveille over the years and can attest to his impeccable reputation of being a fair and honest protector of the people. I know that through his work he has encountered both exciting opportunities to grow with the community but also hard times when tragedy and tough times affected the area. He has given his heart and soul to his work and I have always admired his dedication to the people of Mackinac County and Michigan's First Congressional District.

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