

what devices are available for children and where gaps remain. FDA put out a proposed rule and a direct to final rule simultaneously to implement the provision, but it withdrew the direct to final rule after industry voiced opposition. The regulation has languished ever since.

The failure to implement this provision of the law has made it difficult for FDA to provide Congress information about the availability of pediatric medical devices and to identify unmet medical device needs, according to a GAO report. I am disappointed that this important tracking provision has gone unimplemented for nearly five years, and I hope that FDA will comply with the timeframe included in the legislation to issue a final rule implementing the law no later than December 31, 2013.

Despite these advances, today's bill is a missed opportunity because it fails to address a glaring patient safety issue that affects patients around the country.

Many Americans would be surprised to learn that ninety percent of medical devices are not required to undergo clinical testing in humans prior to being sold. Instead, most devices, including brain stents and hip implants, need only to show similarity to an earlier product to make their way to market.

Under current law, the FDA is required to clear certain medical devices as long as they demonstrate their similarity to an earlier product. This is true even if the new device is modeled after a defective device that caused serious injury or even death.

If the device is indeed similar to the earlier model, flaw and all, FDA's hands are tied. The agency does not have the legal authority to deny approval.

This makes no sense.

We wouldn't fast-track approval of a new drug that was based on one that had been recalled.

We shouldn't do it here, either, with medical devices.

This legislation was an important opportunity to address this medical device safety loophole, but it doesn't. The loophole remains in place and patients are still at grave risk.

Thousands of patients have already been seriously harmed by this loophole. Four years ago, Jaye Nevarez, a 50 year-old mother of three, was a healthy truck driver who earned a decent living, played in a band, and paid her bills on time. Then her doctor implanted bladder mesh, a device that traces its origins back to an older product that had to be recalled for causing serious injury and even death.

Jaye now lives in constant pain. She was forced to quit her job. She can't walk without a cane. She lost her insurance and faces a growing mountain of medical debt. The bank recently began foreclosure proceedings on her home where she lives with her 79 year-old mother.

Jaye isn't the first to be harmed by this loophole. If we fail to fix it, she won't be the last.

As documented in the accompanying report prepared by my staff—"Defective Devices, Destroyed Lives", several medical devices that have been recalled because they severely injured patients continue to be used as models for new devices—many of these are on the market and being implanted in patients today.

I introduced the Sound Devices Act, providing FDA the ability to protect the public from these unsafe devices, but this was not included in the bill.

The definition of insanity is doing the same thing over and over again and expecting a different result. When it comes to medical devices we have an insane policy that makes no sense.

Despite repeated testimony from the FDA that the current law restricts their ability to assure the safety of medical devices, Republicans have refused to acknowledge and address this very dangerous loophole.

This bill must not be the last word on medical device safety. I hope my colleagues will join me to close this medical device loophole so that we can keep the American public safe from harm.

Lastly, I remained concerned about the mandatory clinical trials database that was created in the 2007 FDA Amendments. This registry and results database was meant to directly address issues stemming from a lack of transparency of clinical trials. Several high profile examples, including the drugs Paxil and Vioxx, gained national attention when their manufacturers were found to have suppressed clinical trial data that demonstrated safety and efficacy concerns.

Today, the website requires information about certain clinical trials to be publically posted on the database, but loopholes in the underlying law still allow researchers and companies to avoid publishing unfavorable data, putting human subjects of clinical trials at grave risk. To protect the public from potentially dangerous drugs and medical devices these loopholes must be closed to provide equivalent transparency of all clinical trials. I hope I can work with my colleagues to address this serious issue in the very near future.

#### A TRIBUTE TO KATIE JACOBSON

#### HON. TOM LATHAM

OF IOWA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 31, 2012

Mr. LATHAM. Mr. Speaker, I rise today to recognize and congratulate Katie Jacobson of St. Charles, Iowa for being awarded the Girl Scout Gold Award.

The Gold Award is the highest award that a high school-aged Girl Scout can earn. This is an extremely prestigious honor as less than 6 percent of all Girl Scouts will attain the Gold Award's rigorous requirements.

To earn a Gold Award, a Girl Scout must complete a minimum of 80 hours towards a community project that is both memorable and lasting. For her project, Katie built habitats for the bats in her community that are losing their roosts to deterioration. The work ethic Katie has shown to earn her Gold Award speaks volumes about her commitment to serving a cause greater than herself and assisting her community.

Mr. Speaker, the example set by this young woman and her supportive family demonstrates the rewards of hard work, dedication and perseverance. I am honored to represent Katie and her family in the United States Congress. I know that all of my colleagues in the House will join me in congratulating her in obtaining the Gold Award, and will wish her continued success in her future education and career.

#### RECOGNITION OF NATIONAL STROKE MONTH

#### HON. TERRI A. SEWELL

OF ALABAMA

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 31, 2012

Ms. SEWELL. Mr. Speaker, I rise today in recognition of National Stroke Awareness Month. As the daughter of a multiple stroke victim, I personally know how important it is for people across our nation and this world to be informed of the risk factors, warning signs and side effects of strokes.

In 1989, my father Coach Andrew Sewell suffered a series of strokes that left him wheelchair bound and with limited speech. If not for access to quality healthcare, I know my father would not be alive today nor would he have made the significant strides and advancements in his recovery.

With strokes being the fourth leading cause of death in the United States, as well as a leading cause of serious, long-term adult disability, it is critically important that Americans know the warning signs and the importance of early response.

African Americans are disproportionately affected by this disease due to our higher risk for diabetes, high-blood pressure and obesity, which are key triggers to the disease. African Americans have almost twice the risk of stroke compared to Caucasians.

This year alone, approximately 795,000 strokes will occur or one stroke every 40 seconds!

These statistics can diminish if we diligently exercise proper cholesterol management, blood pressure control, maintain a balanced diet and eliminate smoking. We must remain committed to providing quality healthcare for everyone across this nation.

There is no better time to stress the importance of Affordable Care Act and Healthcare Reform. The Affordable Care Act is the first step toward strengthening our health care system and is already helping improve the lives of so many people in my district, the State of Alabama and across this nation—including my dear father.

Due to the multiple strokes that has left my father wheelchair bound, my mother recently had to purchase a new van with an accessible retro wheelchair lift to transport my father. Without affordable quality healthcare this would not have been possible.

This law puts Americans back in charge of their health care and gives millions of American families better access to healthcare benefits and protections, which are so critical to the welfare of our nation.

Public awareness and education is vital to prevention and rehabilitation. To the families affected, like mine, who cherish every day with a stroke victim, let us stand tall to prevent this debilitating disease from affecting more Americans.

I applaud the efforts of organizations like the National Stroke Association and the caregivers of Stroke victims for bringing greater awareness, care and comfort to those affected.

IN HONOR OF BISHOP H.H. BROOKINS—CONCLUDES A LIFE OF SERVICE

### HON. JESSE L. JACKSON, JR.

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 31, 2012*

Mr. JACKSON of Illinois. Mr. Speaker, the African Methodist Episcopal Church's Bishop Hamel Hartford Brookins—widely known as Bishop H.H. Brookins—went to be with his heavenly father on Tuesday, May 22. He died in Los Angeles at the age of 86.

I first became acquainted with Bishop H.H. Brookins as the Board Chairman of my father's organization, Operation PUSH. He was a great preacher with a commitment to civil rights and economic and political justice on a national and international scale. He served in a variety of AME church districts in the U.S. and Africa throughout his distinguished religious career, and was known as an activist, a visionary and a great church leader committed to justice for all. He was an early supporter and played an important role in mobilizing the religious community in my father's two presidential campaigns.

In 2002 former President Bill Clinton joined a host of religious luminaries, elected officials and celebrities in a tribute to Bishop Brookins, the son of Mississippi sharecroppers who rose to become a Los Angeles and international champion of black political empowerment. The former President praised Brookins for his civil rights legacy and reminisced about the days when the clergyman ministered in a country church in Arkansas while he was the Governor.

Bishop Brookins became active politically in the 1950s when, as a clergyman in Topeka, Kansas he helped to implement the 1954 Brown desegregation decision and plan ordered by the U.S. Supreme Court. In 1965 he worked to quell the Watts riots. He was an architect of Tom Bradley's campaigns for Los Angeles mayor and, while working in Africa, was ousted from Rhodesia because of his work on behalf of the Zimbabwe liberation movement. In 1981 Zimbabwe invited him back for its first presidential inauguration.

Bishop Brookins was born in Yazoo City, Mississippi. He received a Bachelor of Arts degree from Ohio's Wilberforce University and a Bachelor of Divinity degree from Payne Seminary. Prior to his election as a bishop in the African Methodist Episcopal Church, Bishop Brookins served as the pastor of the First AME Church of Los Angeles, California leading the congregation through the building of a multi-million dollar cathedral at its present location on Harvard Boulevard in Los Angeles.

Bishop Brookins is survived by his wife, the Rev. Rosalynn Kyle Brookins, pastor of the Walker Temple AME Church in Los Angeles and their son, Wellington Hartford Brookins and two stepchildren, Steven Hartford Brookins and the Rev. Francine A. Brookins. His family and numerous friends were at his bedside when he died.

IN RECOGNITION OF SAKS HIGH SCHOOL LADY WILDCATS SOFTBALL TEAM FOR WINNING THE 3A STATE CHAMPIONSHIP

### HON. MIKE ROGERS

OF ALABAMA

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 31, 2012*

Mr. ROGERS of Alabama. Mr. Speaker, I would like to request the House's attention to pay recognition to the Saks High School Lady Wildcat's softball team in Saks, Alabama, who recently won the Alabama High School Athletic Association Class 3A State Championship.

Pitcher Taylor West along with her teammates was able to pull off a perfect game to clinch this year's championship title. This is the first State Championship for the Lady Wildcats. They are lead by Head Coach Mike Tucker.

All of us across Calhoun County and East Alabama are deeply proud of these talented young Alabamians. I'd like to congratulate the team, their coaches and Saks High School on this outstanding achievement.

#### PERSONAL EXPLANATION

### HON. STEVEN M. PALAZZO

OF MISSISSIPPI

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 31, 2012*

Mr. PALAZZO. Mr. Speaker, on May 30, 2012 I was unavoidably delayed due to a mechanical problem during travel causing me to miss rollcall vote No. 296 on H.R. 915, the Jamie Zapata Border Enforcement Security Task Force Act. Had I been present for this vote, I would have voted "aye."

#### PERSONAL EXPLANATION

### HON. ROBERT L. TURNER

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 31, 2012*

Mr. TURNER of New York. Mr. Speaker, on rollcall No. 294, I was away from the floor due to a memorial service for first responders at the World Trade Center Memorial in New York. Had I been present, I would have voted "yea."

#### TRIBUTE TO KEVIN DAVIS

### HON. PETE OLSON

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

*Thursday, May 31, 2012*

Mr. OLSON. Mr. Speaker, I rise today to pay tribute to a young man who did not wear a uniform, but did lay down his life on behalf of this great Nation. Kevin Davis, of Houston, Texas lost his life on Christmas Day, 2010 at Kandahar Airfield in Afghanistan when he was struck by shrapnel from indirect fire. Kevin's chest and abdomen were hit and he later succumbed to his wounds.

Kevin worked as a contracting Warehouse man for DynCorp International, supporting our

troops. He was serving as part of the Army's Logistic Civil Augmentation Program in the southern region of Afghanistan. This civil augmentation program is the Army component of a military effort to engage U.S. companies in providing a broad range of support services for U.S. and allied forces during combat, peacekeeping, humanitarian, and training operations.

These services include supply operations, such as the delivery of food, water, fuel, spare parts, and other items. They provide field operations, such as dining and laundry facilities, housing, sanitation, waste management, postal services, and other operations; including engineering and construction, support to communication networks (IT), transportation and cargo services, and facilities maintenance and repair.

Civilians like Kevin Davis provide critical support for the men and women defending our liberty.

After Kevin graduated from Kashmere High School with honors in 1990, he received a certification in Paint and Auto Repairs from Houston Community College. He worked with the Metropolitan Transit Authority as a bus operator and auto body mechanic for 16 years. After working for the Metropolitan Transit Authority, Kevin worked as a civilian contractor providing support for our Armed Forces.

Kevin was also an active and devoted member of Riverwood Missionary Baptist Church. He is survived by his mother, Francis Murray, his sister, Taniesha Davis, and a daughter, Ashley Milburn. Kevin, like the many civilian contractors who provide support to our military, served an important function in the Global War on Terror and his sacrifice for America will never be forgotten.

#### FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012

SPEECH OF

### HON. GENE GREEN

OF TEXAS

IN THE HOUSE OF REPRESENTATIVES

*Wednesday, May 30, 2012*

Mr. GENE GREEN of Texas. Mr. Speaker, this bill is the result of hard work by our committee. I especially want to thank Chairmen UPTON and PITTS and Ranking Members WAXMAN and PALLONE and I am proud that our committee is setting an example for bipartisan compromise and productive governing.

Contained in the FDA Reform Act is the GAIN Act, a bill introduced by Congressman GINGREY and myself, which is aimed at incentivizing the development of new antibiotics that will fight the serious and life threatening infections that mankind will face in the coming years.

The GAIN Act provisions of this bill represent a careful bipartisan balance that appropriately protects patient safety and responsibly offers incentives to innovative drug companies seeking the cures to our world's most deadly bacterial pathogens such as extensively drug resistant tuberculosis, MRSA, and others that we are currently ill-equipped to treat. Currently, we are unable to manage many significant public health threats posed by these pathogens.

While a widespread public health threat is in our future, some people in this country are