she be named Flora, after my grandmother's courageous sister. Flora was very beautiful people told my grandmother. She must have been the oldest, or one of the older ones, as she was married to a doctor and had a child by the time of the massacre. Her husband was arrested and most probably killed soon after. The Turks asked her to convert so that she could become a wife to one of them. They would have spared her and her child if she agreed. My great aunt Flora knew that she would be raped, tortured, and killed if she did not accept their offer. However, she chose not to give in. They must have been marching through a mountainous area. She somehow got away and jumped off a cliff into her death. Some said that she jumped with her child. When I was born, my grandmother requested that my parents name me Flora to continue her sister's legacy.

My grandmother was a strong woman. She continued to live in Cypress with her sister, Maritza, up to the age of 19. Then she moved to Syria where she got married and bore eight children, two of whom died in their childhood. She was widowed too soon and worked hard for her family. Eventually, most of her children immigrated to France and Germany. She moved to Germany with my father and mother. She lived with us for many years and died in our house at the age of 81. Now she rests in peace in the land of the people who took her in as an infant.

It was a privilege to grow up with my grandmother. She was amazing. She was able to sing the German Anthem word for word up to the day she died. She had learned it at the orphanage from her ''Mutter.'' She started her day with prayer and ended her day in prayer. She instilled in me great values such as faith and courage. I learned many things from my grandmother, Araxi.

I am grateful to my Nana for naming me after her courageous sister, Flora. I am grateful that she told me all these stories so that I would know about my heritage and never forget. I am grateful for her many prayers and blessings.

Here I am grandma, telling your story to the whole world! I love you, your granddaughter, Flora

TRIBUTE TO BOB MITCHELL

HON. HAROLD ROGERS

OF KENTUCKY

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 31, 2012

Mr. ROGERS of Kentucky. Mr. Speaker, I rise today to pay tribute to my loyal district administrator, Bob Mitchell, in honor of his retirement after dedicating more than 32 years as my right-hand-man, my confidant, political adviser and tireless ambassador for southern and eastern Kentucky.

Bob Mitchell is arguably one of the greatest political advisers in the history of the Commonwealth of Kentucky. He understands the power of partnerships, regionalization and communication, yet never underestimates the importance of gratitude and humility.

His father, the late Murrell Mitchell, who served as a member of the Knox County School Board, as well as three terms as a Knox County Magistrate, inspired Bob's political interests and philanthropic heart. It is thus his courage of conviction that has driven his work to transform southern and eastern Kentucky and improve the quality of life in our rural region.

With Bob Mitchell at the helm of all district projects, thousands of families now have access to clean drinking water and sanitary waste water systems, are protected by flood-control projects and live without the fear of yearly floods, have better roads to travel on, and have good-paying, stable jobs. He also helped launch and provide guidance to non-profit organizations like the Southeast Kentucky Economic Development Corporation for job creation, Forward in the Fifth for education, The Center for Rural Development, TOUR Southern and Eastern Kentucky to promote tourism, PRIDE for environmental education and clean-ups, as well as Operation UNITE in fighting drug abuse.

Countless organizations and political candidates have coveted Bob Mitchell's impeccable leadership skills. He has served on a litany of boards from financial institutions to non-profit organizations, and assisted with campaigns from county seats to Presidential hopefuls. His legacy will continue to flourish from the seeds of wisdom, hope and inspiration he has planted across our great Commonwealth.

Mr. Speaker, I ask my colleagues to join me in honoring my friend and my partner, Bob Mitchell, on his retirement. My wife, Cynthia and I wish Bob and his wife, Nancy all the best in the years to come.

RECOGNIZING THE ACHIEVEMENTS OF DEBBI FISHER AND RAINIER THERAPEUTIC RIDING

HON. ADAM SMITH

OF WASHINGTON

IN THE HOUSE OF REPRESENTATIVES

Thursday, May 31, 2012

Mr. SMITH of Washington. Mr. Speaker, I rise to honor Debbi Fisher, founder and Operations Director of Rainier Therapeutic Riding. Her work gives active duty servicemembers at Joint Base Lewis McChord and veterans in our community a facility for therapeutic riding and relief from mental and physical injuries.

Debbi founded Rainier Therapeutic Riding in Yelm, Washington in 2008 after nearly 40 years of riding and horse training experience. As the widow of a Marine Pilot and Air Force Colonel, and the mother of a son in the Marines and daughter in the Air Force, she aspired to use her skills to help those who have served our country. She has described horses and servicemembers and veterans as perfect companions.

Rainier Therapeutic Riding is now the largest provider of equine therapy to military personnel in the country, serving 75 people a year at no cost to the individual or the government. They work with the Warrior Transition Battalion and Air Force Medical Flight at Joint Base Lewis McChord to give those suffering from post-traumatic stress syndrome, traumatic brain injuries, and other injuries a place to rediscover a happiness for life.

Mr. Speaker, it is with great honor that I recognize the work of Debbi Fisher and all of the volunteers at Rainier Therapeutic Riding. By giving back to our servicemembers and veterans who have sacrificed so much for our country, Debbi has helped many to vastly change their outlook and improve their happiness.

FOOD AND DRUG ADMINISTRATION REFORM ACT OF 2012

SPEECH OF

HON. EDWARD J. MARKEY

OF MASSACHUSETTS

IN THE HOUSE OF REPRESENTATIVES

Wednesday, May 30, 2012

Mr. MARKEY. Mr. Speaker, I want to thank Chairmen UPTON and PITTS and Ranking Members WAXMAN and PALLONE for their work in bringing to the floor a bipartisan bill that provides FDA additional resources to bring new drugs and medical devices to market. These new resources will enable FDA to improve review times for new product applications and provide companies greater clarity about compliance requirements and their responsibilities.

There are many important policy improvements in this bill. They include:

A reauthorization of the user fee programs for prescription drugs and medical devices, as well as the creation of a new generic user fee program that will help slash current review times for these products.

A reauthorization of two programs that foster the development and safe use of prescription drugs for children.

New incentives for the development of antibiotics, which are needed to increase the number of products in the development pipeline.

Today's bill also includes the reauthorization of legislation I authored in 2007 that has helped spur the development of medical devices for children. The Pediatric Medical Device Safety and Improvement Act, PMDSIA, creates grants that bridge the gap between the people who understand the medical need—doctors and innovators—with the people who can help turn their ideas into devices on the shelves, like manufacturers and federal regulators. Since the grant program's inception, the five Pediatric Device Consortia established as a result of this language have assisted in advancing the development of 135 pediatric medical devices. Currently the consortia are managing 80 active pediatric medical device products.

The FDA Reform Act also extends a provision of PMDSIA that provided profit incentives for companies to develop devices for rare pediatric diseases. The original incentive passed in 2007 solely for pediatric diseases proved immensely successful. Today's bill strikes a compromise to extend this incentive for devices used to treat rare diseases in adults as well, while still retaining the incentive for pediatric devices. I urge Congress does not negatively impact the development of devices for children.

In addition, we will need to ensure that companies using this incentive and making a profit on their device because they got pediatric labeling actually continue to sell their device for use in children and not only for adults. The Pediatric Advisory Committee at the FDA will need to play a vital role in this oversight and in monitoring the number of devices sold for adult use as opposed to the number sold for pediatric use.

PMDSIA also included a requirement that device companies provide FDA with information on the pediatric populations that could benefit from a new device they are looking to sell. This was supposed to help FDA track

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.