

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.