companies at a disadvantage and, more importantly, putting patients at risk.

There was a backlog of 4,700 applications waiting to be reviewed, and the median approval time to get review of a generic drug was 30 months, far surpassing the 180–day timeframe for review as laid out in the Hatch-Waxman amendments in 1984.

Additionally, in 2012, many generic sterile injectable drugs were in shortage, causing doctors and hospitals to scramble to ensure patients were getting the best treatment possible.

To address these problems, Congress passed the first Generic Drug User Fee Amendments (often referred to by its acronym GDUFA or as congressional staff and industry insiders call it—''Ga-DOO-Fa'') as part of the FDA Safety and Innovation Act.

This built on the success of similar agreements that Congress had previously passed between drug and device manufacturers and their regulators in the FDA.

This user fee agreement was the first agreement between the generic industry and the FDA on how to improve the review process for generic drugs.

With the enactment of these amendments, Congress anticipated:

One: that generic drug facilities abroad would be brought up to the same standards as facilities in the United States; and

Two: that American patients would benefit from faster approval of generic drugs. These two actions would bring more competition to the market and lower the price of drugs for consumers.

But there are concerns about the implementation of this program.

Some progress has been made on the backlog of applications for generic drugs—some progress, but certainly not enough. In 2012 there was a backlog of 4,700 pending applications and that has now dropped to just over 3,500 applications pending approval, according to the Generic Pharmaceutical Association.

The HHS Inspector General has reported that the FDA is improving its inspections abroad, one of the important goals of the user fee agreements.

But, the troubling news is that it is taking longer for the FDA to get drugs through the approval process, and according to a survey of generic drug makers, the median approval times have slowed from 30 to 48 months.

According to one estimate, once there are six or more generic competitors, a drug costs about 10 percent of the brand price—so, these slower approval times mean less competition and higher costs for consumers.

This slowdown in approval time is despite the fact that the FDA has received nearly $1 billion in user fees since this law was passed—that's funding that is on top of the money that Congress annually provides to the FDA through the appropriations bill.

That's about $300 million a year, or 20 percent of the total amount that the FDA spent researching, inspecting, and reviewing all drugs—generic and brand name alike—in fiscal year 2015.

I understand that the FDA has met most of the goals laid out in the agreement for industry user fees for regulatory actions, hiring staff, and increasing inspections.

But I look forward to hearing whether these metrics are the most appropriate, given I continue to hear that generic drug approval is too slow from manufacturers and patients.

While industry provides funding according to the agreement, the American taxpayer, through the Congressional appropriations process, provided over 40 percent for the generic drug review program in fiscal year 2014, according to the FDA's financial report.

But the data points that matter to American people are generic drug approval times and the number of approvals, which to them mean increased market competition, a reduction in drug shortages, and more, lower-cost drugs available for patients.

Another issue we're hearing a lot about is drug pricing—and here are some points to consider:

One: While the cost of drugs is a legitimate concern for many Americans—it's part of an even larger problem of rising health care costs.

Just this week, the Congressional Budget Office (CBO) announced in its annual ''Budget and Economic Outlook'' that for the first time, federal spending for the major health care programs (Medicare, Medicaid, SCHIP, Obamacare) represents the largest fraction—more than 60 percent—of the projected growth in mandatory spending in 2016. CBO notes that this spending is partially driven by the increase in per capita health care costs.

Two: While we work to lower the cost of drugs, we need to invest in and incentivize the development of life-saving therapies.

Congress last year added $2 billion in the appropriations process, bringing NIH's total budget in FY2016 up to around $32 billion—but this is still less than what's spent in the private sector.

Members of the Pharmaceutical Manufacturers of America, who only represent a portion of the market, spent over $50 billion in FY2014 alone coming up with new cures and treatments.

The clinical trials required to prove that medicine is safe cost hundreds of millions of dollars, even for the ninety percent of drugs that fail. In addition, the regulatory approval process is lengthy, which also adds costs.

As a result of this effort, biotech and drug companies big and small have done remarkable things to help patients with diseases like HIV, Cystic Fibrosis, and cancer live longer, healthier lives—a critical development we do not want to interrupt.

Third: To best restrain the growth of drug prices we must encourage investment in life-saving therapies, avoid unnecessary regulatory burdens that slow down development and drive up costs, and ensure the marketplace remains competitive.

For the past year, this committee—in a bipartisan way—has been looking at ways to reduce unnecessary regulatory burden so we can get safe, innovative, life-saving therapies into patients' medicine cabinets more quickly.

At the same time, Sens. Collins and McCaskill, leaders of the Aging Committee, have been examining what improvements may be necessary to ensure that the FDA expedites applications for generic drugs to keep the marketplace competitive, which will help keep drug prices down, and I look forward to working with them on that effort.

The generic drug industry really is a remarkable story. Over the last 30 years—generic drugs have gone from a very small fraction of the marketplace to 88 percent. It's hard to imagine what the prescription drug market would look like today without generic drugs.

I look forward to hearing from our witness today to learn more about where Congress can help make improvements to the regulatory process and ensure that the FDA has the tools it needs to create a generic drug review system that functions as Congress intended and as American patients and taxpayers deserve.

ADDITIONAL STATEMENTS

TRIBUTE TO DWAN EDWARDS AND BROCK OSWEILER

● Mr. DAINES. Mr. President, today I wish to recognize two outstanding and nationally prominent pro athletes, Carolina Panthers defensive tackle Dwan Edwards and Denver Broncos backup quarterback Brock Osweiler.

I am so proud that Montana will be well represented in this year's Super Bowl, and I am so proud to honor these men for their leadership and athletic accomplishments.

Dwan grew up in Columbus, MT, and graduated in 1999 from Columbus High School. He then went on to play for Oregon State University and eventually was drafted by the Baltimore Ravens in 2004, where he played for five seasons. In 2010, he was picked up by the Buffalo Bills for two seasons. He signed with the Carolina Panthers in 2012 and is now playing in his 12th NFL season.

Dwan has certainly not forgotten where he is from. He is currently making arrangements to bring former Columbus High School football coach John Smith out to watch Dwan play in his first Super Bowl game. This summer, he will put on the eighth Dwan Edwards Elite Football camp, where he spends a week in Billings helping young players develop their football skills.

Brock represents Kalispell, where he attended Flathead High School. He graduated in 2009 as an honor roll student and was coached by Russell McGarvel. Brock played college football for Arizona State and was drafted by the Denver Broncos in 2012.

During his time playing in the NFL, he has given back to Flathead and its football program by regularly sending letters of encouragement to the high school team and donating a Flathead Football captains board in 2014. The football team's captains' names are etched into the board each year, which serves as a great honor for these young leaders.

My biggest congratulations goes out to both of these fine men for representing the great State of Montana well, both on and off the field. Best of luck to you both in Super Bowl 50 this Sunday. Keep making Montana proud.●

TRIBUTE TO COLONEL JEANNIE LEAVITT

● Mr. HELLER. Mr. President, today I wish to congratulate Col. Jeannie Leavitt on her recent selection as commander of the 57th Wing at Nellis Air Force Base. Colonel Leavitt is the first woman to command the wing, making her the highest ranking female officer to command at Nellis AFB. It gives me great pleasure to recognize her achievement in this historic moment.

Colonel Leavitt joined the U.S. Air Force in 1992 after earning her bachelor's degree in aerospace engineering from the University of Texas and her