

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

master's degree in aeronautics and astronautics from Stanford University. She completed pilot training at the top of her class in 1992, kicking off the start of her successful career. Since then, she has logged over 300 hours of combat, serving in Afghanistan and Iraq, as well as Operation Southern Watch.

In 1993, Colonel Leavitt became the first female fighter pilot and later the service's first woman to graduate from the Air Force Weapons School at Nellis AFB. In addition, in 2012, she became the Nation's first female fighter wing commander when she assumed command of the 4th Fighter Wing at Seymour Johnson Air Force Base in North Carolina, and she will now be the first woman to assume command of the 57th Wing at the Silver State's Nellis AFB. She is truly a role model, demonstrating a great amount of strength and courage.

I extend my deepest gratitude to Colonel Leavitt for her courageous contributions to the United States of America. Her unwavering dedication to her career is commendable, and she stands as a shining example for future generations of heroes. Colonel Leavitt's service to her country and her bravery earn her a place among the outstanding men and women who have valiantly defended our nation.

As a member of the Senate Veterans' Affairs Committee, I recognize that Congress has a responsibility not only to honor these brave individuals who serve our Nation, but also to ensure they are cared for when they return home. Equally as important, it is crucial that female servicemembers and veterans have access to their specific health care needs. There are countless distinguished women who have made sacrifices beyond measure and deserve nothing but the best treatment. I remain committed to upholding this promise for our veterans and servicemembers in Nevada and throughout the Nation and will continue to fight until this becomes a reality.

During her tenure, Colonel Leavitt has demonstrated professionalism, commitment to excellence, and dedication to the highest standards of the Air Force. I am both humbled and honored by her service and am proud to have such a distinguished member of the Air Force serving in the State of Nevada. Today I ask my colleagues to join me in recognizing Colonel Leavitt for all of her accomplishments and wish her well in all of her future endeavors.●

#### TRIBUTE TO JANE ALBRIGHT

● Mr. HELLER. Mr. President, today I wish to congratulate a true role model in the Nevada Wolf Pack community, women's basketball coach Jane Albright, on reaching a significant milestone of 500 collegiate basketball wins. This is a tremendous accomplishment for Ms. Albright, who has dedicated eight seasons to making Nevada women's basketball the best it can be.

Ms. Albright began her career coaching collegiate basketball in 1981, when she served as a graduate assistant for the University of Tennessee. She later spent one season as an assistant coach at the University of Cincinnati before taking on her first role as head coach at Northern Illinois. During her 10 seasons with this university, Ms. Albright led the women's basketball team in its most successful run in Northern Illinois history with a record of 188 wins to 110 losses from 1984-94.

Following her tenure at Northern Illinois, Ms. Albright coached the women's basketball team at the University of Wisconsin, where she revitalized the program. Ms. Albright led this team, which previously had experienced nine losing seasons, to eight consecutive winning seasons. Prior to her tenure with the University of Nevada, Reno, UNR, Ms. Albright served as head coach at Wichita State.

Beginning in 2008, Ms. Albright became a member of the Pack, taking on the role of UNR's head women's basketball coach. Throughout her first year at Nevada, Ms. Albright achieved the most wins as a first-year coach, with an overall record of 18 wins to 14 losses. In that same season, she also picked up her 400th career win when Nevada defeated Northern Iowa. In the 2013-14 season, Ms. Albright led the Wolf Pack in winning 12 Mountain West games, setting a program record for most conference wins in a single season and securing the number three seed for the Mountain West Championships.

She was also awarded the 2014 Carol Eckman Award this season, recognizing her for her commitment to the incredible student athletes on her team. On January 27, 2016, Ms. Albright reached her 500th career win, leading the Pack against San Diego State. Her ability as a coach is remarkable, and we are lucky to have someone like Ms. Albright representing UNR.

Aside from her incredible record as a coach, Ms. Albright also goes above and beyond to keep her team involved in the community, as well as in the classroom. In 2009-10 alone, UNR logged more than 530 hours of service to the city of Reno. Ms. Albright is a shining example of true leadership for our community.

Ms. Albright is an inspiration to many across northern Nevada both on and off the basketball court. Her enthusiasm and passion for her team have not gone unnoticed. Today I join citizens across the Silver State in congratulating Ms. Albright on this incredible achievement and wish her well as she continues to lead the Nevada Wolf Pack.●

#### REMEMBERING MICHAEL A. WERMUTH

● Mr. SESSIONS. Mr. President, today I wish to recognize the life of Michael Wermuth of Birmingham, AL.

Michael Anthony Wermuth was born in Birmingham, AL, in 1946, was com-

missioned in the U.S. Army upon graduating from the University of Alabama, earned his law degree from the University of Alabama School of Law, and practiced law in Mobile, AL, as a partner of the firm Wilkins, Druhan & Wermuth. While in Mobile, Mike became involved in local politics and worked on the senatorial campaign of ADM Jeremiah A. Denton. Upon Admiral Denton's election to the Senate, Mike and his family moved to Washington where he served as Senator Denton's chief counsel and legislative director from 1980 to 1987.

After his time in the U.S. Senate, Mike served in the Department of Justice as a legislative counsel for civil rights and was Deputy Assistant Attorney General for legislative affairs. In 1989, he was named Deputy Assistant Secretary of Defense for drug enforcement policy and was instrumental in the implementation of President George H.W. Bush's national drug control strategy that was highly effective in reducing drug use and importation.

After 30 years of service, Mike retired as a colonel in the Army Reserves. That same year, he joined the RAND Corporation as the director of its homeland security program and was the executive director of a Federal advisory panel on terrorism. During his time at RAND, he worked on a variety of issues including infrastructure protection, emergency preparedness, risk management, border control, and intelligence.

After leaving RAND in 2010, Mike continued his work as a consultant there and served as an adjunct faculty member at the Texas A&M University Bush School of Government and Public Service. He taught graduate level online courses in homeland security defense. His influence in terrorism defense strategy was vast, and his enduring legacy will be his dedication to the stewardship of the next generation of policymakers.

I knew Mike for many years. In Mobile, we served in the same Army Reserve center. He was a conscientious and superior officer with a steady sense of duty and love of country. As a top member of Senator Denton's staff, he was dedicated, loyal, and effective. He was tireless in his work to advance the agenda in which Senator Denton so deeply believed. I can say his support and that of Senator Denton was critical to my appointment as U.S. attorney. In the U.S. Army, the U.S. Senate, the Department of Justice, the RAND Corporation, and as a teacher and lawyer, Mike always excelled. Discipline, work, loyalty, and patriotism were his hallmarks. He was indeed a talented American patriot.

Michael passed away on November 1, 2015. He is survived by his wonderful wife of 35 years, Fran; his children, Ken and Heather; and numerous other family members. His partner throughout, Fran is highly accomplished in her own right having served in top positions within the U.S. Marshals Service. Our