Finally, UK Prime Minister Cameron is negotiating a new settlement between Britain and the 27 other members of the EU prior to a referendum this summer on the UK's continued participation in the EU. Although the Prime Minister has said that the ''best answer'' is for the UK to remain part of a reformed EU, it is up to the British citizens to vote to remain within the Union.

All of this matters greatly to the United States. EU member states include some of our oldest and closest allies in the world. Our partnership with the EU has afforded us the possibility of addressing some of the most challenging international issues—this partnership has made us safer and stronger.

We also draw great economic benefit from a stable EU—the Union is our largest trading partner and our economies are intertwined in beneficial ways for citizens on both sides of the Atlantic. This partnership is vital to our interests, but only works if the EU's institutions are vibrant and able to respond to the challenges before it.

While many of these problems will be up to the EU member states to resolve, I strongly believe that we should stand in solidarity with the Union through this difficult period and take tangible action to support our friends.

First, we must continue to make clear our support for the democratic principles that serve as the basis for the EU and should be clear in speaking out against the growing chorus of illiberal voices. The U.S. should reenergize ties with civil society across the continent, especially in Central and Eastern Europe where strong civil society connections established after the Cold War atrophied as attention shifted elsewhere.

We also need to reinvigorate the transatlantic dialogue—among governments, think tanks, NGOs, and civil society organizations—on these issues. The transatlantic relationship always has and always will benefit from enhanced ties among our people.

The U.S. should also work to develop a new generation of foreign policy and security policy leaders and analysts that focus on Europe and the centrality that the continent has for our interests.

Second, we should support European efforts to bolster energy security across the continent in a way that ensures reliability and decreased dependence on Russian supply.

Third, we should continue to work with Europe on strengthening security, its border controls, and the vitality of the Schengen visa-free zone. This means sharing of intelligence and best practices on how to prevent terrorist attacks before they happen. I also want to applaud the administration's intention to invest $3.4 billion into the European Reassurance Initiative, which will ensure a sustained U.S. military presence in Europe to help deter further Russian aggression.

Fourth, we should continue our robust support for the UN High Commissioner for Refugees, International Organizations for Migration, and several outstanding NGOs which work directly with refugees and migrants across Europe. We should be proud of this commitment and continue to support the most vulnerable populations.

Fifth, we should continue to work closely with the EU and member states on working to ensure that the Minsk II deal is fully implemented. Success to date has been rooted in U.S.-EU solidarity, and we must finish the job—the sanctions regime must remain in place until Minsk II is realized and Crimea is returned to Ukrainian control.

Finally, we should continue our robust support for Ukraine while holding the government accountable to progress in the fight against corruption. I am concerned by the recent departure of Ukraine's Minister of Economy who resigned in protest against the slow pace of reform and anticorruption efforts.

The U.S. Congress passed two pieces of legislation last year supporting Ukraine's economy, Ukrainian civil society, and the government's broad-based reform efforts. Although some progress has been made, we must finish the job.

The success of Ukraine will be the success of Europe and the ideals that have drawn sovereign states to join its ranks for the last 75 years. I call on this body to continue to support Ukraine's reformers throughout civil society and government as they continue to make real strides towards integration with the west and adoption of the democratic ideals that we uphold.

More importantly, I again call upon Ukraine's leaders to prove that they are serious about countering corruption. The international community's patience in this regard exists, but is not limitless. We need to see concrete results soon.

In 2012, the Nobel Peace prize was awarded in recognition of the EU's central role in providing stability in Europe. The chairman of the Nobel committee said the following at the ceremony: ''We are not gathered here today in the belief that the EU is perfect. We are gathered in the belief that here in Europe we must solve our problems together. For that purpose we need institutions that can enter into the necessary compromises. We need institutions to ensure that both nation-states and individuals exercise self-control and moderation. In a world of so many dangers, compromise, self-control and moderation are the principal needs of the 21st century.''

These words continue to ring true today as pressure on the Union grows. Across the ocean here in the U.S., we should resolutely stand in solidarity with our friends in Europe and the principles they embrace. Never before has the EU been so challenged or our transatlantic alliance so valuable. We must bolster our ties this year and renew our commitment to a robust transatlantic relationship.

GENERIC DRUG USER FEE AMENDMENTS: ACCELERATING PATIENT ACCESS TO GENERIC DRUGS

Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD a copy of my remarks to the Senate Committee on Health, Education, Labor, and Pensions.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

GENERIC DRUG USER FEE AMENDMENTS: ACCELERATING PATIENT ACCESS TO GENERIC DRUGS

In December, the president signed into law the Every Student Succeeds Act, a bill to fix No Child Left Behind and proof that this committee can work together to tackle very difficult issues.

But a law not properly implemented isn't worth the paper it's written on, which is why I'm going to be working with Senator Murray to set up a strong oversight process during 2016 to make sure the teachers, governors, chief state school officers, parents and students who counted on us to fix that law see that it's implemented properly.

We're here today for a similar purpose: to conduct oversight of the 2012 Food and Drug Administration (FDA) Safety and Innovation Act—specifically the law's Generic Drug User Fee Amendments, which are fees negotiated between the FDA and generic drug makers to give the agency additional resources intended to speed the review of generic drugs.

This is Congress' first oversight hearing since these agreements were passed in 2012, and it comes at a critical time for patients: Despite the FDA receiving nearly $1 billion in user fees since 2012 as a result of these user fee agreements, performance is not living up to Congress' or patients' expectations, as the number of generic drugs approved per year remains about the same.

The user fee agreements are due to be reauthorized next year, and discussions between the FDA and industry are already underway—making now the appropriate time for us to better understand whether or not these 2012 agreements are working to give Americans better access to generic drugs.

The generic drug program, established by the Hatch-Waxman Amendments over 30 years ago, has had great success increasing competition and lowering drug prices.

The program was created to make it easier for generic drugs to enter the market.

Let me quickly explain how this works: Once a drug is approved by the FDA, for example, Lipitor—which is widely used to help lower cholesterol—no other manufacturer can make that drug for a period of time. When that period of time expires, a manufacturer may make a copy of that drug—and we call that a generic drug.

That generic copy must also have FDA approval.

This generic approval process doesn't include full clinical trials, which often are long and expensive, contributing to higher prices for brand drugs.

As a result, more generic drugs in the market creates competition and lowers prices for consumers.

And today, 88 percent of prescription drugs purchased in the United States are generic drugs.

However, in 2012, 26 years after the law first passed, it became clear the generic drug approval program needed an overhaul.

More generic drugs were coming from overseas. Generic drug companies in China and India were inspected much less frequently than American companies, putting American

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