

about having a partial shutdown. He keeps repeating over and over that he wants a shutdown. Make no mistake about it. He is the only reason there would be a shutdown.

If President Trump wants to throw a temper tantrum and shut down some Departments and Agencies over Christmas, that is, certainly, within his power, but he has two more sensible options available to him. It would be a shame if the country suffered because of a Trump temper tantrum. It is the President's choice.

I yield the floor.

The PRESIDING OFFICER. The Senator from Iowa.

LOWERING DRUG PRICES

Mr. GRASSLEY. Mr. President, millions of Americans woke up this morning and started the day with their doses of prescription medications. Their daily regimens are prescribed by their healthcare providers to treat illnesses and to improve the quality of their lives, and for many Americans, prescription medicine extends and saves their lives. Without their prescription medication, millions of Americans would not survive.

For so many of our loved ones who have diabetes, high blood pressure, cystic fibrosis, epilepsy, or other chronic healthcare conditions, prescription drugs are a basic necessity for their living. Without pharmaceutical treatments or cures, too many family gatherings at Thanksgiving, which has just passed, arguably, would have had fewer plates at the table this holiday season.

As a nation, we are incredibly blessed to live in a country where investment and innovation unlocks cures and treatments. Yet the escalating price of prescription drugs are a consuming concern for too many millions of Americans, even including Iowans who bring up this subject regularly at my county meetings.

I have come to the floor of the Senate to address the sticker shock that greets consumers when they pick up their medicine at the pharmacy or open their medical bills after a hospital visit. Rising drug prices that Americans pay out of pocket are gobbling up a bigger share of income.

For some people on a fixed income, sky-high drug prices are eating up every spare penny they can scrape together to pay for their prescriptions. It is time we talk turkey to our friends at Big Pharma. I don't make fun of our friends at Big Pharma. I use the word "friends" because we all enjoy a longer life and better quality of life because of miracle drugs.

As a fiscal conservative who wholeheartedly believes in free enterprise, I don't want the government intruding unnecessarily in the marketplace. The reason millions of Americans benefit from lifesaving drugs in the first place is due largely to capitalism and the entrepreneurial spirit that drives innovation and opens new frontiers of modern medicine.

I also believe strong intellectual property rights help incentivize compa-

nies to invest in research and development so new cures are found for our loved ones. However, government does have a responsibility to keep a check on unfair business practices and to actually rein in anti-competitive behavior that harms consumers and fleeces taxpayers.

There is a general agreement that these are constitutional as well as legitimate roles for government. Of course, if you are going to protect the consumers and not fleece taxpayers, this can happen in a number of ways.

It happens when brand-name and generic drugmakers game the system to pad their profits at the expense of taxpayers and consumers. It happens when hospitals, middlemen, and providers determine which drugs to prescribe based on its reimbursement and markup from insurers, including public health programs for the military and veterans or the big ones like Medicare and Medicaid.

Throughout my public service in the U.S. Senate, I have established a fundamental commitment to transparency. Remember that transparency, particularly in government, brings accountability, but transparency in the private sector will also bring accountability.

From whistleblower protections to the public's right to know, sunlight sweeps away wrongdoing, strengthens good government, and helps consumers and taxpayers get the most bang for the buck. I have worked across the aisle to apply this standard to help lower drug prices. It is an issue that resonates loudly and very clearly in every household of America.

In fact, Iowans contacted my office a couple of years ago regarding real sticker shock for their EpiPens. The escalating price they were paying for lifesaving anti-allergy medication jumped \$600 for a two-pack. On their behalf, I started digging for answers.

It turned out that Mylan, the EpiPen distributor, had jacked up the price for over a decade during the Obama administration. In fact, from 2006 through 2016, it rose more than 400 percent.

EpiPen is the most widely prescribed epinephrine autoinjector in the United States. Parents, grandparents, daycare providers, and teachers across the country keep their homes, their cars, and their classrooms stocked in case of an emergency.

A 400-percent increase—how was Mylan able to accomplish this? It classified EpiPen as a generic drug instead of a brand-name drug in the Medicaid Drug Rebate Program. Simply, that incorrect classification cost the U.S. Treasury and States big time by allowing Mylan to pay lower rebates.

The watchdog at the Department of Health and Human Services, at my request, found the misclassification may have resulted in the taxpayers and the States overpaying for the drug by as much as \$1.3 billion.

What is more, a competing pharmaceutical company sued Mylan using the False Claims Act—a whistleblower law

I have updated over the years. This anti-fraud tool encourages people to report and expose wrongdoing against the government. In this specific case, this whistleblower exposed fraud against the taxpayers for misusing the Medicaid Drug Rebate Program to the tune of \$456 million.

I would like to share a time-tested lesson I have learned throughout my 30 years of oversight work in the U.S. Senate: When you smell smoke, there is a fire.

The EpiPen misclassification may be the tip of the iceberg. As part of my EpiPen oversight, I requested additional misclassification data from the Office of Inspector General at HHS.

As of early 2018, the Office of Inspector General identified the names of 10 drugs that accounted for 68 percent of Medicaid reimbursements for potentially misclassified drugs just in the year 2016. The EpiPen and some of its variants are included within the group of 10 drugs, as well as a commonly prescribed antibiotic and a commonly prescribed drug for an underactive thyroid condition.

In a nutshell, it appears the same drug companies may be undermining the rebate program by misclassifying commonly prescribed drugs that can be found in medicine cabinets in households all across the United States. That is simply wrong, and I am going to do whatever I can to fix that issue.

Recently, the FDA approved the first EpiPen generic. Of course, that is a good step in the right direction.

As a senior member of the Senate Finance Committee and also the last 4 years as chairman of the Senate Judiciary Committee, my sights are set squarely on lowering drug prices without compromising access for innovative cures and treatments delivered by the American pharmaceutical industry.

Through oversight and even legislation, I am working to set things right. That includes putting a stop to the shenanigans that manipulate regulatory loopholes and unfairly extend monopolies over certain drugs. This happens when a brand name and a generic drugmaker work in cahoots to delay the lower priced generic's entry into the market.

For starters, a bipartisan bill I have with Senator AMY KLOBUCHAR of Minnesota would inject a healthy dose of Midwestern commonsense medicine into Big Pharma with a bill we have that would do away with what we call the pay-for-delay shenanigans. This bill, called Preserve Access to Affordable Generics Act, would end sweetheart deals between brand-name and generic drugmakers that end up costing the American consumer and at the same time the U.S. taxpayers an arm and a leg. It would increase access to more affordable generic drugs sooner rather than later because of the pay-for-delay scheme.

Specifically, our bill would crack down on anti-competitive payoff schemes that effectively rip off taxpayers and consumers. These so-called

reverse agreements delay consumer access to the cheaper generic drug.

I am 100 percent certain that our pay-for-delay bill would help lower drug prices for our consumers and save the taxpayers money through Medicare and Medicaid. That is because generic drugs can be up to 90 percent cheaper than brand-name drugs, and that happens to be a tremendous savings.

Ending these payoff agreements would gut artificially inflated prices consumers are paying for some prescription drugs. Putting an end to these payoff schemes will end the choke hold they put on the market. By doing so, we can restore timely access for affordable generics to reach the market, boost competition, expand consumer choice, and at the same time lower drug prices.

In addition to the pay-for-delay bill that Senator KLOBUCHAR and I have, I am also cosponsor of a bill led by my friend Senator PAT LEAHY that would inject another dose of bipartisan common sense into the pharmaceutical industry. We use the acronym CREATES for this legislation, the Creating and Restoring Equal Access to Equivalent Samples Act. It seeks to stop anti-competitive practices that block lower cost generic drugs from the pharmacy store's shelves. It would help generic companies get the samples they need to manufacture equivalent products.

Right now, a common practice by bad actors in the industry prevents potential generic competitors from obtaining the samples they need to test their drugs or blocks them from participating in shared safety protocols. This practice of deny and delay is fueling deficit spending. That is because the tax-paying public shells out a whole lot more money to fill brand name prescriptions for veterans, the elderly, and the disabled, when the cheaper generic drugs would do the same thing. This would save a tremendous amount of money. We have the scoring by the Congressional Budget Office saying that our bill—the CREATES bill—would result in a \$3.8 billion net decrease in the Federal deficit.

Improving access to lower cost generic drugs while preserving the incentives for innovation and intellectual property rights ought to be seen by my colleagues as a win-win solution.

I hope you will not just take my word for it. More than 80 organizations supported the final passage of the CREATES Act. They would go all the way from the AARP over to the Consumers Union, which tend to be liberal organizations, all the way over to Taxpayers for Common Sense, which I think generally tends to be more conservative.

Our CREATES bill was approved in June by the Senate Judiciary Committee, which I chair, and has 30 Senate cosponsors. In addition to this legislation, I am also keeping tabs on proposed buyouts and mergers in the pharmaceutical supply chain. Without a doubt, increased market integration will impact consumers and taxpayers.

For example, the mergers of Cigna Corporation with Express Scripts Holding Company and the CVS Health Corporation with Aetna may negatively impact consumer choice. According to the Kaiser Family Foundation, once completed, these two mergers would result in just four entities controlling 71 percent of all of Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.

Notwithstanding the consumer benefits of business integration that can include more innovation and cost-saving efficiencies, we can't afford to turn a blind eye to potential negative consequences that consolidation in the U.S. pharmaceutical supply chain may have in the marketplace.

I will wrap up my remarks today with this message for the American people: President Trump made a promise to the people to lower drug prices. His administration is working to deliver on that promise. Most of the stuff that has gone on so far has been within what the law allows the President, through the Secretary of HHS, to do so that Congress doesn't have to be involved in everything. But Congress can surely give support to this program.

The President's blueprint for bringing down prescription drug prices lays out four principles: Boost competition, enhance negotiation, create incentives for lowering list prices, and, lastly, bring down out-of-pocket costs.

Last month, he signed the Patient Right to Know Act into law, so he has the help of some new legislation now. I cosponsored this bill by Senator SUSAN COLLINS to ban what are called "gag clauses," which keep pricing information from consumers every time they visit the pharmacy counter.

The new law prevents health insurance companies from prohibiting pharmacy providers from sharing pricing information with consumers. So now, under the Collins legislation, a pharmacist can alert a customer if their copayment would cost more than paying out-of-pocket, as just an example.

This puts a little bit of transparency into the whole process and lets your pharmacist help you as much as he can to save money. But there are rules that some companies have that you can't share that information.

So along the lines of also hoping to save the consumer some money—or at least to educate the consumer on pharmacy practices and to have more transparency—Senator DURBIN and I pushed for Senate passage of an amendment that supports existing Health and Human Services authority requiring drugmakers to disclose the list price of prescription drugs in direct-to-consumer advertising.

It happens that the House of Representatives rejected our amendment. Nonetheless, the Secretary of HHS is moving forward with our concept to improve transparency by requiring companies to include these same drug prices in their direct-to-consumer advertising.

Another example of where the President, through the Secretary of HHS, has, under present law, authority to move ahead—we wanted to let the Secretary know, through the Durbin-Grassley amendment, that we wanted to back him up in his efforts. Drug companies are already required to include possible side effects in their TV ads. So isn't it commonsense to add to that list price information to further improve consumer decision making? The more information patients and healthcare providers have to make decisions on costs and outcomes, it seems to me, the better off they are.

Finally, I would like to say a word about another commonsense solution to high drug prices. For over 20 years, I have advocated for the safe reimportation of drugs from countries such as Canada. The late Senator McCain, along with Senator KLOBUCHAR, introduced S. 92, the Safe and Affordable Drugs from Canada Act. I am a cosponsor of this bill, and I plan to work to get it enacted into law.

In today's marketplace, there is a giant disconnect between consumers and the prices they pay for their prescription medicines. To many of my constituents in Iowa, it is just plain baffling why this can't be done. Americans have come to expect the best medicine when they need it most. We need to improve the marketplace so that it functions properly to lower drug prices and raise the bar on outcomes.

Looking ahead, our Republican majority here in the U.S. Senate will keep up the momentum to deliver cost savings to the American people. On my watch, I will continue working across the aisle to lower drug prices, restore competition, and increase transparency in the pharmaceutical industry. I welcome the incoming Democratic House majority to join our efforts in behalf of the American taxpayers and consumers.

As Americans count our blessings during this season of Thanksgiving and going into Christmas, we give thanks for the gifts of friends and family who gather together around these celebration tables. I am thankful for good health and the opportunity to serve Iowans. Along these lines, I will do my best to restore competition in the pharmaceutical market and to stop the gravy train that is taking taxpayers for a ride.

I yield the floor.

The PRESIDING OFFICER. The majority leader.

LEGISLATIVE SESSION

Mr. McCONNELL. Mr. President, notwithstanding rule XXII, I move to proceed to legislative session.

The PRESIDING OFFICER. Without objection, the question is on agreeing to the motion.

The motion was agreed to.