

for this bill, but does not actually reduce the cost to the taxpayers. These so-called CHIMPS—we have a name for it now, changes in mandatory program spending—total \$8.5 billion in this bill. Of that amount, an astonishing 88 percent, or \$7.5 billion, results in no net spending reduction over 10 years.

Some of these CHIMPS have been going on year after year. One example is the Crime Victims Fund. Every year Congress says that the crime victims will get the funds they are due under the law next year which, unfortunately for the Crime Victims Fund, has not yet arrived since the annual deferral began in fiscal year 2000. In other words, it is done every year and there seems to be no prospect that this will not continue. Meanwhile, the appropriators get the amount deferred over and over again, enabling ever higher amounts of discretionary spending. It would be like a family delaying a single \$500 home repair for 10 years, and then counting it as \$5,000 in savings, \$500 for every year the repair did not take place. In this case, over the past 3 years the gimmick used in this bill has enabled \$14 billion in higher spending.

The ACTING PRESIDENT pro tempore. The Senator is informed the Senate is in a period for morning business and the time allotted for Senators to speak was 10 minutes.

Mr. SESSIONS. I thank the Chair and ask for 1 additional minute to close.

The ACTING PRESIDENT pro tempore. Without objection, it is so ordered.

Mr. SESSIONS. I am unable to support this bill. By its own standards it fails. It represents everything that is wrong with Washington today. It crams three bills, which should have been considered individually, into one, creating a process that curtails debate on spending at a time when we need more debate, not less. Further, it does virtually nothing to address the fiscal crisis threatening this country. It treats spending caps established earlier this summer as the most that can be saved, not as the starting point for savings, and then uses gimmicks to spend over and above that advertised limit. It is not a serious response to the explosive growth in Federal spending and falls short of the commitment we must make to handle taxpayer dollars honestly and responsibly. It is business as usual. The American people deserve better.

I yield the floor.

The ACTING PRESIDENT pro tempore. The Senator from Minnesota.

#### DRUG SHORTAGES

Ms. KLOBUCHAR. Mr. President, I rise today to talk about a serious public health crisis facing our Nation and to highlight some of the important progress we have made to date. We are currently confronting unprecedented shortages of critical medications. These drug shortages have impacted

people across our country, forcing some patients to delay their lifesaving treatments, or use unproven, less effective, alternatives. In some cases, drug shortages have resulted in patients not getting the kind of treatment they had gotten or being slow in getting their treatment and being left behind. I have been working to address this problem for over a year since I first heard from hospitals, pharmacists, and patients in Minnesota that they were facing shortages of essential medications, particularly chemotherapy drugs. Their urgency led me to send a letter to FDA Commissioner Hamburg, urging the FDA to take action to address this public health crisis.

Over the next few months, I continued to receive calls and visits from constituents, asking help to find medications in short supply. I worked with manufacturers, stakeholders, and the FDA to try to find an appropriate solution to ensure that patients continue to receive the care they deserve and they need.

I would add, while in several cases the crisis was averted, this took hours and hours of individual pharmacists' time, individual doctors' time. At a time when we are trying to be as efficient as possible in our health care system, the last thing we need is to have a doctor or nurse or pharmacist spend half a day to look for medication because there is a shortage.

In February I introduced the Preserving Access to Life-Saving Medications Act with Senator CASEY. This legislation, which has bipartisan support and a total of 17 cosponsors, would give the Food and Drug Administration the ability to require early notification from pharmaceutical companies when a factor arises that may result in a shortage. Today the President issued an Executive order that adopts this framework for an early notification system. The Executive order will do this: It will push drug companies to notify the FDA of any impending shortage of certain prescription drugs; it will expand the FDA's current efforts to expedite review of new manufacturing sites, drug suppliers, and manufacturing changes; and it will direct the FDA to work with the Department of Justice to examine whether drug companies have responded to potential drug shortages by illegally hoarding medications or raising prices to gouge consumers.

This action will help further reduce and prevent drug shortages, protect consumers, and prevent price gouging. This step enhances actions that have already been taken by the FDA and it puts in place additional tools to address drug shortages.

This is something we probably didn't hear about a few years ago, but this year we have learned that drug shortages are having a direct toll on families across America. A couple of months ago I met a young boy named Axel Zirbes. Axel Zirbes is a cute 4-year-old boy from the Twin Cities, with

bright eyes and a big smile. He also happens to have no hair on his head. That is because Axel is being treated for leukemia. When he was scheduled to start chemotherapy earlier this year, Axel's parents learned that an essential drug, cytarabine, was in short supply and might not be available for their son. Understandably they were thrown into a panic and desperately looked into any available alternatives. They even prepared to take Axel to Canada, where cytarabine is still readily available.

Imagine this. You are parents of a 4-year-old, you find out he has life-threatening leukemia, and you cannot get medication which is actually quite commonplace in the treatment of this disease, and you are starting to fly to Canada because our own country somehow has not kept up with the supply of this drug.

Fortunately he never had to go to Canada. At the last minute the hospital was able to secure the medication from a pharmacy that still had a supply. But Axel and his parents, sadly, are not alone. There were 178 drug shortages reported in 2010. Keep in mind, these are not individual stories such as Axel's. These are actually drugs, 178 different drugs across the country, basically affecting millions of patients, that had drug shortages in 2010. That is a dramatic increase from 5 years ago. There were 55 shortages 5 years ago. Think of that increase. For some of these drugs, no substitute drugs are available or, if they are, they are less effective and they may involve greater risks of adverse side effects.

The chance of medical errors also rises as providers are forced to use drugs they are not familiar with. A survey conducted by the American Hospital Association showed that nearly 100 percent of their hospitals experienced a shortage in the past year. Another survey, conducted by Premier Health System, showed that 89 percent of its hospitals and pharmacists experienced shortages that have caused a medication safety issue or an error in patient care.

We want to be doing the opposite. We want to be reducing errors. We want to be giving patients the help they need. It is clear there are a large number of overlapping factors resulting in unprecedented shortages. Experts cite a number of factors that are responsible for the shortages. These include market consolidation, poor business incentives, manufacturing problems, production delays, unexpected increases in demand for a drug, inability to procure raw materials, and even the influence of the gray markets, where people are basically hoarding these drugs when they find out there could be a shortage and then upping the prices, as if things were not bad enough.

Financial decisions in the pharmaceutical industry are also a major factor. Many of these medications are in short supply because companies have

simply stopped production. They decided it was not profitable enough to keep producing them.

Instead of low price, and lower profit, generic drugs, companies are looking at more expensive brandname drugs. Mergers in the drug industry have narrowed the focus of product lines. As a result, some products are discontinued or production is moved to different sites, leading to delays. When drugs are made by only a few companies, a decision by one drug company can have a huge impact on the market.

To help correct a poor market environment or to prevent gray market drugs from contaminating our medication supply chain, we must address the drug shortage problem at its root. The early notification system that would be established under the Preserving Access to Life-Saving Medications Act and the President's Executive order that is advanced today will help the FDA take the lead in working with pharmacy groups, drug manufacturers, and health care providers to better prepare for impending shortages, more effectively manage shortages when they occur, and minimize their impact on patient care.

Just so you know, the FDA already does this with orphan drugs. When there is only one drug and the drug manufacturer thinks they are going to run out of the drug they do tell the FDA so the FDA can step in and maybe look internationally for another drug. You saw that happen with the H1N1 virus. When we had a short supply they went to other countries. They are allowed to do that now, but manufacturers are not required to do it in some of the situations we are encountering now with those 178 drug shortages. That is what our bill does. It basically says if you see a drug shortage coming down the pipe because one or a number of these factors is present, you have to let the FDA now know. You have to work with the FDA because they have successfully averted dozens of drug shortages this year.

We do not pretend this is going to solve everything, but at least it is something we can do right now which will give the FDA the power to go in there and work with the drug manufacturers and try to find other sources so the person who is doing that is not the parent of a 4-year-old kid with leukemia or a pharmacist who is trying to serve customers at his pharmacy, or a doctor trying to treat patients and she has to get on the phone and call a bunch of hospitals to try to find a drug. It simply does not make any sense at all. This is a national problem, not a problem for a 4-year-old boy.

Our legislation would also direct the FDA to provide up-to-date public notification of any actual shortage situation and the actions the agency would take to address them.

Additionally, the bill requires the FDA to develop an evidence-based list of drugs vulnerable to shortages and to work with the manufacturers to come

up with a continuity of operations plan to address potential problems that may result in a shortage.

The bill would also direct the FDA to establish an expedited reinspection process for manufacturers of a product in shortage. This would allow them to get inspected sooner so we can get the drugs to market. With manufacturers providing early notification, the FDA's drug-shortage team, which already exists, can then appropriately use their tools to prevent shortages from happening. As I mentioned, in the last 2 years the FDA, with early notification and more information, has successfully prevented 137 drug shortages. So this is something that actually works.

While the President's Executive order takes steps toward advancing these goals, he has made it clear we must pass this bill in order to protect patients and ensure consumers they have access to the lifesaving medications they need and deserve. So the Executive order helps, but we still need to pass this bill.

I understand this may be a short-term solution to a long-term problem. That is why I have also been working with several of my colleagues on a bipartisan basis to come up with a broad, permanent solution, one that includes methods to address the root causes of drug shortages. This includes Senator MCCAIN, Senator CORKER, and Senator BURR. I also see Senator BLUMENTHAL here, who has been working on this issue. We have Senators—including Senator CASEY and others—working with the HELP Committee who have been working to get this done. At the urging of this bipartisan working group, the FDA held a public workshop in September that brought together patient advocates, consumer groups, health care professionals, and researchers to discuss the causes and the impact of drug shortages and possible strategies for preventing or mitigating future shortages.

In addition to the working group, I have been speaking with a broad range of stakeholders to try to discover why we have seen such a large number of drug shortages that we have not seen in the past. The facts don't lie, and the numbers don't lie. There has been an enormous increase in the number of drug shortages. This current explosion of shortages appears to be a consequence of a lack of supply of certain products to keep up with a substantial expansion in the scope and demand for these products.

Due to the complex nature of these drug shortages, there is no single or simple solution that would solve all problems. A solution will require everyone involved to play a role in mitigating future drug shortages. We must ensure we have the manufacturing capabilities to keep up with demand. One solution may be to provide tax incentives to manufacturers to continue to make drugs that are on the shortage list or to provide other market incentives, such as including exclusivity

pricing similar to that which we give to manufacturers that make orphan drugs. In addition, I have urged the FDA to improve its communication with patients and providers. This will ensure patients and doctors are not the last to know when there is a shortage. I also favor permanent reimportation of drugs from safe countries, such as Canada. Not everyone involved in this issue thinks that is a good idea, but I can tell you, if we were to allow that, that little 4-year-old boy would not have to look at flights to Canada.

One thing is clear: This is a national public health crisis that must be addressed. The President's actions today will provide additional tools to address drug shortages, but more must be done. I will continue to work with my colleagues in the bipartisan working group for a broad permanent solution. I will also continue to work with Senator CASEY, with the Presiding Officer, and with all of the other Senators involved in this, including Senator SUSAN COLLINS, to get our legislation passed. It is common sense. It is not over the top. It simply takes a tool that is used now to avert drug shortages for orphan drugs and expands it so that other drug manufacturers, when they have drugs that are going to experience a shortage, are required to notify the FDA. It gives the FDA that little extra time, whether it is 1 month, 6 months, or 1 year, to look for the drug in other locations. I think it would give us some insight into what is actually going on here so we can fix this.

I yield the floor.

The PRESIDING OFFICER (Mr. BLUMENTHAL). The Senator from Nebraska.

#### HONORING OUR ARMED FORCES

PETTY OFFICER FIRST CLASS CALEB NELSON

Mr. JOHANNES. Mr. President, I rise today to honor a fallen hero, Petty Officer First Class Caleb Nelson of Omaha, Nebraska. Petty Officer Nelson died on October 1, 2011, when his vehicle was struck by an explosive device in Afghanistan. He was on combat patrol with fellow SEAL team members when the attack occurred. His desire to succeed and help others led him to military service.

For Caleb, it had to be the best. For him, that was the Navy SEALs. Military commanders trusted Petty Officer Nelson's judgment and his commitment. He was typically assigned a leading role on search missions, placing the lives of many SEALs in his capable hands. Caleb was in the lead position when he was killed.

The decorations and badges earned during his distinguished service speak to his dedication and to his skill—The Bronze Star with Valor, the Purple Heart, the Navy and Marine Corps Achievement Medal, the Combat Action Ribbon, the Good Conduct Ribbon, the National Defense Medal, the Iraq Campaign Medal, the Afghanistan Campaign Medal, the Global War on