

the hands of special interests with unlimited bank accounts. We need to answer to the American people and not just to the privileged. Our Nation cannot afford a system that says "come on in" to the rich and powerful but then says "don't bother" to everyone else. The faith of the American people in their electoral system is being corrupted by big money. It is time to restore that faith. It is time for Congress to take back control. It is time for a constitutional amendment that will allow real reform.

With that, Mr. President, I yield the floor, and I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant bill clerk proceeded to call the roll.

Ms. KLOBUCHAR. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

DRUG SHORTAGE CRISIS

Ms. KLOBUCHAR. Mr. President, I rise today to talk about the drug shortage crisis that is continuing to spread across the country. I am proud to stand here today with my friend and colleague, Senator SUSAN COLLINS of Maine, who has been a leader on this issue and who shares my concern for so many patients who are struggling to find much needed medication. This is a crisis that has grown to such proportion that current drug shortages have impacted individuals all across the country, forcing some patients to delay their lifesaving treatments or use unproven, less effective alternatives. In some cases, drug shortages have even resulted in patient deaths. Enough is enough. We can no longer just simply talk about this issue and have meetings. We need to act.

Here is one story. A few months ago, I met a young boy named Axel Zirbes. Axel has bright eyes and a big smile. He also happens to have no hair on his head because he has childhood leukemia. When his parents found he had leukemia, and he was scheduled to start chemotherapy treatment last year, they 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, desperately looking for any available alternatives. They even prepared and made plans to take Axel to Canada, where the drug was still readily available. Fortunately, it didn't come to that.

But Axel and his parents are not alone. Earlier this month, I held a forum in Edina, MN, where a woman by the name of Mary McHugh Morrison shared her story of how she struggled with the shortage of the chemotherapy drug Doxil. When Doxil went into shortage last year, Mary was in the middle of her chemotherapy regimen and was shocked when her doctor told

her they had actually run out of the drug necessary to continue her treatment. This is in Minnesota, where we have excellent health care, as you know, Mr. President. Literally, they ran out of the drug in the middle of a chemotherapy treatment.

While trying to get herself added to a wait list, Mary was able to call around to other hospitals and clinics in her area in search of any available Doxil and was able to find extra treatments four separate times. She actually talked to the forum about how she grappled with the ethics of the fact that because she knew people and was able to call around and get this, that she was taking this limited drug out of supply for herself and not for other patients.

However, because of a few delays in the treatment, Mary's doctor told her that her tumor had, unfortunately, returned and that she was no longer responding to Doxil. She is now going without treatment and, depending on her health condition, could be placed on a clinical trial at the Mayo Clinic in March.

But these shortages aren't just affecting cancer patients. There are also shortages in drugs that help people improve their quality of life. Just this week, the Minneapolis Star Tribune reported that hundreds of patients in the Minnesota Sleep Disorder Center at Hennepin County Medical Center have suffered a shortage of Ritalin, Adderall, and their generic equivalents. These shortages have had significant impacts on these patients' quality of life, oftentimes forcing them to pay hundreds more dollars for expensive alternatives or professionals risking their careers to adjust to their diseases and spending extra hours and days of time trying to find ways to fill their prescriptions or their pharmacists doing that or their doctors doing that or their nurses doing that. We know how difficult this health care system is anyway, and now we are putting patients in this position and wasting the time of medical professionals to find drugs that should be readily available.

These are just a few examples of real people who are just trying to deal with their disease, and there are many more like them.

Across the country, hospitals, physicians, and pharmacists are confronting unprecedented shortages. Many of these are generic drug products that have been widely used for years and are proven effective. Many of them are for cancer. The number of drug shortages has more than tripled over the last 6 years—and if you don't believe my stories, listen to this—jumping from 61 drug products that were in shortage in 2005 to more than 200 last year. That is not 200 instances, that is 200 different kinds of drugs that affect hundreds of thousands and millions of patients across this country. A survey by the American Hospital Association found that virtually every single hospital in the United States of America has expe-

rienced shortages of critical drugs in the past 6 months. More than 80 percent reported delays in patient treatment due to a shortage. These aren't just a few stories that come into our office anymore, these are the facts.

For some of these drugs, no substitutes are available or, if they are, they may be less effective and may involve greater risk of adverse side effects. The chance of medical errors also rises as providers are forced to use second- or third-tier drugs with which they are less familiar.

A survey conducted by the American Hospital Association showed that nearly 100 percent of their hospitals experienced a shortage. Another survey conducted by Premier Health System showed that 89 percent of its hospitals and pharmacists experienced shortages that may have caused a medication safety issue or error in patient care.

It is clear that there are a large number of overlapping factors that are resulting in unprecedented shortages. Experts cite a number of factors that are responsible. These include market consolidation and poor business incentives, manufacturing problems, production delays, unexpected increases in demand for a drug, inability to procure raw materials, and even—and this is a new phenomenon—the influence of a "gray market," where middlemen are literally hoarding the drugs because they have heard there is going to be a shortage.

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 wasn't profitable enough to keep producing them. Mergers in the drug industry have narrowed the focus of production lines. As a result, some products are discontinued or production has moved to different sites, leading to delays. When drugs are made by only a few companies, a decision by any one drugmaker can have a large impact.

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. Last year, I introduced the Preserving Access to Life-Saving Medications Act to address this issue. With the support and leadership of Senator COLLINS, Senator BOB CASEY, and others, this bipartisan bill would require drug manufacturers to provide early notification to the FDA whenever there is a factor that may lead to a shortage. This will help the FDA take the lead in working with pharmacy groups, drug manufacturers, and health care providers to better manage and prepare for impending shortages, more effectively manage those shortages when they occur, and

minimize—and that is what we want to do—their impact on patient care. The legislation would also direct the FDA to provide up-to-date public information of a 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. With manufacturers providing early notification, the FDA's drug shortage team—and they do now have a drug shortage team—can then appropriately use their tools to prevent shortages from happening.

If you think this wouldn't work, in the last 2 years the FDA, with more information, has successfully prevented nearly 200 drug shortages. So it does work when they get the information. But nothing requires them to get the information, and that is what we are trying to do today. It is not the end-all, be-all solution for the long term, but at least in the short term, when these patients are experiencing these drug shortages that can impact their treatment, that can impact their lives, it gives the FDA that extra tool to look for alternative drugs. If they can't find them in this country, maybe they can find them in Canada. But it puts the patient first, not the drug companies.

At the urging of the bipartisan work group I have been involved in, the FDA held a public workshop last September that brought together patient advocates, industry, 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 workshop, we have been speaking with a broad range of stakeholders to try to discover why we have seen such a large number of shortages over the past few years. This current explosion of shortages appears to be a consequence of a lack of supply of certain products to keep up with the substantial expansion in the scope and demand for these products. We must ensure we have the manufacturing capabilities to keep up with the demand.

There are a lot of ideas for incentives and pricing, but we also know that those will take a long time to take effect on the immediate shortage problem. That is why we want to get this bill passed—and passed very soon.

The President has issued an Executive order, which is helpful, but it still doesn't get at the very serious problem of the kinds of drug shortages we are seeing. The Executive order pushes drug companies to notify the FDA of impending shortages, expands the FDA's current efforts, and instructs

the FDA to work with the Department of Justice. But there is still much more work to be done. Patients such as Axel or Mary shouldn't have to be burdened with the added stress and worry about whether they have enough medicine. It is time for action. I urge my colleagues to pass our bill.

I now turn it over to my friend and colleague from Maine, Senator SUSAN COLLINS.

THE PRESIDING OFFICER. The Senator from Maine.

Ms. COLLINS. Mr. President, let me first begin my remarks by commending my friend and colleague from Minnesota for leading the way on this very important bill.

There are so many issues that divide us in this Chamber. Surely, this is an issue that should unite us. It is not a Democratic issue. It is not a Republican issue. It is an issue of serious consequence to the American people and to our health care system. I would hope—and the reason Senator KLOBUCHAR and I have come to the floor today—that we can act immediately to pass our bill, get it through the House, and send it to the President.

Physicians, pharmacists, and patients throughout the country are struggling to cope with the surge in shortages of needed drugs which is causing significant disruption in health care and putting patients at risk. I share with my colleague from Minnesota her concern about this critically important problem.

According to the U.S. Food and Drug Administration, the number of drug shortages has nearly quadrupled over the last 6 years, jumping from 61 products in 2005 to a record 231 by the end of November of last year. And there appears to be no end in sight.

Many of the drugs in short supply are vital. They are used in hospitals and cancer centers for anesthesia, for chemotherapy, and for the treatment of infections. There are also continuing shortages of drugs used in emergency rooms and in intensive care units.

I have met with several doctors and other medical professionals and pharmacists in Maine who are extremely concerned about this issue. They have told me that these shortages are causing serious problems around our State and across our Nation, including forcing some medical centers to ration drugs or postpone elective surgeries. Even more tragic, oncologists have told me of situations where they have been forced to change a patient's chemotherapy regime midcourse because they suddenly encountered a shortage of a particular drug. Moreover, for some drugs, such as the leukemia drug Cytarabine, which Senator KLOBUCHAR mentioned as well, there are no effective substitutes.

This crisis is widespread. In a survey by the American Hospital Association, more than 80 percent of our hospitals reported that they have had to delay treatment due to the shortages. Just think what that is like for a patient

who has received the diagnosis of cancer and has started treatment and then finds out the lifesaving drug they need is not available. It is hard enough to cope with the devastating diagnosis. To add to that the fact that the drug you need isn't available is just too much to bear. More than half of our hospitals have said they could not provide some of their patients with the recommended therapy.

Drug shortages are also adding to the cost of care. Hospital pharmacists are having to spend additional time—some 8 to 12 hours per week—dealing with shortages, increasing labor costs by an estimated \$216 million a year.

That is why I joined with my colleague from Minnesota in cosponsoring the Preserving Access to Life-Saving Medications Act. Our bill will provide the FDA with better tools to better manage and, we hope, prevent shortages of lifesaving medications.

First and foremost, it takes the very commonsense step of requiring pharmaceutical manufacturers to notify the FDA of the discontinuance, interruption, or other adjustment in the manufacture of a drug that would likely lead to a shortage. Providing early warning when a drug will not be available will help both physicians and their patients. It builds on its successful model—the FDA's Drug Shortage Program—which encourages manufacturers to report potential or existing shortages so that the problems can be addressed or other manufacturers can ramp up their production. Through this voluntary approach, the FDA was able to avert 195 shortages last year.

Our bill also directs the FDA to provide up-to-date public notification of any shortages, and it directs the FDA to work with manufacturers to establish contingency plans to address drug shortages due to manufacturing problems, such as the shortage of raw materials or reduction in production capabilities.

Our legislation would give the FDA the information and the tools it needs to help address and prevent drug shortages. This, in turn, will help to ensure that our hospitals and health care professionals are able to provide the best care medical science allows. Most important, it will help ensure that patients have access to the medications they need when they need them most.

I am proud to join with my colleague from Minnesota in sponsoring such an important initiative. I urge our colleagues on the HELP Committee to act quickly to report this bill and the full Senate to act without delay to approve it as well. Surely, this is an issue that should bring this Chamber together and that we should act on immediately.

THE PRESIDING OFFICER. The Senator from Minnesota.

Ms. KLOBUCHAR. Mr. President, I ask to speak as in morning business.

THE PRESIDING OFFICER. Without objection, it is so ordered.

Ms. KLOBUCHAR. Mr. President, I thank Senator COLLINS for her great

leadership. This bill is moving. This bill is picking up support across the Nation. Again, we need to get it done. We cannot wait. These patients cannot wait.

CITIZENS UNITED

Ms. KLOBUCHAR. I am here today also to talk about something that is very important to the future of our democracy; that is, campaign finance reform and the Citizens United decision by the Supreme Court which had its second anniversary a few days ago.

I see Senator GILLIBRAND from New York is also here to speak on this important issue. She is a leader. The Presiding Officer has done some very important work in this area as well, which I will get to in a minute. Most fundamentally, I am here to talk about the public lack of trust and our need to ensure that the American people have a government that is responsive to their concerns.

It is vital that the American people have trust and confidence in their government. Right now it is clear they do not have either. The American people believe Washington is focused more on scoring political points for special interests and not looking out for their interests, for the interests of the people of this country, for the interests of the middle class. They have seen the preservation of oil company subsidies while at the same time the price of gasoline has remained painfully high. Simply put, they think the system is broken.

While most people probably do not have the time to study the intricate details of campaign finance law, which unfortunately has loopholes and things written in it that make it hard to figure, the American people have a pretty good sense there is something wrong with how we conduct our elections. The American people know spending on campaigns has gotten out of control and that spending by special interest groups is contributing greatly to that problem—and they are right.

The Supreme Court Citizens United decision has made it profoundly worse by loosening the rules on special interest spending on political campaigns. We are now in a situation where candidates have to report every single contribution they raise over a certain amount. That is good. But literally millions of dollars in special interest money can come in in attack ads, can come in and do whatever it wants, and you literally cannot prove who that person is who put in that money. It shakes the very foundation of our democracy when the people who are voting in these elections cannot even tell where the money is coming from that is paying for the ads.

Citizens United has unleashed a new wave of special interest spending, and the American people have been inundated with negative ads on their televisions. Worse, they are constantly hearing about the increased role that

special interests are playing in our elections, and that heightens their suspicions that Washington is working only for the powerful, only for the people who can pay for issue ads. The public justifiably believes the more money outside groups spend on campaigns the less their voices are heard. How can they have a voice when people are drowning out their voices with multimillions of dollars? This is a big problem and it is something I think we need to address.

The President touched on this issue of money in politics in his State of the Union this week, and in his address last year he took on Citizens United directly. He knows we need change, and I agree. Unfortunately, the Citizens United decision makes it very difficult to take action legislatively. That is why I am a sponsor of a constitutional amendment which would allow Congress to pass laws regulating campaign fundraising and spending.

TOM UDALL has worked on one. I know the Presiding Officer also has a similar bill as well. I hope we can advance this amendment, but I realize it will be an uphill battle, especially as we enter an election year. But we must change this system. In the meantime, even before the election, I am hopeful we will take some steps to make it more transparent so at least we can start finding out who is spending this money—the people of Vermont or the people of New York or the people of Minnesota can find out who is putting in millions of dollars, and they can draw their own conclusions—they are pretty smart—about why they are spending that money.

We need it to be transparent. We also have to stem this great abuse of power, this great amount of money that is coming into the system. But in the end we will need a constitutional amendment.

Mrs. FEINSTEIN. Mr. President, I rise today to join my colleagues in marking the 2-year anniversary of the Supreme Court's decision in Citizens United. I want to express my support for legislation to reverse the harmful impact of this decision and restore accountability, transparency and common sense to our Nation's electoral system.

Nearly 2 years ago, on January 21, 2010, the Roberts Court handed down a 5-4 decision striking down parts of the "Bipartisan Campaign Reform Act."

That decision—Citizens United v. Federal Election Commission—flew in the face of nearly a century of Congressional law and overturned two prior rulings of the Supreme Court.

This case is not alone.

It is part of a pattern of decisions from the Roberts Court that have overturned precedent.

I have a real concern that this Court is going out of its way to rewrite and reinterpret prior law with decisions, I am sorry to say, seem to favor corporate interests over the interests of the American people.

The Citizens United decision may be the most troubling of these activist decisions.

This decision does not only impact one group of people or one area of the law—it affects the very functioning of our elections and the democracy of more than 300 million Americans.

The Court's decision in this case opened the door to unlimited corporate spending in Federal elections.

Let me repeat: unlimited spending.

The Court held that the First Amendment of the Constitution protects the rights of corporations to spend freely—in the millions or even the billions—on election ads to support or defeat a particular candidate.

What does this mean in the real world?

This means that an oil company like ExxonMobil—a company that earned \$45 billion in profits last year—could spend unlimited money to support a candidate who supports more drilling, or to defeat a candidate who opposes more oil drilling.

It means that Xe Services, formerly known as Blackwater, and other defense contractors could spend unlimited sums toward the election of candidates who view their defense positions favorably.

Or large banks like Bank of America would be free to use their corporate treasury to attack candidates who favor financial regulation and consumer protection.

As Fred Wertheimer of Democracy 21 testified at a Rules Committee hearing in 2010, "It would not take many examples of elections where multimillion corporate expenditures defeat a Member of Congress before all Members quickly learn the lesson, vote against the corporate interest at stake in a piece of legislation and you run the risk of being hit with a multimillion-dollar corporate ad campaign to defeat you."

Is this what we want?

Four years ago in 2008, at this same point in the presidential election cycle, \$12.9 million was spent by super PACs in support of candidates.

The fall 2010 midterm elections ushered in this new political landscape with outside groups spending a record \$300 million on political advertisements and other messages. This amount represents a 340 percent increase above 2006 spending levels.

According to the Center for Responsive Politics, the spending by presidential super PACs in this year's election cycle has quadrupled since 2008 to an astonishing \$42.5 million spent as of January 24, 2012.

More money is being spent than ever before.

Do not take my word for it.

Take a look at what is going on in the Republican Presidential primary. Corporations and wealthy individuals are funding these super PACs and spending vast amounts of money to attack candidates.

My concerns with these dramatic increases in spending are heightened by a