I congratulate Ford on this development and applaud its continued excellence in manufacturing in the Commonwealth of Kentucky.

I yield the floor.

RESERVATION OF LEADER TIME

The PRESIDING OFFICER. Under the previous order, the leadership time is reserved.

MORNING BUSINESS

The PRESIDING OFFICER. Under the previous order, the Senate will be in a period of morning business for 1 hour, with Senators permitted to speak therein for up to 10 minutes each, with the time equally divided and controlled between the two leaders or their designees, with the majority controlling the first half.

The Senator from Indiana.

CONGRATULATING SENATOR McCONNELL

Mr. DONNELLY. Mr. President, I would like to congratulate my friend from Kentucky on Ford's expansion there. We have a proud auto building history in Indiana as well. We are extraordinarily proud of all the different folks who help make our country run, who help make our cars go, and in Indiana it is part of who we are. It is great to see expansion in Kentucky as well.

MANUFACTURING JOBS FOR AMERICA

Mr. DONNELLY. Mr. President, I am here today to discuss the most important issue facing Hoosiers—and all Americans—and that is getting a good job.

Good jobs allow us to provide for our loved ones, educate our children, and ultimately retire with dignity. Good jobs are also critical for strong communities and a vibrant economy. That is why I am proud to be part of the group of Senators working on Manufacturing Jobs for America. It is an effort to refocus the Senate on helping businesses create jobs and helping communities pursue economic development in the area of manufacturing.

This effort is aimed at building bipartisan support for modernizing the manufacturing sector, increasing access to capital, strengthening our workforce, and creating the conditions necessary for American manufacturers to grow and create jobs.

I have two bills as a part of this effort, the Skills Gap Strategy Act and the AMERICA Works Act. Both of them are focused on closing the skills gap. There are an estimated 600,000 manufacturing jobs that are unfilled across our country in part because employers cannot find workers with the skills they need to fill these open jobs.

We need to match up unemployed or underemployed Americans with the training and education programs employers need so we can get more Americans into these good-paying, skilled jobs.

Last month my friend, Senator DEAN HELLER, and I introduced the Skills Gap Strategy Act. This directs the Department of Labor to develop a goal-oriented strategy to address our skills gap challenges. In order for every Hoosier who wants a job to have a job, and for Indiana's economy to continue to grow, we must train Hoosiers for the jobs that are available right now.

Our bill examines how we can better use existing resources to prioritize training and education programs and prepare our workforce to hit the ground running on day one.

The Skills Gap Strategy Act requires the Department of Labor to provide recommendations on: increasing on-the-job training and apprenticeship opportunities, helping employers participate more in education and workforce training, and identifying and prioritizing in-demand credentials in existing and emerging industries.

When completing this report, we call on the Department to consider: specific labor barriers contributing to the skills gap; policies that have proven successful in key industries, regions, and countries where employers play a larger role in education and workforce training; and ways to better utilize Registered Apprenticeship and other workforce development programs.

We are also asking the Department of Labor to develop plans with the Departments of Commerce and Education to align education with industry and enhance employer participation in K through 12 and career and technical education programs, to increase preapprenticeship and college credit courses in secondary schools, and to improve school-to-work transitions and connections.

I am a strong believer in being fiscally responsible with Hoosier taxpayer dollars. That is why our bill asks the Department of Labor to focus on these solutions that use existing resources, existing programs, and existing personnel—not new programs or new spending.

Closing the skills gap requires participation from individual workers, the education community, and employers. But we have the ability to help, and a specific plan should be in place to do just that.

Also a part of the Manufacturing Jobs for America effort is another bill I am proud to support that focuses on closing the skills gap. Introduced by Senators HAGAN, HELLER, and myself, the AMERICA Works Act modifies existing Federal training programs so that they place a priority on programs and certifications that are recognized and demanded by industry.

I have heard time after time from Hoosier business owners and educators and workers about the pressing need to close the skills gap and to get more people to work.

To address this issue while not increasing Federal spending, the AMERICA Works Act modifies the Workforce Investment Act, Perkins Career and Technical Education, and Trade Adjustment Assistance to prioritize the credentials that employers need now.

The improvements made in this bill benefit both workers and employers, as workers would know that the time they spend training is more likely to lead to employment in a good-paying job, and employers would know that it is more likely that the people they hire would have the training they need to get the job done on day one.

The Department of Labor estimates there are nearly 4 million job openings in the United States, despite an unemployment rate that is still over 7 percent and despite millions of Americans looking for work. Now is the time to get to work on these jobs and match these people up with the job opportunities that are available out there. That is the most important thing we can be doing.

When Americans are working, we are a stronger nation. The Manufacturing Jobs for America effort to pass bipartisan legislation that everyone can buy into that helps manufacturers and workers is one important way we can move the ball ahead.

I yield back the remainder of my time.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

The PRESIDING OFFICER (Ms. HEITKAMP.) Without objection, it is so ordered.

Mr. MARKEY. Madam President, I ask unanimous consent to speak for up to 10 minutes as in morning business.

The PRESIDING OFFICER. The Senator is recognized.

DRUG QUALITY AND SECURITY ACT

Mr. MARKEY. Madam President, I wish to begin by thanking Chairman HARKIN, Ranking Member ALEXANDER, Senators FRANKEN and ROBERTS, and all of their staffs for their tremendous leadership on this bill. This bill was also developed in concert with our counterparts in the House of Representatives. I extend my thanks to ranking member HENRY WAXMAN and chairman FRED UPTON and their staffs of the Energy and Commerce Committee. What we have now is a bipartisan, bicameral bill that addresses two very serious issues: the safety of compounded drugs and the security of our entire drug supply.

Last fall an outbreak of fungal meningitis stunned the Nation and thus far has claimed the lives of 64 people and has sickened 751 in 20 States. This issue hits home for me because it started in

Massachusetts. At the center of this tragedy was the New England Compounding Center, also known as NECC. It is located in Framingham, MA. I met some of the victims of this terrible outbreak and heard about their struggles, people like Jerry Cohen, a resident of Pikesville, MD, who went to the doctor for routine steroid injections to treat recurring back pain and received two doses that came from the contaminated lots. Jerry suffered a stroke and had to adjust to a new life, dealing with dizziness, nausea, weakness, and exhaustion. Melanie Norwood's mother Marjorie went into a Tennessee hospital to treat an acute back injury she suffered while mowing the lawn. Instead of walking out of the hospital, Marjorie became severely sick, spent months in the hospital and a nursing home, and now has permanent nerve damage and medical bills that are close to putting her into bankruptcy.

For the last decade complaints about sterility, safety, lack of valid prescriptions, and mass production of drugs have been lodged against NECC. Yet the company was allowed to continue operating largely unchecked, falling between the regulatory checks that exist between Federal oversight of drug manufacturers and State oversight of pharmacies.

Sadly, NECC was not an isolated instance. Almost a year ago I issued a report detailing more than a decade of violations and problems at compounding pharmacies all across our Nation. Contaminated IV solutions, tainted steroid injections, and fouled eyedrops permanently impacted thousands of patients' lives across this country and killed or injured dozens across 34 States. The New England Compounding Center, like many large compounding facilities, fell into a regulatory black hole. That is because there are two kinds of compounding pharmacies: the neighborhood pharmacist you have known and trusted for years and the large drug manufacturers operating in the shadows that have slipped through the regulatory cracks.

Traditional compounding pharmacies make custom medication that fits the needs of an individual patient, such as creating a liquid medication instead of a pill for an elderly patient or a child because it is easier to swallow. We are familiar with that corner-store pharmacist who does that for a patient. These pharmacies are an important tool in our medical arsenal and have historically fallen under the jurisdiction of the States. They are the corner pharmacies that people grew up with. They are the corner pharmacies that people trust.

But there has been a recent disturbing trend of larger compounding pharmacies entering the market, making high-risk drugs sold to hospitals and clinics throughout the country. These compounding facilities are operating more as modern-day drug manufacturers rather than the mortar-and-pestle compounders of yesteryear on the corner near your home. They are not on Main Street, and they do most of their business out of site and under the FDA's radar.

In 1997 Congress passed a law to define FDA's role in the oversight of compounding pharmacies, but just 2 days before the new law was to take effect seven compounding pharmacies sued to block its enactment. Since then, the law and the FDA's authority to regulate compounding pharmacies have been mired in litigation and uncertainty. The result is that oversight of even large-scale drug manufacturers, such as NECC, has been largely relegated to the States.

How are the States doing their job? Well, last April I issued an investigative report that took a deep look at how States actually oversee and govern the activities of compounding pharmacies. What I found was a regulatory state of disarray. My investigation found that nationwide most State regulators did not look at the safety of compounding pharmacies. They do not make all their activities and investigations public. Some of them did not even know how many compounding pharmacies exist in their State, and States typically are not equipped to regulate the safety of large companies shipping massive quantities of drugs outside their own borders into States all across our country.

Since the NECC outbreak, some States have made efforts to improve their regulations and guidelines over compounding pharmacies, but the results are not consistent. Within the last month my home State of Massachusetts passed through its house and senate a bill that I am proud to say will put in place the strongest State regulations in the country overseeing the compounding pharmacy industry. However, while Massachusetts has become a national leader in the oversight of compounding pharmacies in the aftermath of what happened at NECC, this does little to protect the residents of other States. It cannot protect residents of Massachusetts from drugs that are shipped in from other States that do not have strong safety standards in place.

The Drug Safety and Security Act in front of us today helps to solve that problem by creating for the first time a national and uniform set of rules for compounding pharmacies that wish to register with the FDA and be subject to FDA oversight and enforcement. The bill also provides transparency by requiring the FDA to publish a list of the name and location of registered facilities that are compounding drugs in large quantities without a prescription. The Drug Safety and Security Act also mirrors several concepts from the VALID Compounding Act of 2013, legislation which I introduced in the House of Representatives. The bill distinguishes between compounders engaging in traditional pharmacy work and those making large volumes of compounded drugs without individual prescriptions. It places limits on the types and quality of ingredients that can be used to compound drugs. It ensures that drugs removed for the market for safety and effectiveness reasons are not compounded. The bill requires reporting of adverse events, such as patient sickness or hospitalizations that could be caused by compounding pharmacies that are registered with the FDA. It provides more information on the label of compounded drugs, including identification of the drug as being compounded—the first time ever that this information will be required.

Because of this bill, for the first time ever, the FDA will know who these large sterile compounding entities are and what they are making. The FDA will be given the resources it needs to conduct inspections of those facilities. For the first time ever, hospitals and health care facilities will have the option of purchasing compounded drugs that are subject to rigorous FDA quality standards and oversight. Because this bill removes the legal ambiguities of existing law, compounding pharmacies will no longer fly under the radar. This bill will go a long way in ensuring that public health is protected and compounded drugs are safe.

I specifically thank Chairman HARKIN and his staff for including in this bill a provision that I authored requiring the GAO to examine whether States and Federal authorities are doing their jobs to properly ensure the safety of compounded drugs.

Congress needs to continue to keep a close eye on the FDA and this industry, holding them accountable for their new responsibilities. This study will assist us in carrying out effective oversight of this new law. We need to ensure that a tragedy like the NECC meningitis outbreak is never repeated.

With the passage of the Drug Safety and Security Act, today we have a clear example of what Congress can accomplish when both sides come together in a bipartisan fashion. We can protect the public, we can hold industry to high but achievable standards, and we can support small businesses that have been doing the right thing for years.

This is a very important, historic piece of legislation. It goes right to the heart of what Congress can do to make sure that when drugs are in interstate commerce, we are protecting people so that the health of their families is, in fact, being protected. That is the essence of what Congress should be doing.

It is a very good day when Congress is working to protect the people of our country. Today is one of those days. Throughout the course of this week we are going to have a discussion about the role the Federal Government has to play in ensuring that the drugs which families in our country use are, in fact, safe for their consumption, that the representations that are made to those families are accurate. We cannot accept a rollback of the protections,

which did happen in this area. That exposed families to the kinds of risks that generations ago were common within our country. It is a big day. It is a historic piece of legislation. I urge its unanimous passage through this body.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. BLUNT. I ask unanimous consent that the order for the quorum call be rescinded.

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

AFFORDABLE CARE ACT

Mr. BLUNT. It has been less than 6 weeks since the President's health care initiative, the Affordable Care Act, was launched. The Web site is still not working, but the Web site will work. Actually, the Web site will be the easiest thing, in my view, that the administration will deal with as they try to solve the problems created by the act itself and, frankly, then the problems that were created by the Web site not working when we started.

What we see happening already in these 6 weeks is that families are losing their current health care coverage, and certainly the cost, in example after example from my State of Missouri and across the country, appears to be going up at substantial levels for many families. A few families are lucky enough that they don't have much additional cost but not very many. A lot of families are simply losing the coverage they have had even though the President said, as we all have been reminded over and over in recent days: If you like your health care plan, you can keep your health care plan.

Apparently, there are a whole lot of caveats on that that weren't said at the time, because people aren't able to keep their health care plan. The Associated Press reported that at least 3.5 million people have received cancellation notices. I heard somebody at the White House the other day say: These individual policies, that is only about 5 percent of all the people in the country. Five percent of all of the people in the country are millions and millions of people. Even if there weren't millions of people, if someone is one of the 3.5 million families who were recently told their health care policy was cancelled—100 percent of their health care policies were cancelled because they don't have one right now—or at least they were told they won't have one sometime between now and the end of the year.

As millions of people are losing their plans, we find out that only a few thousand people are signed up. Reports apparently show that fewer than 50,000 people have been able to successfully get through this system in 6 weeks, a period where the estimate was 500,000 people. So far we have 50,000 people signing up, not 500,000 people. We have millions of people losing their plans, even though everybody was told that if they like their plan, they will be able to keep their plan.

It is estimated now that 7 million people were expected to get coverage by the end of March. Nobody, any longer, thinks that is a number that will come anywhere close to being achieved.

The American people, obviously, would like the President to figure out how to live up to the promise that people can keep the health care they have if they like it. A lot of people are weighing in.

President Clinton, in the last day or so, says we ought to figure out a way to keep the promise. This is not a real reach. This was not a promise made only one time and accidentally stated, this was a promise stated over and over again: If you like your health care plan, you can keep it. If you like your doctor, you can keep your doctor.

We are finding that is not true. Whether it is President Clinton who said we should figure out how to keep that promise, or there are all kinds of bills being filed in both the House and the Senate that would keep the promise, what I think we are going to find out is there are many promises in the Affordable Care Act that aren't going to be kept.

We already know this has a workplace impact that is not good. People are going from full time to part time. People are trying to keep their employee numbers under 50 so they don't have to comply with the law. I have heard from many Missourians who have seen their hours reduced, seen their health care premiums rise, seen their options of insurance limited and their policies being cancelled. They deserve to have the people who made this pledge now keep this pledge.

Congressional Democrats voted for the law. And there are very few laws one could say congressional Democrats voted for the law. This is a law that not a single Republican in the House or the Senate supported.

There were many alternatives available. High-risk pools would work better, medical liability reform, expanding the marketplace where one could buy across State lines, more reporting by healthcare providers of what they charge and what their results are.

The idea that there were no other options, which is widely repeated—that the people who don't want to follow the Affordable Care Act don't want to do anything—is simply not true. When I was a Member of the House of Representatives, I filed a handful of bills, none of which were more than 75 pages long, that would deal with these rifleshot things that would have made the best health care system in the world better. It wasn't perfect, but it was the best health care system in the world, and I think we are in danger of losing that.

The President promised: If you like your doctor, you can keep your doctor. Over and over again, that is not the case. The largest insurer on the Missouri exchange, on the exchange that Missouri voters have access to, doesn't include the largest hospital system. That means thousands of patients won't be able to see the doctors or to go to the 13 hospitals of the largest health care system from the company that was their likely provider. This was the largest insurer—and as of this moment, the largest insurer in our State, the largest health care system—not part of their plan. Your insurance company, hospital, long-time doctor, all should be your choice, not the choice of some government-dictated health care plan. With only one other insurer selling policies in the region where this big hospital system is, people aren't going to be able to go there.

Many States have this same problem. Many States have options that don't include many of their hospitals or many of their health care providers.

People are beginning to look at this and not only be concerned about a violated pledge, but being concerned about somebody besides them interfering with a long-term relationship with the hospital people go to and the doctor they see. Patients across the country are seeing and are likely to continue to see narrower and narrower networks available to them as insurers will try to keep costs down.

With all of the new mandates in the law, one of the things they can control is they can negotiate with the people who would be available to see patients under their plan. That is obviously what has happened.

Smaller networks can require patients to travel farther. People are driving by the doctor's office that they went to for years to get to the doctor they now have to go to. People are passing by the hospital that their family may have gone to for generations to get to the hospital that now is the only hospital available in their area, available under the exchange. This is going to become the routine for Americans who aren't going to be able to keep the insurance they like. They are not going to be able to keep the doctor they like, and in many cases they won't be able to go to the hospital they like.

Last week I told stories of several Missourians who had preexisting conditions and are going to lose those policies when the Missouri high-risk pool goes out of existence.

Another thing we suggested in 2009 was to look for ways to expand the high-risk pools and make them work even better. They were working pretty well. The problem was there was always a waiting list to get into the high-risk pool. This was a way to deal with preexisting conditions. In a State such as ours where 4,300 people are in the high-risk pool, they pay about 135 percent of the normal premium. That is a little more than the normal premium, but they are getting insurance after they got sick. This is a high-risk