

looks as if the per capita use in the rural areas is higher than it is anywhere else, including the inner city or our suburban areas. But no ZIP Code is immune from this; we are all affected by it. In Ohio, over the last week, there have been two incidents where people have overdosed while behind the wheel. In one just a couple of days ago, someone overdosed on heroin while his kids were in the backseat, and he had a bad crash. Luckily, the children were not injured badly. This continues to happen again and again. And of course much crime is being committed to pay for the habit.

This is an effort at the Federal Government level to work with State and local governments and with nonprofits to address this growing problem, the epidemic of prescription drugs and heroin abuse.

I encourage the Judiciary Committee to move swiftly with this legislation. There is a markup scheduled on Thursday so we can move this legislation to the floor of the Senate, get it to the House, and get it to the President for his signature.

There seems to be not only bipartisan but nonpartisan support for this legislation. In other words, this is not a political issue but something that affects us as fathers, mothers, brothers, and sons. I hope the Senate will take on this issue.

I was in Ohio yesterday meeting with some women who are recovering addicts, and they told me their stories. Many of them started on prescription drugs sometimes because of an accident. They talked to me about how the grip of addiction is so great that it requires real courage and real resilience to be able to come through it. We want those women and others to be able to live out their God-given abilities and not to be afflicted by this addiction, which is really a disease. This legislation we have before us is a step in the right direction.

I encourage my colleagues on both sides of the aisle to support it and to move it to the President so we can begin to help local communities, neighborhoods, and our States be able to address this growing problem.

I yield back my time, Mr. President. The PRESIDING OFFICER. The Senator from West Virginia.

#### PRESCRIPTION DRUG ADDICTION

Mr. MANCHIN. Mr. President, first, I say to my colleague from Ohio—Senator PORTMAN, who is a dear friend—that we all have it; you are right, it is nonpartisan. This has no home. This has affected every American family one way or another. There is not a person I know in my State or in the good State of Ohio that doesn't have a family member—immediate family, extended family—or close friend who hasn't been affected by legal prescription drug abuse. We are looking at a whole cultural change that needs to go on, and I am on the floor to share letters with you.

Senator PORTMAN, I am sure you are getting the same letters. I would encourage all our colleagues to read just one letter a week from a family whose lives have been changed. They have lost a husband, they have lost their childhood, or they have lost a dear family member. It has destroyed their family life as they knew it. They can't get a job—a first-time felony offense, and they are out of the workforce now.

If you talk to law enforcement, there is not a law enforcement agency in America today that will not tell you that 80 percent of their crimes are drug related. Theft, arson, robbery—whatever it may be, it is around drug abuse.

So I come to the floor to continue to share the story of millions of Americans—most importantly, of some of my very dear West Virginia family members—who have had this.

I applaud the good Senator from Ohio. All of us are working. This will go through a normal process, I hope. It will be an open amendment process, and we are all going to make a piece of legislation and maybe for the first time start changing the culture in America, starting right here in Washington, DC, with the Food and Drug Administration. I will talk about that too.

West Virginia has been hit the hardest per capita. Just this past year, 600 West Virginians have died—in a State with less than 2 million people. The American people are drowning under the weight of prescription opioid abuse. Nationally, more than 51 people die every day—in my State, Oklahoma, Ohio, all across this great Nation.

The FDA must get serious about the dangers—we have been speaking about this—of prescription drugs, and this will not be accomplished without a significant change in the culture. It starts with them.

Although the FDA announced that the agency will be taking steps in the right direction to address these problems, it is not enough and more needs to be done. Let me explain why. The FDA's No. 1 priority must be public health and well-being—nothing else. Yet time and again the FDA has stood in the way of efforts to address the opioid abuse epidemic and improve public health.

The FDA plays a critical role in the epidemic as the agency overseeing the approval. Let me make sure we understand. This starts with a prescription. A legally licensed company makes medicine for pain reduction, if you will, pain suppressant, an opiate, and then they bring that to the FDA, and the FDA goes through a process of evaluating it to see if it should go on the market. They go through an evaluation—or their committee, basically an oversight committee—and then they say this is a product that should be on the market or should not. Many times the FDA has gone against the advice of their own advisory committee.

These are things we have to protect the American public from. Why?

So last week they decided to slightly improve the agency's response to the

opioid epidemic. I am pleased at this small step, but let me tell you about this small step. They said that now they are going to be serious about the dangers of prescription drugs, and they said they are going to finally start listening—mind you, listening—to the advice of their advisory committee. Oh, that is wonderful; they are going to listen to them now. That means they haven't really been listening to them up until now, but they are going to start now.

What they don't tell you is they are not going to be required to take the recommendation of their experts. A perfect example is Zohydro. It took us 3 years to get all opiates—Vicodin and Lortab, which are the most prescribed pain relievers and pain pills in the country—3 years to get the FDA to change that from a schedule III to a schedule II, even after I went personally, when I was first in the Senate 5 years ago, to the advisory committee and they voted overwhelmingly that, yes, this should be a schedule II. Within the bureaucracy, the FDA took 3 years. The day they did that and made that piece of legislation or that rule saying that now it will be schedule II, we saw the immediate effect. It took 1.1 billion—billion with a “b”—pills off the market. Twenty-two percent of the amount of opioids on the market were reduced immediately within the first year. Within a week of their finally agreeing to go from a schedule III to a schedule II, which controlled the prescriptions, they came out and approved Zohydro against the wishes of their advisory committee, 11 to 2. Now you tell me why that product came to market.

So I have legislation that says: Listen, when you are not going to take their advice and you don't recommend or you don't basically agree with your advisory committee, you have to come to the people's representatives—that is us—and tell us why you think this addictive drug needs to be on the market.

I believe we have to do things and take important steps. What we have basically turned a blind eye to is unbelievable.

Let me explain what I think goes on and what goes on. This is of such an epidemic proportion that we are afraid to talk about it. If you have a child in your family who is addicted, if your mother or father or maybe you or your wife is addicted, you are afraid to talk about it. It is kind of a shame, so we kind of try to take care of it. Guess what. We can't even find treatment centers to help people. And then you can't afford it if you can find it—most people in America—and most of the times you can't.

So there are two things that have to be done. First, and I am as guilty as anybody here—the last 20 years I thought: Boy, if you are going to use these drugs and abuse them, that is a crime. I am going to put you in jail. You are going to pay the fine for that, a penalty.

Well, guess what. It hasn't worked. They go in addicted and come out addicted. All we did by convicting them and putting them in jail is give them a felony. Now they can't get a job. Now they are out of the workforce. Next, they come out more addicted than when they went in.

As Americans, we must say: Listen, this is an illness, and an illness must be treated. You can't just throw them in the jail and say out of sight, out of mind; it will take care of itself. So once we change that—and we have enough courage here politically to do that—then we will start moving in a cultural change that will basically be able to take on this epidemic.

We are fighting on that. I continue to go into all of this, but I have always come here and I have said: Listen, all of you in the State of West Virginia, please get on my Web site, [manchin.senate.gov](http://manchin.senate.gov). It is very simple. And all of us have our Senate Web sites. Share with me your life-altering letter. Tell me what happened.

We have been getting them by the hundreds. They are coming from all over my State, and they are in every State. I am sure Oklahomans will send the Presiding Officer theirs too.

I am going to read two stories. This brings to light everything we are talking about and why we must be successful in fighting this horrific epidemic.

This is Kylie's story:

In 1994 my dad broke his shoulder.

We all have accidents in our families.

He had to have surgery. He was on prescription narcotics from 1994–1996—

Now you tell me why he was allowed to be on them and why the doctor kept prescribing them for 2 years. That is the biggest problem—

he became addicted in those 2 years. After the doctor would no longer prescribe—

Finally, maybe the doctor came to his senses—

him pain medication, he'd illegally purchase them off of the street. His life literally revolved around his pain medication. His pain medication money came before our bills.

There were a few times we could not have Christmas or Easter because he used all of our money to purchase these drugs. I have 2 sisters. Eventually, he started buying more potent drugs when he couldn't find anyone to buy prescription pain pills off of. Heroin, Cocaine, you name it, he'd buy it. My mother eventually filed for a divorce and that made him so much worse. He started using more and more.

He used more because of depression on top of that addiction.

On February 23, 2007, I stayed home from school, I was a junior in High school in Clarksburg. I woke up at 10am, went to check on my dad who had been having drug withdrawals, I found him dead. He'd found drugs and overdosed while I was asleep, leaving me there to find him. It's something I carry with me everyday. I don't have many memories of my father interacting with us kids as a father should. I only have the bad memories of him going above and beyond for drugs. Even back then, if the prescription drug problem wouldn't have been so bad, I feel like he'd still be here today.

I remember exactly how he was laying when I found him. I remember everything.

It's my first thought in the mornings and my last thought at night. It changed my life, taught me a lot of life lessons but it also left me with a lot of heartache.

And unanswered questions—as I told you, the rescheduling took 2 years. Basically, you could get Vicodin and Lortab that were schedule III at this time, and all you had to do was keep calling in. You never had to see the doctor after the first visit. They can give them to you 90 days at a time or even longer. They were like M&M's. So when we went from schedule III to schedule II, that knocked it down. It took at least a billion that we know of off the market, and we are hoping maybe even more. So that is what happened.

This is Helen's story:

My husband and I were married for over 21 years. We had two daughters together and I expected to grow old with him and enjoy our grandchildren. He worked in a factory for over 18 years. Part of his job was moving 55 gallon drums of different types of fluids. He worked full time. Sometimes 6 days a week.

He sprained his back and was prescribed pain medicine. The doctor he was going to gave him the maximum amount—

At that time it would have been more than 90 days probably, and he didn't have to go back because it felt so good—

allowed by law for about six years.

As time went on, he needed a higher dose for it to be effective. Taking more caused him to run out before the next refill. He started going through withdrawals. Instead of going to the emergency room to get help, he took his life. Now I have no husband, my children have no father and my grandchildren do not have a grandpap.

The stigma surrounding all of this is what kept him from getting the help he needed to get off those pills.

We have said it is a silent killer. They were afraid to talk about it. They couldn't go to anybody, didn't know where to turn, and didn't have any types of treatment centers that would bring him off of that.

The Friday before he ended his life, I spoke with a doctor and told him he needed to get off those pills and get dried out. He didn't want to be admitted and they let him go.

They knew he was desperately hooked.

Why do pharmaceutical companies market drugs that cause normal people to give up on their families and life? Why do doctors allow their patients to take something so long and build up such a tolerance for it? I will never find the answers to these questions and it is too late for him now.

It sickens me to read of others going through this and there just doesn't seem to be an end to it.

This is why I am standing here. I face it every day. I go home. There is not a person who doesn't come up to me knowing that basically their lives have been changed and knowing now that they can speak to somebody. I am making it a point to give them the comfort of speaking to me. I protect their identity. I try to get them help.

There has to be a way. As my good friend from Ohio and the Presiding Officer, my good friend from Oklahoma—

this is not partisan. This should not be bogged down because of who gets credit, who doesn't get credit, or whose fault it is. We are all to blame, and we all can share in changing the culture of drugs in America—legal drugs.

Most drug addicts today—people who are addicted—will tell you if they are on heroin or illicit, harder drugs, they started with legal drugs that were in their prescription cabinet, in the medicine cabinet that their mom had or that they had. This is what has to change. This is why—Dr. Robert Califf is being recommended by the President; he is a good man with a stellar resume, a stellar performance, very honorable. But the culture that he comes from is basically from a research institution and a research university that has been funded by the pharmaceutical industry. That is just the way they say it is done. So they are funding the clinical research, and then we are expecting Mr. Califf to come into this industry, into the FDA, and make the wholesale changes.

I need—and I think we all need—for America to find somebody who has gone through a life-changing event and who has all of the experience and all of the education to be able to go into that agency and say: Listen, we are not going to give you a prescription just as a frontline in the first line of defense because I know the chances of it changing your life are greater than my helping you and giving you relief.

Until we have that and until that permeates clear down through, it will not change. Tell me how the CDC—the Centers for Disease Control within the agency of DHHS—is able to start responsibly recommending guideline changes for how we are going to prescribe and how doctors should be trained before they prescribe these life-altering drugs. Then, within the FDA they are fighting against it, and they are within the same agency of the HHS. So it is deep-rooted, and it has to be culturally changed from the top. It doesn't change from the bottom within.

So if this good man would withdraw his name and let us move on, I would be tickled to death, because he is a good person and he can be very helpful in his knowledge. But I don't think he can drive the change that needs to be done for us to save the families and children and moms and dads across America.

I yield the floor.

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

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

Mr. ALEXANDER. Mr. President, I ask unanimous consent to speak as in morning business, and will the Presiding Officer advise me when 20 minutes has expired.

The PRESIDING OFFICER. The Senator will be so notified.

#### INNOVATION PROJECT

Mr. ALEXANDER. Mr. President, today I would like to report some good news about the work of the Senate that should be of interest to every single American family; that is, that we are moving ahead in the Senate on a package of 50 bipartisan proposals that will help move medical devices, medical cures, and medical drugs through the long, expensive, regulatory process and into medicine cabinets and doctors' offices, where they can help patients. We call this our Innovation Project. It is a companion to work that has been done in the House of Representatives already that they call their 21st Century Cures Act. It is also work that President Obama has talked about in important ways. The reason that the House has already done its work, that the President has talked about this in his State of the Union Address, and that we in our HELP Committee in the Senate have been working for a year to develop 50 bipartisan proposals that we hope to bring to the floor of the Senate is because we have never had a more exciting time in biomedical research in America than today. We are talking about actually curing some cancers, not just treating cancers. We are talking about using 3-D printing to actually help replace knees.

I was in a medical device office in Memphis a few weeks ago, and that company told me that in one-third of the cases where it sells knee replacement equipment, it also sells a tool to the doctor made with 3-D printing so that if he or she—the doctor—is replacing the knee of the Senator from Oklahoma, the doctor uses this tool that is just made especially for the knee of the Senator from Oklahoma and virtually eliminates the possibility of a mistake by the doctor in that surgery. The company told me it not only uses 3-D printing in one-third of the cases but that it could easily do it in all of the cases and expects it will soon.

At our hearing about 3 weeks ago, I asked Janet Woodcock, the head of the Center for Drug Evaluation and Research at the Food and Drug Administration, if there had ever been a case of a 3-D printing of a drug, and she said, yes, there had been one. They have used 3-D printing to manufacture a medicine for epilepsy.

That is not all. Last year when the President announced his Precision Medicine Initiative, he introduced a young man whose cystic fibrosis had been cured by a new medicine, which he takes every day. While that only benefits some cystic fibrosis patients, the drugs that are used to cure that number of patients are the same kind of drugs they believe eventually will cure every patient with cystic fibrosis.

On that day, the President announced what he calls his Precision Medicine Initiative and that he wanted

to assemble 1 million human genomes so that if my doctor is prescribing for me a medicine by knowing what my genome is and what that medicine has done in other genomes, he can make a very specific sort of prescription, one that is more likely to help me and less likely ever to hurt me.

I attended the President's ceremony. I told him afterward that we would do our best to incorporate his Precision Medicine Initiative into our work in the Senate on our Biomedical Innovation Project.

The House was making good progress on its 21st Century Cures project. So I told the President: Mr. President, I can't imagine why we can't get a result in this Congress.

Since that time, the President has announced a cancer task force that Vice President BIDEN is leading to work to speed up treatments and cures for cancer. The House has passed its 21st Century Cures Act. In our committee in the Senate during the past year we have held 10 bipartisan hearings, including 6 on how to improve the electronic medical records systems that hospitals and doctors are using. We have had five bipartisan staff working groups that have met or held briefings more than 100 times in the last year, and the result of their work has been 50 bipartisan legislative proposals. As I said, every single one of those has support from Democrats as well as Republicans on the committee.

Today in our committee we debated and approved the first 7 of these bills, which included 12 of the 50 bipartisan proposals I just mentioned. We had an open process. Any Senator who wished to could have offered an amendment. The bills have had so much work on them that there weren't any amendments, but they were important pieces of work.

Our committee probably is the most diverse in the Senate. I know that is saying a lot, but if you look up and down the Democratic and Republican aisle, we span the whole spectrum. Last year we worked together, despite our differences of opinion, and produced a bill to fix No Child Left Behind. A lot of people thought we couldn't do that. I expect the same sort of bipartisan effort led by Senator MURRAY, the senior Democrat on her side, and me as chairman, to work well for us again.

We have a second markup of legislation scheduled for March 9 and a third for April 6. My expectation is that after we meet these 3 times and consider 50 legislative proposals, when we are finished it will all add up to bipartisan companion legislation to the House's 21st Century Cures legislation, and our legislation will include important elements of the President's Precision Medicine Initiative in his Cancer Moonshot.

The 21st Century Cures Act, the House bill, includes \$9.3 billion in so-called mandatory funding over 5 years, mostly for the National Institutes of

Health. Several of President Obama's other proposals in his new budget involve mandatory funding, and several Members of our committee have talked to me about mandatory funding for some of the work we need to do.

Here is my view about mandatory funding: I don't want to get the cart before the horse. When I was Governor of Tennessee and we needed a new road system, people would say to me: Are you going to raise the gas tax? I said we are not going to talk about the gas tax. There are lots of different ways to pay for the road. You can borrow the money. You can use discretionary money. You can raise the fuel tax. You can build a toll road. We are not going to talk about any of that. First, we are going to decide on what we want to do. What we decided to do was to have three big road programs to attract the auto industry suppliers to Tennessee, and it worked.

The decision we made after we decided what we wanted to do was in that case to raise the fuel tax three times because we didn't want any road debt. We have among the best roads in the country and zero road debt, and we have the auto industry. That worked out pretty well for us 30 years ago. I would like to apply the same sort of thinking here.

I don't want to talk about how we pay for something before I decide what the something is. Here is the something I am thinking about. I am thinking about something called the NIH—National Institutes of Health—Innovation Projects Fund; five areas, in addition to the things we normally fund and do that require extraordinary support, one-time support for ideas that have a start and a finish. In other words, they are not built into the budget for a long period of time.

The National Institutes of Health Director would have the authority to direct allocations of this fund to specific areas of importance. The five areas of importance I have in mind are helping the President launch his Precision Medicine Initiative and an American Young Investigators Corps.

We have heard from Dr. Collins, the head of NIH, and many others how important it is to have young investigators have enough money to give them the money to do their research. The BRAIN Initiative, all of us are staggered by the prospect of the personal anguish that Alzheimer's and other brain diseases will cause individuals and their families, and we are excited about the prospect of relieving that anguish. We know how much this is going to cost us—in the tens and tens of billions of dollars. If we can find a way to develop new understandings of neurological disorders, which help discourage Alzheimer's disease or prevent it or deal with it, it saves money as well as saving anguish. A Big Biothink Award—Dr. Collins had suggested this in some of his testimony. During this exciting time, let's let each of the 24 Institutes that fund grant awards at