must be put off until after the election campaign is over. That is what is fair to the nominee and is central to the process.''

The Biden rules recognize that ''Senate consideration of a nominee under these circumstances is not fair to the President, to the nominee, or to the Senate itself.''

The Biden rules recognize that under these circumstances, ''the Senate Judiciary Committee should seriously consider not scheduling confirmation hearings on the nomination until after the political campaign season is over.''

Vice President BIDEN is a friend, as I said three or four times during my remarks, and I say it with the utmost sincerity. I served with him in this body and on the Judiciary Committee for nearly 30 years. He is honorable, he is sincere, and he is loyal to the President he now serves. Because I know these things about him, I can say with confidence that he will enthusiastically support the President and any nominee he submits to the Senate, but I also know this about Vice President BIDEN: He may serve as Vice President, but he remains a U.S. Senator. That is why when he rose to speak in this Senate Chamber for the last time, he shared this with his colleagues:

I may be resigning from the Senate today, but I will always be a Senate man. Except for the title of ''father,'' there is no title, including ''Vice President,'' that I am more proud to wear than that of United States Senator.

If the President of the United States insists on submitting a nominee under these circumstances, Senator BIDEN, my friend from Delaware, the man who sat at a desk across the aisle and at the back of this Chamber for more than 35 years, knows what the Senate should do, and I believe in his heart of hearts he understands why this Senate must do what he said it must do in 1992.

I yield the floor and give back the remainder of my time.

## NOMINATION OF ROBERT CALIFF

Mr. MCCONNELL. Mr. President, drug overdose deaths, driven largely by prescription painkillers, continue to outpace the number of fatalities from traffic accidents in Kentucky. While I recognize the need to protect legitimate patient access to prescription painkillers, the FDA must do more to help us fight back in the midst of today's prescription-opioid epidemic.

The FDA plays a leading role in addressing this epidemic through its drug approval process, in which it is required by Federal law to ensure the safety and effectiveness of all drugs. However, the FDA has been rightly criticized for not recognizing the severity of this significant problem and for not taking greater action to address it.

Over the years, I have heard from many Kentuckians concerned about FDA's lax attitude in this area, with many of the belief that the agency simply has not taken its role in fighting the prescription opioid epidemic seriously.

To try and push the FDA in the right direction, I contacted the agency in both 2012 and 2013 to warn of the problems with allowing generic, crushable opioids to be made available without the introduction of abuse-deterrent features. As a result, the FDA announced in April 2013 that it had decided to prohibit a generic version of a certain opioid that lacked abuse-deterrent features.

I also cosponsored a measure in the last Congress that aimed to push the FDA to encourage the development and use of abuse-deterrent formulations of prescription opioids, which make them harder to crush and abuse.

Additionally, I joined more than 20 Senate and House Members last October in a letter to OMB's Administrator of Information and Regulatory Affairs, Howard Shelanski. We urged him to help us tackle the prescription-drug abuse epidemic by taking down barriers in the Medicaid repayment system that actually discourage manufacturers from developing the very same abuse-deterrent formulations that I have been pushing the FDA to encourage.

I recently met with Dr. Robert Califf, the FDA Commissioner nominee we will consider this evening. We had a productive meeting in which I expressed my concerns about the agency's past insensitivity to the opioid crisis, along with my desire to see the FDA play a more prominent role in addressing this prescription-opioid epidemic.

Dr. Califf shared his proposed plan to reassess the agency's approach to approving and regulating prescription painkillers. Dr. Califf also acknowledged that a cultural shift will be needed within the FDA if the potential for addiction and abuse of prescription opioids is to be taken more seriously. He assured me that, as head of this important agency, he would be the kind of leader our country needs when it comes to confronting this growing epidemic.

I believe Dr. Califf understands the dire nature of the opioid epidemic, and accordingly, I believe he is today the right person to lead the FDA in a new direction. That said, confirming Dr. Califf will be just the beginning of a much longer and enduring effort on everyone's part; he and the FDA should expect continued rigorous oversight in the way the agency deals with prescription opioids moving forward.

Mr. LEAHY. Mr. President, today the Senate will consider the nomination of Dr. Robert Califf to head the Food and Drug Administration. For too long, the FDA has been without a Senate-confirmed commissioner, and, given the scope and reach of the agency, action on Dr. Califf's nomination is welcomed. After speaking with him and carefully reviewing his record, I have decided to support this nomination.

Consumers depend on the FDA to ensure that food, medicine, and products sold in this country are safe. The agency has oversight of one-quarter of all consumer goods sold in the United States, including nearly $1 trillion in foods, drugs, medical devices, cosmetics, and supplements. The Commissioner must supervise this critical work with independence from outside influence. Some Senators have raised concerns about Dr. Califf's record as a researcher who worked closely with drug companies and have questioned his ability to make decisions free from the influence of the multibillion dollar pharmaceutical industry. After speaking with Dr. Califf and reviewing his record, I believe that he will conduct himself with integrity and in the best interest of the public.

While the head of the FDA must be an independent voice, we should not discount the benefits having a Senate-confirmed Commissioner who understands the importance of medical research and the potential to advance lifesaving treatments. Under Dr. Califf's leadership, the Duke Clinical Research Institute made advances in drugs that dissolve blood clots, cut the risk of heart attacks and strokes, and lower cholesterol. As director of the Duke Translational Medicine Institute, Dr. Califf worked closely with the National Institutes of Health, the FDA, and the Institute of Medicine to help ensure scientific discoveries are translated into usable treatments. I believe that Dr. Califf's understanding of the importance of research in promoting lifesaving treatments and his ability to navigate potential conflicts that can arise with drug-industry funded research will be an asset to him as the leader of the FDA.

Dr. Califf and I also discussed other issues of importance before the FDA, including the labeling of generic drugs. For several years, I have led a group of nearly 40 Democrats in Congress in pressing the FDA to require generic drug manufacturers to update their safety labeling, instead of simply mirroring the brand companies' warnings, as they do now. Generics fill over 80 percent of prescriptions, but injured patients have no remedy against them if their product is mislabeled. Patients who are injured by a brand-name drug can seek justice, but they have no remedy if, like countless Americans, the drug that injures them is a generic. All drug manufacturers should be required to improve the warning information they give to doctors and consumers. Americans have waited 3 years for the FDA to finalize their rule regarding the labeling of generics, and I intend to continue to urge the FDA, and Dr. Califf if he is confirmed, to move forward on this critical issue.

The next Commissioner of the FDA must also work to promote safer alternatives to powerful prescription painkillers and to remove from the market older, less safe drugs. Dr. Califf and I discussed the FDA's recent announcement to expand access to abuse-deterrent formulations of these powerful

drugs to help address the opioid epidemic in this country. While it is a step in the right direction, the FDA can and must do more. I appreciate Dr. Califf's commitment to redouble the agency's efforts in combatting this issue, while working closely with other governmental agencies that can oversee the prescribing of these drugs. I expect to work closely with the agency on this issue and will continue to press Dr. Califf to take action in this area.

I hope that the FDA will also recognize the significant concerns that I and others in Vermont and other maple producing States have for the harm being done to maple sugar producers' income as a result of potentially false and misleading labeling of products that contain neither maple syrup nor real maple flavor. I recently meet with sugarmakers in Vermont who are asking for a strong and thorough investigation into possibly misrepresentative labeling of food products whose labels incorrectly indicate the presence of maple syrup and request appropriate enforcement action where warranted. The tradition of sugaring is significant not only to our cultural heritage in Vermont and throughout New England, but to our efforts to strengthen the working landscape and local agriculture in rural parts of our States.

Vermont's cheese industry, particularly raw milk cheese producers, have also raised concerns about FDA overreach. While I fully support the FDA's efforts to ensure the safety of our Nations' food supply, I believe that standards set by the FDA must be scientifically based and must address a known threat to public health. There have been some positive steps forward, and the FDA has recently met with these producers, agreeing to hand over the FDA's data on the standards they had set. I hope that progress continues, and I look forward to hearing how these discussions and data sharing is going.

We know that food safety will also be high on the priority list for the FDA as it works to implement the Food Safety Modernization Act, FSMA. A landmark piece of legislation, FSMA was passed in 2011 to ensure the production of safe foods; yet the farmers and processors in Vermont and across the country are in need of science-based, clear technical assistance to aid in their compliance with this new set of rules. I was proud to learn recently that the University of Vermont was recently chosen to lead the Northeast Center to Advance Food Safety. This new collaboration will advance understanding and practice of improved food safety among the region's small and medium-sized produce growers and processors as they learn to comply with these new complex food safety standards.

The FDA has been without a Commissioner for nearly a year and with no shortage of issues to address. I am pleased the Senate is moving one step closer to filling this position with tonight's vote. I look forward to working with Dr. Califf on the many pressing issues before the FDA.

The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. MARKEY. Madam President, today we are about to begin consideration of the nomination of Dr. Robert Califf to lead the Food and Drug Administration. This is a historic time at that agency. It has a record which is not enviable in terms of the way in which it has been dealing with the opioid prescription drug epidemic in our country.

I want to give just a very brief history of what has been happening on that issue. About 20 years ago, the FDA was asked to approve OxyContin—which is just a shortened form of oxycodone—continuously going into the bloodstreams of Americans. Purdue Pharma represented that this would be a safer way of having prescription opioids go into the American medical system. Nothing could have been further from the truth because oxycodone—the material inside of OxyContin—is molecularly very similar to heroin.

So when one has a bottle of OxyContin or oxycodone continuously in your cabinet—30 pills, 60 pills or more—you are talking about having a bottle in your medicine cabinet that is very close to being heroin. Now if someone said to you that your child or family member is now taking something that is very close to heroin, that would have a profound impact on you—but that is never quite explained to the American public. That is something that was not understood at the time because Purdue Pharmaceutical company was representing that it was safe to take OxyContin. It turned out that was not the case.

Today we have an epidemic in the United States. More than 30,000 people in 2014 died from this prescription drug heroin epidemic which is ravaging our country. This is a dramatic increase from 1996, when we really didn't even talk about it in our country. More than 30,000 people died in 2014. The number most likely was much higher last year. The number, most likely, will be even higher this year as well. Here is the story—80 percent of all people who are dying in the United States from heroin overdoses started on prescription opioids. Eighty percent of all people who died in 2014 from heroin overdoses started on prescription opioid painkillers. So the pathway into this heroin epidemic is quite clear. It is the Food and Drug Administration approving these new prescription opioid pills without the proper safeguards having been put in place to ensure that it doesn't make the problem worse rather than improving the problem.

That is why the debate on Dr. Robert Califf is so important. The Food and Drug Administration is saying they will not empanel expert advisory panels to review the approval of each one of the new prescription opiates that are in the pipeline right now at the FDA. What is the evidence that will cause big problems? Well, back in 2012 the FDA had to consider Zohydro. Zohydro was a new prescription pain opioid. They empaneled a group of advisers—experts—to look at the drug. By 11 to 2, the expert advisory panel said: No, do not approve this new drug, unless we establish a whole new system or standard in America for addiction, abuse, for diversion of these drugs. Don't do it. The FDA ignored the advisory panel and approved Zohydro, with experts all across America attacking the FDA for not understanding how fundamentally the culture in our country had changed since 1996 with the first approval of OxyContin.

Moving forward, the FDA decided it would not empanel expert advisory panels at all because they knew most likely they would vote no. So on new drugs such as Hysingla or Targiniq, there were no advisory panels at all because it was said by those companies that there are abuse deterrents that are inside those new opioids.

What does that mean? Abuse deterrent is basically going to the issue of whether that new pill—that new drug—can be crushed to be used for purposes other than what is intended, which is to be a painkiller. However, if the individual just continues to take the pills in the bottle as they are prescribed and they do it on a continuous basis, they run a high risk of becoming addicted.

The warning went out from all of these outside groups that expert advisory panels were needed. The FDA ignored them. Then we hit August of 2015. Believe it or not, Purdue Pharma wanted to get approval for 11- to 16-year-olds to have OxyContin. Remember, this is heroin equivalent. This would go to 11- to 16-year-olds. What they decided to do was to not have any advisory panel at all on that issue in August of 2015. This is despite the fact that it was controversial, that it had tremendous social impact on our society, and that the FDA's own guidance says that expert advisory panels are needed on drugs of that nature when pediatric dosing or child prescribing is in question. The FDA just ignored it.

I put my hold on Dr. Califf's nomination. Senator MANCHIN put his hold. We are raising this issue. We are saying to the FDA that we need advisory panels. We need a change of culture at the FDA. This just cannot continue.

The FDA said they would look at it. The FDA said they would study it. Then the FDA announced 2 weeks ago that there would be no advisory panels for any of the new opioids which are in the pipeline over at the FDA because they are ''abuse deterrent.'' Abuse deterrent is an oxymoron. It is a contradiction in terms. It is like jumbo shrimp. There is no such thing as an abuse deterrent inside of a bottle of pills that have the same molecular constitution as heroin, especially if we are talking about giving it to kids age 11 to 16 in our society.

By the way, if you want to know why there has been a spike in the number of

breaking-and-entering crimes in people's homes, with people breaking in and looking for these bottles of pills, I will tell you why. Each one of these pills can be worth upward of $80 apiece on the streets of America. Hear that number? For a bottle of 60 with 80 milligrams is worth between $4,000 and $5,000 on the streets of America. That is why they want to break into your house. They don't take the TV. They are looking for that bottle of medicine because that is how much it is worth. That is how much they can sell it for.

When do we begin to get real about the fact that it is a bottle of heroin-equivalent in people's homes?

Ultimately, when all their prescriptions are finished off and they can't get it anymore from the doctor, they wind up with heroin at $5 a bag in the street. So America, it doesn't matter which community in America we are talking about. It can be Boston, West Virginia, Kentucky, California, it is all the same story, the same pathway in, for 80 percent of all those who overdose on heroin in our society. They are still looking for that heroin-like experience.

So we have a big issue that the FDA is not responding to, which is why I don't believe Dr. Califf should be confirmed until we have a change at the FDA, and they are not going to do it. We have to make sure they understand it is a coalition of pharmaceutical companies and physicians which have created this epidemic in our country. We are reaching a point where we are going to have a Vietnam war equivalent of people dying every single year inside of the United States on an issue created largely by the pharmaceutical and physician community in our society. So when do we start getting real about it? When do we start having a reality check, that while we are 5 percent of the world's population here in the United States, we consume 80 percent of all of the prescription painkillers in the world? Mix well, wait 20 years, and a pandemic has broken out across our country.

The FDA has a responsibility to ensure that we put the protections in place, that the warnings are there, that the dosage is correct, and that the preventive measures are used to reduce dramatically the number of families who are going to be devastated by this issue.

When people have back pains, when people have issues other than the most life threatening, we have to begin to discuss how long we want these people to be on something that has the same molecular constitution as heroin. It is a big issue. Lower back pain, broken legs—there is perhaps a greater danger from the prescribing than there is from the actual underlying injury in terms of the long-term consequences for these families.

We have to have this discussion in our country. We have to have the kind of discussion that says that heroin overdoses in our country have quadrupled in the last 14 years—quadrupled—and 80 percent of it started with prescription opioids. We have to have this discussion.

Dr. Califf has been nominated as the new head of the FDA. They are not going to change business as usual at the FDA. They are not going to do it. They have already announced it. They don't want to hear from experts. Their slogan at the FDA is no experts need apply to come in and give advice to the pharmaceutical companies and to the FDA. No warnings are needed from anyone with regard to what this industry has been doing to our country and what the FDA has been approving. So this issue is one that absolutely is at the top of the list of the things we have to deal with in our country.

Last year, the Food and Drug Administration, the agency that actually approves how much of this opioid painkiller can be sold in—and the way the system works is individual companies go to the Food and Drug Administration, tell them how much they want to have approved, and then the FDA never tells the rest of the world how much they allowed each company to, in fact, manufacture in terms of the painkiller, the opioid. They give an aggregate number, but they never tell you how much each company got approved.

What I would like people to do in their minds right now is to think for a moment how many prescription opioid pain pills—equivalent in oxycodone, other opioids—were approved by the Food and Drug Administration last year. Just pick a number. How many pills total? Do you have a number in your head? I am going to give you the answer: 14 billion. Can I repeat that? There were 14 billion prescription opioid pills approved for a country of 300 million. That is a bottle for every single adult—a bottle, again I tell you—with the material that has the molecular equivalency of heroin inside the cabinets of people inside the United States of America.

This has to stop. It has to end. I understand it is a good business model for the companies manufacturing these things, but it is not good for America, and it is not good for the families in our country. The FDA has to stop them. That is why Senator MANCHIN, Senator BLUMENTHAL, and others who are going to be speaking on this issue—we don't think Dr. Califf should be approved until they change business as usual, until they make a commitment that they are going to change business as usual at the Food and Drug Administration. They are supposed to be the guardian of our public health. They are supposed to be the arbiters of what is safe for Americans to consume, but they have not been doing the job. I am not talking about 1996 anymore; I am talking about 2015 and 2016. I am talking about right now with the evidence of this national tragedy manifesting itself in every community in our country.

The least that the Senate should be able to say is that it tried, really tried, to deal with this issue that has been created by the pharmaceutical and the physician community. It will not be enough to say that we are going to authorize $1.1 billion for treatment, although we need treatment because there are millions of people who are going to need it in our society.

We have to go back to the root causes of this problem, this flood of drugs that have gone into this society, the lack of prescribing education that physicians have to undergo. The FDA indicates that only 10 percent of physicians in America voluntarily even get educated with regard to what are the consequences of having a bottle of molecularly similar heroin pills to be put inside the cabinets of Americans—10 percent of physicians. That is just plain wrong, ladies and gentlemen. We have to make sure that the education is there for the physicians who need it. We have to make sure that the pharmaceutical companies do not get permission to be able to get these new pills approved until there is a new standard for abuse, a new standard for addiction, a new standard for the diversion of these pills, a new standard for what abuse deterrent means because right now, again, it is a contradiction in terms.

You can still get addicted by taking an Oxy or a Percocet over and over again, day by day. You are going to get just as addicted. It is not an abuse deterrent if that is how you are going to be taking it. You still wind up with the same problem.

We need to get real here. There is no bigger issue in our country. There is no more profound change that has taken place on the streets of our country. When it increases by fourfold in just 14 years, what is on the horizon for our society if we don't put an end to it?

Working with other Senators, I intend to continue to explain this problem to other Members. I could not have a better partner than the Senator from Connecticut, Senator BLUMENTHAL, who as attorney general in the State of Connecticut and now as a Senator has focused laserlike on this issue. We are both committed to making sure that education of physicians becomes an indispensable part of the remedy—the Rx that we in the Senate put on the books—so that at a minimum that education is made mandatory for every physician who is going to be handing out these pills to otherwise unsuspecting Americans.

I will just finish this way. One patient came up to me and said: You know, when a doctor says to you that these pills for your family member are good, you are not going to second-guess the physician. You are going to assume that because the physician gave them to you, they must be good.

And then this man said to me that he and his wife looked back and said: Should we have known more? Should we have done something different? Should we have tried to protect that other family member?

No, it should be the FDA. It should be the DEA. It should be the physicians. It should be the prescribers. They are the ones that should have the responsibility, not the guilt that they are giving to families all across the country that they should have known more. No, ladies and gentlemen, this is the time for us to finally act on this issue.

I yield to the great Senator from the State of Connecticut, Senator BLUMENTHAL.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. BLUMENTHAL. Madam President, I am so honored to follow my great friend and very eloquent advocate from Massachusetts, Senator MARKEY, who said much more powerfully than I can our reasons for opposing Dr. Robert Califf as the nominee for the head of the FDA. To say it very simply, this agency needs drastic reform. It needs an overhaul in the way that it approves these powerful painkilling substances that can be a gateway to addiction, whether to opiates or whether to heroin. I am proud to stand on the floor with Senator MARKEY, Senator MANCHIN, and others who feel that more must be done, that our Nation is lagging in addressing an epidemic.

It is truly a public health hurricane that is sweeping Connecticut and our country. I have done roundtables around my State that are among the most moving public experiences of my service in the Senate and, indeed, my time for 20 years as attorney general on any public issue. It is an issue that concerns Iowa as well as every other State in the country. It is an issue that should bring us together on a bipartisan basis to address this true public health crisis.

My reason for opposing Dr. Califf is, very simply, the failure of the FDA to recognize its own shortcomings and the prospect that there will be no change in the way the FDA is responding or failing to respond to this crisis if he is confirmed. With his confirmation, all that we can see ahead is more of the same.

That is unacceptable. The FDA must be part of the solution or it will continue to be part of the problem. There is no question that the solution to this problem has to be multifaceted. In the roundtables that I have held around our State and in my conversations with the experts in this field and in the meetings that I have conducted with public health officials around the State with recovering addicts and their families, law enforcement, as well as public officials, I have seen that there is no single solution. There is no one-size-fits-all for recovering addicts, for communities, for different parts of the country. There has to be an emphasis on law enforcement because cutting off the supply has to be an objective, and law enforcement needs and deserves more support from this Nation and from the Congress. There has to be an emphasis on treatment and services. We are not going to arrest our way or jail our way out of this public health crisis, nor is treatment alone a sufficient solution. Part of the solution has to be more action from the FDA to oversee, scrutinize, and stop the pipeline of painkillers and opioids that are continuing to deluge our community.

The urgency of this crisis is clear. In 2015 my State had more than 700 prescriptions leading to overdose deaths. These fatal overdoses are also avoidable. The number of opioid-related deaths around the Nation has skyrocketed, and behind every one of these heartbroken families and communities is a realization that more must be done. We depend on the FDA to deal with these kinds of problems. The American people rely on this agency to implement a strong, regulatory approach to protect them.

Unfortunately, the FDA has utterly and abjectly failed to protect the American people against the epidemic of opioid overuse. The FDA has a troubling history in this area, and I am well familiar with it because I highlighted it when I was the attorney general of our State, asking for stronger warnings for patients and consumers, asking for better oversight of oxycodone and related medicine, and asking for better supervision and education of the prescribers. And I asked in letters, in petitions, and in legal actions. In effect, the FDA has fueled this crisis by approving too many drugs with too little analysis. Too often, it has failed to use an advisory committee when approving a new opioid painkiller. It has demonstrated a troubling preference for speed over safety. It has expedited consideration at the risk of public health.

It is essential to have an independent panel of experts to review and advise the agency on its approval of any opioid painkiller, giving the public a chance to provide input before a product comes to market. Unfortunately, in addition to instances where no advisory committee has been convened, the FDA has simply approved new drugs over committees objections. This failing to listen to warnings from experts harms public health and safety and confidence and credibility of this agency.

One example, which some of my colleagues may remember, concerns the FDA's approval of the drug Zohydro. This high-dose, extremely potent opioid, which lacks abuse-deterrent properties, was approved in 2014 despite strong objections from the scientific advisory panel that approved it. That panel voted 11 to 2 against approving the drug.

The questionable oversight tactics the FDA has employed so far leave me with serious doubts about its ability to implement its recently released action plan. In this plan, the agency committed to convening advisory committees when approving any opioid painkiller that is not abuse-deterrent. This approach is, very simply, insufficient.

We have seen how dangerous opioids can be. All opioids, whether or not they are classified as abuse-deterrent, should be reviewed by an independent advisory committee. And even if an opioid is classified as abuse-deterrent, that doesn't mean it cannot be abused or that an advisory committee shouldn't be consulted. The FDA itself recognizes that abuse-deterrent technology is in its infancy and independent advice is therefore essential.

Unfortunately, instances where the FDA has failed to listen to its advisory committees are not limited to the context of drug approvals. In 2012 the agency recognized that opioids could lead to a number of dangerous outcomes—addiction, accidental overdose, and death. In response, the FDA implemented a risk-management strategy for extended-release opioids, including requiring education for prescribers on safe prescription practices and the potential for abuse and addiction. Two years have passed—2 years since the first of these trainings was made available—but the FDA has yet to release information showing how many prescribers have been trained and educated on responsible prescribing practices. The FDA has ignored my call for this information to be released.

The FDA has ignored the recommendations from two advisory committees that a similar strategy should be used for immediate-release opioids as well—a crucial issue, given that 91 percent of all opioids prescribed are in this category.

I urge my colleagues to join with me in sending a signal to the FDA that more effective scrutiny and actions are vitally important. The FDA has failed to take this crisis seriously. Until it does, it is failing the American people. And a new FDA head must indicate there will be a sea change—a fundamental overhaul—in the way FDA oversees and protects the American people.

I would like to highlight as well the crucial importance of finalizing the deeming rule, which is necessary to ensure the agency's authority over all tobacco products—also pertaining to addiction; the drug is nicotine—and that is essential to ensure that not only cigarettes but also e-cigarettes—that the companies that make them cannot market to children and to people who may be led to addiction to that drug.

I am determined that the Nation do better in addressing this urgent crisis—a public health hurricane sweeping this country, as disastrous as any physical crisis of tornadoes or floods, maybe, in destroying lives and jeopardizing our national security.

I am pleased to yield back to my colleague Senator MARKEY and to be joined by my great friend and colleague Senator JOE MANCHIN of West Virginia.

Mr. MARKEY. I thank the Senator from Connecticut, and we intend on continuing this battle right through this entire confirmation process and beyond. Unless we stop it now, FDA is

not going to stand for ''Food and Drug Administration,'' it is going to stand for ''fostering drug addiction.'' That is what it has been doing. It has to change the way it does business. It has to respond to this addiction and abuse crisis in our country. It has to be the cop on the beat. It has to understand its responsibility to not allow this flood of drugs to go into our society, and we have to begin the battle now.

I urge all Members to vote no on this nomination. This is not directed personally at Dr. Califf but directed at an agency which has allowed this flood of drugs into our society without putting the proper protections in place.

I now yield to the great Senator from West Virginia, who has dedicated his career as Governor and as Senator to leading on this issue.

The PRESIDING OFFICER (Mr. COATS). The Senator from West Virginia.

Mr. MANCHIN. First of all, Mr. President, I want to say to my colleagues, Senator MARKEY of Massachusetts and Senator BLUMENTHAL of Connecticut, this doesn't have a partisan home. This is not a Democratic or Republican issue. This is an epidemic that is devastating our entire country. It doesn't matter whether someone comes from affluence or is socioeconomically challenged. Rich or poor, it makes no difference. What side of the track you live on makes no difference. This is an epidemic that hits us all in its devastation.

If Senators will just talk to their communities, their law enforcement officials, they will tell you that over 80 percent of all crimes are drug-related. Look at the cost, look at the economy, and look at the devasation in the cost of lives it is taking. Something has to be done.

We are expected to vote to confirm the President's nominee for Commissioner of the FDA, Dr. Robert Califf. Let me say this about our President, President Barack Obama: I think he is taking this seriously. He has come to the State of West Virginia, and I am very appreciative of that. He has seen firsthand the devastation it has taken in all aspects of life in West Virginia. We are a State that is hit as hard as if not harder than other States. It is the No. 1 killer in my State. There are more people dying by legal prescription drug abuse than any other cause. So the President came there and he saw that. I am just asking the President to make that major commitment to our having a cultural change by giving us someone who will shake it up from the top.

I believe Dr. Califf is a good man. I really do. I believe he is a qualified man. I met with him and spoke with him, and I directly asked him—I said: Dr. Califf, you come from a culture where basically the large pharmaceutical industry that supplies these types of products to the market and expects the FDA to approve them are the people who have supported you for the last 20 years. It is just human nature that that is hard to change and hard to say no to.

So with that being said, I said that I think we need a cultural change. I think he understands that and respects my position. I respect his. I just think he is the wrong person at this time of need for the position. We need to shake it up. He is going to continue to serve as Deputy Commissioner of the FDA's Office of Medical Products and Tobacco, but the Commissioner of the agency must be someone willing to lead in a different direction. With 51 Americans dying every day due to an opioid overdose, the FDA now more than ever needs a Commissioner who is a champion committed to changing the way this agency handles opioids.

As I have said many times before, my State of West Virginia has been hit hardest. Drug overdose deaths have soared by more than 700 percent since 1999. We lost 600 West Virginians to opioids last year alone. But that is not the only problem in West Virginia. Since 1999 we have lost almost 200,000 Americans to prescription opioid abuse.

I am here today to urge all my colleagues, before they take their vote today, to think about the citizens of their States who are suffering from prescription drug abuse. Think about all those you know who have lost a loved one due to this epidemic. Each and every one of us here knows someone whose life has been wrecked by legal prescription drug addiction.

This is a silent killer. There is not a person whom I know in any community or any group in any setting whom I can't look at and say: There is not one of you in this room who doesn't know someone in your immediate family or among your extended family or friends who hasn't been affected. That is how rampant this is, but it is something we don't speak about much. We are concerned. It could be our son, could be a brother or a sister, could be a mother, father, aunt, or uncle, but we don't want to talk about it. We are afraid it has been stereotyped.

We need a culture change. As the agency overseeing the approval of these addictive drugs, the FDA plays a critical role in this epidemic, and as my dear friend from Massachusetts, Senator MARKEY, said, the FDA might have to change what it stands for. It really has fostered this drug addiction more than any other agency. Think about the fact that it is being produced legally, approved by the Federal Government in a legal way, and it is being prescribed in legal ways. We are the most addicted Nation on Earth. Over 80 percent of the opioids consumed in the world are consumed by 5 percent of the world's population, that 5 percent all living in this great country of ours. Something is wrong. Something is wrong, and everyone should be concerned about this.

I tell our children and grandchildren, Mr. President, when I speak in schools—I say: You don't have to worry about another country ever taking us over militarily. We have the greatest military the world has ever known. We have the strongest economy, and we are the only ones who can correct the mistakes we have made in our economy because it is so strong. They do not think they have to take us on militarily or be worried about overtaking our economy; they are going to sit back and wait until we become so addicted we can't function. This is what we are dealing with, and this is why it is of such importance.

The agency has been so callous about their approach to this epidemic. As a matter of fact, time and time again they have failed to consider the public's health. One would assume that if the Food and Drug Administration makes a decision that something is good and consumable, they would have looked at the effect it has on the public, the health and well-being of the citizens of this great Nation. Yet it has actively stood in the way of addressing this opioid abuse epidemic—and not only not considering it but prohibiting others from doing it.

For years, the FDA delayed before finally agreeing to reschedule hydrocodone—to reschedule. Let me explain where I am coming from. When I first came to the Senate in late 2010, early 2011, I said: My goodness, we have Vicodin and Lortab, the most prescribed opioids on the market—more than any others. OxyContin had already been moved to a schedule II, and Vicodin and Lortab were schedule III. It took us 3 years to get the FDA to reschedule Vicodin and Lortab and all opioids to a schedule II. It took 3 years—and after their own advisory committee overwhelmingly recommended that it be rescheduled. That means a doctor can only give out a 30-day supply at one time without a doctor visit. Under a schedule III, they can give out 90 days and continue to just call it in without seeing a doctor. They were putting this stuff out like they were M&Ms. So that changed and we finally got that done, but it took forever to get it done and we never could understand why.

Since that change went into effect, we have seen the number of prescriptions for hydrocodone products, such as Vicodin and Lortab, fall by 22 percent. We know it worked because they were overprescribing. So 22 percent—that is 26 million fewer prescriptions and 1.1 billion fewer pills on the market. That is how much just that one change—it took 3 years but should have been done in 3 weeks. It took 3 years because the FDA stalled their decisionmaking. Then, after finally making the important step after 3 years, the next day—the next day that that was done—the FDA approved the dangerous drug called Zohydro. The next day, after 3 years of waiting to get all opiates to a schedule II, they came out and recommended Zohydro and approved it, even when their own experts—their

own advisory committee made up of experts—recommended 11 to 2 against bringing this most powerful, lethal drug on the market.

This drug has ten times the hydrocodone of Vicodin and Lortab, with the capability of killing an individual with just two pills, and just recently the FDA approved OxyContin for use for children 11 years of age. Can you believe that? They did that without having any experts or any advisory committee's consent or recommendations. This decision means that Pharma is now legally allowed to advertise OxyContin to pediatricians under certain circumstances.

We have seen the devastating impacts of this type of advertising, and we have years of evidence that shows that drug use at an early age makes a child more likely to abuse drugs later in life. These decisions illustrate the FDA's inability to consider public health and assess the realities of this deadly epidemic. While I recently accepted the agency's decision to finally start listening to the advice of its expert advisory committee—they have just decided now they are going to start listening to their advisory committees. No way have they decided to take their recommendations. They are just going to listen. While this might be a step in the right direction, finally, of their listening and basically taking the advice of experts but not acting on it, I think is absolutely meaningless.

The change at the FDA needs to be fundamental, and it needs to come from the top. We need a leader who changes the current way of thinking. Unless a major cultural change is implemented at the FDA, similar instances will continue to occur into the future. Meanwhile, our Nation's opiate epidemic continues only to worsen, and our friends and families are further torn apart by the impact of addiction.

If Dr. Califf is confirmed today, I do not feel confident that this culture change is going to take place. Dr. Califf has close financial ties with the pharmaceutical industry. Between 2010 and 2014, Dr. Califf received money through his university salary and consulting fees from 26 Pharma companies, including opiate manufacturers. In the past, Dr. Califf has actually described the FDA regulation as a barrier—not a safeguard for public health, but a barrier.

I believe the FDA needs new leadership, new focus, and a new culture. Dr. Califf's past involvement with the pharmaceutical industry shows that he would not be the person to do that. He would not have the impact or leadership capabilities the Nation needs to stem the tide of the opioid crisis. I believe the FDA must break its cozy relationship with the pharmaceutical industry and, instead, start a relationship with the millions of Americans impacted by prescription drug abuse. It is because of this belief that I am urging my colleagues to vote against the confirmation of Dr. Califf.

My office has been absolutely flooded with stories from West Virginians and Americans who want their voices heard. I am going to read just a couple of letters because I think it is important to know the impact of these letters. I absolutely want you to hear it. And I know every State has been impacted the way my State has.

This is Susan's story:

My name is Susan. I am from West Virginia and I am the mother of three children, ages 20, 16, and 14. My oldest son's name is Zack. Zack is an addict.

Zack grew up in a small town with his mother, father, brother, and sister. He played sports throughout his childhood including football, baseball, wrestling, and basketball. He got good grades in school. He went to church with his grandparents and wanted to be a preacher until the age of 11 or 12.

My husband and I divorced when Zack was 13, and it deeply affected Zack. We moved to a new town where Zack and his brother and sister started into a new school system. Around the age of 15–16 Zack started self-medicating with nerve pills——

The PRESIDING OFFICER. I hate to interrupt the Senator, but the time has expired.

Mr. MANCHIN. I didn't think there was a time barrier on this. I am so sorry. I ask unanimous consent to continue at least this letter.

The PRESIDING OFFICER. Is there objection?

Mr. ALEXANDER. Mr. President, reserving the right to object. The Senator from Washington has 5 minutes to go. I have 10 minutes to go. The vote is at 5:30. So I guess——

Mr. MANCHIN. I should be done here in about 2 or 3 minutes. If I can just finish this letter—I have many more, but I will come back later.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, I ask unanimous consent that following the Senator's remarks, I be allowed 6 minutes and the Senator from Tennessee be allowed 10 minutes.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

Mr. MANCHIN. Mr. President, I thank my colleagues.

The PRESIDING OFFICER. Is there objection to the request of the Senator from West Virginia?

Without objection, it is so ordered.

Mr. MANCHIN. Continuing:

Around the age of 15–16 Zack started self-medicating with nerve pills, smoking pot, and drinking. Zack did his first stint in rehab at the age of 16. He went to Florida to a rehab facility because they were able to arrange everything including his flight before we even got a call back from any facility in our state. Zack was in treatment 60 days and returned home. He was clean for several months and then started using again. Zack graduated to using pain pills. From there he started shooting up pain pills. A child who had a horrific fear of needles was now injecting opiates to escape his painful reality. Zack was robbing people and living house to house and on the streets. Then when he figured out heroin was a cheaper fix and more accessible, this became his new drug of choice. Zack was arrested and given the chance to go to rehab again. He completed another 2 trips to rehab, one being 60–90 days and another being around 30. He came home, relapsed and went to jail for 4 months due to failed drug tests. He spent 4 months in regional jail without receiving one counseling session or any help with substance abuse. When he was released from jail he was very lost and didn't know what to do with his life. He was clean several months before relapsing again.

Zack is now in a peer recovery program in West Virginia. He is 20 years old and on his 4[th] stint in rehab. He is fighting for his life in this program along with about 120 other men. He has been to jail, and has lost close to 20 people in his life due to overdoses.

Being a mother of an addict is a nightmare. From learning your child has this disease to fighting with insurance companies and doctors to get your child treatment. When Zack was a juvenile, I was told by treatment providers that insurance companies did not consider substance abuse in children a life threatening disorder. I had to run up in a house when he ran away and handcuff him and take him to a hospital high as a kite. I had CPS called on me for having my intoxicated son handcuffed because I wasn't a police officer. I had mental hygiene warrants lost. My son was released by a hospital at a moderate risk to suicide and because of that treatment centers wouldn't even consider admitting him into their program. I was told by hospital staff that if I had a medical card instead of private insurance or if my child was a ward of the state, they could get him more help. I contemplated quitting my job in order to get a medical card for my son. I have been asked by rehab to take out loans in order to get my son help. I have had to borrow thousands of dollars from my family in order to get my son into treatment.

I have driven my child to hospitals while he is nodding in and out and I was crying so hard I couldn't see. I have stayed up for 24 hours in a row watching my son detox in hospitals. I have followed ambulances for miles transferring him [to] facilities. I have missed Christmases, Thanksgivings, and birthdays with my son. I have gone months and months without a good night's sleep. I would cringe every time the phone rang or there was a knock on the door. No mother should ever have to just wait on that phone call or for that [knock] on the door.

I have also had to sit my other 2 children down and explain to them that I don't love them any less than I do their brother. I have had to tell them I have to dedicate more time to Zack because I know the 2 of them will be okay but I have to try and keep their brother alive.

You see this epidemic is not only affecting the person who is the addict. It is destroying families and communities. Siblings are forgotten. Marriages and relationships are being destroyed. Entire families are getting PTSD. Crime is at an all-time high. The list goes on and on. The whole system is broken when it comes to treating mental illness and addiction. Until we get the money to fund treatment and more treatment centers, this epidemic will continue to get worse.

If my child had cancer, or any other chronic disease, he would be able to get immediate treatment. He would be able to get good treatment. Addiction is a disease that may start with a poor choice, but is ultimately a disease. Until we are able to provide adequate treatment immediately to those suffering we will continue to lose a generation of people. I pray that no one else has to experience the pain my family and my son has experienced, but unfortunately, this disease has entered into every community, every neighborhood, and into most families. It's

just a shame that we live in the greatest nation in the world and this is our reality.

Mr. President, I thank my colleagues for allowing me that. I am very concerned about where our country is going and the role the FDA plays. We need a cultural change.

I thank my colleagues.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, I want to start by expressing my appreciation to Dr. Califf for accepting this nomination and continuing to offer his expertise in service of families and communities nationwide.

I am glad this evening to have the opportunity to talk about the progress the FDA has made in recent years, the challenges that lie ahead, and why I believe Dr. Califf has the necessary leadership, background, and experience to guide the FDA at this very important time.

The FDA oversees a quarter of all the goods sold in the United States, including more than $1 trillion in medical devices, cosmetics, and supplements. So the FDA Commissioner has a very critical responsibility to support health and well-being in this country.

I am pleased that in recent years important progress has been made to improve FDA's services for patients and families, from approving the highest number of new drugs and biologics in 2014, to making progress toward a 21st-century food safety system as the Food Safety Modernization Act is implemented. These are important steps that have no doubt made a difference for families, but the FDA still faces significant challenges as we look ahead.

As I have discussed with Dr. Califf, the FDA must continue to encourage the development of safe, effective cures and treatments for the chronic illnesses that impact far too many families across the country. The agency should prioritize tackling the threat of antibiotic resistant infections, such as the ones linked to the contaminated medical devices in my home State, and it should do more to ensure patients can always trust that the medical devices used in their care are safe and effective, including by building a robust postmarketing surveillance system for devices. The FDA should continue to strengthen its generic drug and biosimilar programs and needs to play a role in ensuring that all patients and families have access to the prescription drugs they need.

In addition, our country faces urgent public health challenges that the FDA must help to address. To name a few, we need to move forward on making sure families have access to nutritional information and on ensuring our food supply is both safe and healthy. We need to put all the agency tools to work to stop tobacco companies from targeting our children. And we need to tackle the epidemic of opioid abuse that is ending and ruining lives in communities nationwide.

I was pleased to see that the FDA put forward an action plan to help protect our communities from that crisis, and I look forward to working together with all of our colleagues to address that area.

Another critical priority is ensuring the FDA always puts science over politics. As some on the floor today will remember, several of my colleagues fought long and hard to ensure that medical expertise, not ideology, governed decisionmaking on the sale of Plan B over the counter. Women and families have to be able to trust the FDA to not play politics with their health.

After careful consideration and review, I am confident that Dr. Califf would contribute leadership and expertise as we work to tackle all of these challenges. He is a strong nominee for the role of FDA Commissioner. He has an impressive history of leadership and management experience, especially at Duke University, where he led one of our largest academic clinical research organizations. He would bring to this new role a record of advancing medical breakthroughs on challenging illnesses through clinical trials and working to translate NIH lab discoveries into usable medical treatments for patients. Our review of his record demonstrates a longstanding commitment to transparency in relationships with industry and working to ensure academic integrity. Dr. Califf has made clear he will continue to uphold those values and prioritize a strong, independent FDA as Commissioner. His nomination received letters of support from 128 different physician and patient organizations, as well as the strong, bipartisan support of the members of our HELP Committee.

I have approached this nomination focused on the best interests of families and communities in my State and across the country and in making sure the FDA puts them first in all its work. I believe Dr. Califf would be a valuable partner in this effort as FDA Commissioner. So I encourage all of our colleagues to join me in supporting his nomination, and I look forward to working with all of us to strengthen health and well-being for the families and communities we serve.

I yield the floor.

The PRESIDING OFFICER. The Senator from Tennessee.

Mr. ALEXANDER. Mr. President for the information of Senators, the vote will be in about 10 minutes, following my remarks, and I want to make my remarks because of the importance of this nomination.

I join the Senator from Washington State in urging our colleagues to vote to end debate on the nomination of Dr. Califf and then tomorrow to vote for him.

We are very fortunate to have a man of this distinction accept this position. I congratulate the President for his nomination. I note, as the Senator from Washington said, that his nomination has been widely applauded across this country and received strong bipartisan support in our committee after an intense investigation.

I ask unanimous consent to have printed in the RECORD, following my remarks, a list of 124 organizations that have submitted letters in support of Dr. Califf's nomination to our committee. The list does not include press releases or other statements of support that were not submitted to the committee.

Dr. Califf will be in charge of the Food and Drug Administration. That agency is responsible for the safety and effectiveness of our Nation's medicines, devices, and other medical products in protecting our country's food supply.

It is not too much to say that this job affects virtually every single American. It is a huge job. The FDA affects nearly every single American and regulates about one-quarter of all consumer spending in the United States—about $4 trillion annually. It is responsible for product areas as diverse as prescription drugs for humans as well as for animals, for medical devices, for biologics, for cosmetics, over-the-counter medications, food, and tobacco.

To accomplish this, the FDA employs 15,700 full-time employees worldwide, with an annual total budget of $4.505 billion from funds appropriated by the Congress and user fees paid by the industries it regulates. Managing an enterprise of this size is no small undertaking. It requires strong leadership and a steady hand.

Last year, on September 17, the President nominated Dr. Califf. My staff and I reviewed the nomination carefully. I found him to be well qualified to take charge of the FDA. He is one of the Nation's leading cardiologists. He was a professor at one of the Nation's top medical schools for over 30 years. He is an expert on clinical research. He has been recognized by the Institute for Scientific Information as one of the top 10 most cited authors, with more than 1,200 peer-reviewed publications. He has managed large organizations, including the Duke Clinical Research Institute as a founding director. In his current position, he is FDA's Deputy Commissioner for Medical Products and Tobacco, in which capacity he oversees the regulation of products including human drugs, biological products, medical devices, and tobacco.

He has conducted scores of important clinical trials and has advised and worked on research with some of the Nation's leading pharmaceuticals and biopharmaceutical companies.

In addition, Dr. Califf, like every full-time nominee, has been through an indepth process to review his background. Before the President even announced his nomination, there was an extensive vetting by the White House and the FBI. He submitted paperwork to the Office of Government Ethics, which carefully reviewed that information looking for conflicts of interest.

The form he submitted is public and includes every source of income over $200, every asset worth more than $1,000, and every potential conflict that the Office of Government Ethics determined would require a recusal.

Before our committee held a hearing, Dr. Califf answered 37 pages of questions from the bipartisan leadership of the committee, including confidential questions on financial information, and he responded to written followup questions. His responses included over 3,000 pages of articles and lectures my staff and Senator MURRAY's staff reviewed and any Member of the Senate could review.

On November 17, the HELP Committee held a hearing on his nomination. He provided testimony and took questions. Afterward, he answered 100 pages of written questions. Throughout this process, we have carefully reviewed everything submitted and not found anything that would call into doubt Dr. Califf's ability to lead the FDA fairly, ably, and impartially.

I am pleased to support his nomination. I am pleased the full Senate now will have an opportunity to vote on that nomination in a prompt way.

Dr. Califf's nomination comes at an important time for the FDA. For the past year, the FDA has been operating without a confirmed Commissioner. There are important issues there. It needs a confirmed Commissioner to provide the leadership that will carry the agency into the future.

One issue that has been on many of our minds is how to make sure American patients have access to affordable drugs. Of course, the FDA's job is not to set drug prices. I am pleased Dr. Califf agreed at his confirmation hearing that he understands the FDA's role is to make sure that drugs are safe and effective, not to regulate their price, but the FDA can help lower drug prices by approving generic drugs and other products as quickly as it possibly can so there is more choice and competition in the market.

There are thousands of applications for generic drugs sitting at the FDA awaiting approval. Addressing this backlog, and reviewing new applications as expeditiously as possible, will allow lower-cost drugs to be available to patients. I am confident the FDA can improve its performance. Just last month, our committee held a hearing on this issue and the FDA was optimistic about making progress.

We also needed a confirmed Commissioner who can guide the agency to make sure it keeps pace with medical innovation. There has never been a more exciting time in medical research than today. We know more about biology and medicine than ever before, and knowledge is being applied in innovative ways.

We are talking about actually curing, not just treating cancers. We are using 3–D printing to help doctors replace knees. In one case the FDA has approved a drug to treat epilepsy that is made by 3–D printing. The President has announced a Precision Medicine Initiative designed to promote personalized treatments to take into account an individual's genes, environment, and lifestyle. These are exciting developments.

First, the FDA needs to make sure that regulation is appropriate. Too much regulation could reduce investment. Not enough regulation could lead patients to getting therapies that are not safe and effective.

At the same time, the FDA will need to make sure its policies and its procedures, many of which were adopted decades ago, are capable of addressing the technologies of today and tomorrow. Second, as we continue to make medical advances, the FDA will need to keep up with the science and rely on expertise outside the FDA when appropriate. Doing that will require a leader who can manage a large and complex organization—not just on big policies that make headlines but on day-to-day matters such as hiring and training scientists on the core mission and integrating information technology.

Medical products take more time and money to discover, develop, and reach American patients than ever before. We hear stories about drugs and devices that are available to patients outside the United States before they become available here, often because it is difficult for manufacturers to navigate the FDA's often unclear approval requirements. It often takes over a decade to develop a drug that gains marketing approval in the United States. According to one recent study, the costs have tripled in the last 10 years.

Senator MURRAY and I are working with our colleagues on our committee on bipartisan legislation to help get safe, cutting-edge drugs, medical devices, and treatments into Americans' medicine cabinets and doctors' offices more quickly.

We held a markup on February 9, in which we approved seven important bills with bipartisan support that will help both manufacturers and the FDA to get innovative treatments to patients more quickly. They are all bipartisan bills.

Senators BENNET, WARREN, BURR, and HATCH offered the Advancing Targeted Therapies for Rare Diseases Act of 2015, S. 2030. If you are the parent of a child suffering from a rare disease like Cystic Fibrosis, this bill increases the chances that researchers will find a treatment or cure for your child's disease. It does that by allowing researchers to reuse good data they have collected, because it is hard to find enough patients for a clinical trial studying a rare disease with multiple genetic mutations.

Senators BURR and FRANKEN offered the FDA Device Accountability Act of 2015, S. 1622. If you are one of the millions in our country who will need a medical device such as a pacemaker or knee implant, this bill will help drive the faster development of better devices—cutting unnecessary red tape from the review process for these devices.

Senators BALDWIN and COLLINS offered the Next Generation Researchers Act, S. 2014. If you are a smart young scientist who wants to find a cure for cancer, this bill will help the National Institutes of Health create opportunities for you to get funding for your research, so that you don't head to another country or into another field. It will also help you pay back more of your student loans.

Senators KIRK, BENNET, HATCH, MURKOWSKI, ISAKSON, and COLLINS offered the Enhancing the Stature and Visibility of Medical Rehabilitation Research at NIH Act, S. 800. If you are one of the millions of Americans with disabilities, illnesses and chronic conditions that require medical rehabilitation—maybe you suffered a stroke and need to relearn how to walk—this bill will help ensure that the government is supporting research that will help you have the best chance at rehabilitation.

Senators ISAKSON and MURPHY offered the Advancing Research for Neurological Diseases Act of 2015, S. 849. If you are the child of a parent with Parkinson's, this bill will help speed a treatment or cure for your parents' disease by helping researchers have access to more data on neurological diseases.

Senator MURRAY offered the Preventing Superbugs and Protecting Patients Act, S. 2503. If you suffer from something as common as indigestion, or perhaps something scarier like cancer, that requires putting a scope down your throat to diagnose or better understand your ailment, and this bill will help ensure that the scope the doctor uses is clean and doesn't give you an infection.

I offered with Senator MURRAY the Improving Health Information Technology Act, S. 2511. If you are anyone who has ever changed doctors or needs to see a specialist and you want to be sure the new doctor you are seeing knows your medical history so he or she can help you best, this bill takes several steps to get health records flowing between doctors, hospitals, and patients to help realize the promise of health information technology by turning these systems from something that doctors and hospitals dread into something that actually helps patients.

We will be taking up more of these proposals in March and in April.

The next FDA Commissioner will have a lot of work to do, both to implement the legislation we are passing and to take the existing authority and make sure we help patients as best we can. He will be dealing with one-quarter of the consumer spending in the United States and affecting virtually every American. He is the right person for this job.

I strongly encourage my colleagues to vote for Dr. Califf, first today, to end debate on the nomination, and tomorrow, once that has ended, to confirm him in this important position.

I yield the floor.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

ORGANIZATIONS IN SUPPORT

DR. ROBERT CALIFF—NOMINEE FOR COMMISSIONER OF FOOD AND DRUGS

The following 124 organizations have submitted letters in support of Dr. Califf's nomination to the Committee on Health, Education, Labor & Pensions. The list does not include press releases or other statements of support that were not submitted to the Committee.

Accelerate Brain Cancer Cure, Accelerated Cure Project for Multiple Sclerosis, Action to Cure Kidney Cancer (ACKC), Addario Lung Cancer Medical Institute, Adenoid Cystic Carcinoma Research Foundation, Alliance for Aging Research, Alliance for Lupus Research, Alpha-1 Foundation, American Academy of Pediatrics, American Association for Cancer Research (AACR), American Cancer Society Cancer Action Network, American College of Cardiology (ACC), American Heart Association, American Sleep Apnea Association, American Society for Reproductive Medicine, American Society of Clinical Oncology (ASCO), American Statistical Association, Association of American Cancer Institutes (AACI), Association of American Medical Colleges.

BCM Families Foundation, Bert's Big Adventure, Bonnie J. Addario Lung Cancer Foundation, C-Change, Cancer Research Institute, Cancer Support Community, CancerCare, Celiac Disease Foundation, Center for Medical Technology Policy, CEO Roundtable on Cancer, Chase After a Cure, Childhood Cancer Guides, Children's Cause for Cancer Advocacy, Citizens United for Research in Epilepsy, Clinical Research Forum, Coalition of Cancer Cooperative Groups, COPD Foundation, Cure AHC, Cure SMA, CureHHT, Cutaneous Lymphoma Foundation, DC Candlelighters Childhood Cancer Foundation, Depression and Bipolar Support Alliance, Dysautonomia International, Dystonia Medical Research Foundation, Eastern Cooperative Oncology Group (ECOG), EveryLife Foundation.

Facing Our Risk of Cancer Empowered (FORCE), FasterCures, a center of the Milken Institute, FH Foundation, Fight Colorectal Cancer, Foundation Fighting Blindness, Foundation for Mitochondrial Medicine, Foundation for Prader-Willi Research, Friedreich's Ataxia Research Alliance, Friends of Cancer Research, Gastroparesis Patient Association for Cures and Treatments, Genetic Alliance, Geoffrey Beene Foundation, Glaucoma Research Foundation, Grandparents In Action, Heart Failure Society of America, Heathcare Leadership Council, Hematology/Oncology Pharmacy Association, Hepatitis Foundation International, Institute for Clinical Bioethics, Institute of Catholic Bioethics, International Myeloma Foundation, JDRF, Kids v. Cancer, Leukemia & Lymphoma Society, Lung Cancer Alliance, LUNGevity Foundation, Lupus and Allied Diseases Association, Lupus Research Institute, LymeDisease.org, Lymphangiomatosis & Gorham's Disease Alliance.

Martin Truex Jr. Foundation, Mattie Miracle Cancer Foundation, Melanoma Research Alliance, Men's Health Network, MLD Foundation, MPN Research Foundation, Multiple Myeloma Research Foundation, Muscular Dystrophy Association, Myotonic Dystrophy Foundation, National Alliance on Mental Illness (NAMI), National Alopecia Areata Foundation, National Brain Tumor Society, National Health Council, National Multiple Sclerosis Society, National Organization for Rare Disorders (NORD), National Patient Advocate Foundation, National PKU Alliance, NCCS, New England Journal of Medicine, New York Stem Cell Foundation, Oncology Nursing Society, Oncology Nursing Society (ONS), Pac2, Parent Project Muscular Dystrophy.

Pediatric Congenital Heart Association, Personalized Medicine Coalition, PFO Research Foundation, Phelan-McDermid Syndrome Foundation, Prevent Cancer Foundation, Progeria Research Foundation, Prostate Cancer Foundation, Reflex Sympathetic Dystrophy Syndrome Association, Research!America, Rett Syndrome Research Trust, Sjögren's Syndrome Foundation, Society of Women's Health Research, Solving Kids' Cancer, Sophia's Fund, St. Baldrick's Foundation, Stand Up To Cancer, T1D Exchange, The ALS Association, The diaTribe Foundation, The Hide and Seek Foundation, The Nicholas Conor Institute, The Swifty Foundation, USAgainstAlzheimer's, Wake Up Narcolepsy.

## EXECUTIVE SESSION

## EXECUTIVE CALENDAR

CLOTURE MOTION

The PRESIDING OFFICER. Pursuant to rule XXII, the Chair lays before the Senate the pending cloture motion, which the clerk will state.

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on the nomination of Robert McKinnon Califf, to be Commissioner of Food and Drugs, Department of Health and Human Services.

Mitch McConnell, John Cornyn, Lamar Alexander, Bill Cassidy, Chuck Grassley, Pat Roberts, John Barrasso, Richard Burr, Tim Scott, Orrin G. Hatch, Michael B. Enzi, Johnny Isakson, John Boozman, Cory Gardner, Roger F. Wicker, Thom Tillis, Roy Blunt.

The PRESIDING OFFICER. By unanimous consent, the mandatory quorum call has been waived.

The question is, Is it the sense of the Senate that debate on the nomination of Robert McKinnon Califf, of South Carolina, to be Commissioner of Food and Drugs, Department of Health and Human Services, shall be brought to a close?

The yeas and nays are mandatory under the rule.

The clerk will call the roll.

The legislative clerk called the roll.

Mr. CORNYN. The following Senators are necessarily absent: the Senator from Missouri (Mr. BLUNT), the Senator from Texas (Mr. CRUZ), the Senator from Arizona (Mr. FLAKE), the Senator from Nevada (Mr. HELLER), the Senator from North Dakota (Mr. HOEVEN), the Senator from Florida (Mr. RUBIO), the Senator from Alabama (Mr. SHELBY), the Senator from Pennsylvania (Mr. TOOMEY), and the Senator from Louisiana (Mr. VITTER).

Mr. DURBIN. I announce that the Senator from New Jersey (Mr. BOOKER), the Senator from Pennsylvania (Mr. CASEY), the Senator from North Dakota (Ms. HEITKAMP), the Senator from Missouri (Mrs. MCCASKILL), and the Senator from Vermont (Mr. SANDERS) are necessarily absent.

The PRESIDING OFFICER (Mr. LANKFORD). Are there any other Senators in the Chamber desiring to vote?

The yeas and nays resulted—yeas 80, nays 6, as follows:

[Rollcall Vote No. 24 Ex.]

YEAS—80

| | | |
|---|---|---|
| Alexander | Fischer | Murray |
| Baldwin | Franken | Paul |
| Barrasso | Gardner | Perdue |
| Bennet | Gillibrand | Peters |
| Boozman | Graham | Reed |
| Boxer | Grassley | Reid |
| Brown | Hatch | Risch |
| Burr | Heinrich | Roberts |
| Cantwell | Hirono | Rounds |
| Capito | Inhofe | Sasse |
| Cardin | Isakson | Schatz |
| Carper | Johnson | Schumer |
| Cassidy | Kaine | Scott |
| Coats | King | Sessions |
| Cochran | Kirk | Shaheen |
| Collins | Klobuchar | Stabenow |
| Coons | Lankford | Sullivan |
| Corker | Leahy | Tester |
| Cornyn | Lee | Thune |
| Cotton | McCain | Tillis |
| Crapo | McConnell | Udall |
| Daines | Menendez | Warner |
| Donnelly | Merkley | Warren |
| Durbin | Mikulski | Whitehouse |
| Enzi | Moran | Wicker |
| Ernst | Murkowski | Wyden |
| Feinstein | Murphy | |

NAYS—6

| | | |
|---|---|---|
| Ayotte | Manchin | Nelson |
| Blumenthal | Markey | Portman |

NOT VOTING—14

| | | |
|---|---|---|
| Blunt | Heitkamp | Sanders |
| Booker | Heller | Shelby |
| Casey | Hoeven | Toomey |
| Cruz | McCaskill | Vitter |
| Flake | Rubio | |

The PRESIDING OFFICER. On this vote, the yeas are 80, the nays are 6.

The motion is agreed to.

Cloture having been invoked, the clerk will report the nomination.

The senior assistant legislative clerk read the nomination of Robert McKinnon Califf, of South Carolina, to be Commissioner of Food and Drugs, Department of Health and Human Services.

The PRESIDING OFFICER. The Senator from Florida.

Mr. NELSON. Mr. President, I ask unanimous consent to speak as in morning business.

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

(The remarks of Mr. NELSON pertaining to the introduction of S. 2558 are printed in today's RECORD under ''Statements on Introduced Bills and Joint Resolutions.'')

Mr. NELSON. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The senior assistant legislative clerk proceeded to call the roll.

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

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

FILLING THE SUPREME COURT VACANCY

Mr. MCCONNELL. Mr. President, I recently joined my good friend from