and promote research and treatment development. That funding legislation dedicated significant new resources to the fight against the opioid epidemic. It helped fund groundbreaking research into the field of regenerative medicine. With its passage, Congress took one more critical step forward in the advancement of medical research and addiction treatment.

The Senate will soon have another opportunity to move ahead in the fight against this devastating disease by voting to confirm Dr. Scott Gottlieb to oversee the Food and Drug Administration.

The FDA plays a central role in the approval of new drug treatments and therapies. An important part of the 21st Century Cures Act provided an accelerated pathway for the FDA to approve regenerative medicines. I look forward to having a Commissioner like Dr. Gottlieb, who is committed to the development of groundbreaking medicines and treatments to combat serious illnesses.

Additionally, the FDA will continue to be a crucial partner as States like Kentucky continue their fight against the opioid epidemic. The FDA plays an important regulatory and oversight role in combating this crisis. I have encouraged the agency to incentivize the approval of safer, more abuse-deterrent formulations of drugs, and I am glad when they have concurred. These types of constructive policy decisions show an FDA that is ready to join the fight against heart-breaking disease and opioid abuse, and I am proud to support that kind of rigorous oversight from the agency.

Dr. Gottlieb has the necessary experience to serve in this key role. Not only has he worked in hospitals, interacting directly with those affected by disease and treatment, but he has also developed and analyzed medical policies in both the public and private sectors. He formed his perspectives on the dynamic public health sector by overseeing medical research and innovation projects.

In 2005, Dr. Gottlieb was appointed the FDA’s Deputy Commissioner for Medical and Scientific Affairs. He also has served as senior adviser to the FDA Commissioner and as the agency’s Director of Medical Policy Development.

As a practicing physician with a wealth of policy experience, Dr. Gottlieb has the necessary qualifications to lead the FDA at this critical time. The Senate voted to advance his nomination last night on a bipartisan basis, and I look forward to his confirmation.

RESERVATION OF LEADER TIME

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

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

EXECUTIVE SESSION

EXECUTIVE CALENDAR

The PRESIDING OFFICER. Under the previous order, the Senate will proceed to executive sessions to resume consideration of the Gottlieb nomination, which the clerk will report.

The assistant bill clerk read the nomination of Scott Gottlieb, of Connecticut, to be Commissioner of Food and Drugs, Department of Health and Human Services.

The PRESIDING OFFICER. Under the previous order, the time until 12:30 p.m. will be equally divided in the usual form.

The assistant Democratic leader, Mr. DURBIN. Mr. President, I ask unanimous consent to speak as in morning business.

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

RUSIA INVESTIGATION

Mr. DURBIN. Mr. President, this weekend we saw a peaceful democratic election in France, one of our key Western allies in the bedrock of European stability after two terrible wars in the last century. What happened before the election in France? There was a massive cyber attack on the leading candidate, the one who prevailed, Emmanuel Macron. Whom do experts suspect was behind this cyber attack trying to manipulate another Western election, trying to foster mistrust in that nation’s democratic institutions? Not surprisingly, Russia.

Yet none of this should surprise anyone. Not only had Russia been subsidizing Mr. Macron’s opponent, Marine Le Pen, who is seen as more sympathetic to Moscow, not to mention trying to interfere in Dutch and German elections as well, but we were warned about this by our own intelligence agencies many months ago.

In early October last year, the United States intelligence community detailed Russia’s attack on America’s election and warned us that other attacks would follow. During a recent trip to Eastern Europe, a Polish security expert warned me that if the United States didn’t respond to an attack on its own Presidential election by the Russians, Putin would feel emboldened to keep up the attacks to undermine and manipulate elections all through the free world.

What has this administration and this Congress done to respond to the cyber act of war by the Russians against America’s democracy? Has President Trump clearly acknowledged Russia’s attack on the U.S. and forcefully condemned the actions? No. Has President Trump warned Russia to stop meddling in the United States and other democratic elections in France, Germany, and other countries? No. Has President Trump made an overt effort to undermine his own intelligence agencies’ conclusions that Russia interfered in the election? No. Has President Trump taken steps to help protect the States from foreign interference in our election? No. Has President Trump taken steps to protect the American people from the security threat of Russian cyber interference? No.

What does this administration and this Senate do when Russia interferes in a U.S. election? Nothing. The Russian cyber attack has been an act of war—a cyber act of war by the Russians.

That’s why I’m asking my colleagues to join me in a vote to confirm Dr. Scott Gottlieb. He has the necessary qualifications to lead the FDA at this critical time. The wealth of policy experience, Dr. Gottlieb has served as senior adviser to the FDA Medical and Scientific Affairs. He also has served as acting chief for the FDA’s Deputy Commissioner for Medical and Scientific Affairs. He also has worked as a practicing physician with a wealth of policy experience, Dr. Gottlieb has the necessary qualifications to lead the FDA at this critical time. The Senate voted to advance his nomination last night on a bipartisan basis, and I look forward to his confirmation.

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Quite simply, the failure of this President and Congress to address the cyber security threat is a stunning abdication of responsibility to protect the United States and our democratic values.

As if the conclusions of 17 U.S. intelligence agencies weren’t enough to rattle the Kremlin, what emerged just over the recent April recess. For example, Reuters reported that a Russian Government think tank, controlled by Russian dictator Vladimir Putin, developed a plan to swing our 2016 Presidential election to Donald Trump and undermine voters’ faith in our electoral system.

The institute, run by a retired senior Russian foreign intelligence official, appointed by Putin, released two key reports, one in June and one in October of last year.

In the first, it argued that “the Kremlin launch a propaganda campaign on social media and Russian state-backed global news outlets to encourage US voters to elect a president who would take a softer line toward Russia than the administration of then-President Obama.”

The second warning said: “(Pre)sidential candidate Hillary Clinton was likely to win the election. For that reason, the Kremlin planned to use its pro-Trump propaganda and instead intensify its messaging about voter fraud to undermine the US electoral system’s legitimacy and damage Clinton’s reputation in an effort to undermine her presidency.

It was also recently disclosed that the FBI obtained a Foreign Intelligence Surveillance Court warrant to monitor the communications of former Trump campaign foreign policy adviser Carter Page on the suspicion that he was a Russian agent. Add this to the ever-growing list of suspicious relationships between those in the Trump circle and Russia, from Michael Flynn to Paul Manafort, to Roger Stone, to Felix Sater.

In fact, just last month, the Republican House Intelligence Committee chair, JASON CHAFFETZ, and the ranking Democratic member, ELIJAH CUMMINGS, said General Flynn may have broken the law by failing to disclose on his security clearance forms payments of more than $65,000 from companies linked to Russia. Yet, incredibly, the White House continues to stonewall requests for documents related to General Flynn.

White House ethics lawyer during the George Bush administration, Richard Painter, wrote of this stonewalling: “US House must subpoena the docs. . . . Zero tolerance for WH [White House] covering up foreign payoffs.”

Is it any wonder why, in recent testimony to Congress, FBI Director Comey acknowledged an investigation of Russian interference in our election, which
he said included possible links between Russia and Trump associates.

Finally, over the recession—on tax day, to be precise—there were nationwide protests calling on President Trump to take the necessary step to dispel concerns by releasing his taxes once and for all. The $8.2 trillion Russian economy is one of the Trump business empire. In 2008, Donald Trump, Jr., said Trump’s businesses “see a lot of money pouring in from Russians.” He was despite his father incredulously saying this just a few months ago: “I have nothing to do with Russia—no deals, no loans, no nothing!”

It appears that the Russians were some of the few willing to take on the financial risk required to invest in Trump’s precarious business deals. Any such Russian money, combined with the President’s refusal to formally separate himself from his business operations during his Presidency, demand the release of his tax returns. Trump himself is aware of the large numbers of American military leaders who were made aware of the serious questions as to how much Russian money is part of the Trump business empire. In 2008, General Sally Yates was subject to blackmail by the Trump White House on national security matters. The President continued to invite Putin and other highly sensitive national security matters during his Presidency, demanding that the highest adviser warn them that the highest adviser was compromised by the Russians.

But the occasional subcommittee hearing like this is not enough. We need an independent, bipartisan commission with investigative resources and the power necessary to dig into all of the unanswered questions. Until we do, the efforts of this committee or the House Intelligence Committee will have to be a conscious effort on a national basis by an independent commission.

For President Trump, these issues do not appear to be relevant, yet there is a simple way to resolve the many questions that remain:

First, disclose your tax returns and clear up, among other questions, what your son said in 2008 about a lot of Russian money pouring into your family business.

No. 2, answer all the questions about campaign contacts with the Russians, including your former campaign manager Paul Manafort, former National Security Advisor Michael Flynn, and former policy advisor Carter Page.

No. 3, quite simply, explain the reports of repeated contacts between your campaign operatives and Russian intelligence.

No. 4, answer all the questions about your close friend Roger Stone’s communications with the floor leader at the Kremlin, and the flood of Wikileaks’ having and using, in strategically timed releases when your campaign was struggling, information that had been hacked by the Russians from your opponent’s campaign.

No. 5, explain your ties to Russian foreign businessman Felix Sater, who worked at the Bayrock Group investment firm, which partnered with your business and had ties to Russian money.

No. 6, provide all requested documents to Congress related to Michael Flynn, who concealed his payments from the Russian interests. If there is nothing to hide, this is your chance to clear up things once and for all.

To my Republican colleagues I say again that these Russian connections may constitute a national security crisis. We need to have the facts. How long will we wait for these desperately needed answers before we establish an independent commission investigation. We have done this before and are faced with previous attacks on America?

Finally, how long will we sit by before passing additional sanctions on Russia for their cyber attack on the United States of America? That attack makes November 8, 2016, a day that will live in cyber infamy in America’s history. It is time for the Republicans and the Democrats to show the appropriate concern for this breach of our national security.

We have a bipartisan Russian sanctions bill ready to go to the Senate Foreign Relations Committee. What are we waiting for?

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

The PRESIDING OFFICER. The clerk will call the roll.

The assistant bill clerk proceeded to call the roll.

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

The PRESIDING OFFICER (Mr. FLAKE). Without objection. It is so ordered.

Mr. MARKEY. Mr. President, I rise today to speak in opposition to the nomination of Dr. Scott Gottlieb to lead the Food and Drug Administration.

The FDA Commissioner is our Nation’s pharmaceuticals, but for years the FDA has granted unfettered access to Big Pharma and its addictive opioid painkillers to the American public. The result is a prescription drug, heroin, and fentanyl epidemic of tragic proportions and the greatest public health crisis our Nation currently faces.

At a time when we need its leader to break the stronghold of big pharmaceutical companies on the FDA, Dr. Scott Gottlieb would be nothing more than an agent of Big Pharma. Dr. Gottlieb’s record shows that he doesn’t support using the tools that the FDA has at its disposal to minimize the risks to public health from the misuse of prescription opioids.

The current opioid epidemic is a man-made problem. It was born out of the greed of big pharmaceutical companies and aided by the FDA, which willfully green-lighted supercharged painkillers like OxyContin. But, in order for us to understand this public health emergency and the critical role that leadership at the FDA has played and will continue to play in this crisis, we need a brief history lesson. We need to understand where these opioids come from.

In 1898, a German chemist introduced heroin to the world—a reproduction of an earlier form of morphine believed to be nonaddictive. The name “heroin” was derived from the German word “heroisch,” which means “heroic.” That is, saw men described the way they felt after taking the new drug.

In the first decade of the 20th century, doctors were led to believe that heroin was nonaddictive and prescribed it for many ailments. But heroin addiction soon became prevalent, so the government began to regulate its use, including arresting doctors who prescribed it to those who were already condemned. The name “heroin” was derived from the German word “heroisch,” which means “heroic.” That is, saw men described the way they felt after taking the new drug.
addicted, and the medical community began to stop prescribing it. Inevitably, the addicted turned to illegal markets to feed their dependence.

Wariness toward prescribing opioid-based painkillers for anything other than terminal illnesses or severe pain permeated the medical community through the 20th century, all the way up until the late 1970s and the early 1980s. At that time, the international debate broke out on pain management. The question was asked: Was it humane to allow patients to suffer needlessly through pain when opioid-based medications were available?

Many advocates for increased use of painkillers pointed to a 1980 letter to the New England Journal of Medicine, which concluded that only 1 percent of patients who were prescribed opiate-based painkillers became addicted to their medication. Known as the Porter and Jick letter because it was named after the two Boston researchers who conducted and authored the letter, it fueled a belief that opiate-based prescription drugs were not addictive. It was a belief that began to permeate the medical community.

But the medical community was not the only one Scoped the problem with Porter and Jick’s conclusions. They had only collected data on patients who were receiving inpatient care. As you can imagine, the percentage of patients who became addicted to opiates while in the hospital was only a tiny fraction of the patients who received opiate prescription drugs in an outpatient setting.

But the medical community was not the only one ignoring the danger of opiates not being addictive. With the FDA’s 1995 approval of the original OxyContin, the original sin of the opiate crisis, we can literally point to the starting point of this epidemic. The FDA approved the original version of OxyContin, an extended-release opioid, and believed that it “would result in less abuse potential since the drug would be absorbed slowly and there would not be an immediate ‘rush’ or high to promote abuse.”

In 1996, Purdue Pharma brought OxyContin to the market, earning the company $38 million in sales just that year alone. Purdue Pharma claimed OxyContin was nonaddictive and couldn’t be abused, and the FDA agreed. Neither of those claims turned out to be true.

Purdue Pharma built a massive marketing and sales program for OxyContin to 2000. Purdue Pharma’s sales force more than doubled, from 318 to 671 sales representatives. In 2001 alone, Purdue gave out $40 million in sales bonuses to its burgeoning sales force. These sales representatives targeted healthcare providers who were more willing to prescribe opioid painkillers.

As a result of these sales and marketing efforts from 1997 to 2002, OxyContin prescriptions increased almost tenfold, from 670,000 in 1997 to 6.2 million prescriptions in 2002. Then, in 2007, Purdue Pharma paid $600 million in fines and other pay-
Amazingly, this bill is even devastating to our veterans. That is what I would like to focus on for the remainder of my time this morning.

You would think that when the House of Representatives was writing its bill, Members would be more careful to make sure that our veterans, who put their lives on the line for our country, wouldn’t be hurt by their legislation. In their haste to cobble together a bill that could pass the House, the Republican majority actually made it more likely than ever that veterans would deny the means of affording private healthcare. Many of the people who we honor for their service, many of our brave veterans and maybe more—another broken promise, saying one thing and doing another. Many of the people who support Donald Trump don’t want to embrace that idea, but it is happening in issue after issue. They will see it—saying one thing and doing another. That is another reason for Senate Republicans to scrap this bill, scrap repeal, and once and for all dealing with Donald Trump’s total and near-bipartisan ways to improve our healthcare system.

Today, we Democrats will be sending a letter to the Republican leadership laying out our position on healthcare. All 48 of my Senate Democratic colleagues have signed it. It has been our position all along: We are ready to work in a bipartisan, open, and transparent way to improve and reform our healthcare system.

Look, we have made a lot of progress in the last few years. Kids can now stay on their parents’ plan until they are 26. Women are no longer charged more for the same coverage. There are more Americans alive before. These are good things. We ought to keep them and then build on our progress.

To our Republican friends we say this. Drop this idea of repeal. Drop this nightmare of a bill, TrumpCare, which raises costs on our veterans, and come work with us on ways to reduce the cost of premiums, the cost of prescription drugs, and other out-of-pocket costs. We can find ways to make our healthcare system better if we work together. TrumpCare is not the answer. I want to thank my friend from Massachusetts for the courtesy. I yield the floor back to the Senator. The PRESIDING OFFICER. The Senator from Massachusetts.

Mr. MARKEY. Mr. President, I thank our leader for his great leadership on all of these national security and healthcare issues. I think he has injected some common sense into how the American people should be viewing each and every one of those very important issues. His national leadership is greatly appreciated.

Let me turn and yield to the great Senator from the State of New Hampshire, where this opioid epidemic has hit hardest of all, Senator HASSAN. The PRESIDING OFFICER. The Senator from New Hampshire.

Ms. HASSAN. I thank Senator MARKEY. Mr. President, I, too, want to thank Leader SCHUMER for his remarks and his work on national security and on opioid, heroin, and fentanyl crisis, which is the greatest public health and safety challenge that the State of New Hampshire faces and which I know many other States face as well.

I rise today to support the nomination of Dr. Scott Gottlieb to serve as the Commissioner of the Food and Drug Administration. It is the responsibility of the Food and Drug Administration, starting with its Commissioner, to protect consumers and stand up for public health.

I have serious concerns about Dr. Gottlieb’s record. I also have additional concerns from his nomination hearing about his stance on critical priorities for people in New Hampshire and across the Nation.

As I mentioned, and as Senator MARKEY has detailed, as well, the most pressing public health challenge facing New Hampshire is the heroin, fentanyl, and opioid crisis. I want to thank the Senator from Massachusetts for his leadership and work in helping to identify the root causes of this terrible epidemic. Today, I met New Hampshire, and I met with the Drug Enforcement Agency leaders and personnel there. I heard updates from those on the frontlines about the latest developments in the substance misuse crisis. We discussed the spread of the dangerous synthetic drug carfentanil, which is 100 times stronger than the already deadly drug fentanyl.

A report released this week by New Hampshire showed the economic impact of alcohol and substance misuse costs. It costs New Hampshire’s economy now over $2 billion a year. It is clear that we need to take stronger action to combat this crisis. I want to continue partnering together with those on the frontlines and at every level of government. We need to be developing new tools and leveraging the ones we have to combat this crisis.

When we cannot afford to do is to institute policies that would take us backward. Unfortunately, Dr. Gottlieb has been opposed to the creation of one of the key tools that the FDA has at its disposal—risk evaluation and mitigation strategies, otherwise known as REMS. The agency uses REMS—including, as a strategy, prescriber training—to try to stem the risks associated with certain medications.

The FDA should be making REMS stronger and making sure that all opioid medications carry. We don’t need a Commissioner who opposed the very creation of the REMS program, as Dr. Gottlieb did. In the midst of a public health challenge as serious as this epidemic, we should be taking—and we have to take—an all-hands-on-deck approach. The fact that Dr. Gottlieb was opposed to the very creation of REMS raises questions about what strategies the FDA would support under his leadership.

There is another issue involved in this nomination of deep concern to the people of New Hampshire. I am concerned about Dr. Gottlieb’s record of putting politics ahead of science when it comes to women’s health. To compete economically on a level playing field, women must be able to make their own decisions about when and if to start a family. To fully participate not only in our economy but also in our democracy, women must be recognized for their capacity to make their own healthcare decisions, not just men.

Mr. President, who lobbied for this bill down to the individual Member, it is another giant broken promise to the working people and, in this case, to our veterans.

President Trump made improving the healthcare of our veterans a theme of his campaign. Just a few weeks ago, he said that “the veterans have poured out their sweat and blood and tears for this country for so long and it’s time that they are recognized and it’s time that we now take care of them and take care of them properly.”

His healthcare bill, TrumpCare, would deny the means of affording private insurance to as many as 7 million veterans and maybe more—another broken promise, saying one thing and doing another. Many of the people who...
Unfortunately, this administration has made clear that it is focused on an agenda that restricts women’s access to critical health services, including family planning.

Dr. Gottlieb’s record has demonstrated that he supports that agenda. During his time in the Bush administration, Dr. Gottlieb was involved in a controversial and unquestionably delayed in approving the emergency contraceptive Plan B for over-the-counter use.

I am concerned that under his leadership, the FDA will play political games with women’s health once again. I am afraid that he will disregard science-based decisions under pressure from this administration. Dr. Gottlieb’s nomination rises too many questions about whether he will put political interests ahead of science and ahead of the safety of consumers.

I hope that he has learned about the priorities of Senators and the constituents they represent throughout the nomination process and that he proves to be a stronger Commissioner than his record suggests. But in voting today, I cannot overlook that record, so I will vote against his nomination, and I urge my colleagues to do the same.

I yield the floor.

The PRESIDING OFFICER (Mr. STRANGE). The Senator from Massachusetts, Mr. MARKEY. Thank you, Mr. President.

I thank Senator HASSAN for all of her great leadership as Governor of New Hampshire and now the Senator from New Hampshire. The epidemic has hit New Hampshire very hard, harder than any other place. Her leadership is absolutely outstanding. I thank her for all of her leadership on this nomination as well.

As we look at this issue, we realize that a whole epidemic was being created, and this epidemic was being created because of approvals of “abuse-deterrent” opioids since 2010. I put “abuse-deterrent” in quotes because it was extremely deceptive because too many people felt “abuse-deterrent” meant they could not ultimately become addicted to the medicine. The damage has now been done. The prescription painkiller abuse became rampant across the country. We had become the United States of Oxy, and the opioid epidemic was on its way to becoming an opioid epidemic because when those who were addicted to Oxy could no longer afford $60 for a 60-milligram pill, they opted for low-priced heroin, which is why we should not be surprised that so many individuals who began abusing heroin in the 2000s, 75 percent reported that their first opioid was a prescription drug.

Taking advantage of the new demand for heroin, an incredibly sophisticated network of drug traffickers from Mexico and in every State in the United States, and now they are branching out from large urban areas into our suburbs. These systems collided in a perfect storm that has caused the epidemic we are experiencing today: the overprescription of opioid painkillers that were approved by the FDA, the over-the-top sales and marketing programs by a deceptive and deep-pocketed pharmaceutical giant that went unimpeded for years, and an overabundance of heroin flowing into the United States from Mexico and South America. All of that has led us here.

We know that nationally opioid overdoses kill more people than gun violence or auto accidents. Every single day in America, we lose more than 91 people to an opioid-related overdose. Nationally, nearly half of all opioid overdose deaths involve a prescription opioid that was approved by the FDA and often prescribed by a physician. In Massachusetts, in 2016, 2,000 people died from an opioid overdose.

Who is the typical victim of an opioid overdose? Who is the typical substance abuser? The answer is that there is none. This epidemic does not discriminate on the basis of age or gender or race or ethnicity or economic status. It does not care if you live in a city or in the middle of the country. It does not care if you have a white-collar or a blue-collar job. The 50-year-old White male attorney is just as likely to become addicted to prescription drugs or heroin as the 22-year-old Latina waitress. Opioid addiction is an equal opportunity destroyer of lives.

Those addicted to opiates are too often stealing from their friends, their families and neighbors, or complete strangers to fuel their addiction. Cars are broken into, and valuable stereo systems are left intact, while a few dollars in change are stolen. Homes are broken into, and flat-screen television sets remain untouched, while children’s piggy banks go missing.

The opioid epidemic is also causing immeasurable harm to the families of those in the unbreakable grip of opioids. Too often, I hear the stories of parents who have drained their entire life savings to provide the treatment and recovery programs necessary to beat this addiction. Many times, it results in bankruptcy filings that were unimaginable only a few short years ago.

The opioid crisis is robbing people of their friends, their families, and their loved ones. It is robbing them of their livelihood. It is robbing them of their freedom as they look out from behind prison bars. All too often, it is robbing them of their lives.

If we don’t act now, we could lose an entire generation of people. As this opioid crisis explodes in my State of Massachusetts and in every State in the country, we need an FDA leader who will understand that universal healthcare does not mean that every doctor and every American have access to a bottle of prescription opioids.

Last year, more than 33,000 mothers, fathers, children, and loved ones were robbed of their potential when they died of an opioid overdose, but Dr. Scott Gottlieb has openly questioned the value of the Drug Enforcement Administration’s enforcement against doctors and pharmacies to prevent prescription opioids from entering the illicit market. The DEA is an over prescription drug cop on the beat, but Dr. Gottlieb wants to give that role to bureaucrats at the Department of Health and Human Services, an agency that has consistently failed at any kind of enforcement.

At the same time, Dr. Gottlieb has also publicly stated his opposition to the FDA’s risk plans, so-called REMS—meaning risk evaluation and mitigation strategies—for the use of these opioids. That is what is used to address the safety of opioid painkillers. These vital tools that the FDA has to manage the risk should be made stronger, but Dr. Gottlieb argues that they should not exist at all. Risk evaluation and mitigation strategies should not exist at all. With the overwhelming majority of heroin users reporting that their addiction began with prescription opioids, Dr. Gottlieb believes drug safety does not need strong oversight. That is simply irresponsible.

We are suffering this public health epidemic because Big Pharma pushed pills they knew were dangerous and addictive. The FDA approved them, often without expert counsel, and doctors, they do not have mandatory education on these drugs, prescribed them to innocent families all across our country. It is a vicious and deadly cycle that has turned this Nation into the United States of Oxy, and it must stop.

Dr. Gottlieb’s Big Pharma formula is simple: Take away the DEA oversight over prescription opioids and give that authority to the FDA. Then, at the same time, limit the FDA’s ability to utilize its full oversight authority over these addictive products. That would leave a mostly unregulated marketplace for big pharmaceutical companies and their opioid painkillers to thrive, while American families pay the highest price they can: the life of someone in their family.

Perhaps most alarming is Dr. Gottlieb’s connection to a specific pharmaceutical company called Cephalon. Last month, a Washington Post story revealed that Dr. Gottlieb based his work on behalf of one company, Cephalon, to raise the amount of the addictive opioid fentanyl that the company could market at the same time the prescription painkiller epidemic was exploding. The Washington Post story detailed how Dr. Gottlieb advocated for the DEA—the Drug Enforcement Administration—to raise the quota of fentanyl that Cephalon could manufacture and put on the market, even while the company was under investigation for pushing doctors to prescribe the addictive painkiller for headaches and back pain when it was meant for late-stage cancer patients.
These aggressive and off-label promotion tactics were out of the Perdue Pharma playbook that got us into this opioid crisis in the first place.

Cephalon ultimately pleaded guilty in 2006 to illegally promoting the fentanyl drug and paid a $225 million fine. This relationship is deeply disturbing.

Dr. Gottlieb seems to believe that pharmaceutical profits are more important than the public’s health. When the opioid epidemic was taking deadly hold, Dr. Gottlieb advocated to put even more addictive fentanyl onto the market when it was not appropriate or necessary.

Dr. Gottlieb said during his confirmation hearing that the FDA unwittingly fueled the opioid epidemic, but he is guilty of intentionally pushing an addictive prescription opioid onto the American public just to benefit one company instead of working to prevent this massive public health crisis. Dr. Gottlieb’s actions have made the opioid crisis worse.

Serious questions remain about Dr. Gottlieb’s association with Cephalon, which was fined hundreds of millions of dollars for violating FDA rules under the watch of FDA Commissioner Gottlieb. Scott Gottlieb was then hired by a law firm as an expert witness used to defend the actions of Cephalon in court.

In advance of this floor vote, I and a group of other Senators questioned Dr. Gottlieb on his work and the extent of his historical and financial relationship with Cephalon, but we received nothing that shed any light on his relationship with the company.

We cannot have a leader at the FDA who has worked on behalf of a company that aided and abetted the prescription drug and heroin epidemic.

Sadly, Dr. Gottlieb is yet another example of President Trump’s lack of commitment to address the opioid crisis. President Trump believes that if we just build a border wall, well, we will end this opioid crisis.

We don’t need a wall, President Trump, we need treatment.

President Trump’s support for the repeal of the Affordable Care Act and the legislation the House passed just last week means coverage for opioid-use disorders for 2.8 million people could be ripped away. President Trump has proposed slashing the research budget of the National Institutes of Health by 18 percent, undercutting our ability to better understand addiction and come up with alternative, less addictive pain medication.

If President Trump and his Republican allies are committed to combating the opioid crisis, they should release their plan for addressing this crisis, including committing to quickly release the remaining $500 million authorized last year in the 21st Century Cures Act, and plan for investing more Federal dollars into understanding, release the remaining $500 million assistance, including committing to quickly addressing the opioid epidemic that aided and abetted the prescription drug crisis.

The FDAs leadership at the FDA is in a prime position to ensure the terminology used for promoting a drug is not confusing or misleading. At this time of crisis, we need a leader at the FDA who recognizes the dangers of prescription painkillers, who will stand up to big pharma and reform the FDA to prevent addiction before it takes hold. Dr. Scott Gottlieb is not that individual.

The FDA’s nomination signals a continuation of FDA policy that has cultivated and fueled the opioid epidemic. I strongly oppose Dr. Gottlieb’s nomination and call on my colleagues to join me in voting no.

Mr. President, I yield back the floor.

The PRESIDING OFFICER. The Senator from Maryland is recognized.

HEALTHCARE LEGISLATION

Mr. VAN HOLLEN. Mr. President, I join my colleagues in opposing the nomination of Dr. Gottlieb and thank him for laying out his positions.

The FDA, of course, is an important part of our healthcare system, and just last week we saw the House of Representatives jam through a piece of legislation that would wreak havoc on our healthcare system. In fact, many people are appropriately calling what they did “healthcare” because it represents a huge transfer of wealth away from caring for patients to the very wealthiest in our country, including many powerful special interests.

I think everybody understands—Republicans, Democrats, Independents alike—the Affordable Care Act is not perfect and specifically that we need to address the issues within the Affordable Care Act exchanges. We need to address those issues to lower the deductibles, lower the co-pays, and make it more affordable. There are some very straightforward ways of doing that.

One good idea is to create a public option within the Affordable Care Act exchanges, a Medicare-for-all-type choice. What will that do? It will create more competition. That could drive down the price of insurance within the Affordable Care Act exchanges, and it will ensure that you have a provider everywhere in the United States in every community of this country. Even better, the Congressional Budget Office, the last time they looked at it, concluded that it would save taxpayers $160 billion over 10 years, so it would reduce our deficit.

The House Republican healthcare bill doesn’t try to fix the exchanges. What it does is blow up the Affordable Care Act and in the process wreaks havoc on our entire healthcare system. You don’t have to take my word for it. Just take a look at the long list of groups that have come out strongly opposed to the House bill, starting with patient advocacy groups, such as the American Lung Association, the American Diabetes Association, the American Heart Association, the American Cancer Society, and the list goes on. These are groups that care about patients, they don’t care about politics, and they are strongly opposed.

How about those who are providing care to those patients? Well, here is a partial list of the groups that are strongly opposed: the American Academy of Family Physicians, and the list goes on. The American Hospital Association opposes this, and the American Nurses’ Association, and the American Academy of Pediatrics, the American Academy of Family Physicians, and the list goes on. These are groups that care about patients, they don’t care about politics, and they are strongly opposed.

Let’s look at the hospital groups. The American Hospital Association strongly opposes this; the Children’s Hospital Association opposes this; and the list goes on. It is opposed by those who are spending all their time advocating for patients and opposed by those who provide care to patients.

Then you have a long list of senior groups, including AARP, that strongly oppose this because the House bill discriminates against older Americans—people over 50 years old—because it allows insurers to charge them a whole lot more for their healthcare than they currently have to pay.

These groups don’t care about politics. They don’t care about politics. They care about patients and their healthcare system, and it should tell us all a lot that they are opposed and strongly opposed to this bill. Now, why is that?
This House bill is rotten at its core. Its foundation was rotten when the Congressional Budget Office first looked at it, and then they made it even worse. Let’s look at the foundation of this, which the Congressional Budget Office had a chance to look at. I do want to remind the Presiding Officer that the head of the Congressional Budget Office was selected by the chairman of the House Republican Budget Committee, the House Budget Committee, the Republican chairman and the chairman of the Senate Budget Committee, a Republican chairman. They took a look at that first foundation of the House bill, and here is what they concluded. This is right in their report; that 24 million Americans would lose their access to affordable healthcare. That is on page 2 of the nonpartisan Congressional Budget Office report.

Why is that? It is because they take a wrecking ball to Medicaid and a wrecking ball to the exchanges. They don’t make the exchanges better. They don’t drive down the prices. They make the exchanges worse, and they take a big whack at Medicaid. In fact, they also take a cut at Medicare. In fact, if you go back in this CBO chart, I will just refer people to page 3. Sometimes you just have to dig deep in these reports to get to the bottom line. There is an $883 billion cut that consists of about $840 billion cuts to the Medicaid Program to the States, and $48 billion in cuts to the Medicare Program, and I should emphasize that will actually make the Medicare Program somewhat more insolvent. You add it up, you have $880 billion in cuts to Medicare and Medicaid combined.

I remind people that the Medicaid funding not only went to provide more access to people for healthcare through expanding Medicaid, which many States have talked about and Governor Kasich was the leader there. I am not saying that, but this bill also cuts the core Medicaid Program to the States, and two-thirds of that money goes to care for seniors in nursing homes and people with disabilities. So it puts all of them at risk. That is $880 billion in cuts to Medicare and Medicaid and people who need healthcare.

What is the other big number in the House bill? Well, $900 billion is the amount of the tax cuts in what is being described as a $900 billion tax cut. That billion dollar cut at the top of it. They added a provision that would eliminate the essential benefits package. These are the provisions that ensure that when you are buying an insurance policy, you are getting something that will be there when you need it rather than a junk policy—the policies people used to get, where they found out after they got sick, “Uh-uh, we are not paying for that.” said the insurance companies “because look here at the back of page 100, last paragraph, fine print, you are not covered for that.” That is why we had an essential benefits package for things like maternity care, mental health care, coverage for substance abuse. I hear a lot of talk about the problems with the opioid epidemic. Those are real problems that are hurting families around the country. That was part of the essential health benefits—not there in the House bill.

Then, to add insult to injury, they took out the requirement that you have coverage for preexisting conditions in an affordable way. You know, people can play word games all they want. You are going to make a change that is meaningful when it is really only a cosmetic change, when it is really only a small change that then provides some kind of rationale or excuse for supporting a House bill that is rotten at its core.

For example, someone may say: Well, let’s do a little more by way of covering opioid addiction. That would be a good idea. But that doesn’t salvage a bill that is fundamentally flawed. That doesn’t salvage a bill that at its core cuts $880 billion from Medicaid and Medicare to provide a tax cut of over $900 billion, most of which goes to wealthy people and corporate special interests.

I would say to all the other people who are on employer-provided healthcare, which are the majority of Americans: Beware, because that House bill will affect you too.

I just want to read a portion from something that appeared in The Upshot public health section of the New York Times—“G.O.P. Bill Could Affect Employer Health Coverage, Too.” They write:

About half of all Americans get health coverage through work. The bill would make it easier for employers to increase the amount that employees could be asked to pay in premiums, or to stop offering coverage entirely. It also has the potential to weaken rules against companies who, for example, are avoiding deducting how much employees can be asked to pay in deductibles or co-payments. So for anyone who is getting coverage through their employer, beware because this is going to have harmful effects on you.

I want to close with one of the many stories that I have received—and I
know many of us have received from our constituents—about how that House bill would wreak havoc in their lives. Here is one that I received:

I’m 29 years old and was just diagnosed Feb. 24th with breast cancer. . . . I buy insurance myself, and did so with the assistance from the ACA. Without that program in place, I might not have gone in when I felt this lump. I might have waited much longer, just to see if it was too late. Without this program, I would be bankrupted by the screenings alone just to find out I am dying. I just want to make this political—but this is my life. It will literally be or life or death for so many of us.

This is a life-or-death issue for tens of millions of our fellow Americans. I urge the Senate to flatly reject the House healthcare-wealthcare bill, which is rotten to its core.

Let’s focus on the issues in the exchanges. We can do that if people of good faith want to work from scratch to address that issue, but let’s not blow up the Affordable Care Act and jump on our constituents and tens of millions of other Americans in the process.

I yield the remainder of my time.

The PRESIDING OFFICER. The Senator for Ohio.

Mr. BROWN. Mr. President, I particularly appreciate the comments of my colleague from Maryland about the Affordable Care Act. The fact is, they are taking insurance from 200,000 Ohioans right now who are getting opioid treatment because of the Affordable Care Act, and the vote in the House of Representatives would turn those 200,000 families upside down. They should have listened to themselves. Then to go to the White House and celebrate—that is just the ultimate despicable, political act. I just can’t imagine that in the 21st century people would actually do that.

The FDA has incredible influence over Americans’ lives, and the Commissioner of the Federal Food and Drug Administration will lead the agency dedicated to ensuring that our food and medicine and food supplies are safe. More on that in a moment.

It is the job of the FDA Commissioner, and has been for decades, to be an independent check on big pharmaceutical companies, to crack down on Big Tobacco, and to oversee the safety and efficacy of new prescription drugs, including, most essentially in the last few years, opioid painkillers. Unfortunately, Dr. Scott Gottlieb’s record gives me serious concern, as Senator Mark Warner has pointed out so well, that this Commissioner will fall short on all of these measures.

We know the havoc that opioid painkillers have wreaked on communities across the country. My State of Ohio has had more overdose deaths from heroin, OxyContin, Percocet, opioids, morphine-based opioids; we have had more deaths than any other State in the United States of America. In my State and across this country, people are because of the opioid epidemic; 91 Americans, including 12 Ohioans, will die today—91 Americans, 12 Ohioans will die today—from opioid overdoses.

The Commissioner will have a lot of tools to fight this epidemic that is ravaging our families and our communities. We need all hands on deck to fight this crisis. We need the FDA.

Unfortunately, Dr. Gottlieb’s record indicates he believes the opioid epidemic and the FDA’s authority to rein in prescription painkillers and other drugs seriously, which is why I cannot support his nomination.

I don’t want to point fingers, but there are a host of reasons for this epidemic. One of them clearly is the proliferation of prescriptions and the manufacture of so many of these opioids. They are getting to market, and doctors are prescribing them, and pharmacists are filling them.

I don’t point fingers at individual people and even individual industries; we are all at fault and not doing this right. But Dr. Gottlieb has had a cozy relationship with big drug companies for decades as an insider, and an advisor, and as member of the board for a number of these companies. He supported allowing those same companies to rush their drugs, including potentially addictive opioid painkillers, onto the market before we were sure they were safe—right at a moment.

He has called into question the Drug Enforcement Administration’s authority to police opioids, despite the fact that these drugs are often sold on the black market. He has defended industry’s efforts to bring new drugs and devices with minimal safety oversight. He has refused to answer questions about his previous work for pharmaceutical companies that make the opioid fentanyl. We know he participated in a meeting on their behalf at the time that the company was under FDA investigation for pushing off-label uses of fentanyl.

Anyone who thinks we need more fentanyl on the market in many of Ohio’s 88 counties or the coroner’s office. Imagine this: In some counties, the coroner’s office has had to bring in refrigerated semitrailers to keep up with the growing body count from the lives lost to overdoses. Think of that; just think of that picture bringing in refrigerated semitrailers to keep up with the growing body count from opioid deaths.

Let Mr. Gottlieb explain himself to the parents, the children, and the friends who have one child or this deadly drug. A friend of my wife’s, a woman she knew growing up, lost her son to fentanyl. He had a 2-year-old child. He was starting to come clean. My understanding is that he relapsed, and he passed away just a few days ago. We need a leader at the FDA who will step up the agency’s efforts to fight this addiction epidemic, which is tearing families upside down. It rips up communities. We need a Commissioner who will fight this epidemic, and not one who will roll over for his Big Pharma friends. We need a strong public health advocate to address probably the worst public health crisis of my lifetime, a public health advocate who will continue to stand up to Big Tobacco with strong rules for all tobacco products, including newer products like e-cigarettes, which are particularly appealing to kids.

The opioid crisis is certainly a bigger health crisis that we face right now, and tobacco is an ongoing public health crisis. We have made huge victories; we have made huge strides and have had huge victories in this country. Young people smoke in significantly lower numbers than they used to. Tobacco companies don’t much like that, so they have introduced e-cigarettes. Tobacco companies are buying more and more of the manufacturing capabilities of Big Tobacco. The FDA hasn’t stepped up the way it should. I implore Dr. Gottlieb to do that, but there is no evidence so far that he cares enough to.

Once again, his extensive business dealings call into doubt whether he can seriously serve as the people’s cop on the beat when it comes to policing Big Tobacco. Dr. Gottlieb invested in an e-cigarette company—the new FDA Commissioner. He probably will be compelled today to tell us that because he is a Trump nominee, no matter their ethics, no matter their background, no matter their inability to serve well, no matter their lack of qualifications for a whole host of their responsibilities, almost every Republican—it is sort of like when one bird flies off a telephone wire, they all do, and they have voted for almost every one of these nominees.

But think of this: Dr. Gottlieb’s job is public health, his job is to police Big Tobacco. His job is to stand between these multimillion-dollar marketing executives and the 15-year-old who is attracted to these e-cigarettes with the flavors and the colors and the marketing, and he has invested in the past in e-cigarette companies. To think that we need more of the manufacturing capabilities of Big Tobacco, one who is in charge—must put the people’s safety over drug company profits, whether it is addictive painkillers or e-cigarettes.

I don’t think Dr. Gottlieb is the right person for this. I hope I am wrong. I plan to vote no. I hope he proves me wrong. If he does, I will come back to the floor and applaud him. But from his background, from his statements, from his qualifications, from his investments, from his business background, I don’t think he fits the bill.

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

Mr. President, I withdraw the suggestion.

The PRESIDING OFFICER. So noted.

RECESS

Mr. BROWN. Mr. President, I ask unanimous consent that the Senate stand in recess as under the previous order.