House of Representatives

The House was not in session today. Its next meeting will be held on Friday, August 4, 2017, at 1 p.m.

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Senate

WEDNESDAY, AUGUST 2, 2017

The Senate met at 10 a.m. and was called to order by the President pro tempore (Mr. HATCH).

PRAYER

The Chaplain, Dr. Barry C. Black, offered the following prayer:

Let us pray.

Holy God, You make the clouds Your chariot and walk upon the wind. You illuminate the darkness with Your presence and provide for the salvation of our souls. Great is Your faithfulness. Today, make our lawmakers heirs of peace, demonstrating that they are Your children, as they strive to stay within the circle of Your loving providence for their lives. May they take pleasure in doing Your will, knowing that by so doing, they are fulfilling Your purposes in our world.

Lord, You are never far from us, but often we are far from You. So show us Your ways and teach us Your paths. Thank You that Your mercy is from everlasting to everlasting upon those who come to You with reverence. May Your glory endure forever.

We pray in Your great Name. Amen.

PLEDGE OF ALLEGIANCE

The President pro tempore led the Pledge of Allegiance, as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

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RECOGNITION OF THE MAJORITY LEADER

The PRESIDING OFFICER (Mr. COTTON). The majority leader is recognized.

WORK BEFORE THE SENATE

Mr. MCCONNELL. Mr. President, as I said yesterday, the Senate has more work ahead this legislative period, including passing the FDA user fees legislation and confirming a number of nominees.

We have made important progress already, and just last night we passed the critical Veterans Choice legislation. That bill, which is now on its way to the President’s desk, will allow many veterans to bypass long wait and travel times at VA facilities by accessing private care.

We also confirmed several nominees. We confirmed eight officials who will be critical to advancing administration policy in the Defense Department. It is a good start, but we have other nominees to confirm for many other positions, both security- and nonsecurity-related, across many different agencies and departments. In the national security realm, for instance, we must confirm nominees for the Department of Homeland Security, Department of State, and the intelligence community.

The Senate also came together to confirm a well-qualified judicial nominee for the Eleventh Circuit Court of Appeals, as well as the Director of the Federal Bureau of Investigation, Christopher A. Wray. The position of FBI Director is one of great importance when it comes to protecting the American people, especially at a time when we face a range of threats both at home and abroad. Wray’s impressive credentials, demeanor, and commitment to the rule of law make clear that he is the right person to lead the Bureau in its efforts to keep our communities safe. The work of an FBI Director is difficult, but I am confident that Wray is capable of shouldering this important responsibility and that he will lead the FBI with the strength and professionalism that the position demands.

Our work on nominees continues today. We will, for instance, take a procedural vote on the nomination for the National Labor Relations Board later this morning. But there is more to do. I was pleased to hear the Democratic leader reaffirm his interest in working with us now to clear more nominees before the conclusion of this work period. Many of these nominees have been held up far too long, leaving the administration without a number of key officials at various agencies.

I look forward to our Democratic colleagues working with us to finish up the FDA user fees legislation that I mentioned earlier, as well. Members will continue to work on other issues in the meantime, such as tax reform, which is one of the things the Senate—led by the Finance Committee—will turn its collective attention toward after the State work period.
These are some of the key goals of tax reform. They sound like goals we should all share, regardless of party. For years, the tax-writing committees have focused on this particular subject—holding hearings, soliciting input from stakeholders, and considering the views and priorities of Members, both on and off these committees. They are eager now to begin the process of developing tax reform legislation that achieves the shared goals I outlined above.

The administration and congressional leaders stated:

We have always been in agreement that tax relief for American families should be at the heart of our plan. . . . And we are now confident that . . . there is a viable approach for ensuring a level playing field between American and foreign companies and workers, while protecting American jobs and the U.S. tax base.

Our expectation is for this legislation to move through the committees this fall under regular order, followed by consideration on the House and Senate floors. There is a great deal of bipartisan consensus about what ails our Tax Code, and my hope is that our friends on the other side of the aisle will join us in a serious way to address it, because the people deserve a tax system that works for them instead of against them. They deserve a tax code that encourages companies to bring jobs home instead of encouraging them to leave. These are sins of omission, such as failing to address an outdated tax code that has made American companies less competitive in a global economy and, as a result, has moved investment and jobs offshore.

The time has come to fix this so we can take now to grow the economy and to help middle-class families finally get ahead. It is no secret that the current Tax Code is overly complex and highly punitive and makes it harder for individuals and small businesses to succeed.

Fortunately, we now have a once-in-a-generation opportunity to fundamentally rethink it. It has been over three decades since that last happened. In the years since, the international economy has grown much more competitive. American workers and American businesses have only found it harder to keep up with foreign contenders. Put simply, the rest of the world is running circles around us in this area, making it more difficult for American firms to hire, invest, and compete.

The time has come to fix this so we can help our economy grow and help the individuals and families we represent realize their true potential. For families, we want to make their taxes simpler and lower. For small businesses, we want to provide the conditions they need to form, invest, and grow. For all American businesses and their employees, we want to ensure they have the best chance to compete with foreign enterprises and succeed.

We want a tax system that encourages American companies to bring jobs home again.
input, promising the Republicans would again use reconciliation to lock us out of the process, repeating the same mistake they did with healthcare.

Leader McConnell’s announcement just came a few hours after 45 Members of the Democratic caucus signed a letter saying we were open to bipartisan discussions on tax reform. We had three simple, straightforward principles. Let me read the Democratic principles on tax reform: First, don’t cut taxes for the top 1 percent—the top 1 percent. They are doing fine, God bless them.

Second, don’t increase the debt and deficit, something many of my colleagues on the other side of the aisle have been talking about for a long time.

Third, negotiate in a fair and open process, not reconciliation but hearings, amendments, the things that have made America great and have brought to the Senate the acclaim over the decades it has had.

Now, I would like to know which of these principles the majority leader does not agree with. I would like to know, is he closing the door on bipartisanship, so dearly waivered to cut taxes on the top 1 percent? The wealthy are doing great right now—God bless them—but they don’t need another tax break while middle-class families and working Americans are struggling. Many of us on this side of the aisle suspect that to some, that is the No. 1 motivation—not tax reform, not close loopholes, not clean up the system but give that top 1 percent a huge tax break to please so many like the Koch brothers.

Again, I would ask the leader: Are you closing the door on bipartisanship simply because you want to cut taxes on the top 1 percent or maybe the leader is closing the door on bipartisanship because he has a fervent desire to blow up the deficit? That sure doesn’t sound like something Republicans have been interested in over the years—they have been spending lots of time, with good reason, deficit scolding and debt scolding—or is my friend from Kentucky, our majority leader, closing the door on bipartisanship because he thinks reconciliation, which means you exclude the Democrats from the get-go, is a good process because he doesn’t want to have hearings, because he doesn’t want amendments, and maybe it is the same reason on healthcare? Maybe they are ashamed of their proposal. I would like to see somebody on the floor get up and say: We believe in tax cuts for the top 1 percent. That is why we want to do this.

But, no, they want to hide it, cloak it, give a crumb to the middle class, and say: See, we are helping you. We all know that what happens after we have a big deficit, they come back and say: Now, let’s cut Social Security, now let’s cut Medicare because we don’t have the money. We don’t have the money because they cut taxes on the rich, the very wealthy.

I don’t know which of these three principles the majority leader is against, but when he closed the door on bipartisanship and he closed the door on this letter which simply outlined our principles, that is all we wanted to do, give him notice we agree on these three things, at least on our side—which one or all of them made him close the door? We believe we could work together on tax reform, but the majority leader has drawn down the curtain before the play has even begun. Republicans will spend the entire first year of this Congress trying to pass their agenda on reconciliation, a process that deliberately excludes Democrats, excludes hearings, excludes amendments, with no shred of bipartisan input. Just like with healthcare, I believe it will be another dead-end road for Republicans.

I tell my friend the majority leader—I quote his speech in 2014, entitled “Restoring the Senate.” I truly believe—I truly believe that Leader McConnell believes in the institution of the Senate, and he has shown examples of that most recently when he said we don’t want to change the rules, despite President Trump pushing to do that, but here is what he said in 2014: When the Senate is allowed to work the way it was designed, it arrives at a result acceptable to the American people. If we only spend, I believe it will be another dead-end road for Republicans.

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Those are the majority leader’s words. Well, if you believe that, my dear friend from Kentucky, then why are you instituting reconciliation, the exclusionary process, before we even begin the debate? And why—might the American people think that you learned the lesson of healthcare that that process doesn’t work?

The American people want to see us work together. We may not always succeed. It may not be easy. It is hard work, but we ought to try. This assembly by line of partisan legislation—no Democratic input, no hearings, no amendments—is not what any of us want to see. It is not what the American people are calling out for, and it will not produce good, stable law. Again, it is up to the majority leader to reconsider these three principles probably supported by 80 percent of the American people. Why aren’t our Republicans supporting them? Why are they running away from them?

TRADE

Mr. SCHUMER. Finally, Mr. President, on the issue of trade, according to reports, the Trump administration is preparing an open investigation into China’s trade practices, focusing on economic espionage and the theft of intellectual property.

I certainly applaud the sentiment. I have been decrying for years how the Chinese have been taking advantage of us in a way that has sent trillions of dollars of American wealth to China and millions of jobs to China so we should certainly go after them. The question is, do we have the investigatory power or is what we are committed to doing on the deal that was promised in June? Tough talk and tweets are cheap, but strong and decisive action on trade is
required. American workers have wait-
ed too long for our country to crack
down on abusive trade practices that
rob our country of millions of good-
paying jobs.

Today, I am proud to announce that
the Democratic Party will be laying
out our new policy on trade, which in-
cludes, among other things, an inde-
pendent trade prosecutor to combat
trade cheating, not one of these endless
WTO processes that China takes advan-
tage of over and over again; a new
American jobs security council that
will be able to review and stop foreign
acquisitions of U.S. companies if they
are likely to have a detrimental effect
on U.S. jobs; penalties for Federal con-
tractors that outsource jobs; stronger
"Buy American" rules; and an out-
sourcing tax on companies that leave
the United States.

On the issue of NAFTA negotiations,
we are laying out a set of tough prin-
ciples that must be a bottom line for
any new NAFTA text. I voted against
NAFTA in 1994. That was 22 years ago.
We have seen how it has hurt us in so
many ways. There have been some ben-
efits, but overall the loss of jobs is
painful. More jobs and higher wages
have to be our guiding principle, and it
needs full transparency with workers
and the public at the table, not just
corporations.

So I hope the administration—and I
always said when I heard Donald
Trump campaign that my views on trade
are probably closer—I am closer to
to his views than I was to either Presi-
dent Obama’s or President Bush’s. I
hope he will listen to us and work with
us. These are good things to do. We can
do them quickly. We can save jobs, cre-
ate good-paying jobs. But I say to the
President: We don’t need another in-
vestigation, another study that lan-
guishes for months and maybe even
years. We need strong, bold action on
trade, and Democrats will offer those
strong bold ideas later this morning.

Mr. DURBIN. Mr. President, many
times over the last 6 months, I have
come to the floor on the issues and to disagree with President
Trump. It is clear that we have very
profound political differences when it
comes to the issues that face us, but I
come to the floor this morning in an
unusual position to express my grati-
dude to President Trump for a position
he has taken, which I think is the right
position for America.

Let me explain. Five years ago,
President Barack Obama created the
Deferred Action for Childhood Arrivals
Program, known as DACA. It enabled
approximately 790,000 talented young
people to contribute more fully to this
country. They are teachers, nurses, en-
gineers, small business owners, and
more. DACA, which was an Executive
action by President Obama, provides a
temporary legal status to immigrant
students who arrived in the United
States as infants, toddlers, and chil-
dren. They have to come forward under
this Executive action and register with
our government for a substantial fee
for processing. Then they have to submit themselves to a
criminal and national security back-
ground check. If they are successful,
they are given 2 years of temporary re-
lied from deportation.

This program is based on the Dream
Act, a bill that I first introduced in the
U.S. Senate 16 years ago—in 2001. That
bill would give undocumented students
who grew up in this country a chance
to become legal and to earn their way
to citizenship.

These young people have come to be
known as Dreamers. They came to the
United States under the age of 16, some
of them 1 or 2 years old. They grew up
in the United States, going to our pub-
lc schools, singing the “Star Spangled
Banner,” pledging allegiance to the
only flag they have ever known, the
American flag. They are American in
every way except for their immigration
status. We are all invested in them, as
you can tell—invested in their education, bringing them up in American
schools. I can’t believe it makes any
sense for the future of our country to
squander their talents by deporting
them to countries that many of them
have never even visited.

A recent study by the Center for
American Progress finds that ending
DACA, President Obama’s Executive
action, would cost our economy at
least $28 billion, which is 7% of our
domestic product over the next 3 years. The Insti-
tute on Taxation and Economic Pol-
cy estimates that the 1.3 million
young people eligible for DACA pay $2
billion each year in State and local
taxes.

As I said at the beginning, I have had
many differences with President
Trump, particularly on the issue of im-
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They have gone to our schools. All they are asking for is a chance.

When we introduced the Dream Act a week or so ago, Senator GRAHAM said that the young people who have received DACA should be treated fairly and not have the rug pulled out from under them. LINDSEY GRAHAM is right.

Over the years, I have come to the floor nearly 100 times to tell the stories of these Dreamers and to make it personal so that we come to know who they are and why I have taken the time to make sure they are recognized. These are the stories that put a human face on the DACA Program and on the Dream Act. They show what immigration actually means to our country in real terms.

This is Juan Martinez. When he was less than 2 years old, Juan was brought to America from Mexico. He grew up in Dallas, TX, with his parents and brothers. He was an honor student in high school. He graduated and was valedictorian with a 3.9 GPA, a member of the National Honor Society, an active member of the debate team, and in student government.

He was an accomplished student, but he was also a very active community volunteer. Juan helped organize food drives at the local food banks, he cared for children at recreation centers while their parents worked, and he volunteered in soup kitchens.

In his senior year of high school, he applied to his dream school—one of my dream schools, Georgetown University, and he was accepted. As a college student, Juan has studied international politics, concentrating on security, minorinig in the Arabic language. In his first year of college, Juan was elected as a student senator.

In his spare time here in Washington, he mentors disadvantaged high school students so that they can apply successfully for college. His dream one day is to work for our government, to help our country—the country that he calls home—and to make the world a safer place.

Juan sent me a letter, and this is what he said:

Thanks to DACA I can focus on my studies without worrying that it may all be taken away from me any second. I have always thought of myself as an American, but it is thanks to DACA that I can begin to truly feel like one, too. And that feeling is something I am thankful for every single day.

Juan and other Dreamers have so much to contribute to this country. But without DACA, without a similar protection, Juan could be deported back to Mexico, a country where he hasn't been since he was 2 years old.

Would we be a stronger nation if we lost Juan Martinez—if he were deported? I don't think so. I think the answer is clearly no.

When we introduced the Dream Act last week, Senator LINDSEY GRAHAM said: “The moment of reckoning is coming.”

I would say to the President first: Again, thank you. Thank you for allowing DACA to continue under your administration. Thank you for keeping your word to me and so many others when you said that these young people don’t have to worry. But we are reaching a moment, Mr. President, when we have to come together and do something. We believe you need us so that we can pass important legislation and you can sign it—legislation that will give these young people the protection they deserve, the opportunity they seek, the chance to make America a greater nation.

I know the reality of this issue. I know it from both political sides. I witnessed it for over a decade. I know it is not popular, Mr. President, that you have taken this position, to stand behind the Dreamers and those protected by DACA, but you told me that you thought it was the right thing to do, and I am sure you still feel that way.

Your new Chief of Staff, General Kelly, and I have had many conversations. I think that he, too, thinks that legislation is necessary to protect these young people. I hope we can come together. I stand ready. Senator GRAHAM stands ready.

We have a bipartisan coalition prepared to work with you.

Let’s not let this decision be made in a courtroom somewhere far from Washington. Let’s take on our responsibility, yours as President and ours in the Senate, to address this critical issue that really cries out for justice. This is the time to do it. The concern, anxiety, and stress is higher than ever among these populations of people affected by DACA and the Dream Act and, of course, their families as well. I hope you will join us in creating a legal option that will defend the DACA Program and will work with us in Congress to make the Dream Act the law of the land so that we can say to young people like Juan Martinez and hundreds of thousands of others like him that we will give you your chance—give you your chance to prove that you can become a valuable part of America’s future, give you a chance to make America a stronger nation, that is all they have asked for, and that is something we, on a bipartisan basis with the President, should give them.

I yield the floor.

The PRESIDING OFFICER (Mr. DAINES). The Senator from Texas.

Mr. CORNYN. Mr. President, I note in this morning’s news that insurance companies that provide health insurance policies on the ObamaCare exchanges are projecting that insurance premiums will go up about 30 percent next year.

Since 2013, we have seen the nationwide average of premiums go up 105 percent. That was before this latest announcement. We know that in 2017, the national average increase in premiums was 25 percent, and in Arizona, for example, it was 145 percent.

So why did all of the Senate Democrats vote against making progress on a solution toward these runaway premiums I have talked about ad nauseam on the Senate floor?

We have almost become numb to the pain people across this country are experiencing because of the skyrocketing rate of their insurance premiums, and we know that 28 million, roughly, have dropped out and are uninsured. In my State alone, because of the individual mandate, which is the penalty the government imposes for one’s failing to buy a government-approved health insurance plan—the President knows because I got the figures from him—more than 400,000 Texans who earn less than $25,000 a year paid the penalty because they could not afford to buy the insurance. All in all, about 2 million Texans paid this penalty because of the individual mandate.

When we tried to do something about that last week, in working with our House colleagues, what was the response from the other side? It was crickets—silence. Unfortunately, the people who were hurt by ObamaCare are still being hurt by ObamaCare.

Now, here is the narrative. I have already seen it on social media and have read about it in The Washington Post and elsewhere. Some people are saying: Well, the reason insurance companies are saying that premiums are going to go up 30 percent next year is that President Trump will not commit to the subsidies for insurance companies, the so-called risk adjustments.

That is utterly false. How do they explain the 105-percent increase from 2013 to currently? How do they explain last year’s increase in insurance premiums, 25 percent, on average, and 145 percent in places like Arizona before President Trump even took office? It is a demonstrably false narrative, and I cannot tell you how disappointed I am that we were not able to make some progress toward a solution on behalf of the people whom I represent, but also on behalf of the people whom we all represent across the United States. I dare say, as we search for a path forward, we ought to get our facts straight, and the idea that premiums are going to go up 30 percent next year, unless something changes, is a product of the failure of ObamaCare. It is nothing that this administration has done or will do that has caused that. So let’s get our facts straight because starting down the wrong road is absolutely essential to coming up with real solutions.

WORK BEFORE THE SENATE

Mr. President, we sometimes are our own worst enemy in the U.S. Senate. We do something really important, really good, and really bipartisan, and then we do not tell anybody about it. We leave it to them to discover it for themselves. Last night, for example, we passed major, bipartisan, bicameral legislation to continue the Veterans Choice Program, and so much is polarized here in Washington and people are hungry for bipartisanship and solution-oriented leadership,
when they get it on something like the Veterans Choice Program, we do not talk about it. This is really important to our veterans—people to whom, I believe, we have a solemn commitment as a result of their service to our country.

Over the last few years, we have heard how the Veterans Health Administration has been plagued by inefficiency, unaccountability, and poor quality of care. The VA has been hindered too long by unnecessary bureaucratic hurdles, which have been incredibly frustrating and deadly. I am afraid, in some cases, for our veterans. We have heard stories about veterans having to travel hours to get medical care, sometimes causing them to accept lower quality care or to forgo that care entirely. Sadly, in some cases, veterans turn to coping mechanisms, self-destructive activity—self-medication or alcohol abuse—because they simply cannot get access to genuinely helpful medical care.

The Veterans Choice Program was designed to help address that by ensuring that veterans could receive timely appointments with doctors or facilities of their choice. If they had to drive too far or if they had to wait too long for an appointment at a veterans facility, we said: You could show up at your local healthcare provider, and we will pay for it through the Veterans Choice Program.

The VA Choice and Quality Employment Act of 2017 continues that important program and guarantees veterans that they will have access to care without interruption. This bill also strengthens the VA’s ability to recruit, train, and retain its valuable workforce, which will help the VA continue to improve veterans’ care. I am proud to say that the Senate should continue to work with the VA to get the agency back on track and right its wrongs. For the sake of quality of care and of service to our veterans for whom, I believe, we have a sacred obligation, a solemn commitment, based on their service to our country.

Next, we will focus on another important piece of legislation. This is authorizing the Food and Drug Administration’s user fee program. This is how the Food and Drug Administration actually considers and approves new drugs and medical devices while also maintaining a high-quality level of care and of service to our veterans for whom, I believe, we have a sacred obligation, a solemn commitment, based on their service to our country.

It is critical, now more than ever, that every American who voted for President Trump win this election. It is our duty, our responsibility, to carefully consider their qualifications before coming together to confirm them. We, as senators and representatives, have heard how the American people and the electoral college that President Trump won the election and that Hillary Clinton lost. That is how they, somehow, justify their consistent foot-dragging and obstruction when it comes to the President’s nominees for important offices, including his Cabinet.

It is the President’s prerogative to nominate whom he wants to serve in the executive branch. It is his duty, our responsibility, to carefully consider their qualifications before coming together to confirm them. Now, we have had people who had been waiting months for their nominations to be confirmed and approved by a large majority in both chambers, based upon an almost unanimous votes of the Senate, which tells me we were delaying those votes unnecessarily. If they truly were controversial, I think it would be reflected in the votes for their confirmations, but that is not the case.

Let me just name one—our former colleague, Kay Bailey Hutchison, who has been nominated to serve as the Ambassador to NATO. I cannot think of a more qualified person than my good friend, the former Senator from Texas. Our country needs leadership in Brussels, at NATO, to help counter Russian aggression and threats and intimidation against our allies in the region, but that is just one example.

Last night, the Senate confirmed the FBI Director—I am grateful for that—but they also confirmed—again, in the dead of night when nobody was paying attention—eight other Department of Defense nominees. Now, if our Democratic colleagues had good reason to delay those confirmations because they felt like they were controversial, that is their right, but evidently they were willing to let those people who had been nominated to the Department of Defense be confirmed, basically, by consent after months and months of delay.

We have a lot of other nominations that are backlogged due to the unfortunate obstruction and foot-dragging of our Democratic colleagues, and I, for one, do not think we ought to leave in August—this month—without a big, robust package of the confirmations of these noncontroversial nominees.

It is time to get over the election. That was on November 8. We need to see a difference between elections and the responsibility of governing. Regardless of who wins the election, we still have the responsibility to govern.
The question is, Is it the sense of the Senate that debate on the nomination of Marvin Kaplan, of Kansas, to be a Member of the National Labor Relations Board, 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 North Carolina (Mr. BURR) and the Senator from Arizona (Mr. McCAIN).

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

The yeas and nays resulted—yeas 50, nays 48, as follows: 

[ROLL CALL Vote No. 183 Leg.]

YEAS—50

Alexander  Flake  Perdue
Barrasso  Gardner  Portman
Blumenthal  Graham  Risch
Boozman  Grassley  Roberts
Capito  Hatch  Rounds
Cassidy  Heinrich  Rubio
Cochran  Hoeven  Sasse
Collins  Inhofe  Scott
Corker  Isakson  Shelby
Cornyn  Johnson  Sasse
Cotton  Kennedy  Sinema
Crapo  Lankford  Sullivan
Cruz  Lee  Thune
Daines  McConnell  Tillis
Enzi  Moran  Toomey
Ernst  Markowski  Wicker
Fischer  Paul  Young

NAYS—48

Baldwin  Gillibrand  Murray
Bennet  Hassan  Peters
Blumenthal  Heinrich  Reed
Brown  Harkin  Sanders
Cantwell  Hirono  Schatz
Cardin  Kaine  Schumer
Carper  King  Shelby
Casey  Klobuchar  Stabenow
Coons  Leahy  Tester
Cortez Masto  Manchin  Udall
Donnelly  Markey  Van Hollen
Duckworth  McCaskill  Warner
Durbin  Menendez  Warren
Feinstein  Merkley  Whitehouse
Franken  Murphy  Wyden

NOT VOTING—2

Burr  McCain

The PRESIDING OFFICER. On this vote, the yeas are 50, the nays are 48.

The motion is agreed to.

The Senator from Washington.

Mrs. MURRAY. Mr. President, I come to the floor today to stand up for the workers President Trump is failing. As a candidate running for President, Mr. Trump promised workers that he would put them first and that he would bring back good-paying, respectable jobs to their communities, but since day one, President Trump has done the exact opposite. He has rolled back worker protections and made it harder for families to be more secure.

Now, this doesn’t come as a surprise to me, especially when I look at President Trump’s record as a businessman. We all know that strong unions have helped to create our middle class, and for many working families in the 20th century, a good union job, or the right to collective bargaining, helped them move up the economic ladder. But over the past year, we have seen a decline in unions and union membership across the country. As a result of that, our economy has started to favor corporations and those at the top. This paved the way for President Trump and Intel to ship out the jobs of their workers, with little recourse for everyday people who are the backbone of our country.

The National Labor Relations Board gives workers the opportunity to file charges against corporations when they are illegally fired or when corporations retaliate against workers for exercising their rights. President Trump should be familiar with the NLRB, as he has even conceded about Mr. Kaplan’s record as a businessman.

The following Senators served on the Board—Democrat or Republican—because they understand the labor issues better than anyone. They have long careers working on labor issues, either as lawyers or as law professors. Many of them have spent time as staffers on the NLRB board. In other words, they understand the labor issues better than anyone. They may have a unique perspective on it one way or the other—sort of pro-management or pro-labor—but there is no question that previous nominees and previous members of the Board know labor law.

Marvin Kaplan doesn’t fit this profile. He is not a lawyer with any relevant labor experience. He has no record and no public positions on relevant labor law. What he is is a well-connected Capitol Hill staffer. His only qualification, that I can find, is that he has drafted some legislation for a committee in the House of Representatives. That does not stack up against the resumes of any other member who has served on the Board—Democrat or Republican.

This lack of experience is dangerous. It means he will not know the intricacies and the historical development of labor law. He will simply be a rubberstamp who brings a political agenda to the Board, because he has no on-the-record opinions on these issues of his own.

That was clear from the hearing on his nomination, when he would not properly commit to recuse himself from any issues he had worked on and to approach issues with an open mind, which brings me to the second reason. If somehow Senators can make an excuse for his lack of experience, we can’t
deny that this is the opposite of the message that Congress should have received during the 2016 election.

In November, Americans made clear that Washington had failed working families and that we have not done enough to stand up for American workers.

Now here we are about to confirm a nominee to the NLRB, and the only experience he has is that he has drafted legislation to hurt American workers.

That Board is about to face some important decisions. They could reverse a decision that holds big companies accountable for how their contractors treat workers. The future of American workers and their ability to organize will be influenced by this Board, which includes any members confirmed by the Senate.

If Mr. Kaplan is appointed, it will further silence workers who already feel that they aren’t being heard in Washington, DC.

A vote for Mr. Kaplan is a vote that ignores the voices of American workers. It is a vote that further politicizes the NLRB at a time when we need to shore up our institutions against blind, corrosive ideology.

I urge my colleagues to vote no on this nominee.

I yield the floor.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

The PRESIDING OFFICER (Mrs. Ernst). Without objection, it is so ordered.

Mr. CASEY. Thank you, Madam President.

I rise to speak in opposition to the nomination of Marvin Kaplan to serve as a member of the National Labor Relations Board. Mr. Kaplan has spent much of his career as a staff member in Congress, where he worked to undermine unions and the rights of workers to bargain collectively.

A key role of the National Labor Relations Board is to preserve the right of workers to bargain collectively. The Board itself is charged with enforcing the National Labor Relations Act, which Congress passed in 1935 in the depths of the Great Depression. The act gave workers the right to join unions, and it encouraged and promoted collective bargaining as a way to set wages and settle disputes over working conditions.

The law that passed in the 1930s—and is still in effect today—is not simply a benefit to workers; it also benefits businesses, and it also benefits the economy. Section 1 of the act says, in pertinent part: “The inequality of bargaining power between employers and workers ... substantially burdens and affects the flow of commerce, and tends to aggravate recurrent business depressions, by depressing wages and the purchasing power of wage earners.”

There are a lot of important words there. When you have inequality of bargaining power, the findings of the Congress at the time said that would burden the flow of commerce. So that tells you the impact on commerce. It also says that when you have inequality of bargaining power, that aggravates business depressions, and the result of that is depressing wages and depressing purchasing power.

Everyone here knows that when we are measuring the American economy today—I am sure this has been true for many generations but especially today—the consumer pays a substantial role in our economy. So if that consumer, that worker has lower wages, that is not good for anyone. So giving workers the right to both organize and collectively bargain allows them to demand higher wages, thereby increasing wages and increasing purchasing power which is so critically important. That, in turn, of course, increases consumption and demand for goods, which, of course, increases production and employment. So all of these tied together—wages and benefits affect the economy, not just the worker and his or her family.

I believe there is now a concerning trend to weaken the National Labor Relations Act and to tilt the Board against workers. Mr. Kaplan’s nomination is another sign of this disconnect between the rhetoric of the administration claiming to be pro-worker and its actions that are of late anything but pro-worker. The administration claims it is here to support workers, but at every turn, we have nominees who have spent their careers working in the opposite direction.

We know that in the 1950s and 1960s, the economy worked well for working Americans because 35 percent of workers were in a labor union. The decline of unions, the decline of the workers’ voice, and the decline of collective bargaining have helped to lead us where we are today—stagnant wages over a long period of time, as well as power, wealth, and income, of course, concentrated at the top.

So we know that unions helped workers to win higher wages, job security, and unprecedented benefits, including paid holidays, paid vacations, and retirement pensions that gave those workers and their families a measure of security, but it also increased their purchasing power and it also, of course, strengthened the economy. American family incomes grew by an average of 2.6 percent per year from 1947 through 1973, with every sector of society seeing its income roughly double.

We know now that in the last number of years, it has been a different story. Families across Pennsylvania and the United States know that the story is much different. It is not a coincidence that union membership has declined from its peak of 35 percent of private sector employment in the 1980s to less than 7 percent of private sector employment today. This is all the more reason to stop this assault on workers and labor unions.

Nominees with a partisan history of working to undermine unions should not be confirmed to the National Labor Relations Act or undermine the National Labor Relations Board. Mr. Kaplan has devoted his career—imagining such a thing—to working to strip workers of their rights and trying to undermine the National Labor Relations Board should not be confirmed to the National Labor Relations Board.

Madam President, I yield the floor.

I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The bill clerk proceeded to call the roll.

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

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

Mr. BROWN. Madam President, during his campaign, President Trump railed against a lot of big companies headquartered in Ohio and across the country. He told them he would look out for them.

In a letter I sent to the President 2 days after the election, on November 10 or 11, asking the President to work to renegotiate NAFTA, insisting on “Buy American” provisions and infrastructure, the President scrawled across the top of the letter: “I will never let down workers.”

He said he would look out for them, but too often the people he puts in charge are along the lines of the latest nominee to the National Labor Relations Board, Marvin Kaplan. Mr. Kaplan has devoted his career—imagining such a thing—to working to strip workers of their rights and trying to undermine workers’ voices and to undermine labor protections. Someone who views unions and collective bargaining as a threat to be dealt with rather than as essential rights to be protected has no business serving on the National Labor Relations Board.

The National Labor Relations Board was created, in part, at this desk. Then Senator Hugo Black of Alabama, in the early 1930s, sat at this desk. At this desk, one of the pieces of legislation he wrote was the minimum wage law. One of the other pieces of legislation he worked on with Senator Wagner was the National Labor Relations Act. In those days, people understood that you had created the National Labor Relations Act to strengthen workers, to create workers’ rights, and to protect those workers.

Mr. Kaplan’s nomination sets that on its head. It is the latest in a long, long line of evidence that we in this country
simply don’t value work the way that we used to. Workers have continually seen their rights undermined. Workers’ wages have been stagnant. People who work hard and play by the rules don’t have the standard of living they had in our parents’ generation or even half of a generation ago.

We see companies refusing to pay overtime to workers who have earned it. We see companies misclassify workers so that companies can pay them less. The percentage of CEO compensation going up and up. Yet for the broad middle class in this country, for people who aspire to be middle class, for low-wage workers, they have simply not gotten a raise for the last 20 years. So then, are we going to appoint somebody to the National Labor Relations Board—the President says we are going to confirm somebody to the National Labor Relations Board—who has devoted his entire career to undermining workers, to taking away overtime, to scaling back workers’ protections, and to scaling back wages—all these things we as a country never stood for?

I don’t know what is happening in this country that we think it is right to deny people their wages, to take away overtime, to basically hit workers day after day after day in their pocketbooks, all while productivity goes up, profits go up, and while executive compensation goes up.

When I was a kid, the average CEO-to-worker ratio of pay was about 35 to 1 or maybe even less than that. Today it is often 300 or 400 to 1. The CEO will make 300 times what the average worker in the same company makes. How much is enough? What moral principle says to pay a CEO 300 or 400 times what a worker makes? How much do they need? Why do they keep doing that?

They keep doing that in part because of people like Mr. Kaplan, who always sides with the CEOs against the workers. As we think about this, I think every everybody in this body can learn something from Pope Francis. At the end of June, Pope Francis spoke to workers in Italy at the Italian Confederation of Trade Unions. He was talking about something we do not think about much in this town that really ought to be at the heart of everything we do. He talked about the value and the dignity of work. An employer—a CEO—cannot say that he is usually a ‘he’—values work when he takes away workers’ rights. He cannot say he appreciates the dignity of work, when he scales back their wages or cheats them out of their overtime or takes away, by misclassification, the dollars she has earned.

When Pope Francis talked about the dignity and value of work, he meant all work. He meant looking out for the little guy whether she punches a time clock or fills out a timesheet or makes a salary or earns tips, whether she is a contract worker or a temporary worker or a salary or earns tips, whether she is a contract worker or a temporary worker or a salary or earns tips, whether she is a contract worker or a temporary worker or a salary or earns tips, whether she is a contract worker or a temporary worker or a salary or earns tips, whether she is a contract worker or a temporary worker or a salary or earns tips.

Yet too often that work—the cooperation that gives life purpose and that powers our country—does not pay off for the people who are doing it. While corporate profits are up, the GDP by executive salaries have exploded upward, wages have barely budged. Workers simply have not shared in the wealth they have created.

I went to an auto plant once after the passage of the North American Free Trade Agreement. At my own expense, I flew to Texas. I was representing a congressional district in Northeast Ohio then. I rented a car with a friend, went across the border from New Mexico, and I visited an auto plant in Mexico. It was an American company, but it was in Mexico.

This auto plant looked just like an American auto plant. It was clean, and it was up-to-date. In fact, it was newer than most of our auto plants. The floors were clean, the workers were working hard, and the technology was up-to-date.

Do you know the difference between the American auto plant and the Mexican auto plant? This Mexican auto plant did not have a parking lot because the workers did not make enough. They were not paid enough by this American auto company. They were not paid enough in Mexico to buy a car. The workers who had not been respected, profits were going up, the GDP was going up, executive salaries were going up, and the workers were not sharing in the wealth they created.

This is a universal problem. It affects blue-collar workers, and it affects white-collar workers. It is in the industrial heartland of Ohio, and it is on the farmlands of Iowa. It is a problem on both coasts. People earn less. People cannot save for retirement. People feel less stable—all while working harder, all while producing more for their employers, which feeds right into huge executive compensation, but they do not share in the wealth they create for their companies. They are also less likely to have a union card that protects them.

So the President’s appointment to the National Labor Relations Board is pretty much a guy who has tried to make sure unions do not get a foothold in one company and 50 companies.

The Pope spoke about the labor group. He said it performs an “essential role for the common good.”

He said:

It gives voice to those who have none... unmasked the powerful who trample on the rights of the most vulnerable workers, defends the cause of the foreigner, the least, the discarded.

This is the Pope talking.

Think about airline baggage handlers. Airline baggage handlers used to make a good union wage. They used to work for United. They used to work for American. They used to work for Delta. Now they work for private companies that are contracted by United, American, and Delta. Airline baggage handlers’ wages in the last 10 years have dropped 40 percent. They are working just as hard—they are probably working harder—but they are making 40 percent less than they used to.

Again, the Pope said:

... unmasked the powerful who trample on the rights of the most vulnerable workers, defends the cause of the foreigner, the least, the discarded.

The capitalization of our time does not understand the value of the trade union because it has forgotten the social nature of the economy, of the business. This is one of the greatest sins.

We know from rightwing attacks on the other movement from so-called right-to-work bills to Mr. Kaplan’s efforts to undercut rules that protect workers, that too many in this country do not understand the value of the trade union.

Right now, in Mississippi, auto-workers at Nissan are organizing and trying to form a union, and the corporation has responded. This foreign corporation has responded with despicable intimidation tactics. This is one of the most powerful, profitable companies in the world that is attacking workers one at a time in Mississippi.

One worker said: “There is no atmosphere of free choice in the Canton plant—just fear—which is what Nissan intends.”

It is shameful the lengths that this corporation is going to—all to prevent workers from bargaining for fair pay. It is why we need a strong, not an undercut, weakened, emasculated National Labor Relations Board. We need a strong National Labor Relations Board to defend these workers and defend our laws on the books because an attack on unions is an attack on all workers. It is an attack on our economy as a whole because it depresses wages.

There is the idea that you give tax cuts to the richest people in the country and that you make sure executive salaries are $5- and $10- and $15 million. You squeeze workers so they do not get increases. Is that a good economy? No. The money does not trickle down and build the economy. You build the economy from the middle out. We know that.

In the 1990s, we built the economy from the middle out, with 22 million private sector jobs during the Clinton years. In the Bush years, they had two
huge tax cuts for the rich under the Wall Street Journal theory that it would trickle down and everybody would be better. There was literally no net private sector job increase during the Bush years. There were 22 million private sector jobs in the middle class cut, and zero net growth in the Bush years. That is because, during the Bush years, they believed the economy was built from the top down. It is not large businesses that drive the economy—it is the workers. That is how you grow the economy from the middle class out. If work is not valued, Americans cannot earn their way to better lives for their families no matter how hard they work.

That is what I think of when I hear Pope Francis talk about the social nature of our economy. Work has to support families and communities. Today businesses seem to be more focused on cutting costs than on investing in their workforces. Workers are often nothing more than a line item in a budget cost to be minimized. More businesses use temp workers, more businesses use contractors—look at the airlines—and more businesses use subcontractors. They pay a lower wage. They provide less job security. They pull back on their retirement benefits. They undercut health benefits, and they take away legal protections. We have to change this.

This spring, I laid out a plan to make work pay off by raising wages and improving benefits, retirement, giving workers more say and more power in the workplace, encouraging companies to invest in their greatest asset—the American worker. My plan to restore the value of work has to include the labor movement. Modernizing labor law means recognizing the right of all workers, even those in alternative work arrangements, to collectively bargain for higher pay and better wages.

Pope Francis concluded:

There is no good society without a good union, and there is no good union that is not reborn every day in the peripheries that does not transform the discarded stones of the economy into its cornerstones.

We are a country of discarded stones—of people who rose from humble beginnings and joined together to build institutions that were greater than any one of us. We need laws that reflect that—reflect the dignity of work and that reflect, as in the Pope's words, the dignity of every discarded stone, of each and every American who works too many hours for too little pay.

The last thing we need for the National Labor Relations Board is another nominee who does not value work, who demeans work, and who devalues the workers and the unions who do it. Everyone in this town ought to listen a little more to Pope Francis and a little less to big banks, and a little less to Wall Street. Maybe, then, we will start to make hard work pay off again for American workers. We can start today by rejecting this anti-worker nominee.

I yield the floor. (Disturbance in the Visitors' Gallery.)

The PRESIDING OFFICER. Expression of approval or disapproval is not permitted in the Gallery.

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

The PRESIDING OFFICER. The clerk will call the roll.

Mrs. FISCHER. Madam President, I ask unanimous consent that the order for the quorum be rescinded.

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

HONORING NEBRASKA’S SOLDIERS WHO LOST THEIR LIVES IN COMBAT

Mrs. FISCHER. Madam President, I rise to continue my tribute to Nebraskas’s heroes and the current generation of men and women who lost their lives defending our freedom in Iraq and Afghanistan. Each of these Nebraskans has a special story to tell.

CORPORAL MATTHEW ALEXANDER

Madam President, today, I recall the life and the service of Army CPL Matthew Alexander, a native of Greta, NE.

Matthew was drawn to the military at a young age. His parents Mel and Monica and brother Marshall described him as always eager to be part of a team. He practiced martial arts, played the piano, and participated in band as a kid. As a member of the Greta High School band, Matthew helped to organize the uniforms and shoes before concerts to ensure that all of the band members were ready to perform. He helped his band mates play at their best, and his caring and compassionate nature stood out among his classmates.

Matthew and his wife Kara had been friends since childhood. Kara described the teenage Matthew as somebody who could not sit still and who loved to learn. He took a keen interest in history and English classes in high school. He was also comfortable in talking with anyone and often referred to the mothers of his friends as “Mom.” Kara recalled how Matthew always had a grin or a smile on his face. Matthew also loved his church youth group, and he embraced his Lord and Savior, Jesus Christ.

Matthew always wanted to be a soldier, and the 9/11 terrorist attacks further solidified his desire to defend his country. He enlisted in the Army shortly before graduating from Greta High School in May of 2004, and he shipped off to basic training that summer.

After he finished training, Matthew attended the Advanced Individual Training to become an infantry soldier. This was the first step toward his dream of joining the Army Special Operations Forces. He was assigned to the 5th Battalion, 20th Infantry Regiment, 3rd Brigade Division, 2nd Infantry Division, and like both of his grandfathers, Corporal Alexander was stationed at Fort Lewis in Washington State.

When he first arrived, his unit had just returned to Fort Lewis from a deployment. Matthew had to wait until the end of the deployment overseas. He did not like that delay. As a brave soldier, eager to defend his country, Matthew wanted to be in the fight. Several months later. Matthew’s unit deployed to Mosul, Iraq. They assisted with the training of the Iraqi militia. Then, the beginning of Operation Iraqi Freedom, Mosul has been the center of battle. The fighting escalated in 2006 during the Sunni awakening. During the training of Iraqi forces and while conducting combat patrols, troops in Mosul encountered enemy attacks on a daily basis.

Matthew returned home on leave in February of 2007, and he proposed to Kara. They were married 2 weeks later, on February 14, Valentine’s Day. Regarding the beginning of Operation Iraqi Freedom, Kara simply explained that Matthew felt strongly about being married before he returned to combat.

When Matthew returned to Iraq, he learned that his unit had moved to Baghdad. The Baghdad Offensive began in March. The enemy used hit-and-run tactics to harass Allied forces that were trying to control the city. During April and May, the fighting intensified, and casualties were high. Some likened the fierce fight to the close quarters of the combat of Vietnam.

It was in this heat of battle that CPL Alexander showed heroism and leadership when an IED hit a Bradley Fighting Vehicle on one of his missions. As Matthew’s section rushed to the burned Bradley, the other vehicle commander told him to block off the southern approach and prevent the enemy from attacking up the road. While the Bradley continued to burn and take fire, Matthew acted without further instructions, and he saved lives. He set up his vehicle to prevent the attacking enemy forces from shooting accurate fire into those helping with that rescue operation. For his valor, Matthew received the Army Commendation Medal.

One of the members of Matthew’s platoon, SSG Mark Grover, remembered Matthew feeling surprised to have been recommended for the honor. He said that he was just doing the right thing to protect his fellow soldiers.

Days before a mission on Sunday, May 6, Matthew called home to talk to his mother Monica and to Kara. Tragically, this was the last time he spoke to loved ones. While on the mission, an improvised explosive device detonated near his vehicle, killing him instantly.

Corporal Alexander was laid to rest on May 18, 2007, in a rural cemetery between Greta and Elkhorn, NE. Hundreds of Patriot Guard riders lined the procession route, and over 1,500 people filled Greta High School to say their final goodbyes. Staff Sergeant Grover traveled to Greta to represent the
Third Platoon, nicknamed the “Gladiators,” at the service. Grover was riding in the armored vehicle just in front of the one carrying Matthew at the time of the explosion. He said that the entire company loved Matthew and that he was one of the best soldiers in the platoon.

To honor Matthew’s life, his family established Matt’s Music Memorial. The charity helps children interested in music but who can’t afford an instrument, and they receive one from the local community. As Matthew’s father Mel put it, Matthew had two passions: music and the military. However, you didn’t need money to join the military.

CPL Matthew Alexander is truly a hero. He served with great compassion and respect.

I join Nebraskans and Americans across our country in saluting his willingness and his family’s sacrifice to keep us free, and I am honored to tell his story.

Thank you, Madam President.

I yield the floor.

The PRESIDING OFFICER. The majority leader.

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

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

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

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

The PRESIDING OFFICER (Mr. Tillerson). Without objection, it is so ordered.

TRIBUTE TO FALLEN SOLDIERS’ MOTORCYCLE BRIDGE RIDE

Mr. MERKLEY. Mr. President, a few moments ago, I had the opportunity to meet with a group called the Tribute to Fallen Soldiers. They have an annual cross-country motorcycle ride in honor of soldiers who died during combat. The motorcycle brigade escorts the Fallen Soldiers Memorial Flame from Eugene, OR, all the way to Arlington National Cemetery. Along the way, they visit Gold Star families—families who have a loved one who died on the battlefield in service to the United States.

One couple who came today was Terry Burgess and Elizabeth Burgess, whose son Bryan lost his life fighting in Afghanistan, and they shared with me, in the military tradition, a medal. Mr. President, I ask unanimous consent to use a visual aid.

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

Mr. MCCONNELL. Mr. President, this medal has a picture of their son. It says: “In memory of SSG Bryan A. Burgess, who lived from April 23, 1981, through March 29, 2011.” On the back of it, it has a picture of a memorial that shows a pair of boots and a rifle and a hat and “never forget.”

The Tribute to Fallen Soldiers is about never forgetting our fallen soldiers. We put them into situations of enormous stress and challenge and danger, and they are there for all of us. In those particular situations, time and again, one of our soldiers loses their life. So may we never forget our soldiers who have died, our soldiers who have been wounded, and may we continue to reach out to Gold Star families to provide a community of support to them.

I completely respect and appreciate the Tribute to Fallen Soldiers’ motorcycle brigade that rides across the country visiting with Gold Star families, making sure they have that community of support and making sure they know that the sacrifices of their son or daughter are not forgotten.

TRANSGENDER MILITARY BAN

Mr. President, while focusing on the military, I want to shift to another aspect of military service, and I am going to start by thinking about the foundation of our country, our “we the people” Nation. “We the People” are the first three words of our Constitution, the mission statement of our Nation. We are not a nation that is founded of, by, and for the powerful, not a nation founded to govern of, by, and for the privileged, but for the people. It was a very deliberate strategy of our Founders to reject the type of structure in America that they saw in Europe, where government became beholden and in servitude to simply the powerful class.

Throughout our history, we have strived to live up to this vision of a nation where every individual has the opportunity to thrive. Time after time, we have broken down barriers, we have overcome discrimination, and we have thrown open the doors of opportunity for women, for African Americans, for immigrants, for the disabled.

Freedom, said President Lyndon Baines Johnson, “is the right to be treated, in every part of our national life, as a person equal in dignity and promise to all others.” So we strive to reach that perspective, that point where our vision of the pursuit of happiness embraces freedom as Lyndon Baines Johnson described it—the goal of justice requires sacrifice, every exertion, and passionate concern of dedicated individuals.” And it is with that tireless exertion, that passionate concern, that dedication, that we have made progress time and time again. But last week, we did not make progress. Last week, we fell back from this vision of opportunity, the freedom to engage in our national life with the respect and promise accorded to all others. This step back came in the form of an attack by President Trump and Attorney General Sessions on our LGBTQ Americans. President Trump announced a ban on transgender Americans serving in the military, and Attorney General Sessions filed an amicus brief in Zarda v. Altitude Express arguing that discrimination is completely legal under the law, including the 1964 Civil Rights Act.

Well, let’s talk for a moment about our members of the military who have joined the military because they believe they have gone through significant training—and I am not just referring to boot camp but the ongoing training in specialty after specialty—they can operate that radar effectively that provides warning to an entire ship, or that communication device to make sure that patrol is where it is supposed to be and able to follow instructions in the field, or any of the hundreds of specialties within the military that these individuals step forward and gain training on. Each one of them is significant to the overall success of the entire unit.

That is something President Trump didn’t understand last week when he attacked and said that he is going to throw our transgender individuals out of the military.

What is important isn’t whether you are gay or lesbian or transgender, it is whether you serve with your heart and soul and sinew the purpose of the security of the United States, and those individuals who do are respected within their units. They contribute to those units. The lives of each member depend on the success of the other team members. They are a team. And to reach in, in a cavalier fashion, as the President did this week and say “I am going to rip thousands of these team members out of their units” is wrong in so many ways. It is disrespectful, of course, of those individuals and their dedicated service to our Nation. It is disrespectful and damaging to the units in which they serve and provide those various skills which they have worked so hard to acquire and which we have worked so hard to make sure they have the chance to acquire. And it certainly damages the security of the United States of America to eject individuals with those talents and that training from our military. Therefore, that should be reversed.
By the way, it was done without consultation with our military leaders. A Commander in Chief proposing a policy through a tweet without consulting with the experts who have dedicated their lives to the national security of our Homeland and of itself is a real betrayal of responsibility.

Attorney General Sessions filed an amicus brief in Zarda v. Altitude Express, and this brief says that Title VII of the Civil Rights Act, which provides protection against discrimination based on race, color, religion, national origin, and sex, does not provide protection against discrimination in terms of one’s LGBT status. By the way, that is the opinion of what court after court has ruled.

What happened, one might ask, to the President Trump who, as Candidate Trump, said: “Thank you to the LGBT community!” As a candidate, he said: “I will fight for you.” What happened to the President who, after the attack on the Pulse nightclub in Orlando, said in a tweet: “Will fight for you.” This last week, the President did not fight for your community; instead, he attacked that community, and he apparently approved of Attorney General Sessions attacking that community.

This is why we need the Equality Act. The Equality Act would clarify that when we say no discrimination on the basis of sex, that is broadly applying to one’s status of who they are or whom they love.

If we go back to President Johnson’s presentation of the issue in America, where every individual—the matter of freedom is that you have the opportunity to be treated as having the same promise and be treated with the same respect as everyone else, that it is all about being able to thrive in the United States, or to put it quite simply, not having a door slammed in your face when you go to rent an apartment, not having a door slammed in your face when you go to a restaurant or a movie theater, not having a door slammed in your face when you seek to be part of a jury. That is what freedom is in this country. That is the freedom that Attorney General Sessions and President Trump are seeking to rip away from a sizable share of Americans, and that is simply wrong. That is why we need the Equality Act—to make sure that this is remedied. That is why we need the courts to stand up against discrimination on the basis of who you are and whom you love.

It has been a week in which the President attacked and damaged our military and Attorney General Sessions attacked and betrayed and attempted to steal freedom from a vast swath of Americans. That is a very sad week, and we in this Chamber should stand up and say: That is not OK. We will fight for the security of the United States of America, and we will fight for opportunity for every American.

Thank you, Mr. President.

The PRESIDING OFFICER (Mr. COTTON). The Senator from Missouri.

RURAL BROADBAND

Mr. BLUNT. Mr. President, August is Rural Broadband Month at the Federal Communications Commission. The Commerce Committee just today put forward nominees for the Commission, and I am proud to support them. But I want to talk today specifically about highlighting the importance of broadband in rural America and rural Missouri.

In January of this year, I joined a number of my Senate colleagues on a bipartisan letter to President Trump regarding the importance of broadband and expanding its access to all of the country and, particularly, the parts of our country that are not currently served.

As part of any infrastructure legislation that the Congress is talking about, I think we and the administration need to consider policies that advance infrastructure not just solely in terms of roads, bridges, and ports, which I support; particularly where the Presiding Officer and I live, in Arkansas and Missouri. That transportation network means so much to us, but also important is how people are able to communicate and compete. High speed internet cannot be overlooked as we consider what our infrastructure should look like going forward.

Broadband can be delivered by wireless or wireline technology. It can be brought to customers by traditional communications companies in rural areas. Often, now, rural electric co-ops show great interest and capacity to do this, as do others. Following the significant steps that Congress took to deregulate the market as part of the 1996 Telecommunications Act, the broadband industry has really responded. They invested a lot of money. In fact, they invested $1.5 trillion of private money to deploy better and faster networks. If you have access to one of those networks, you know what a difference it makes.

In 2015 alone—that is the last number I have access to—the investment by traditional wireline companies, wireless companies, and cable providers was $76 billion. All of that is really good, except that there is a real divide between the rural areas of my State and the rural areas of the country and the other more populated areas.

Some people say: Oh, that is just a myth; there is no digital divide. I would have them look at any number of articles. One article in the Wall Street Journal in June made the point that 39 percent of the United States’ rural population lacks access to broadband. That sounds like a pretty big divide to me—that 39 percent of the entire rural population of the country doesn’t have broadband, and 61 percent of rural Missourians lack access to broadband. These numbers are not acceptable.

Most private investment has been directed, as you would assume it would be, toward high populations, highly populated and easily accessed areas, and future customers. This is like the same problem the country had 100 years ago transitioning to telephones. It was hard to get a telephone to a house that was 5 miles away from the nearest house, as opposed to a house that was in that rural area building to the nearest apartment. It is a lot harder to do that. The government at that time said that there would be a universal service fee on phone bills, and then use that money to ensure that everybody would have access to what was obviously seen as a really important way to communicate. The concept of Universal Service was enshrined in the 1996 act. It said that rural households should have the same access to advanced telecommunications enjoyed by their urban counterparts. It is a good goal for a lot of reasons.

I saw some figures this week. When looking at the overdose deaths and the opioid problems in the country, they are much greater in more rural areas than they are in urban centers. In our State, Kansas City, our biggest city by population and any of the five counties that touched it weren’t anywhere close to the top list of other areas in our State that had this problem. It matters when you are not connected. It matters when opportunities that you otherwise would have simply aren’t there because somehow a service that is essential to our society today isn’t available to you in the same way it is available to others. I am not saying it should be free to some and cost other people something, but it should be available to you in the same way that it is available to others in our society, as the 1996 Telecommunications Act stated.

Broadband is always there. We have to have it if we are going to compete in the world economy. Many people in rural America are able to do that in ways that nobody would have dreamed about 10 years ago, but not everybody has that same access.

Certainly, it is critical for schools and libraries. Just today, a parent was telling me that students can’t do their homework anymore unless they can get internet access somewhere close to where they live. Students depend on the internet for education and opportunity where we live today.

A revolution has taken place in agriculture. The great food-producing economy that we have produces more food at the same time that it produces more food with fewer people. So that creates some displaced people who otherwise would have had those jobs, but
it also uses wireless infrastructure, data, and GPS structures to decide what should happen in a field at a given time in that part of the field. There are data centers, autonomous systems, and fiber optics that are a part of agriculture today. If you are linked to broadband and you are in your combine and have a problem, sometimes that problem can be solved in a couple of minutes by quickly accessing your system, seeing where the problem is, setting what you need to set and moving on, as opposed to the other option, which is calling the repair person, having the technologist come out with their computer, hook it up to your combine, and 5 or 6 hours later, at a time when you are in the critical moments of your annual livelihood, suddenly you are working again, when you could have been working 5 or 6 minutes later if you had been connected like many farmers are today. 

Broadband is more than just economic opportunity. Rural hospitals and health clinics are able to use telemedicine to bring services at a level that otherwise would not be available. This is particularly important in mental and behavioral health. A lot of people are every bit as comfortable or more comfortable with telehealth than they are with somebody in the room with them. Also, with intensive care, suddenly all of the resources that may be available away are there right there at the point where questions are asked and that information is handled. Suddenly, somebody’s life is saved because of the capacity to have that kind of communication.

For years I have tried to lead when I could, and joined my colleagues when they were leading, with numerous letters to the FCC urging it to reform the Universal Service Program for the digital era. Most people who don’t have a line to their home have a way to get a phone in their hand now, but they don’t have a way to get this important way to communicate and to compete. It is frustrating, when we see the limited resources we have—the government resources—to put into something like this to see limited funds go to places where you are just creating another provider and more competition, except that the second provider has government money on its side to compete with the first provider that went in who didn’t have the same kind of resources.

The President recently designated Ajit Pai to be the Chairman of the FCC. We are finally seeing the Commission take actions to address rural broadband. In February, I wrote to the Chairman and urged him to act on the $2 billion available for rural broadband and open this money up to auction so new entrants into the field, like electric co-ops, can competitively bid alongside everybody else. The FCC has decided to do that. Today the Commission will consider a notice to initiate the pre-auction process for this money to deploy fiber optics in parts of Missouri. This will complement other initiatives underway, as the FCC looks at how to address rural broadband. They have launched a $4.5 billion auction for mobile wireless service in rural areas. They are suspending out-of-date rules that forced small carriers to raise telephone rates, a network that was proceeding to reduce costs for companies upgrading from copper to fiber optic networks—another FCC initiative. They are launching a broadband advisory committee. These are all steps in the right direction to think in the right direction. Suddenly, there can be a kind of thing happen in other parts of the country if we work to be sure we have an equity of opportunity. One of the major things that will provide that will be having access to broadband that works. I hope we can continue to fight that fight and see the progress we have made just in the last 6 months. I suggest the absence of a quorum.

The PRESIDING OFFICER. The bill clerk proceeded to call the roll.

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

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

Mr. PETERS. Mr. President, as we head into the month of August, many Americans are planning to spend time along our beautiful coasts. Our country is fortunate to have such a wide variety of natural resources along the Gulf of Mexico, Alaska, Hawaii, and the east and west coasts. However, I am partial to America’s best coast: The 4,500 miles of U.S. coastline along the Great Lakes.

Our coastal resources make it possible to move cargo around the world. They provide opportunities for outdoor recreation like fishing and boating and trips to the beach. Our coasts are not only beautiful, providing some of the most scenic vistas and picturesque landscapes our country has to give, these ecosystems also provide many tangible benefits. They serve as flooding buffers, critical habitats for fish and wildlife, and locations for ports and other marine infrastructure.

In the Great Lakes, our freshwater resources contain one-fifth of the entire world’s fresh water and provides drinking water for over 40 million people. We must be stewards of these areas.
so that future generations can also benefit from them. In order to do so, we must properly document and keep track of this precious resource.

That is why I partnered with Senator Young to introduce the bipartisan Great Lakes Environmental Sensitivity Index Act of 2017 to require NOAA to update environmental sensitivity index maps and map products. The bill passed unanimously out of the Commerce Committee this morning by a voice vote and now heads to the full Senate for consideration.

Environmental sensitive index—or ESI—maps provide an inventory of our valuable natural and human-use resources along our coasts. These maps chronicle sensitive ecosystems and the presence of various species as they migrate through regions and habitats for threatened and endangered species. They also document where we can access coastal resources from beaches and parks to docks, ferries, and boat ramps.

We must maintain an up-to-date inventory of these precious coastal resources so that we know exactly where we need to focus our response efforts in a worst-case scenario of a harmful oil or chemical spill. A comprehensive understanding of these resources and their vulnerabilities is critical to both deploying the right response effort when a spill or accident occurs and assessing the damage and restoration efforts needed after the fact.

In places like the Straits of Mackinac, where a 64-year-old oil pipeline sits at the bottom of the lake bed, it should be our top priority to have a current inventory of what shoreline resources could be impacted by a pipeline leak. Models have shown that a pipeline spill in the Straits of Mackinac could likely result in oil reaching the shores of Mackinac Island within hours, which would be an absolute catastrophe for Michigan’s top tourist attraction.

ESI maps don’t just help with oil spill response; they can also be used for coastal development activities, and they even have significant research applications. They provide a clear reference point prior to natural disasters or major storms that may damage, destroy, or significantly alter resources along our coasts. Decision makers at the local and State level may use them for restoration efforts or to make informed decisions about how to balance all of the various uses in that coastal zone.

ESI maps need regular updates in order for them to be truly effective. These updates are happening now for other areas of the country. Stretches of the west coast, along the Gulf of Mexico, and along the east coast have all received updates over the last 5 years.

One region is continually absent from these updates: my home region of the Great Lakes. In fact, the last comprehensive updates for some of the Great Lakes were completed over 20 years ago, but Lake Erie and parts of Lake Michigan haven’t been updated for over 30 years. This bill gives the proper direction and resources to make sure these long overdue updates move forward.

Supporters of the bill so far include the Great Lakes Charter Boat Association, the Coastal States Organization, the Great Lakes Commission, the Alliance for the Great Lakes, the National Wildlife Federation, the Great Lakes Fishery Commission, and the group For Love of Lake. For Love of Lake is a non-profit with nearly 3,300 miles of coastline in Michigan, the second-most coastline of any State in the Nation, we need to update Great Lakes environmental sensitivity index products as soon as we can.

Modernizing these maps will provide a better picture of what resources could be at risk in the event of a disaster and will be an important tool to help us keep our Great Lakes safe and clean for future generations.

I look forward to working with Senator Young and the rest of my colleagues in the Senate to move this bill forward and make sure that we have the tools we need to make the best decisions for the Great Lakes, no matter the challenges and opportunities facing us.

Thank you.

Mr. ALEXANDER. Mr. President, today the Senate will vote on the confirmation of Marvin Kaplan to be a member of the National Labor Relations Board, NLRB. I am glad that we are moving this nomination because the National Labor Relations Board needs to function as intended.

The board hasn’t been full in nearly 2 years. I am certainly not the only one of us who thinks a full Board is important. One Democratic senator said at a hearing on May 18, 2013: “I strongly support a fully functioning NLRB with five members. I think confirming the entire slate will ensure that the NLRB is working for American workers and American employers.”

Another said the same thing: “What we don’t need now—the last thing we need here in Washington or across the country—is more rancor, more division, more ideology, at a time when we need this Board fully functioning. We need five people to get confirmed here. Any Senator who is standing in the way of getting five people confirmed and having a functioning Board has a lot of explaining to do . . .”

Then-Chairman Harkin said in September of this year how the NLRB fully staffed and able to do its work will send a strong message to the American people that yes, Washington can work, and our government can function.

The National Labor Relations Board has five members with 5-year, staggered terms, and a general counsel with a 4-year term. There is no statutory requirement regarding party affiliation, but the tradition has been for the President to appoint members on a 3-2 ratio favoring the administration, with nominations for the two minority seats recommended by the Senate minority leader.

While we may often disagree with the opinions of the nominees for the other party’s seats—many of us have ensured they had an up or down vote. For example, since 2013, I have voted for closure for two board members and the current general counsel who I then voted against confirmed.

Marvin Kaplan has been nominated for a position that has sat vacant for 23 months since President Obama declined to nominate a Republican for the then-minority seat. My hope is that this nominee will help restore some balance to the labor board.

After years of playing the role of advocate, the Board should be restored to the role of neutral umpire. Board partisanship didn’t start under President Obama, but it became worse under him. When the Board is too partisan, it creates instability in our Nation’s workplaces and does not serve the intent of the law—which is stable labor relations and free flow of commerce.

For example, under President Obama, the Board took three harmful actions, including the joint employer decision—which threatened to destroy the American dream for owners of the Nation’s 780,000 franchise locations; the ambush elections rule, which can force a union election before an employer and many employees have a chance to figure out what is going on; and the micro-union decision, which gave facts of employees within single stores a path to forming their own unions.

Nominee Marvin Kaplan is currently chief counsel for the Occupational Safety and Health Review Commission, where he has served since August 2015. From 2009 to 2015, Kaplan worked as counsel for the House Education and Workforce Committee and the House Oversight and Government Reform Committee.

Today some Senators have argued about Mr. Kaplan’s experience practicing law. I want to note that Mr. Kaplan is in fact well-qualified under the National Labor Relations Act statute. He is an experienced lawyer. He earned his law degree at Washington University in St. Louis and is a member of the New York and New Jersey State bars. The years he has spent considering cases and writing opinions at the Occupational Safety and Health Review Commission, OSHRC, are an excellent preparation for the work of the National Labor Relations Board, NLRB. I will be pleased if there have been a number of NLRB members confirmed with limited experience representing clients in labor law matters.

Mr. Kaplan has an admirable record of public service spanning a decade. He could have taken a number of different career paths, but he chose public service, and that should be praised. There is bipartisan respect for Mr. Kaplan.

At a July 2015 business meeting of the House Education and the Workforce Committee, Ranking Member Bobby Scott said this of Mr. Kaplan: “A lot is said about the working relationships around here and how bad
they are from time to time. Staff can contribute to that. I just would like to say that Mr. Kaplan has not been part of that; he's been very cooperative even when you disagree. We have been able to work with my staff, have had good working relationships, and those cooperative relationships, I want to add my two cents worth to your congratulations and God speed."

Mr. Kaplan was nominated to be a member of the NLRB on June 29, 2017. We held a hearing on July 13, and he completed all paperwork in accordance with the HELP Committee's rules, practices, and procedures. Our rules require that their HELP paperwork be submitted 5 days before their hearing. We received Mr. Kaplan's HELP paperwork and his Office of Government Ethics, OGE, paperwork on June 26, 17 days before his hearing. Mr. Kaplan also offered to meet with all HELP members. Mr. Kaplan met with 19 of them—5 Democrats. Following the hearing, Mr. Kaplan responded to 53 questions for the record, QFRs, or 81 if you include subquestions, and those responses were provided to Senators prior to the markup. The HELP Committee favorably reported out his nomination on July 19.

Recent comparisons show that this process was far from rushed. In comparison, under Chairman Harkin, the HELP Committee held hearings and markups on NLRB nominees with far less time for consideration. For former Board member Kent Hirozawa's seat, which Mr. William Emanuel has been nominated to fill, Mr. Hirozawa's hearing was held 7 days after his nomination, and his markup was held the next day. Former Board member Nancy Schiffer's hearing was held 7 days after her nomination. The HELP Committee also held a markup on her nomination the next 5 days. Committee members were not able to get responses to any QFRs from Kent Hirozawaz or Nancy Schiffer before being forced to vote on them.

I look forward to voting against this nominee. I hope the Senate will take up the nomination of William Emanuel, also for the NLRB, very soon, so we have a full board.

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

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

Mr. CRUZ. Mr. President, I stand here today to speak about the devastation befalling Venezuela—the people raging in the streets against unfair elections, the dissidents being seized from their homes and detained by security forces, and those starving without food and water.

Venezuela—one of the most richly resource countries in Latin America—is being dismantled by Nicolas Maduro and his flailing Chavista regime. It is a human tragedy impacting more than 30 million people who are literally witnessing society collapse around them.

This is not just a bella ciao, sadly, speak for themselves. According to estimates from the International Monetary Fund, Venezuela's GDP contracted by almost 20 percent last year, with inflation reaching some 550 percent and unemployment soaring to more than 25 percent. The Pharmaceutical Federation of Venezuela estimates that the country suffers from an 85-percent shortage of medicine and a 90-percent deficit of medical supplies, including those needed to treat various types of cancer.

Men and women, young and old, are going hungry. Thanks to Maduro's destruction of the Venezuelan currency, flour, cooking oil, and other basic commodities have disappeared from store shelves. Students and teachers leave school hungry, and end having to decide whether to stand in line, hoping to receive a loaf of bread as a week's meal. The most vulnerable are going on what are called Maduro diets—skipping meals and reducing their food consumption.

And Maduro's actions are clear. The would-be dictator is threatening to seize businesses that don't produce enough and has told Venezuelans that doing without makes them tougher. Thousands of Venezuelans have crossed borders in search of food. While we as a country can't do anything about it, Mr. President, I urge you to continue to stand and fight for the freedom of this hemisphere and for democracy.

Leading a free Venezuela, a post-Chavista government, and God speed.''

This was not Maduro's first power grab. Earlier this year, his handpicked supreme court temporarily dissolved Venezuela's duly-elected National Assembly and stripped its members of immunity in what the head of Organization of American States called a "self-coup." The regimebacktrack after ferocious pressure and condemnation.

But this week's actions make plain Maduro's intent to complete the process begun under his mentor, Hugo Chavez, to transform Venezuela into a full socialist dictatorship. We have seen that socialism doesn't work. We have seen the ravages of government control of the economy. The Venezuelan people are suffering, and when combined with dictatorship, it is a toxic mix.

Maduro's actions must continue unchallenged. I support the Treasury Department's sanctions, and I urge the Treasury Department to work with our colleagues in the Treasury Department to work with our colleagues in the State Department and other foreign asset control agencies to target Venezuelan officials, including Maduro, placing him in the ignominious company of Kim Jong Un and Robert Mugabe. We must keep the pressure on and continue to isolate and delegitimize Maduro's regime, for he has turned his country into a failed state with its billions in infrastructure investments, and Russia, with its growing control over Venezuela's energy sector, and Iran, whose Hezbollah proxy launderers money with Maduro's acquiescence.

Yet Maduro is not without opposition. Brave men and women in the tens of thousands have taken to the streets to demand a better future for themselves and their families. Many dozens have been killed by the regime's security forces, and hundreds have been detained. These freedom-loving people represent the best of Venezuela and fearlessly follow in the footsteps of generations of dissidents against Socia dictatorship.

Just yesterday, Maduro's security forces seized two prominent opposition leaders—Leopoldo Lopez and Antonio Ledezma—for daring to criticize his regime on social media. These two men passed away in the middle of the night, leaving their loved ones traumatized and frantic without information.

To Lilian and Mitzi, the wives of these two extraordinary men, I want to say that you are two of the strongest people I have ever been blessed to meet. You inspire me. Your husbands' fight inspires me and millions of Americans and people across the globe. I urge you to continue to stand and fight for the freedom of this hemisphere and for democracy.

I look forward to welcoming Leopoldo and Antonio back to freedom and, I hope, they will play leading roles in a free Venezuela, a post-Maduro Venezuela.

Members of my own family have lived through this sort of oppression in Cuba, where a lawless government can raid your home without warning, arbitrarily detain your relatives and neighbors, and ensure that you hardly, if ever, see them again.

To Lilian and Mitzi, I will continue to raise your voice and to call for action—real action—to help Leopoldo, Antonio, and every other Venezuelan willing to stand and risk everything to live in a free and prosperous democratic country. It is well past time to consign Chavismo to the dustbin of history.

To the millions of Venezuelans waiting in lines for food, clothes, and medicine, struggling with galloping inflation, fearful of Maduro's henchmen detaining their friends and families or gunning them down in the streets, and
thinking themselves helpless in the face of their country's decay, you are not alone and should not be afraid.

America and our allies will help see you through this crisis and help you recover. Each new outrage from the Maduro regime only makes our solidarity stronger. You are strong and Maduro is weak. You are Venezuela's future, and Maduro is its past. You will win, and Maduro will lose.

Venezuela is not the private preserve of a busdriver turned authoritarian thug in a tracksuit,” but instead Venezuela is a proud and free nation with brighter days ahead, brighter days of liberation, and we tell you that there are reasons, and we tell you that there are reasons that the farmworkers who picked that produce or the farmers living near it were exposed.

A few years ago, Claudia Angulo—about 10 years ago, Claudia Angulo—was exposed to pesticides related to sarin gas. It has been in use since it was developed by Dow Chemical over 50 years ago. Today, it is most often used on fruits and nuts, including strawberries, citrus, apples, and pecans from my home State of New Mexico. It is also used on grains and vegetables like broccoli and cauliflower.

The chemical they were exposed to is called chlorpyrifos, a neurotoxic pesticide related to sarin gas. It has been in use since it was developed by Dow Chemical. It has long been known that exposure to chlorpyrifos can be deadly. After years of study, researchers in the United States and a number of other countries now believe there is a strong connection between chlorpyrifos exposure and mental disability, ADHD, and memory deficit in children. They believe the chemical damages children's developing brains, even if they are exposed before birth. Latino children, whose parents are exposed to the pesticide, and grow up near fields treated with it, are at the greatest risk.

Scientists believe the pesticide poses a threat even to children exposed to it from produce in the grocery store or through drift. The connection is so strong that scientists at the Environmental Protection Agency recommended that the EPA ban all uses of the pesticide in 2015. The agency had already negotiated a ban on household use 15 years earlier.

This March, the EPA Administrator Scott Pruitt ignored his own scientists and the body of scientific evidence that chlorpyrifos is dangerous. Instead, he reversed course and refused to ban chlorpyrifos. That was the day I rise to talk about this danger to our children.

When moms and dads feed fruits and vegetables to their children, they are trying to do the right thing. They shouldn't have to worry that these foods are laced with dangerous nerve agents. They shouldn't have to worry that the farmworkers who picked that produce or the farmers living near it were exposed.

I have been part of the fight to protect public health and the environment from toxic chemicals most of my life. I remember when Rachel Carson published “Silent Spring” in 1962. My father, Stewart Udall, was her champion when she was fiercely attacked by the chemical industry.

Just over a year ago, I led the bipartisan effort to reform the broken Toxic Substances Control Act. I spent several years working to reform how the EPA regulates chemicals, fighting to stand up a credible program that could be respected, that could restore confidence in the EPA on chemical safety.

I am very disappointed to have to do this, to introduce a bill on a related matter, pesticide regulation. Normally, I would argue that Congress should stay out of the business of regulating individual chemicals. That is why the EPA was created, to make thoughtful, science-based decisions on issues that affect public health and the economy.

In his first decision at the EPA, the Administrator turned authoritarian thug in a tracksuit,” he refused to do: ban chlorpyrifos. Children, Farmers, and Farmworkers from Nerve Agent Pesticides Act—do what the EPA Administrator Scott Pruitt refuses to do: ban chlorpyrifos.

Let's look at the reasons for banning chlorpyrifos. There are very good ones. There are three reasons, I believe, this bill is necessary. First, Administrator Pruitt is wrong. The science is established that chlorpyrifos is a threat to health in its current use. The EPA has studied and studied the toxicity of chlorpyrifos for over a decade. I have talked to the scientists who have been studying it for over 30 years.

In a December 2014 risk assessment, the EPA found chlorpyrifos caused unsafe drinking water contamination. Based on that assessment, the EPA formally proposed, in December 2015, to revoke the use of chlorpyrifos on food. As recently as December 2016, the EPA reaffirmed its determination.

The pesticide is intended to act on the nervous system of insects, but it can act on the human nervous system as well. It can cause symptoms like nausea, vomiting, convulsions, respiratory paralysis—as Bonnie Wirtz and farmworkers in California experienced. In extreme cases, it can kill.

More worrisome, even low-level exposure of chlorpyrifos to developing fetuses in young children can interrupt the development processes of the nervous system. Exposure during gestation or childhood is linked with lower birth weight, slower motor development, and attention problems.

Long-lasting effects on child brain development from in utero exposure also include impaired perceptual reasoning and working memory and underdeveloped intellectual development by age 7. Exposure to organophosphate pesticides like chlorpyrifos is associated with changes in cognitive, behavioral, and motor performance. In plain English, chlorpyrifos damages children's brains.

Second, chlorpyrifos was one of the most widely used household insecticides until the EPA raised concerns in 2000–17 years ago. Household use was phased out. That same year, the EPA discontinued use of chlorpyrifos on tomatoes altogether and restricted its uses on apples and grapes. Currently, chlorpyrifos is still widely used in agriculture, but its use is on the decline.

In 2012, EPA required no spraying within 500 feet of residential inhabited areas, including homes, play fields, daycare centers, hospitals, and other public places. Growers are already working to find alternatives.
The third reason is, scientists, doctors, advocates, I and many of our colleagues were shocked when Administrator Pruitt changed course on chlorpyrifos in March, choosing to wait until 2022—5 years from now.

The American Academy of Pediatrics wrote to Administrator Pruitt in June telling him that “EPA has no new evidence indicating that chlorpyrifos exposures are safe.” As a result, EPA has no basis to allow continued use of chlorpyrifos, and its insistence on doing so puts all children at risk.

The science hasn’t changed since the EPA proposed to ban chlorpyrifos in 2015 and in 2016. Only the politics have.

The law should protect Americans from unsafe pesticides. Under the Food Quality Protection Act, the EPA Administrator “may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is necessary to prevent unreasonable adverse effects on the economy.”

“Safe means . . . that there is a reasonable certainty that no harm will [come] from aggregate exposure.”

If the Administrator can’t determine that a pesticide is safe, the Administrator must revoke or modify the tolerance.

In the case of chlorpyrifos, Administrator Pruitt did not determine that the pesticide is safe with reasonable certainty, nor could he. Instead, he hid behind the fact that the issue requires years more study.

This issue has been the subject of litigation for many years. When the EPA asked the Federal court overseeing the lawsuit for a mere 6-month extension for more study, the court gave a resounding no. It called the request “another variation on the theme of ‘partial reports, missed deadlines, and vague promises of future action’ that has been repeated for the last nine years.

The EPA Administrator has now given himself a 5-year extension. He is failing to follow the Food Quality Protection Act, and he is tying up the Federal Government in more unnecessary and wasteful taxpayer-funded litigation. In the meantime, children, farmers, and farmworkers are at risk because the Administrator refuses to follow the law.

It doesn’t stop there. Administrator Pruitt is trying to dismantle protections for farmworkers. The EPA is proposing to delay two rules vital to protecting our Nation’s farmworkers: The agricultural worker protection standard and the certificate of pesticide applicators rule. Farmworkers have one of the highest rates of chemical exposure among U.S. workers. They are regularly exposed to pesticides. Despite the urgent need to protect them and their families, they actually are less protected than other workers.

We need to know why Administrator Pruitt is choosing to believe a chemical company over respected scientists at his own Agency and around the world, but we can follow the money and guess one reason. While the President and the Administrator ignore science and the law, they have not ignored Dow Chemical Company. Dow gave the President $1 million for his inauguration. Its CEO attended the signing ceremony. Now, the President issued his Executive order requiring agencies to roll back what he called unnecessary regulations. The CEO even got the signing pen. And the CEO met with Administrator Pruitt shortly before the Company got to ban one of Dow’s big moneymakers.

Administrator Pruitt may choose to put aside science, public health, and environmental protection in favor of big chemical profits, but Congress should not. I urge all of my colleagues, especially those across the aisle, to stand with me and pass this protection for children, families, farmers, and farmworkers.

I thank my co-sponsors and the co-sponsors that are coming aboard every day: Senators BLUMENTHAL, BOOKER, DURBIN, GILLIBRAND, HARRIS, MARKEY, MERKLEY, and CARDIN.

There have been many public health and labor groups that have stood up on this front. Here are just some of them today: National Hispanic Medical Association, Learning Disabilities Association of America, Farmworker Justice, Project TENDR, United Farm Workers, Earthjustice, GreenLatinos, Labor Council for Latin American Advancement, LULAC, National Resources Defense Council, Environmental Working Group, Pesticide Action Network, Pineros y Campesinos Unidos del Noroeste, Mana, and others.

The pesticide registration information act is currently moving through Congress. This gives Congress the opportunity to address chlorpyrifos use and worker protection. This bill is a good start for those discussions.

I yield the floor.

The PRESIDING OFFICER (Mr. GARDNER). The Senator from Connecticut.

VETERANS LEGISLATION

MR. BLUMENTHAL. Mr. President, sometimes bipartisanship and comity do work. They have in the last 24 and 48 hours on two measures that are critically important to help our Nation’s veterans have access to benefits and healthcare that they vitally need, that they deserve, and that they have earned. Those measures relate to appeals reform and to the Choice Program.

Last night the Senate passed by unanimous consent—which means without any objection—H.R. 2286. the Veterans Appeals Improvement and Modernization Act of 2017.

I am proud to have worked on this measure with the chairman of the VA Committee, Senator ISAKSON, when I was a member when that committee during the last session. I thank him for his leadership, his vision, and his commitment to this very important cause.

This bipartisan measure now goes to the President. It provides a significant step toward securing benefits veterans have earned. Once these reforms are fully funded—and they should be—our Nation’s veterans will no longer be bogged down by a cumbersome, time-consuming, and aggravating process that denies them fair and full consideration when they appeal their claim’s denial. This reform will begin—it is only a beginning—a better system involving transparency now. I hope that for veterans and their families.

As ranking member of the Senate Veterans’ Affairs Committee, I heard testimony that the Department of Veterans Affairs appeals process desperately needs updating and reform. We all in this body have heard from our constituents again and again about the about the antiquated delay and burden-some process that exists today. The average wait time on an appeal today is more than 2 years, whereas the average wait time on an appeal is 5 years. Nearly half a million veterans are caught in a quagmire—often a quicksand—of repeated consideration, unable to claim benefits because of the VA’s existing backlog.

Between fiscal year 2015 and fiscal year 2017, the number of pending appeals increased from about 380,000 to 470,000. That is an increase of more than 20 percent. The increase in those cases is due to veterans seeking treatment and/or health care services from a decision by the Veterans Benefits Administration. This reform is vitally important because it gives Secretary Shulkin the authority to test the new system before its full implementation.

I know it will take time to implement these changes. It should take less time than is predicted because the Veterans Administration owes it to our heroes—the men and women who have served and sacrificed for our Nation. My constituent caseworkers in Hartford have tried to assist manyindividual veterans with their claims, and these efforts must continue around the country in all of our offices even as these new reforms are implemented.

The second area where we joined together in a bipartisan way relates to the Choice Program. We have agreed to continue funding by providing $2.1 billion and authorizing 28 new leases for medical facilities across the country to improve access to the high-quality care now denied at VA hospitals. If you mistake this action is a down payment, not the final word. I am going to continue to champion further reforms to
make sure we improve VA healthcare and enhance access to VA medical facilities. I am particularly concerned by recent findings made by the VA inspector general, Michael Missal, about a troubling lack of cooperation from non-VA providers relating to chronic pain treatment. To put it very simply and bluntly, the lack of information sharing makes opioid addiction far more likely than it should be, especially among veterans who seek care from private providers through the Choice system.

Connecticut was one of the first States in the country to have a statewide prescription drug monitoring program. I urged Secretary Shulkin at a hearing last year to make sure the VA prescription drug monitoring program exchanges information with the State system, which has data from private providers. The sharing of information is vital to prevent doctor shopping and excessive prescriptions. Without it, veterans potentially are susceptible to weaknesses and gaps that enable them to seek excessive prescriptions of opioid pain killer treatment that can lead to addiction and worse.

We cannot allow the Veterans Choice Program to exacerbate opioid addiction. We must do everything we can to stop the opioid epidemic that is ravaging our communities. As Senator MANCHIN of West Virginia and other colleagues have made clear, the VA must close the information gap on opioid prescriptions through improved opioid safety initiative guidelines and enhanced prescription drug monitoring programs. While we work in Congress to reform the Choice Program, I call on the VA to immediately take certain commonsense steps, none of them novel or original. They have been identified by the inspector general:

First, require all participating VA Purchased Care providers to receive and review evidence-based guidelines for prescribing opioids.

Second, implement a process to ensure all Purchased Care consults for non-VA care include a complete, up-to-date list of medications and medical history.

Third, require non-VA providers to submit opioid prescriptions directly to a VA pharmacy for dispensing and recording in the patient’s VA electronic health record. According in the patient’s VA electronic health record.

Fourth, ensure that if facility leaders determine that a non-VA provider’s opioid prescribing practices conflict with the guidelines, immediate action is taken to ensure the safety of all veterans receiving care from that non-VA provider.

These are basic protections for our veterans. They are protections against overprescribing opioids or negligent misconduct—and worse—on the part of non-VA providers and others.

We are beginning on a path to better information sharing between those prescription drug monitoring programs at the State level for non-VA providers and the VA facilities and providers who care for our veterans directly. That information sharing is not a luxury or convenience; it is a necessity.

We must help veterans of every era with de-addiction from dangerous dispositions and effective healthcare that also protects them from opioid addiction. I am hopeful the Senate will quickly pass the Harry Walker Colmery Veterans Educational Assistance Act, which has been unanimously approved by the House, to make comprehensive improvements to the GI bill. I helped to draft this measure and lead it, and I am proud the House has approved it.

We must also help veterans of all eras suffering from toxic exposure and make sure we award a Congressional Gold Medal to the American Legion and make USERRA protections for our servicemembers meaningful and enforceable. These steps are part of an unifying effort that we owe our veterans. We cannot shirk that duty. We cannot postpone it. It is an obligation, not a convenience.

I look forward to moving forward with these efforts, as we have done with Choice, and with the appeals reform, and to learning what we know already—that we can work together across the aisle when it comes to keeping faith with our veterans and making sure that no veteran of any era is left behind.

I yield the floor.

The PRESIDING OFFICER. The Senator from Arkansas.

TRIBUTE TO BILL REED

Mr. BOOZMAN. Mr. President, I rise today to recognize Bill Reed, an Arkansas who is retiring after more than 34 years of dedicated service at Riceland Foods, the world’s largest miller and marketer of rice.

Bill is a member of the company’s senior management team whose responsibilities include government affairs, public relations, and the Riceland Sustainability Initiative. His interest in agriculture at a young age led him to pursue degrees in this field. Bill earned a bachelor’s degree with honors in plant and soil science from the University of Tennessee and a master’s degree in agricultural journalism from the University of Wisconsin.

In 1976, he moved to the Natural State to work as a State specialist with the University of Arkansas Cooperative Extension Service. He has continued his commitment not only to Arkansas but to Arkansas agriculture for more than 40 years.

Bill is recognized as one of the most passionate advocates on behalf of the Arkansas rice industry. Bill is constantly looking out for the rice farmers and businesses by promoting policies to grow the industry and pushing for expanding markets. His advocacy extended beyond the boundaries of agriculture. He was always ready to lend a hand to me or to my staff on any issue important to Arkansas.

He shares his passion for agriculture throughout the State, country, and the world as a representative of Riceland on numerous boards and trade associations, including the USA Rice Federation and the National Council of Farmer Cooperatives. In addition, Bill serves as chairman of the Arkansas Rice Industry Council, vice president for agriculture of the Arkansas State Council on Economic Education, and vice chairman of the board of visitors of Phillips Community College of the University of Arkansas.

He is a faithful servant of Jesus Christ and is leading his life as Christ calls us to do. In recent years, Bill began seminary school, and his retirement from Riceland will allow him to pursue the ministry full time and help people in need. I appreciate Bill’s friendship, and I am confident that he will excel in this role, just as he had done as an advocate for Arkansas rice. I wish him well in all of his future endeavors and look forward to the great work he will continue to do in helping the great State of Arkansas.

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

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

LEGISLATIVE SESSION

Mr. M. C. CONNELL. Mr. President, I ask unanimous consent that the Senate proceed to legislative session and that following my remarks the Senate resume executive session as under the previous order.

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

AFG AND SAFER PROGRAM REAUTHORIZATION ACT OF 2017

Mr. M. C. CONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 168, S. 829.

The PRESIDING OFFICER. The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (S. 829) to reauthorize the Assistance to Firefighters Grants program, the Fire Prevention and Safety Grants program, and the Staffing for Adequate Fire and Emergency Response grant program, and for other purposes.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Homeland Security and Governmental Affairs, with an amendment to strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ‘‘AFG and SAFER Program Reauthorization Act of 2017’’.
SEC. 2. REAUTHORIZATION OF ASSISTANCE TO FIREFIGHTERS GRANTS PROGRAM AND THE FIRE PREVENTION AND SAFETY GRANTS PROGRAM.


(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (b) of such section is amended by striking “2017” and inserting “2023”, and by striking “prior to the date of the application for the assistance” and inserting “prior to the date of the application for the grant”. Subsection (c)(2) of such section is amended by striking “subsection (a)(1)(B)” and inserting “subsection (a)(1)(F)”.

(c) MODIFICATION OF WAIVER AUTHORITY.—Subsection (j)(1)(B) of such section is amended by striking “subsection (a)(1)(B)(ii)” and inserting “subsection (a)(1)(F)”.

(d) MODIFICATION OF LIMITATION.—Subsection (c)(2) of such section is amended by striking “prior to November 24, 2003” and inserting “prior to the date of the application for the grant”.

(e) MODIFICATION OF WAIVER AUTHORITY.—Subsection (d)(1)(B) of such section is amended by striking “subsection (a)(1)(E)” or (c)(2) or (c)(4)”.

(f) REPEAL OF AUTHORITY FOR CERTAIN USE OF GRANT AMOUNTS TRANSFERRED TO ASSISTANCE TO FIREFIGHTERS GRANTS PROGRAM.—Subsection (a)(1)(B) of such section is amended by striking “and to provide” and all that follows through “firefighters”.

(g) EXPANSION OF STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANT PROGRAM.—Subsection (a)(1)(B) of such section, as amended by subsection (i), is further amended by inserting “or to change the status of part-time or paid-on-call (as defined in section 33(a)) firefighters to full-time firefighters” after “firefighters”.


(a) IN GENERAL.—The Administrator of the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, may develop and make widely available an electronic, online training course for members of the fire and emergency response community on matters relating to the administration of grants under sections 33 and 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229 and 2229a).

(b) REQUIREMENTS.—The Administrator of the Federal Emergency Management Agency shall ensure that any training developed and made available under subsection (a) is—

(1) designed to provide financial, legal, and technical information to emergency response community members.

(2) designed to be consistent with fiscal and technical requirements, standards, and guidelines:

(3) developed in consultation with the National Fire Protection Association, the International Association of Fire Chiefs, the National Fire Marshals Association, the National Association of Professional Fire Marshals, and the National Fire Academy;

(4) developed in consultation with representatives of each state and local fire department;

(5) developed in consultation with representatives of the National Fire Protection Association; and

(6) designed to address the needs of all emergency responders.


(a) IN GENERAL.—The Administrator of the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, shall develop and implement a grant monitoring and oversight framework to mitigate and minimize risks of fraud, waste, abuse, and mismanagement relating to the grant programs under sections 33 and 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229 and 2229a).

(b) ELEMENTS.—The framework required by subsection (a) shall include the following:

(1) Developing standardized guidance and training for all grant recipients.

(2) Conduct of periodic reviews of grantees.

(3) Conducting periodic assessments.

(4) Ensuring that grantees comply with the standards of cost accounting.

(5) Ensuring that grantees have appropriate oversight and monitoring systems in place.

(6) Ensuring that grantees have appropriate oversight and monitoring systems in place.

(c) PROVISION OF OVERTURE AND MONITORING.—The Administrator of the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, shall develop and implement a grant monitoring and oversight framework to mitigate and minimize risks of fraud, waste, abuse, and mismanagement relating to the grant programs under sections 33 and 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229 and 2229a).

(d) PROVISION OF OVERTURE AND MONITORING.—The Administrator of the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, shall develop and implement a grant monitoring and oversight framework to mitigate and minimize risks of fraud, waste, abuse, and mismanagement relating to the grant programs under sections 33 and 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229 and 2229a).

SEC. 5. FRAMEWORK FOR OVERSIGHT AND MONITORING OF THE ASSISTANCE TO FIREFIGHTERS GRANTS PROGRAM AND THE FIRE PREVENTION AND SAFETY GRANTS PROGRAM, AND THE STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANT PROGRAM.

(a) FRAMEWORK.—Not later than 90 days after the date of the enactment of this Act, the Administrator of the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, shall develop and implement a grant monitoring and oversight framework to mitigate and minimize risks of fraud, waste, abuse, and mismanagement relating to the grant programs under sections 33 and 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229 and 2229a).

(b) ELEMENTS.—The framework required by subsection (a) shall include the following:

(1) Developing standardized guidance and training for all grant recipients.

(2) Conduct of periodic reviews of grantees.

(3) Conducting periodic assessments.

(4) Ensuring that grantees comply with the standards of cost accounting.

(5) Ensuring that grantees have appropriate oversight and monitoring systems in place.

(6) Ensuring that grantees have appropriate oversight and monitoring systems in place.

(c) IMPLEMENTATION.—The framework required by subsection (a) shall be implemented by the Administrator of the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, and shall be reviewed by the Federal Emergency Management Agency, acting through the Administrator of the United States Fire Administration, not later than 180 days after the date of the enactment of this Act.

(d) REPORT.—The Federal Emergency Management Agency shall submit to the Congress a report on the implementation of the framework required by subsection (a), including a description of the risks of fraud, waste, abuse, and mismanagement relating to the grant programs described in subsection (a).
agreed to, and the motions to reconsider be considered made and laid upon the table, all en bloc.

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

The resolution (S. Res. 199) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, is printed in the RECORD of June 22, 2017, under “Submitted Resolutions.”

The resolution (S. Res. 225) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, is printed in the RECORD of July 20, 2017, under “Submitted Resolutions.”

The resolution (S. Res. 227) was agreed to.

The preamble was agreed to.

The resolution, with its preamble, is printed in the RECORD of August 1, 2017, under “Submitted Resolutions.”

HARRY W. COLMERY VETERANS EDUCATIONAL ASSISTANCE ACT OF 2017

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of H.R. 3218, which was received from the House.

The PRESIDING OFFICER. The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (H.R. 3218) to amend title 38, United States Code, to make certain improvements in the laws administered by the Secretary of Veterans Affairs, and for other purposes.]

There being no objection, the Senate proceeded to consider the bill.

Mr. DURBIN. Mr. President, I am pleased that today the Senate is unanimously passing the Harry W. Colmery Veterans Educational Assistance Act of 2017, known as the Forever GI Bill, which would make important improvements to the GI bill.

The bill removes time restrictions on using the GI bill, enabling future recipients to use benefits their entire lives as opposed to waiting within the current 15-year timeline. It provides 100 percent GI bill eligibility to Purple Heart recipients. It also increases GI bill funding for Reservists, Guardsmen, dependents, surviving spouses, and surviving dependents.

While the bill includes many provisions I support, I also have ongoing concerns about institutions of higher education, especially for-profit colleges, which prey on veterans using GI bill benefits. I do not believe this bill goes far enough to provide the type of protections we owe to our servicemembers and the kind of institutional accountability that taxpayers deserve.

I am particularly concerned that the Forever GI Bill does not address the 90/10 loophole which incentivizes for-profit colleges to aggressively recruit and prey on veterans. Under current law, for-profit colleges are prohibited from receiving more than 90 percent of their revenue from Federal taxpayers, but due to a loophole in the law, such revenue does not count Department of Veterans Affairs GI bill or Department of Defense Tuition Assistance funding. This means that, by targeting veterans and servicemembers, for-profit colleges can actually receive 100 percent of their revenue directly from Federal taxpayers.

And many do. According to data released by the Department of Education in 2016, 193 institutions received more than 90 percent of their revenue from Federal taxpayers when Department of Education, Department of Veterans Affairs, and Department of Defense funds were counted together. I have long called for this loophole to be corrected and for the percentage of Federal revenue to be returned to the original 85 percent. I will soon reintroduce legislation, the Protecting Students and Taxpayers, POST, Act, to address this issue.

While not addressed in the Forever GI Bill we are passing today, I look forward to working with my colleagues—including Sen. Sanders, who has authored another bill on this topic which I support—service members, veteran service organizations, and others to consider this and other important accountability concerns.

Mr. MCCONNELL. I ask unanimous consent that the bill be considered read a third time and passed and the motion to reconsider be considered made and laid upon the table.

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

The bill (H.R. 3218) was ordered to a third reading, was read the third time, and passed.

REDESIGNATING CERTAIN CLINICS OF THE DEPARTMENT OF VETERANS AFFAIRS LOCATED IN MONTANA

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Committee on Veterans’ Affairs be discharged from further consideration of S. 1282 and the Senate proceed to its immediate consideration.

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

The clerk will report the bill by title.

The senior assistant legislative clerk read as follows:

A bill (S. 1282) to redesignate certain clinics of the Department of Veterans Affairs located in Montana.

There being no objection, the Senate proceeded to consider the bill.

Mr. MCCONNELL. I ask unanimous consent that the Daines-Tester substitute amendment at the desk be considered and agreed to, the bill, as amended, be read a third time and passed, and the motion to reconsider be considered made and laid upon the table.

The PRESIDING OFFICER. Is there objection?

Without objection, it is so ordered.

The amendment (No. 749) in the nature of a substitute was agreed to as follows:

(Purpose: In the nature of a substitute)

Strike all after the enacting clause and insert the following:

SECTION 1. REDESIGNATION OF CERTAIN DEPARTMENT OF VETERANS AFFAIRS CLINICS IN MONTANA.

(a) DAVID J. THATCHER VA CLINIC.—

(1) DESIGNATION.—The clinic of the Department of Veterans Affairs located at 2687 Palmer Street in Missoula, Montana, shall after the date of the enactment of this Act be known and designated as the “David J. Thatcher VA Clinic.”

(2) REFERENCES.—Any reference in any law, regulation, map, document, paper, or other record of the United States to the clinic referred to in paragraph (1) shall be considered to be a reference to the David J. Thatcher VA Clinic.

(b) DR. JOSEPH MEDICINE CROW VA CLINIC.—

(1) DESIGNATION.—The clinic of the Department of Veterans Affairs located at 1775 Spring Creek Lane in Billings, Montana, shall after the date of the enactment of this Act be known and designated as the “Dr. Joseph Medicine Crow VA Clinic.”

(2) REFERENCES.—Any reference in any law, regulation, map, document, paper, or other record of the United States to the clinic referred to in paragraph (1) shall be considered to be a reference to the Dr. Joseph Medicine Crow VA Clinic.

(b) LOCAL DISPLAY.—For purposes of subparagraph (A), a local public display of the name of the clinic referred to in paragraph (1) carried out by the United States through the use of Federal funds shall include the English name, Dr. Joseph Medicine Crow, and the Crow name, Dakaak Baako, of Dr. Joseph Medicine Crow.
EXECUTIVE SESSION

EXECUTIVE CALENDAR—Continued

The PRESIDING OFFICER. Under the previous order, the Senate will resume in executive session.

The PRESIDING OFFICER. The Senator from Massachusetts.

Ms. WARREN. Mr. President, for months the American people have been gripped by the sideshow surrounding President Trump. It seems like every day another shoe drops on the Russia investigation, another White House staffer is fired, and President Trump tweets something that upends the government and causes our allies to move even further away from us.

Despite all of this commotion, all of the drama, and all of the disorganization, there is one thing that Trump and the Republicans in Congress have carried out since day one with complete precision: They have carried out a comprehensive all-out assault on American workers. Day by day, week by week, month by month, President Trump and congressional Republicans have acted to undermine the safety and economic security for working Americans.

Just observe what they have done. On December 18, President Trump nominated Andrew Puzder, who was then CEO of fast food giants Hardee’s and Carl’s Jr., to lead the Department of Labor. His first major announcement affecting workers was to nominate a man who made his fortune on the backs of hard-working Americans to the top position in government charged with protecting American workers.

On February 1, just days after he was inaugurated, President Trump delayed a rule protecting workers from workplace exposure to a lethal cancer-causing substance called beryllium. On February 3, President Trump released his budget blueprint, proposing to slash funding from the Department of Labor, including the complete elimination of workers’ safety training programs, programs for older workers, and funding for workers with disabilities. And on June 3, President Trump proposed exempting the construction and shipbuilding industries from the rule to protect workers from lethal cancer-causing beryllium, a move that could prove fatal to workers in these industries.

That is a pretty despicable record—despicable before they get slammed over and over. Today, Senator McConnell has brought us down to the floor to sock it to American workers one more time before he sends us home for summer recess. Today, we are voting on the nomination of Marvin Kaplan to the National Labor Relations Board.

Pause here for just a second. The NLRB is probably the most important independent Federal agency that you have never heard of. They are responsible for protecting the legal rights of workers to come together and bargain with their bosses for higher wages and better working conditions.

Starting a union is not easy. Large employers fight union organizing campaigns tooth and nail. They hire armies of union-busting lawyers to run smear campaigns against the unions or to delay or kill organizing efforts.

That is why the NLRB is so very important—to serve as a referee that ensures employers play by the rules and workers get a chance to exercise their legal rights. It is the NLRB’s job to stand up for workers—workers like the nearly 4,000 workers at the Nissan plant in Northampton, MA, where nearly 300 service employees were elected to be represented by SEIU 1199.

With a Republican Congress and President determined to deliver the knockout blow to the middle class, hard-working Americans need an NLRB that is on their side. President Trump’s nominee to the NLRB, Marvin Kaplan, has no experience practicing labor law, but we actually know where he stands on protecting workers.

As a Republican House staffer, here is what he has done. He spent years actively working to strip workers of their right to organize under the law. He spent years working to overturn rulings by the NLRB that would protect workers’ rights. He worked on the legislation to delay union election by at least 35 days, giving employers and their armies of lawyers and lobbyists more time to fight off organizing efforts. He worked on legislation to make it easier for workers to file unfair labor practice complaints. He has even fought efforts to ensure that Americans get paid the overtime they deserve.

So after 8 months, the Republicans are about to go on vacation, but not in the way they jam the NLRB with a new anti-worker nominee. The biggest problem in Washington is that this place works great for giant employers and for giant corporations with armies of lawyers and lobbyists. But workers and their families just get ignored. President Trump doesn’t seem to have any problem turning his back on millions of hard-working people, but that is not what we are here for.

I will be voting against Marvin Kaplan, and I urge my colleagues to do the same.

I yield the floor.

Are there any other Senators in the chamber desiring to vote?

The question is, Will the Senate advise and consent to the Kaplan nomination?

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

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

Under the previous order, all post cloture time is expired.

The question is, Will the Senate advise and consent to the Kaplan nomination?

Mr. TILLIS. Mr. President, I ask for the yeas and nays.

The PRESIDING OFFICER. Is there a sufficient second?

There appears to be a sufficient second.

The clerk will call the roll.

The senior assistant legislative clerk proceeded to call the roll.

Mr. CORYN. The following Senators are necessarily absent: the Senator from North Carolina (Mr. BURR) and the Senator from Arizona (Mr. MCCAIN).

The PRESIDING OFFICER (Mr. LEE). Are there any other Senators in the Chamber desiring to vote?
The result was announced—yeas 50, nays 48, as follows:

[Roll Call Vote No. 184 Ex.]

**YEAS—50**

Alexander
Barrasso
Blunt
Boozman
Capito
Collins
Coons
Corker
Collins
Cochran
Cornyn
Cotton
Crapo
Cruz
Daines
Emhoff
Ernst
Fischer
Flake

**NAYS—48**

Baldwin
Benning
Blumenthal
Booker
Brown
Cantwell
Cardin
Carpenter
Cassidy
Cassidy
Cochran
Collins
Reed
Rhode Island
Ron Johnson
Ruben
Risch
Shaheen
Shaheen
Sasse
Sasse
Sasse
Sasse
Shelby
Sherrod Brown
Shelby
Shorter
Senator...

**LEGISLATIVE SESSION**

**MORNING BUSINESS**

The PRESIDING OFFICER. Under the previous order, the motion to reconsider is considered made and laid upon the table and the President will be immediately notified of the Senate’s action.

The nomination was confirmed. 

The PRESIDING OFFICER. Under the previous order, the motion to reconsider is considered made and laid upon the table and the President will be immediately notified of the Senate’s action.

**UNITED STATES INTELLIGENCE PROFESSIONALS DAY**

Mr. WARNER. Mr. President, I ask unanimous consent that the Committee on the Judiciary be discharged from further consideration of S. Res. 222 and the Senate proceed to its immediate consideration.

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

The clerk will report the resolution by title.

The senior assistant legislative clerk read as follows:

A resolution (S. Res. 222) designating July 26, 2017, as “United States Intelligence Professionals Day.”

There being no objection, the Senate proceeded to consider the resolution.

Mr. WARNER. I ask unanimous consent that the time be extended to, in the preamble be agreed to, and the motions to reconsider be considered made and laid upon the table with no intervening action or debate.

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

The resolution (S. Res. 222) was agreed to.

The preamble was agreed to.

(The resolution, with its preamble, is printed in the Record of July 19, 2017, under “Submitted Resolutions.”)

Mr. WARNER. Mr. President, for several years now I have regularly come to this floor to publicly acknowledge the contributions made by our great Federal employees. This is a tradition I inherited from one of our former colleagues, Senator Ted Kaufman of Delaware. Senator Kaufman, who had been a longtime staffer himself before he served as a Senator, would come to this floor on a regular basis to acknowledge and celebrate the tireless work and occasional heroics performed by many of our Federal employees. When Senator Kaufman left this body, I gladly picked up that mantle and since then have come to the floor to draw attention to the extraordinary contributions of many of our Federal workers.

Over the past few years, this recognition has included a Social Security executive who eliminated a claims backlog; more quickly meet the urgent needs of thousands of Social Security recipients with grave terminal illnesses. We have also celebrated the work of a Department of Homeland Security official who saved taxpayers $750 million by streamlining her agency’s procurement processes, and we proudly highlighted the story of a group of engineers at NASA Langley Research Center in Virginia, who, in 2010, designed a capsule that proved to be crucial in saving the lives of 33 Chilean miners who were trapped underground.

Today, I wish to focus for a moment on one such group of outstanding Federal employees—those who work across our Nation’s intelligence agencies to keep our Nation safe. Most of these professionals work in anonymity. Their families and loved ones.

The PRESIDING OFFICER. The resolution was agreed to.

The result was announced—yeas 50, nays 48, as follows:

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Today, I wish to focus for a moment on one such group of outstanding Federal employees—those who work across our Nation’s intelligence agencies to keep our Nation safe. These are professionals who are trusted with one of the most sensitive and dangerous jobs in America—protecting our Nation from attack. For their service, the risks they take and the sacrifices they make every day and because they do not hear this near—
which is a law that I introduced with Senator MICHAEL BENNET of the State of Colorado.

RACE for Children is sorely needed, as it would close a loophole that exists in current Federal law and prompt companies—pharmaceutical companies—to examine the safety and the efficacy of powerful cancer drugs and how they work on children. This, in turn, will provide doctors with the necessary tools to properly treat children battling cancer.

Pediatric cancer is a leading cause of death by disease among children. A startling statistic: One in every 285 children is diagnosed with cancer before the age of 20. While the reality is that researchers are continuing to make significant advances to treat and cure cancer for adults, the progress to develop safe drugs for pediatric cancer sadly lags far behind.

One of the problems is that current law, the way it is today, directs pharmaceutical companies to study the safety and the efficacy of adult drugs on children. So if you develop a drug on diabetes or disease or anything for adults, it also requires you to do some of that on children because you want to make sure that it works on both populations and you don’t want to keep a drug out of the market for children. If you develop a drug for children, you have to test it on children. Of course, this requirement is only in place if the FDA believes that there is a pertinent need—in essence, a condition that children suffer from. There are some conditions that are unique to adults and there are few, if any, adult populations who have that disease, so maybe they would decide it wasn’t pertinent to require it.

However, this provision in the law specifically exempts cancer drugs. In essence, it says to a pharmaceutical company: If you are going to study the safety and the efficacy of a drug on adults, if there is a pertinent need, if there is a real population out there that is suffering, you have to test it on children, you have to test it on children, as well, except if it is a cancer drug. One of the reasons that exemption is in there is because technology—medical technology at the time that law was put in place—didn’t allow researchers to target the genetic structure of cancer. In essence, at the time, it didn’t allow them to say: We can go in and find the genetic markers of a specific cancer and test against it. That is why it didn’t have that requirement.

Now, however, we do have that capability. Today, the technology exists to pinpoint the similarities in adult and childhood cancer genomes. So the technology has reached a point where you can treat the specific genome of a cancer whether it is in an adult or in a child. That is how far the technology has advanced, but the law has not been updated to keep up with it. The result is that the approach of adult cancer of cancer need to be made, and we don’t know if they work on children because they haven’t been forced to test it.

So the RACE for Children’s Act, which is a law that Senator BENNET and I offered and is included in the FDA reauthorization, closes that loophole.

Let me say that getting to this point here wasn’t as straightforward. So I do need to take a moment to thank the chairman, Senator ALEXANDER of Tennessee, and obviously Senator BENNET, but also the pediatric cancer community, including organizations like the Live Like Bella Foundation. In my hometown of Miami, Lambs for Life, the Alliance for Childhood Cancer, St. Jude’s, St. Baldrick’s, Nemours Children’s Hospital, Arnold Palmer Hospital, the American Cancer Society, and so many others that came together to the table to address this important issue in a way that would not limit future innovations for cancer treatment. It has taken over a year and a half to reach this point, and I am grateful to all of them for their participation because I would not be standing here giving this speech without it.

Suffice it to say that, tragically, many of my colleagues in Congress, here in the Senate but also across the country, have been affected by cancer. Whether you are fighting cancer yourself or it is your child, your sister, your brother, your cousin, your friend, I want to make one thing clear: You are not alone in your struggle.

I would venture to say that I do not know anyone who hasn’t been impacted by pediatric cancer. I have it in my own family, and some have confronted it in theirs, in loved ones and children who went to school with your kids. In fact, Live Like Bella Foundation was founded for a young girl by the name of Bella from Miami. She was a classmate of my nephew in grade school, and she lost her battle with cancer. Her father has been a tireless advocate for this cause. He moved heaven and Earth to try to reach a point where they could find a cure for her. That did not come in time. He has now made it the mission of his life to honor her life by continuing this work. So we have all been impacted in some way.

As I said, unfortunately, across this country this disease is a reality. I want to share some stories of a few of the children who have been impacted by cancer and who have impacted our office and helped us to make this a priority over the last year and a half.

The first is the story of a young boy named Jeremy. He is only 5 years old and has been in treatment for 4 of those 5 years. He has had more than 150 surgeries so far, and ultimately had to have his eyes removed because of cancer, which left him completely blind, obviously.

Then there is Tatum, who was diagnosed with a rapidly developing brain tumor just before she was supposed to start kindergarten. Her parents were told by the doctors that they should take her home and they should enjoy the little time they had with Tatum because they had no options to treat her.

There is Princeton, who was diagnosed with cancer when he was 5 years old. He is now 7. In those 2 years he has undergone 6 chemo cycles, a bone marrow transplant, 9 surgeries, 12 rounds of radiation, and 6 cycles of immunotherapy. Because of this intense and time-consuming treatment schedule, Princeton built friendships with others who were also in the hospital for treatment. Sadly, he has lost many of these friends to cancer.

Princeton’s best friend was Trevor. Trevor passed away right before Princeton’s birthday party. Princeton came to my office asking the Senate to do more for kids like them. Here is what 7-year-old Princeton said: “I don’t want my friends to die, and I don’t want me to die.”

There is the story of Derek. He was a healthy, happy baby until he developed an aggressive form of cancer and it provided him with 2 years of life—sometimes it feels as though, perhaps, our service here doesn’t make much of an impact. But from time to time, we have unique opportunities to slightly alter the arc of history and potentially help people. Standing here today, I can’t tell you if there will be
1,000 children, 100,000 children, or 5 children who will benefit from a cancer treatment because of this new requirement in which these adult drugs will have to be tested on children. We don’t know.

Standing here today, believing that we all walk on Earth and our days are numbered to the glory and grace of God, frankly, we don’t know if one of our own children, God forbid or someone we deeply love or one of our children’s classmates will be impacted by pediatric cancer. But we know that I in about 300 children will be. So the chances are that at some point, we will once again have someone we care deeply about impacted. We hope that when that moment comes, if it does, that there will be options for their parents and their doctors and that they will have the opportunity to use for them treatments that perhaps would not have been available, had this requirement not been in the law. That is why I hope my Senate colleagues will join me in supporting this initiative.

In fact, sometimes we give these speeches with a sense of mystery: If this passes; if it doesn’t pass; there is no reason this isn’t going to pass. We all expect the authorization bill to pass. I imagine when people vote on this tomorrow, they will read the title of the bill, “FDA Fee Reauthorization.” It sounds like taking care of the normal course of business—it is important, by the way—that this is just this bureaucratic exercise normal course of business—it is important in its own right, by the way—that this is just this bureaucratic exercise tantamount in its own right, by the way—that this is just this bureaucratic exercise. It sounds like taking care of the normal course of business—it is important in its own right, by the way—that this is just this bureaucratic exercise tantamount in its own right, by the way—that this is just this bureaucratic exercise.

VERMONT POLICE CHIEF’S RESPONSE TO PRESIDENT TRUMP

Mr. LEAHY. Mr. President, Brandon del Pozo proudly serves as the chief of police in Burlington, VT—Vermont’s largest city. He arrived in Vermont 2 years ago, after serving for nearly two decades with the New York Police Department, where he rose through the ranks and learned hard lessons on the streets of such a large urban center. One needs only to sit with Chief del Pozo for a short while to understand his commitment to community service and to community service.

So it comes as no surprise that Chief del Pozo grew alarmed when he heard President Trump recently tell a law enforcement gathering that police should not be too nice” to those who are placed under arrest, seeming to suggest that police should go against the very policies that exist to protect against police misconduct. We cannot tolerate this kind of public comment and certainly not from the President of the United States. There is nothing the President understands more about than the role of police in protecting the public, and the trust the public has in law enforcement.

One needs only to sit with Chief del Pozo for a short while to understand his commitment to community service and to community service. As a doctoral candidate holding three master’s degrees, Chief del Pozo is well studied in the rules of engagement. He is also a talented writer. In an essay he submitted to CNN, Chief del Pozo responded directly to the President’s comments. He wrote: “Policing requires—dealing with the emotions cops are bound to feel when they witness the worst things one person can do to another. It is criminals who act on these emotions and attack other people. Restraint is what separates policing from vigilism.

Now we have a President who appears to want police to satisfy their primal urges. Either as a joke—as White House press secretary, Sarah Huckabee Sanders has now suggested—or as one of many true things that have been said in jest. President Donald Trump addressed a roomful of officers on Long Island on Friday and invited them to be “rough” with their suspects. He advised them to be free with their hands as they shoved arrestees into squad cars, to “not be too nice.” His grin and his pause for an ovation erased any uncertainty about his message.

An elected official could only say what Trump said if he didn’t understand policing. People who’ve gained this type of experience know the real possibility of a cop losing his temper, how hard we have to guard against it, and how much it would erode the trust we strive for between police and the people they serve.

It also seems like the President doesn’t understand certain things about America. There has been enough confirmed police brutality here to send chills down the spine of a reasonable person watching the President and a crowd of cops joke and laugh about it. It’s like laughing about the dire consequences of inadequate health care, or the opioid crisis.

It’s also clear that President Trump has never had to face an arrested police officer: The cop sits there in front of you, replaying a moment in his mind, wishing he could take it back. He put on the uniform to be one of the good guys, and now he’s on the opposite side of the table. He worries about supporting his family.

The way to get our officers to retire some day is with a career and a pension and not have to worry about facing the person they pulled over, not even the person they arrested. Remember, they served their country, not just their job. It’s too bad that Trump has never had to face an arrested police officer: The cop sits there in front of you, replaying a moment in his mind, wishing he could take it back. He put on the uniform to be one of the good guys, and now he’s on the opposite side of the table. He worries about supporting his family.

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likely explanation is that the President has a talent for bringing out the darker side of people, and this was another example of it. What we witnessed will drive a deeper and perhaps necessary conversation. We have the opportunity to learn from this.”

Mr. ENZI. Mr. President, I ask unanimous consent to have printed in the Record a copy of the commitment letters from the Secretary of Health and Human Services to the Chairman of the Senate Finance Committee, Labor, and Pension subcommittee and to the Senate and the chairman of the Committee on Energy and Commerce of the House of Representatives regarding reauthorization of the Biosimilar User Fee Act, Prescription Drug User Fee Act, and Medical Device User Fee Amendments.

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


Hon. Lamar Alexander, Chairman, Committee on Health, Education, Labor and Pensions, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: The Generic Drug User Fee Amendments of 2012 (GDUFA) enacted as title III of the Food and Drug Administration Safety and Innovation Act (FDACA) [Pub. L. 112–144], expires at the end of Fiscal Year 2017. With this letter the Administration is providing our recommendations for the reauthorization of GDUFA for the Fiscal Years 2018–2022 (GDUFA II).

Under GDUFA, the revenues generated from fees paid by the generic pharmaceutical industry have been used to expedite the process for the review of applications to support and augment regulatory science and drug development. The expenditure of these funds is in accordance with the statute and provides resources to meet the performance goals and procedures that were developed by the Food and Drug Administration (FDA) in consultation with representatives from the regulated industry, to develop reauthorization legislation that would build upon and enhance the success of the program. In addition, we have compiled with the statutory requirements to solicit public comments on our recommendations, and the summary of public comments is posted on the agency web site.

Our recommendations build upon the success of existing programs and performance goals with step-wise improvements allowing FDA the resources to establish a generic drug review program that can keep up with the ever-expanding generic drug industry. The recommendations will bring all Abbreviated New Drug Applications (ANDAs) under a common review goals scheme which calls for faster review cycles of 10 months for standard ANDAs and eight months for priority ANDAs. Priority status will be reserved for drug shortages, first generics, sole source generics and other public health priorities. The negotiated recommendations provide that FDA will communicate definitions of drug shortages, first generics, sole source generics and other public health priorities.

The negotiated recommendations will average approximately $493.6 million per year, adjusted annually, for GDUFA II.

Throughout this process, the FDA has solicited input and worked with various stakeholders, including representatives from academia, patient organizations, the generic pharmaceutical industry, and health provider groups, and negotiated with the regulated industry, to develop reauthorization legislation that would build upon and enhance the success of the program. In addition, we have compiled with the statutory requirements to solicit public comments on our recommendations, and the summary of public comments is posted on the agency web site.

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Throughout this process, the FDA has solicit...
The agreement also establishes a robust Pre-ANDA program for complex products. The program will include meetings with applicants, guidance development and regulatory science improvements aimed at allowing applicants with complex products to submit more complete applications and FDA to be more prepared for such submissions. FDA has committed to working closely with Congress in order to reauthorize the program in a timely manner. The Office of Management and Budget has advised that the bill and the enclosed performance goals are in accord with the Administration’s program.

Sincerely,

SYLVIA BURWELL,
Secretary.

DEPARTMENT OF HEALTH &
Human Services,

Hon. GREG WALDEN,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Generic Drug User Fee Amendments of 2012 (GDUFA) enacted as title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), expired at the end of Fiscal Year 2017. With this letter the Administration is providing our recommendations for the reauthorization of GDUFA for the Fiscal Years 2018-2022 (GDUFA II).

Under GDUFA, the revenues generated from fees paid by the generic pharmaceutical industry have been used to expedite the review of generic drugs and to support and augment regulatory science and drug development. The expenditure of these funds is in accordance with the statute and provides resources to meet the performance goals and procedures that were developed by the Food and Drug Administration (FDA) in consultation with representatives of regulated industry. FDA estimates that the fees negotiated in GDUFA II will average approximately $493.6 million per year, adjusted annually for inflation.

Throughout this process, the FDA has solicited input and worked with various stakeholders, including representatives from consumer, patient, academic research, and health provider groups, and negotiated with the regulated industry. We would be pleased to brief your staff on the details and want to work closely with Congress in order to reauthorize the program in a timely manner. The Office of Management and Budget has advised that the bill and the enclosed performance goals are in accord with the Administration’s program.

Sincerely,

SYLVIA BURWELL,
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The program will include meetings with applicants, guidance development and regulatory science enhancements aimed at allowing applicants with complex products to submit more complete applications and FDA to be more prepared for such submissions.

The agreement also establishes a robust Pre-ANDA program for complex products. The program will include meetings with applicants, guidance development and regulatory science enhancements aimed at allowing applicants with complex products to submit more complete applications and FDA to be more prepared for such submissions.

Lastly, the agreement would revamp the user fee structure. GDUFA II will be funded at a level commensurate with the volume of ANDA submissions—the primary workload driver of the program. This will allow FDA the resources necessary to meet all of its commitments in a timely manner. The Office of Management and Budget has advised that the budgeted performance goals and procedures that were developed by the Food and Drug Administration (FDA) in consultation with representatives of regulated industry. FDA estimates that the fees negotiated in GDUFA II will average approximately $493.6 million per year, adjusted annually for inflation.

Our recommendations build upon the successes of GDUFA and its predecessor, the Generic Drug User Fee Act, GDUFA, reauthorization for fiscal years 2018 to 2022, known as GDUFA II.

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

GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROGRAM ENHANCEMENTS FISCAL YEARS 2018–2022

I. Submission Review Performance Goals

A. Original ANDAs and ANDA Amendments

B. PASs and PAS Amendments

C. Unsolicited ANDA and PAS Amendments

D. DMFs

E. Controlled Correspondence

F. GDUFA I Bridging

II. Original ANDA Review Program Enhancements

A. ANDA Receipt

B. ANDA Review Transparency and Communications Enhancements

C. Review Classification Changes during the Review Cycle

D. ANDA Approval and Tentative Approval

E. Dispute Resolution

F. Other ANDA Review Program Enhancements

III. Pre-ANDA Program and Subsequent Mid-Review-Cycle Meetings for Complex Products

A. Rationale for Pre-ANDA Program, Guidance on Enhanced Pathway for Complex Products

B. Controlled Correspondence

C. Product-Specific Guidance

D. Product Development Meetings

E. Pre-Submission Meetings

F. Inactive Ingredient Database Enhancements

G. Regulatory Science Enhancements

H. Safety Determination Letters

I. Other Pre-ANDA Program Enhancements

IV. DMF Review Program Enhancements

A. Communication of DMF Review Comments

B. Teleconferences to Clarify DMF First Cycle Review Deficiencies

C. DMF First Adequate Letters

D. DMF Renewal Letter

E. Guidance on Post-Approval Changes to Type II API DMFs

F. Facilities

G. Guidance on Risk-Based Site Selection Models

H. Outreach to Foreign Regulators on Risk-Based Site Selection Models

I. Export Support and Education of Other Health Authorities

J. Communications to Foreign Regulators

K. Communication Regarding Inspections

L. GDUFA II Facility Compliance Status Database

VI. Enhanced Accountability and Reporting

A. Resource Management Planning and Modernized Time Reporting

B. Financial Transparency and Efficiency
The performance goals and procedures of the FDA, as agreed to under the first reauthorization of the GDUFA, are summarized below.

### TABLE FOR SECTION I(A)(1) AND (2): ORIGINAL ANDAS

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Goal</th>
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<tbody>
<tr>
<td>Standard Original ANDAs</td>
<td>90% within 10 months of submission date.</td>
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<tr>
<td>Priority Original ANDAs</td>
<td>90% within 8 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Standard Major ANDA Amendments</td>
<td>90% within 10 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Priority Major ANDA Amendments</td>
<td>90% within 8 months of submission date if preapproval inspection not required.</td>
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### TABLE FOR SECTION I(A)(3)–(5): ANDA AMENDMENTS

<table>
<thead>
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<th>Submission Type</th>
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<tbody>
<tr>
<td>Standard Major ANDA Amendments</td>
<td>90% within 8 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Priority Major ANDA Amendments</td>
<td>90% within 6 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Standard and Priority Minor ANDA Amendments</td>
<td>90% within 3 months of submission date.</td>
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### TABLE FOR SECTION I(B)(1) AND (2): PASs

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Goal</th>
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<tbody>
<tr>
<td>Standard PAS Major Amendments</td>
<td>90% within 6 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Priority PASs</td>
<td>90% within 8 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Standard and Priority Minor PASs</td>
<td>90% within 3 months of submission date.</td>
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### TABLE FOR SECTION I(B)(3)–(5): DMFs

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<tr>
<th>Submission Type</th>
<th>Goal</th>
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<tr>
<td>Standard API DMFs</td>
<td>90% within 6 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Priority DMFs</td>
<td>90% within 8 months of submission date if preapproval inspection not required.</td>
</tr>
<tr>
<td>Standard and Priority Minor DMFs</td>
<td>90% within 3 months of submission date.</td>
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### TABLE FOR SECTION I(D): DMFs

<table>
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<tr>
<th>Submission Type</th>
<th>Goal</th>
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<tbody>
<tr>
<td>Type II API DMF</td>
<td>90% of initial completeness assessments within 60 days of the later of the date of DMF submission or DMF fee payment.</td>
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</table>
E. Controlled Correspondence

1. Review and respond to 90 percent of controlled correspondences within the applicable review goal.
   a. Review and respond to Standard controlled correspondences within 60 days of the date of submission.
   b. Review and respond to Complex correspondences within 120 days of the date of submission.

2. In the case of controlled correspondence that raises an issue that relates to one or more pending post-preliminary petition reviews, the 60- or 120-day time period starts on the date FDA responds to the petition (if there is one only petition) or last pending petition.

3. FDA will respond to 90% of submitter requests to clarify ambiguities in the controlled correspondence response within 14 days of receipt of the request. The response to the submitter’s request will provide clarification or advice concerning the ambiguity in the controlled correspondence response.

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<tbody>
<tr>
<td>Standard Controlled Correspondence</td>
<td>90% within 60 days of submission date.</td>
</tr>
<tr>
<td>Complex Controlled Correspondence</td>
<td>90% within 120 days of submission date.</td>
</tr>
</tbody>
</table>

FDA will review and respond to 90% of submitter requests to clarify ambiguities in the controlled correspondence request within 14 days of receipt.

F. GDUF A I Bridging

1. Continue to review and act on ANDAs and ANDA amendments, PASs and PAS amendments, and controlled correspondences submitted prior to October 1, 2017 that have been assigned GDUF A I goal dates pursuant to the GDUF A I review metrics applicable to those submissions.

2. Review and act on 90% of ANDAs and ANDA amendments with Target Action Dates (TADs) by the goal date. The TAD for an ANDA or ANDA amendment becomes its GDUF A II goal date. (Attachment A shows how FDA, until September 30, 2017, assigned TADs to ANDA amendments not subject to GDUF A I review goals.)

3. Review and act on 90% of ANDAs and ANDA amendments pending FDA as of October 1, 2017 that were not subject to GDUF A I goal dates and either (a) were not previously assigned TADs or (b) were previously assigned TADs that came due prior to October 1, 2017, remaining pending in the same review cycle as of October 1, 2017, by GDUF A II ANDA and ANDA amendment goal dates that FDA will assign on October 1, 2017. No such goal date shall be later than July 31, 2018.

4. Review and act on amendments received on or after October 1, 2017, to any ANDAs submitted prior to October 1, 2017, pursuant to the amendment review goals set forth in (A)(3)–(5) of this section.

II. ORIGINAL ANDA REVIEW PROGRAM ENHANCEMENTS

A. ANDA Receipt

1. FDA will strive to determine whether to receive ANDAs within 60 days of the date of ANDA submission.

2. To enable FDA to rapidly determine whether to receive an ANDA pursuant to 21 Code of Federal Regulations (CFR) 314.101, and with consideration of final agency guidelines that address ANDA receipt determinations, FDA will apply that ANDA to document legibility; and on deficiencies potentially resolved with information in the ANDA at original submission, in order to provide applicants with an opportunity for resolution within 7 calendar days. If such a deficiency is resolved within 7 calendar days, that deficiency will not be a basis for an ANDA refusal.

3. At the time of receipt, FDA will notify the applicant in the acceptance letter whether the ANDA or PAS is subject to priority or standard review.

B. ANDA Review Transparency and Communications Enhancements

To promote transparency and communication between FDA and ANDA applicants, FDA will apply the enhancements below to the review of all ANDAs. The goal of these program enhancements is to improve predictability and transparency, promote the benefits of flexibility of the review process, minimize the number of review cycles necessary for approval, increase the overall rate of approval, and facilitate greater access to generic drug products.

1. FDA will issue the appropriate Information Request(s) (IRs) and/or Discipline Review Letter(s) (DRLs) from each review discipline as soon as the discipline has completed its review, with the first IRs and/or DRLs at about the mid-point of the review.

2. Following IR classification status at about the mid-point of the review, IRs and/or DRLs will, as appropriate, continue from each review discipline on a rolling basis.

3. Neither IRs nor DRLs stop the review clock or add to a GDUF A goal.

4. If an applicant is unable to completely respond within the time frame requested by FDA, including any extensions that may be granted by FDA, then FDA will generally issue a Complete Response Letter (CRL).

5. FDA will continue to issue IRs and/or DRLs late in the review cycle, until it is no longer feasible, within the current review cycle, for applicant to develop and FDA to review a complete response to the IR and/or DRL.

6. FDA should continue to work through the goal date if in FDA’s judgment continued work would likely result in an imminent tentative approval that could prevent for-for of 180-day exclusivity or in an imminent approval.

7. FDA will strive to act prior to a goal date when the review is done and there are no outstanding issues.

8. If in the ordinary course a Regulatory Project Manager learns that a major deficiency is likely forthcoming, the RPM will notify the Authorizer Representative that a major deficiency is likely forthcoming. If the RPM determines that a major deficiency raises concerns or seeks additional information regarding the forthcoming major deficiency, the RPM will encourage the Authorizer Representative to review the forthcoming deficiency upon receiving it.

9. If in the ordinary course an RPM learns that FDA is likely to miss the goal date for the submission, the Regulatory Project Manager of the Authorizer Representative of the outstanding discipline(s), the general nature of the delay (when possible), and the estimated time-frame for receiving the response.

10. The Authorized Representative may periodically request a Review Status Update. In response to the Authorized Representative’s request, FDA will timely provide a Review Status Update.

11. FDA will include in the CRL its basis for classifying a responding amendment Major.

12. Applicants may opt for a post-CRL teleconference to seek clarification concerning deficiencies identified in a CRL. FDA will grant requests for teleconferences requested by applicants upon receiving first cycle major complete response letters. FDA will also grant appropriate requests for teleconferences requested by applicants upon receiving subsequent major complete response letters or minor complete response letters. FDA will provide a scheduled date for 90 percent of post-CRL teleconferences within 10 days of the request for a teleconference, and conduct 90 percent of post-CRL teleconferences held on the FDA-proposed date, within 30 days of receipt of the written request.

C. Review Classification Changes During the Review Cycle

To promote transparency and communication between FDA and ANDA applicants, FDA will apply the enhancements below to the review of all ANDAs. The goal of these program enhancements is to improve predictability and transparency, promote the benefits of flexibility of the review process, minimize the number of review cycles necessary for approval, increase the overall rate of approval, and facilitate greater access to generic drug products.

1. FDA will issue the appropriate Information Request(s) (IRs) and/or Discipline Review Letter(s) (DRLs) from each review discipline as soon as the discipline has completed its review, with the first IRs and/or DRLs at about the mid-point of the review.

2. Following IR classification status at about the mid-point of the review, IRs and/or DRLs will, as appropriate, continue from each review discipline on a rolling basis.

3. Neither IRs nor DRLs stop the review clock or add to a GDUF A goal.

4. If an applicant is unable to completely respond within the time frame requested by FDA, including any extensions that may be granted by FDA, then FDA will generally issue a Complete Response Letter (CRL).

5. FDA will continue to issue IRs and/or DRLs late in the review cycle, until it is no longer feasible, within the current review cycle, for applicant to develop and FDA to review a complete response to the IR and/or DRL.

6. FDA should continue to work through the goal date if in FDA’s judgment continued work would likely result in an imminent tentative approval that could prevent forfeiture of 180-day exclusivity or in an imminent approval.

7. FDA will strive to act prior to a goal date when the review is done and there are no outstanding issues.

8. If in the ordinary course a Regulatory Project Manager learns that a major deficiency is likely forthcoming, the RPM will notify the Authorizer Representative that a major deficiency is likely forthcoming. If the RPM determines that a major deficiency raises concerns or seeks additional information regarding the forthcoming major deficiency, the RPM will encourage the Authorizer Representative to review the forthcoming deficiency upon receiving it.

9. If in the ordinary course an RPM learns that FDA is likely to miss the goal date for the submission, the Regulatory Project Manager of the Authorizer Representative of the outstanding discipline(s), the general nature of the delay (when possible), and the estimated time-frame for receiving the response.

10. The Authorized Representative may periodically request a Review Status Update. In response to the Authorized Representative’s request, FDA will timely provide a Review Status Update.

11. FDA will include in the CRL its basis for classifying a responding amendment Major.

12. Applicants may opt for a post-CRL teleconference to seek clarification concerning deficiencies identified in a CRL. FDA will grant requests for teleconferences requested by applicants upon receiving first cycle major complete response letters. FDA will also grant appropriate requests for teleconferences requested by applicants upon receiving subsequent major complete response letters or minor complete response letters. FDA will provide a scheduled date for 90 percent of post-CRL teleconferences within 10 days of the request for a teleconference, and conduct 90 percent of post-CRL teleconferences held on the FDA-proposed date, within 30 days of receipt of the written request.

D. ANDA Approval and Tentative Approval

If applicants submit and maintain ANDAs consistent with the statutory requirements for approval under 21 C.F.R. Part 314 and 216, including information concerning notice (21 CFR 314.95), litigation status (21 CFR 314.107), and commercial marketing (21 CFR 314.109), then FDA will approve ANDAs in the first review cycle; to approve potential first generics on the earliest lawful ANDA approval date, if known by FDA; and to approve ANDAs first to file Paragraph IV ANDAs so as to avoid forfeiture of 180-day exclusivity.

E. Dispute Resolution

1. An applicant may pursue a request for reconsideration within the review discipline at the Division level or original signatory authority, as needed.

2. The Office of Generic Drugs (OGD) Office of Regulatory Operations Associate Director will track each request for Division level reconsideration through resolution.

3. Following resolution of a request for reconsideration, the applicant may pursue a formal dispute resolution above the Division level, pursuant to procedures set forth in the September 2015 Guidance, Formal Dispute Resolution: Appeals Above the Division Level.

4. FDA will respond to appeals above the Division level within 30 calendar days of the request for a formal dispute resolution. FDA will also grant appropriate review decisions and provide a schedule for the review decision. FDA will also grant appropriate review decisions and provide a schedule for the review decision.
III. PRE-ANDA PROGRAM AND SUBSEQUENT MID-DRUGS WERE VOLUNTARILY WITHDRAWN FROM SALE IMPORTANT. FOR EXAMPLE, OTHER PROGRAM FUNCTION DOES NOT IMPLY THAT THE PROGRAM FUNCTION IS NOT IMPORTANT. FOR EXAMPLE, OTHER PROGRAM FUNCTIONS INCLUDE DETERMINATIONS WHETHER LISTED DRUGS WERE VOLUNTARILY WITHDRAWN FROM SALE FOR ANY REASON OR EFFICACY AND ANDA PROPRIETARY NAME REVIEWS.

A. Rationale for Pre-ANDA Program, Guidance on Enhanced Pathway for Complex Products

The goal of the pre-ANDA program is to clarify regulatory expectations for prospective applicants early in product development, assist applicants to develop more complete submissions, promote a more efficient and effective ANDA review process, and reduce the number of cycles required to obtain ANDA approval, particularly for Complex Products.

1. FDA will issue guidance describing an enhanced pathway for Complex Products, including policies and procedures for Product Development Meetings, pre-submission meetings, and mid-review cycle meetings. An ANDA applicant who was granted a Product Development Meeting has the option of a pre-submission meeting with FDA and also the option of a mid-review-cycle meeting with FDA to discuss policies and procedures to be set forth in the guidance.

B. Controlled Correspondence

1. FDA will review and respond to standard controlled correspondence and to complex controlled correspondence with meaningful responses that can more consistently inform drug development and/or regulatory decision making pursuant to the applicable metric goals.

C. Product-Specific Guidance

1. FDA will issue product-specific guidance identifying the methodology for developing drugs and generating evidence needed to support the approval, for 90 percent of new chemical entity New Drug Applications that are approved on or after October 1, 2017, at least 2 years prior to the earliest lawful ANDA filing date.

2. This goal shall not apply to Complex Products. FDA will strive to issue guidance for a Complex Product as soon as scientific recommendations are available.

3. FDA will continue to develop and issue product-specific guidance based on requests from industry and public health priorities as set forth in the CDER Prioritization MAP.

4. Industry may request that FDA develop product-specific guidance via email to genericdrugs@fda.hhs.gov. After considering industry and stakeholder input, FDA will post the list on FDA’s website.

D. Product Development Meetings

1. FDA will grant a prospective applicant a Product Development Meeting if, in FDA’s judgment:
   a. The requested Product Development Meeting is needed.
   b. Development of a Complex Product for which FDA has not issued product-specific guidance or
   c. An alternative equivalence evaluation (i.e., change in study type, such as in vitro to clinical) for a Complex Product for which FDA has issued product-specific guidance.

2. If the prospective applicant submits a complete meeting package, including a data package and specific proposals,
   a. A controlled correspondence response would not adequately address the prospective applicant’s questions, and
   b. A Product Development Meeting would significantly improve ANDA review efficiency.

3. FDA will grant or deny 90% of Product Development Meeting requests within the applicable goal.
   a. In FYs 2018 and 2019, the goal is 30 days from receipt of the request.
   b. In FYs 2020, 2021 and 2022, the goal is 14 days from receipt of the request.

4. FDA will conduct Product Development Meetings granted pursuant to the applicable goal.
   a. In FY 2018, FDA will conduct 60 percent of such meetings within 120 days of granting them.
   b. In FY 2019, FDA will conduct 70 percent of such meetings within 120 days of granting them.
   c. In FY2020, FDA will conduct 80 percent of such meetings within 120 days of granting them.
   d. In FYs 2021 and 2022, FDA will conduct 90 percent of such meetings within 120 days of granting them.

5. FDA will conduct 90 percent of Product Development Meeting Goal by either conducting a meeting or providing a meaningful written response that will inform drug development and/or regulatory decision making to the prospective applicant, within the applicable goal date.

6. Unless FDA is providing a written response to satisfy the Product Development Meeting goal, FDA will provide preliminary written comments at the Pre-Product Development Meeting (and aspire to provide the written comments 5 calendar days before the meeting), and will provide meeting minutes within 30 calendar days following the meeting.

E. Pre-Submission Meetings

1. Prospective applicants may request and FDA will conduct pre-submission meetings, subject to Section III(A)(1). An applicant’s decision not to request a pre-submission meeting will not prejudice the receipt or review of an ANDA.

2. FDA will grant or deny 90% of pre-submission meeting requests within the applicable goal.
   a. In FYs 2018 and 2019, the goal is 30 days.
   b. In FYs 2020, 2021, and 2022, the goal is 14 days.

3. If an applicant did not have a Product Development Meeting, FDA may grant a pre-submission meeting if in FDA’s judgment the pre-submission meeting would improve review efficiency.

4. FDA will conduct pre-submission meetings granted pursuant to the applicable goal.
   a. In FY 2018, FDA will conduct 60 percent of such meetings within 120 days of granting them.
   b. In FY 2019, FDA will conduct 70 percent of such meetings within 120 days of granting them.
   c. In FY2020, FDA will conduct 80 percent of such meetings within 120 days of granting them.
   d. In FYs 2021 and 2022, FDA will conduct 90 percent of such meetings within 120 days of granting them.

5. If appropriate to the purpose of the meeting, FDA will provide preliminary written comments 5 calendar days before each meeting, and meeting minutes within 30 calendar days of the meeting.

F. Mid-Review-Cycle Meetings for Complex Products

As set forth in guidance issued pursuant to Section III(A)(1), the Project Manager and other appropriate members of the FDA review team will call this meeting to provide the applicant with an update on the status of the review of their application. An agenda will be sent to the applicant prior to the mid-review-cycle meeting. The Project Manager will coordinate the specific date and time of the telephone call with the applicant.

G. Inactive Ingredient Database Enhancements

1. By October 1, 2020, FDA will complete enhancements to the Inactive Ingredient Database so users can perform electronic queries to obtain accurate Maximum Daily Intake and Maximum Daily Exposure information for inactive ingredients. Such notices will include each change made and, for each change, the information replaced.

H. Regulatory Science Enhancements

FDA will conduct internal and external research to support fulfillment of submission review and pre-ANDA commitments set forth in Sections I and II, respectively.

1. Annually, FDA will conduct a public workshop to solicit industry and stakeholders for inclusion in an annual list of GDUFA II Regulatory Science initiatives. Interested parties may propose regulatory science initiatives via email to genericdrugs@fda.hhs.gov. After considering industry and stakeholder input, FDA will post the list on FDA’s website.

2. If industry adopts a GDUFA II regulatory science working group, then upon request of the working group to the Director of the Office of Research and Standards in the Office of New Drugs, FDA will meet with the working group twice yearly to discuss current and emerging challenges and concerns. FDA will post minutes of these meetings on its website.

3. Annually, FDA will report on its website the extent to which GDUFA regulatory science-funded projects support the development of generic drug products, the generation of evidence needed to support efficient review and timely approval of ANDAs, and the evaluation of generic drug equivalence.

1. Safety Determination Letters

1. FDA aspires to continually improve the effectiveness of its pre-ANDA activity.

2. The absence of a GDUFA II commitment for a specific program function does not imply that the program function is not important. For example, notwithstanding the absence of a GDUFA II commitment, FDA aspires to respond to Suitability Petitions in a more timely and predictable manner.

IV. DMF REVIEW PROGRAM ENHANCEMENTS

A. Communication of DMF Review Comments

1. FDA will ensure that DMF review comments are published and issued at least in parallel with the issuance of review comments relating to the DMF for
Type II API DMF and submission mechanisms to the review of the referencing ANDA. FDA will issue a no further comment letter.

2. DMP holders must request such teleconferences in writing within 20 business days of issuance of the first cycle DMP deficiency letter and must specifically address the issues to be addressed. FDA may initially provide a written response to the request for clarification, but if the DMF holder indicates that a teleconference is still desired, FDA will schedule the teleconference.

3. FDA will strive to grant such teleconferences within 30 days, giving priority to DMFs based on the priority of the referencing ANDA.

4. In lieu of a teleconference, the DMF holder may submit a request for an email exchange between FDA and the DMF holder. The request must identify specific issues to be addressed. After FDA responds to the request, if the DMF holder may submit a request for a teleconference, FDA will respond, to one follow up email to obtain additional clarification.

C. DMF First Adequate Letters

1. Once a DMF has undergone a full scientific review, open issues related to the review of the referencing ANDA, FDA will issue a First Adequate Letter.

D. DMF No Further Comment Letters

1. Once a DMF has undergone a complete review and the ANDA referencing the DMF has been approved or tentatively approved, FDA will issue a no further comment letter.

E. Guidance on Post-Approval Changes to Type II DMFs

1. By October 1, 2018, FDA will issue a guidance regarding post-approval changes to a Type II API DMF and submission mechanisms for ANDA applicants who reference the Type II API DMF.

V. FACILITIES

A. Guidance on Risk-Based Site Selection Model—Issue a guidance explaining the Agency’s risk-based surveillance model for human pharmaceutical manufacturing establishments, including a discussion of the risk factors incorporated in the model and how the model is used to prioritize inspections. Additionally, FDA will publish the risk-based site selection model to facilitate feedback.

B. Outreach to Foreign Regulators on Risk-Based Site Selection Model—Undertake outreach activities to better inform other pharmaceutical regulators of FDA’s risk-based surveillance model.

C. Export Support and Education of Other Health Authorities—Support the export of safe and effective pharmaceutical products by the U.S.-based pharmaceutical industry, including but not limited to timely updates to FDA’s Facility Compliance Status Database as described below, and educating other health authorities. FDA’s surveillance inspection program and the meaning of inspection classifications.

D. Communications to Foreign Regulators—Upon request or written or email request by an establishment physically located in the U.S. that has been included as part of a marketing application submitted to a foreign regulatory authority, FDA will provide within 30 days of the date of receipt of the request a written communication to that foreign regulator conveying the current compliance status for the establishment.

E. Communication Regarding Inspections

1. By May 31, 2018, when FDA conducts an application-related inspection of a facility or site named in the ANDA, PAS, or associated Type II DMF and identifies outstanding issues that could prevent approval of an ANDA or PAS, the applicant will be notified that issues involve either IR, RDL, or RCR pursuant to Section III(B) above.

2. By October 1, 2018, FDA agrees to communicate to the facility owner final inspection classification that cannot be negligibly impacted by any pending application within 90 days of the end of the inspection. FDA agrees to ongoing periodic engagement in discussions with industry to provide updates on agency activities and seek stakeholder feedback.

F. GDUFA II Facility Compliance Status Database–Effective October 1, 2019, FDA will update its publicly available database that describes the compliance status of GDUFA self-ID facilities and sites. Compliance status is based on the most recent inspection or related FDA action for facilities involved in any manufacturing activities subject to Current Good Manufacturing Practices (CGMP) inspection and for sites involved in the conduct or analysis of bioanalytical or clinical bioequivalence/bioavailability studies conducted to support an ANDA. The database will be updated every 30 days and will reflect FDA’s final assessment of the facility or site following an FDA inspection and review of the inspected entity’s timely corrective action observations. The public website containing the database will also include an explanation of terms used to describe the compliance status of facilities and sites.

VI. ENHANCED ACCOUNTABILITY AND REPORTING

A. Resource Management Planning and Modernized Time Reporting

FDA is committed to enhancing management of the GDUFA program in GDUFA II.

1. FDA will conduct activities to develop a resource management planning function and modernized time reporting approach in GDUFA II. FDA will staff a planning team responsible for planning and for publishing a GDUFA program resource management planning and modernized time reporting implementation plan no later than fourth quarter of 2018.

2. FDA will obtain through a contract with an independent third party an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource needs of the human generic drug review program and how to monitor and report on those needs moving forward. The report will be published by the end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing the resource needs of the program and tracking resource utilization across the program elements.

B. Financial Transparency and Efficiency

FDA is committed to ensuring GDUFA user fee resource planning, allocation, and reporting in an efficient and transparent manner. FDA will conduct activities to enhance the financial administration of the GDUFA program to help identify areas to enhance operational and fiscal efficiency. FDA will also conduct activities to enhance transparency of how GDUFA program resources are used.
A. Act on an application—means FDA will either issue a complete response letter, an approval, a tentative approval, or a refusal-to-receive action.

B. Ambiguity in the controlled correspondence response—means the controlled correspondence review and/or final response which requires a clarifying action on the part of FDA, that carries with it, in FDA’s judgment, a lack of clarity.

C. Appropriate, with respect to a request for a post-CRL teleconference—means a complete and clear request for a teleconference where the applicant’s goal is to gain an understanding of specific deficiencies and expectations for resolution.

D. Authorized Representative—means the authorized point of contact identified in the applicant’s letter of authorization or Form 3820, Details of Correspondence Related to Generic Drug Development, or at the conclusion of the first DMF review cycle. A complete response letter (CRL) refers to a letter used to convey preliminary thoughts or possible alternative approach would benefit from early scientific engagement.

E. As a change to facility information—means a change to information in the Pre-Submission Facilities Correspondence that causes FDA to re-evaluate the facility’s assessment (i.e., assess the impact of the change on its previous recommendation), such as a change in facility (as described by address, FDA Establishment Identification (FEI) number, or Data Universal Numbering System (DUNS) number), change in operator (s) performed by a facility, addition of a new facility, withdrawal of a facility used to generate application materials or intended for commercial production, or a change in inspection readiness (i.e., a facility is no longer ready for inspection).

G. Complex Product—generally includes 1. Products with complex active ingredients (e.g., peptides, polymeric compounds, complex mixtures of APIs, naturally sourced ingredients); complex formulations (e.g., liposomes); complex routes of delivery (e.g., locally acting drugs such as dermatological products and complex ophthalmological products and otic dosage forms that are formulated as suspensions, emulsions or gels) or complex dosage forms (e.g., transdermals, metered dose inhalers, extended release injectables);

H. Complex controlled correspondence—means controlled correspondence involving evaluation of clinical content.

I. Bioequivalence protocols for Reference Listed Drugs with Risk Evaluation and Mitigation Strategies (REMS) and Elements To Ensure Safe Use (ETASU), or

J. Requested evaluations of alternative bioequivalence approaches within the same study type (e.g., pharmacokinetic, in vitro, clinical).

K. Discipline review letter (DRL)—means a letter used to convey preliminary thoughts on possible deficiencies found by a discipline reviewer and/or review team for its portion of the pending application at the conclusion of the discipline review.

L. Earliest ANDA approval date—the first date on which no patent or exclusivity prevents full approval of an ANDA.

M. First adequate letter—a communication from FDA to DFM holder indicating that the DFM has no open issues related to the review of the referencing ANDA. Issued only at the conclusion of the first DFM review cycle that determines the DFM does not have any open issues.

N. First generic—any received ANDA (1) that is a first-to-file ANDA eligible for 180-day post-approval exclusivity, (2) for which there are no previously approved ANDAs containing a patent(s) or exclusivities and (2) for which there is no previously approved ANDA for the drug product.

O. Information Request (IR)—means a letter that is sent to an applicant during a review to request further information or clarification that is needed or would be helpful to allow completion of the discipline review.

P. Major amendment—means a major amendment as described in CDER’s December 2001 Guidance for Industry: Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications.

Q. Mid-review-cycle meeting—after the last key discipline has issued its IR and/or DRL, for ANDA that is subject of a pre-submission meeting or pre-submission meetings, CDER will schedule a teleconference meeting with the applicant to discuss current concerns with the application and next steps.

R. Minor amendment—means a minor amendment as described in CDER’s December 2001 Guidance for Industry: Major, Minor and Telephone Amendments to Abbreviated New Drug Applications.

S. Complete response—refers to a full division-by-division response to all of the deficiencies that FDA has identified in an abbreviated application (including pending amendments) or a DFM that must be satisfactorily addressed before the ANDA or DMF is ready for inspection, a description of the modifications or intended for commercial production, or a change in inspection readiness (i.e., a facility is no longer ready for inspection).

T. Pre-submission meeting—means a meeting in which an applicant has an opportunity to discuss and explain the format and content of an ANDA to be submitted. Although the proposed content will not be discussed, pre-submission meetings will not include substantive review of summary data or full study reports.

U. Priority—means submissions affirmatively identified as eligible for expedited review pursuant to CDER’s Manual of Policy and Procedures (MAPP) 5200.3, Prioritization of Generic Application Development, or full study reports.

V. Product Development Meeting—means a meeting involving a scientific exchange to discuss specific issues (e.g., a proposed study design, alternative approach or additional study expectations) or questions, in which FDA will provide targeted advice regarding an ongoing ANDA development program.

W. Review Status Update—means a report issued by the RPM available to the Authorized Representative to update the Authorized Representative concerning, at a minimum, the categorical status of relevant review disciplines and next steps for approval at that time. The RPM will advise the Authorized Representative that the update is preliminary only, based on the RPM’s interpretation of the submission, and subject to change at any time.

X. Safety determination letter—a letter from FDA stating that a bioequivalence study that is not comparable to applicable REMS for the Reference Listed Drug.

Y. Standard—means submissions not affirmatively identified as eligible for expedited review pursuant to the CDER Prioritization MAPP.

Z. Standard controlled correspondence—means correspondence corresponding to a letter from FDA that is not comparable to applicable REMS for the Reference Listed Drug.

AA. Target Action Date (TAD)—Under GDUFIA I, FDA’s aspirational deadline for issuing a pre-DMF notification of the ANDA and/or a complete response amendment or equivalent IR to an original ANDA.
Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD a copy of the commitment letter for the Medical Device User Fee Amendments of 2017.

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

MDUFA PERFORMANCE GOALS AND PROCEDURES, FISCAL YEARS 2018 THROUGH 2022

I. SHARED OUTCOME GOALS

The performance goals and procedures agreed to by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (“FDA” or “the Agency”) for the medical device user fee program in the Medical Device User Fee Amendments of 2017, are summarized below.

FDA and the industry are committed to protecting and promoting public health by providing timely access to safe and effective medical devices. Nothing in this letter precludes the Agency from protecting the public health by exercising its authority to provide a reasonable assurance of the safety and effectiveness of medical devices. Both FDA and the industry are committed to the spirit and intent of the goals described in this letter.

1. SHARED OUTCOME GOALS

The program and initiatives outlined in this document are predicated on significant interaction between the Agency and applicants. FDA and representatives of the industry agree that the process improvements outlined in this letter, when implemented by all parties, would, should reduce the average Total Time to Decision for PMA applications and 510(k) submissions, provided that the total funding of the device review program adheres to the assumptions underlying the program as described in the Guidance on “Revised Performance Goals and Procedures for FY 2017.”

A. Pre-Submissions

For Pre-Submissions in which the applicant requests a meeting or teleconference, FDA will continue the Pre-Submission program as described in the Guidance on “Revised Performance Goals and Procedures for FY 2017.” The Pre-Submission Program and Meetings with FDA Staff will be initiated by written communication that a) identifies the reason for the request, which could be a) an unsolicited amendment, and b) a written communication that a) identifies the reason for the request, which could be a) an unsolicited amendment, and c) if the submission included a request for a meeting or teleconference and FDA intends to reach agreement with the applicant regarding a meeting date within 30 days.

B. 510(k)

For 510(k) submissions received beginning in Fiscal Year 2018, the average Total Time to Decision goal for FDA and industry is 116 calendar days.

For 510(k) submissions received beginning in Fiscal Year 2019, the average Total Time to Decision goal for FDA and industry is 112 calendar days.

For 510(k) submissions received beginning in Fiscal Year 2020, the average Total Time to Decision goal for FDA and industry is 108 calendar days.

For 510(k) submissions received beginning in Fiscal Year 2021, the average Total Time to Decision goal for FDA and industry is 112 calendar days.

For 510(k) submissions received beginning in Fiscal Year 2022, the average Total Time to Decision goal for FDA and industry is 108 calendar days.

Meetings and teleconferences related to the Pre-Submission will normally be limited to 1 hour unless the applicant justifies in writing the need for additional time. FDA may extend the time for such meetings and/or teleconferences.

Applications will be responsible for developing draft minutes for a Pre-Submission meeting or teleconference and provide the draft minutes to FDA within 15 calendar days after the applicant receives FDA’s edits, unless the applicant indicates that there is a
disagreement with how a significant issue or action item has been documented. In this case, within a timely manner, the applicant and FDA will conduct a teleconference to discuss the issue and FDA. At the conclusion of that teleconference, within 15 days FDA will finalize the minutes either to reflect the resolution of the issue or note that this constitutes a point of disagreement.

FDA intends that feedback the Agency provides in a Pre-Submission will not change, provided the information submitted in a Pre-Submission is consistent with that provided in the Pre-Submission and documented in the Pre-Submission, and that the data and other information submitted in the Pre-Submission does not raise any important new issues materially affecting safety or effectiveness. The minutes described above will serve as the record of the Agency’s Pre-Submission feedback. Modifications to FDA’s feedback will be limited to situations in which FDA concludes that the feedback does not adequately address important new issues materially relevant to a determination of safety and/or effectiveness or substantial equivalence. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

By October 1, 2018, the Agency will update the Guidance for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff to include: additional information to assist applicants in determining the need for a Frequent Interactions or Pre-Submission interaction, examples of frequently asked Pre-Submission questions that have been productive in Pre-Submission interactions, and edits to reflect the revised process outlined above. FDA will provide an opportunity for the public to comment on the updated guidance. No later than 12 months after the close of the public comment period, the Agency will issue a final guidance. FDA will implement this guidance once final.

B. Original Premarket Approval (PMA), Panel-Track Supplements, and Premarket Report Applications

The performance goals in this section apply to all Original Premarket Approval, Panel-Track Supplement, and Premarket Report Applications, including those that are accepted for priority review (previously referred to as expedited).

FDA will communicate with the applicant regarding whether the application has been accepted for filing review within 15 calendar days of receipt of the application. This communication consists of a fax, email, or other written communication that a) identifies the reviewer assigned to the submission, and b) acknowledges acceptance/rejection of the submission based upon the review of the submission against objective acceptance criteria outlined in a published guidance document and consistent with the statute and its implementing regulations.

If the application is not accepted for filing review, FDA will notify the applicant of those items necessary for the application to be considered accepted for filing review.

For those applications that are accepted for filing review, FDA will communicate the filing status within 45 calendar days of receipt of the application.

For those applications that are not filed, FDA will communicate with the applicant the specific deficiencies and the information necessary for filing.

If the application is filed, FDA will communicate with the applicant through a Substantive Interaction within 90 calendar days of the filing date of the application for 95% of submissions.

When FDA issues a major deficiency letter, that letter will be based upon a complete review of the application and will include all deficiencies. All deficiency letters will include a substantive interaction with objective acceptance criteria (e.g., a specific reference to applicable section of a rule, final guidance, recognized standard unless the entire or most of document is applicable). In the instance when the deficiency cannot be traced in the manner above and relates to a scientific or regulatory issue pertinent to the determination, FDA will cite the specific scientific or regulatory issue pertinent to the determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

For submissions that do not require Advisory Committee input, FDA will issue a MDUFA decision within 180 FDA Days for 90% of submissions.

For submissions that require Advisory Committee input, FDA will issue a MDUFA decision within 320 FDA Days from receipt of the accepted submission for 90% of submissions. FDA will issue a MDUFA decision within 320 FDA Days of the Advisory Committee recommendation, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. The Office Director shall review each request for Advisory Committee input for appropriateness and need for this input. If in any one fiscal year, the number of submissions that require Advisory Committee input is less than 10, then it is acceptable to combine such submissions with the submissions for the following year(s) in order to meet the performance goals outlined in this section. If the number of combined years’ submissions will be subject to the performance goal. If the number of submissions that require Advisory Committee input is less than 10 for FY 2022, it is acceptable to combine such submissions in the prior year to form a cohort of 10 or more submissions: in such cases, FDA will be held to the FY2022 performance goal for the combined years’ submissions.

To facilitate an efficient review prior to the Substantive Interaction, FDA will encourage and incentivize submission of a complete application, submission of an unsolicited major amendment prior to the Substantive Interaction, and submission of a pre-submission document. If the number of FDA Days that have elapsed, Submission of an unsolicited major amendment after the Substantive Interaction extends the FDA Day goal by the number of FDA Days equal to 75% of the difference between the filing date and the date of receipt of the amendment. Requests from FDA that a submission be made will not be considered unsolicited.

For all PMA submissions that do not reach a MDUFA decision by 20 days after the applicant has provided written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the application and their respective deficiencies. The information provided will reflect appropriate management input and approval, and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks. Issues should be reviewed through an interactive review. If all of the outstanding issues are adequately presented through written correspondence, FDA and the applicant can agree that a meeting or teleconference not necessary.

For PMA submissions that receive a MDUFA decision of Approvable, FDA will issue a decision within 180 FDA Days of the sponsor’s response to the Approvable letter, as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations.

In addition, information about submissions that miss the FDA Day goal will be provided as part of FDA’s Performance Reports, as described in Section VI.

C. 180-Day PMA Supplements

FDA will communicate with the applicant through a Substantive Interaction within 90 calendar days of receipt of 95% of submissions.

FDA will issue a MDUFA decision within 180 FDA Days for 95% of submissions.

D. Real-Time PMA Supplements

FDA will issue a MDUFA decision within 90 FDA Days for 95% of submissions.

E. De Novo Submissions

FDA will issue draft and final guidance that includes a submission for 95% of submissions to facilitate a more efficient and timely review process.

The deficiencies identified will be based upon a complete review of the submission and will include all deficiencies. All deficiency letters will include a statement of the basis for the determination, consistent with the deficiencies cited are relevant to a classification determination. Any subsequent deficiencies will be limited to issues raised based on information provided by the applicant in its response, unless FDA concludes that the deficiencies identified do not adequately address important new issues materially relevant to a determination of safety or effectiveness. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

Requests related to post-approval studies, if applicable, and revisions to draft labeling will typically be addressed through interactive review with deficiencies. All deficiency letters will include all deficiencies. All deficiency letters will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks.

F. 510(k) Submissions

FDA will issue a MDUFA decision within 180 FDA Days for 95% of submissions.

FDA will issue a MDUFA decision within 150 FDA Days of receipt of the submission for: 50% of de novo requests received in FY 2018; 55% of de novo requests received in FY 2019; 60% of de novo requests received in FY 2020; 65% of de novo requests received in FY 2021 and 70% of de novo requests received in FY 2022. At Industry’s request and as resources permit, but not to the detriment of meeting the quantitative review timelines, if a final decision has not been rendered within 180 FDA Days, FDA will discuss with the applicant the outstanding issue preventing FDA from reaching a decision. This discussion will reflect appropriate management input, and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each party to complete their respective tasks.
accepted for review within 15 calendar days of receipt of the submission. For those submissions that are not accepted for review, FDA will notify the applicant of those items necessary for the submission to be considered accepted.

This communication includes a fax, email, or other written communication that a) identifies the reviewer assigned to the submission, and b) acknowledges acceptance/rejection of the submission based upon the review of the submission against management acceptance criteria outlined in a published guidance document. This communication represents a preliminary review of the submission and is not indicative of deficiencies that may be identified later in the review cycle.

FDA will communicate with the applicant through a Substantive Interaction within 60 calendar days of receipt of the submission for 95% of submissions.

Deficiencies identified in a Substantive Interaction, such as a telephone/email hold or Additional Information Letter, will be based upon a complete review of the submission and will include all deficiencies. All deficiency letters will include a statement of the basis for the deficiencies (e.g., a specific reference to applicable section of a rule, final guidance, or regulatory standard). For deficiencies that are not adequate, with an estimated date of completion, including all outstanding issues with the application preventing FDA from reaching a decision. The information provided will reflect appropriate management input and approval, and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each task to complete their respective tasks. Issues should be resolved through interactive review. If all of the outstanding issues are resolved through written correspondence, FDA and the applicant can agree that a meeting or teleconference is not necessary.

In addition, all submissions that miss the FDA Day goal will be provided as part of FDA’s Performance Reports, as described in Section VI.

In addition:
1. Hold CLIA Waiver Vendor Days, with the first to occur before the end of FY2018.
2. Permit discussion of both 510(k) and CLIA waiver submissions.
3. Specifically permit discussion of appropriate reference/comparator for both 510(k) and CLIA waiver submissions in Pre-Submissions.
4. Provide a status report on completion and issuance of revisions to Section V of the Guidance on “Recommendations for CLIA Waiver Applications” to include appropriate use of comparable performance between a waived user and moderately complex laboratory user to demonstrate accuracy.

H. Original Biologicals Licensing Applications (BLAs)
FDA will review and act on standard original BLA submissions within 10 months of receipt for 90% of submissions.

FDA will review and act on priority original BLA submissions within 6 months of receipt for 90% of submissions.

I. BLA Efficacy Supplements
FDA will review and act on standard BLA efficacy supplements within 10 months of receipt for 90% of submissions.

FDA will review and act on priority BLA efficacy supplement submissions within 6 months of receipt for 90% of submissions.

J. Original BLA and BLA Efficacy Supplement Resubmissions
FDA will review and act on Class 1 original BLA and BLA efficacy supplement resubmissions within 2 months of receipt for 90% of submissions.

FDA will review and act on Class 2 original BLA and BLA efficacy supplement resubmissions within 6 months of receipt for 90% of submissions.

K. BLA Manufacturing Supplements Requiring Prior Approval
FDA will review and act on BLA manufacturing supplements requiring prior approval within 4 months of receipt for 90% of submissions.

L. MDUFA Decision Timelines
For “CLIA Waiver by application” submissions, FDA will issue a MDUFA decision for 90% of the applications that do not require Advisory Committee input within 150 FDA days.

For “CLIA Waiver by application” submissions FDA will issue a MDUFA decision for 90% of the applications that require Advisory Committee input within 250 FDA days. If in any one fiscal year, the number of submissions issued by Application category is less than 10, then it is acceptable to combine such submissions with the submissions for the following year(s) in order to form a cohort. Submissions, upon which the combined years’ submissions will be subject to the performance goal.

For all CLIA waiver by application submissions and dual submissions that do not reach a decision by 20 days after the applicable FDA Day goal, FDA will provide written feedback to the applicant to be discussed in a meeting or teleconference, including all outstanding issues with the application preventing FDA from reaching a decision. The information provided will reflect appropriate management input and approval, and will include action items for FDA and/or the applicant, as appropriate, with an estimated date of completion for each task to complete their respective tasks. Issues should be resolved through interactive review. If all of the outstanding issues are presented through written correspondence, FDA and the applicant can agree that a meeting or teleconference is not necessary.

In addition, all submissions that miss the FDA Day goal will be provided as part of FDA’s Performance Reports, as described in Section VI.

In addition, FDA will:

1. Hold CLIA Waiver Vendor Days, with the first to occur before the end of FY2018.
2. Permit discussion of both 510(k) and CLIA waiver permissions.
3. Specifically permit discussion of appropriate reference/comparator for both 510(k) and CLIA waiver submissions in Pre-Submissions.
4. Provide a status report on completion and issuance of revisions to Section V of the Guidance on “Recommendations for CLIA Waiver Applications” to include appropriate use of comparable performance between a waived user and moderately complex laboratory user to demonstrate accuracy.
D. Training

FDA will continue to improve training for new and existing reviewers under this agreement. FDA will achieve Kirkpatrick Level 3 for curriculum-based premarket training throughout the year. Workforce performance behavior change and evaluate the effectiveness of the impact of curriculum-based premarket training activities on relevant premarket program metrics and goals (Kirkpatrick Level 4) by the end of FY 2020. FDA training efforts will also be closely coordinated with the Quality Management Unit described in item 1.3 above to provide more targeted and personalized training to staff.

E. Time Reporting

FDA will implement complete time reporting by the end of MDUFA IV such that data from time reporting can be used to conduct workload analysis and capacity planning.

F. Fee Setting, Fee Collections, and Workload

FDA will seek authority to eliminate the fifth-year offset provision and to maintain and use any and all fee collections, including collections over the statutory total revenue targets.

If the collections are in excess of the revenue targets, any such collection in excess is given the workload, or in excess of inflation-adjusted statutory revenue targets, FDA and industry will work together to assess how best to allocate resources to improve performance on submission types with performance goals and/or quality management programs, using, as input for the discussion: workload information, performance objectives, and ongoing reported performance.

IV. PROCESS IMPROVEMENTS

A. Interactive Review

The Agency will continue to incorporate an interactive review process to provide for, and enhance, visual and verbal communication between FDA and applicants to facilitate timely completion of the review process based on accurate and complete information. Interactive review entails responsibilities for both FDA and applicants. As described in the guidance document, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMA, PMA Supplements, Original BLAs, and BLA Supplements,” both FDA and industry believe that an interactive review process for these types of premarket submissions should facilitate timely completion of the review based on accurate and complete information. Interactive review is intended to facilitate the early identification of deficiencies and evaluation by FDA of premarket submissions and is expected to support reductions in total time to decision. The interactive review process contemplates increased informal interaction between FDA and applicants, including the exchange of scientific and regulatory information.

B. Deficiency Letters

By October 1, 2017, the Agency will publish a level 2 update to the final guidance “Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA; Final Guidance for Industry and FDA Staff” to reflect the following:

- All deficiency letters will include a statement of whether deficiencies cited are relevant to a marketing authorization decision (e.g., 510(k) clearance, PMA approval, and de novo classification).
- Any additional best practices identified by quality audits and/or the Independent Assessment will be incorporated in updates to the guidance, as appropriate.
- FDA will train staff and managers on this process improvement and the updated guidance.

C. Device Accessories

FDA and Industry will explore additional mechanisms for a streamlined, resource minimal pathway to reclassify accessories previously classified as class III devices as a part of a PMR if this meet the requirements of a low or moderate risk device.

D. Enhanced Use of Consensus Standards

FDA will establish an Accreditation Scheme for Conformity Assessment (ASCA) Program using FDA-recognized consensus standards. FDA will define the “scheme” and oversee the Conformity Assessment (CA) model and ensure that there is appropriate interaction with parties that serve as Accrediting Bodies (ABs) to accredit test laboratories (TLs). When a device type using the “scheme” is evaluated according to a specific recognized standard, an accredited TL, FDA intends to rely on the results from the accredited TL for the purpose of premarket submission and approval. The determination that a device conforms with the standard without the need to address further questions related to standards conformance. Assuming that it meets established criteria as outlined in the ASCA program, a device company’s internal TL will be eligible to participate in the ASCA program. FDA training will not be required beyond where the TL except as part of a periodic quality audit or if FDA becomes aware of new information materially relevant to safety and/or effectiveness.

Specific actions that FDA will undertake include the following:

1. Conduct a Public Workshop by the end of FY 2018 to discuss objectives for the establishment of ABs and TLs. Discussion would include areas (specific FDA-recognized consensus standards) where the ASCA Program can be piloted to maximize initial impact of new and existing CA activities and potential new areas.

2. Hold educational sessions with stakeholders by the end of FY 2018 about the purpose of the ASCA Program.

3. Develop and initiate the pilot of the ASCA Program with stakeholder input by the end of FY 2020.

a. FDA intends to pilot inclusion of recognized standards of public health significance where specific pass/fail criteria are part of the standard.

b. Develop an internal IT system to track CA activities of the ASCA Program.

c. Establish a process for accreditation of ABs and TLs. FDA will issue draft guidance by the end of FY 2019 and issue final guidance within 12 months post initiation of the pilot.

a. In limited circumstances, the FDA may directly accredit third-party TLs. For example, FDA could accredit third-party TLs if FDA has not identified and recognized an AB within 2 years after establishing the tenets of the ASCA program.

b. Establish a process for reaccreditation and the suspension or withdrawal of accreditation of poor performing ABs and TLs. FDA will publish a rule by the end of FY 2019 and final guidance within 12 months post initiation of the pilot.

3. Establish a process for reaccreditation and the suspension or withdrawal of accreditation of poor performing ABs and TLs. FDA will publish a draft and issue final guidance within 12 months post initiation of the pilot.

7. Establish a publicly-accessible website listing third-party ABs. ASCA will also use the FDA-recognized consensus standard(s) for which they are accredited.

8. FDA, in consultation with stakeholders, will identify appropriate recognized consensus standards for consideration as part of the pilot as the specific focus for ASCA.

9. FDA’s report on the viability of, an ASCA program which utilizes the scheme identified in guidance to include utilization of appropriate operational and/or device-specific areas, at least one of which will be device-specific.

b. Standards included as part of the ASCA Program will need to have well established endpoints/acceptance criteria built into the standard to allow effective tracking of TL competence.

FDA will provide an annual report on the progress of the ASCA program.

FDA will work with stakeholders for further improvement on interactive reviews and/or consideration for expansion.

E. Third Party Review

The Agency will take the following actions to improve the Third Party Review program:

1. Strengthen the process for accreditation of Third Parties

   a. Provide training for Third Parties seeking accreditation by FDA. This training shall include the opportunity for Third Parties to access the guidelines and other information as appropriate.

   b. When FDA’s expectations for a particular device type change, FDA will have in place a process to communicate information to the Third Parties and to industry.

2. By the end of FY 2018, establish a plan for eliminating routine re-review by FDA of Third Party reviews and implement plan within 12 months.

3. Implement a program to audit reviews conducted by accredited Third Parties

   a. Provide tailored re-training to accredited Third Parties based on the results of audits.

4. By the end of FY 2018, issue draft guidance outlining criteria for reaccreditation of 3rd Parties and the suspension or withdrawal of accreditation of a Third Party. FDA will issue final guidance within 12 months of the conclusion of the public comment period.

5. Publish performance of individual accredited Third Parties.

   a. Provide training for Third Parties seeking accreditation by FDA. This training shall include the opportunity for Third Parties to access the guidelines and other information as appropriate.

6. Require the independent assessment of the Third Party Review Program to evaluate efficiency including the circumstances when FDA re-reviews were conducted; and to suggest process improvements.

The Agency will seek greater authority to tailor the program. Specifically, FDA intends to expand the scope of the program to some product classes that require clinical data and to remove product codes from eligibility when appropriate, such as if/when safety signals arise.

As resources permit, FDA will identify pilot device areas to be the specific focus of an effort where FDA would work with third-party partners to ensure that information allowing for high quality Third Party reviews could be made available to provide a proof of concept in certain device areas and enable the development of a broader successful program.

F. Patient Engagement & the Science of Patient Input

The Agency will take the following actions to advance patient input and involvement in the regulatory process. Where appropriate, the Agency will leverage public-private partnerships (PPPs) to advance these actions.

1. Strengthen patient and other specific expertise and staff capacity to respond to submissions containing applicant-
proposed use of publicly available and validated, voluntary patient preference information (PPI) or voluntary patient reported outcomes (PROs). These staff will provide submissions for medical device trial consultants to industry during study planning.

2. By the end of FY 2020, hold one or more public meetings to discuss the topics below and provide input and next steps:
   a. Discuss approaches for incorporating PPI and PRO as evidence in device submissions, as well as other ways of advancing patient participation.
   b. Discuss ways to use patient input to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention;
   c. Public meetings should include specific examples of approaches for PPI and PROs to ensure clarity and understanding by workshop attendees; and
   d. Identify priority areas where decisions are preference-sensitive and PPI data can inform regulatory decision-making, in order to advance design and conduct of patient preference studies in high impact areas. Publish the public meeting agendas and meeting minutes for public comment following the public meeting.

3. FDA will undertake several activities to improve the regulatory predictability and impact of PROs, including:
   a. Clarity to device review divisions that use of PROs is voluntary and may be one potential outcome of a non-competing safety or effectiveness finding (or elements of either or both, such as in a composite endpoint). Consistent with least burdensome principles, applicants may use alternative approaches.
   b. Modify the guidance to outline a flexible framework for PRO validation evidentiary thresholds, which may depend on the particular regulatory use of the PRO.
   c. Work on developing a model for "bridging studies" to make efficient use of existing validated PROs which may be improved, or adapted to other subpopulations or other regulatory uses in a more streamlined and expeditious manner than creating novel PROs.
   d. The existing dispute resolution process should be used in the event of disagreement between the Federal Register Notice and the Agency on the need for PPI or PRO.

G. Emerging Diagnostics

FDAs will work with industry to continue the pilot for emerging diagnostics started under 10.

H. Real World Evidence (RWE)

1. The Agency will use user fee revenue to support the National Evaluation System for health Technology (NEST) by providing funding for the NEST Coordinating Center and hiring FDA staff with expertise in the use of RWE. The NEST governing board will include no fewer than 4 representatives of the trade associations that participated in the MDUFA IV negotiations (AdvaMed, MDMA, MITA, and ACLIA), with each association appointing an individual to serve. Industry representation on the NEST governing board will make up at least 25% of the governing board membership. The representative from each trade association may be part of the staff of the association appointed from a member company. If any of the trade associations elects not to participate on the NEST governing board or for any additional reason is not allocated to Industry, the participating trade associations will determine how to fill any vacant Industry positions. The governing board also will include, but may not be limited to, representative from patient organizations. By the end of FY2019, NEST will implement pilots for at least two products codes (and related product codes), one of which will cover devices approved through the PMA process and the other of which will cover devices cleared through the 510(k) pathway. The NEST Coordinating Center will seek ways in which to make NEST financially self-sustaining so as not to rely on MDUFA user fees in the long term unless FDA agrees that continued user fee support is warranted and provides a sufficient return on investment.

2. FDA will contract with an organization to serve as the NEST Coordinating Center to facilitate use of real world evidence to support premarket activities. The contract will specify actions the Coordinating Center will take to achieve, including:
   a. Establish a framework to fund pilot projects to determine the usability of RWE for:
      i. Expanded indications for use
      ii. New clearances/approvals
      iii. Improved malfunction reporting
   b. No later than October 1, 2020, the Coordinating Center will hold a public meeting to review and evaluate the progress and outcomes (as of the date of the public meeting) of the pilots the pilot(s) described in (H)(1) above, FDA will conduct an assessment that the PRO to reflect what has been learned from the pilots as how to best use in operational use.
   c. The pilots will take place over a period of three years, including data analysis and the Coordinating Center will issue a publicly available report of the results.
   d. The pilots will include devices not currently subject to a registry.
   e. At the conclusion of the pilots, an independent panel, long-term that evaluate the strengths, limitations, and appropriate use of RWE for informing premarket decision-making for multiple device types.
   f. If warranted based on the results of the pilot(s) described in (H)(1) above, FDA will revise its guidance on the use of RWE to reflect what has been learned from the pilots as how to best use in updated use.

3. The Agency will establish criteria for streamlining MDR requirements.
   a. For most, if not all, device procedes, FDA will provide policies of such devices that will cover or devices in those protocols to report malfunctions on a quarterly basis and in a summary format. FDAs will publish the list of eligible devices, Class III devices, as appropriate, and will provide a summary list.
   b. FDA may determine that devices under a new protocol in existence for less than 2 years are not eligible for reporting of malfunctions on a quarterly basis and in a summary format.
   c. If new type of malfunction occurs that the manufacturer has not previously reported to FDA, the manufacturer must submit an individual report. The manufacturer will notify FDA when the issue has been resolved, using current requirements per 21 C.F.R. 803, 806.
   d. FDA will maintain on its website the list of eligible device procedes for which manufacturers are permitted to report malfunctions on a quarterly basis and in a summary format.
   e. FDA will establish a mechanism at the time it publishes the list of eligible devices under 3(a) that permits stakeholders to request FDA provide feedback on the list.
   f. Nothing in this section precludes the Agency from requiring individual malfunctions reports from a specific manufacturer and/or for a specific device if necessary to protect public health. In these situations, FDA will notify the manufacturer they are required to provide feedback on the report and provide an explanation for that decision and the steps necessary to return to eligibility for quarterly summary MDR reporting procedures.

4. FDA will not require postmarket surveillance studies (i.e., 522 Studies) for devices for which registries and/or other real world data (RWD) sources exist. RWD sources, including RWE, has access to the information/data in the RWD source and has determined that the information/data in the RWD source is sufficient to support the place of a postmarket surveillance study.

I. Digital Health

The Agency will build expertise and streamline and align FDA review processes with software lifecycles for Software as a Medical Device (SaMD) and software inside of medical devices (SiMD). Specifically, the Agency will:

1. Establish a central digital health unit with FDA’s Office of Device Design at the Agency to ensure proper coordination and consistency across the Agency. The Agency will reorganize behaviors that such existing reviews could be reassigned to the digital health unit, while retaining and not disrupting the existing digital health talent within the review divisions who have expertise with such digital health device.

2. Utilize Technical Experts as appropriate or when requested by the manufacturer for submissions that include SaMD, SiMD, interoperable devices, or otherwise incorporate novel digital health technologies:
   a. Develop software and digital health technologies expertise ("Technical Experts") to provide assistance for premarket submissions that include SaMD, SiMD, interoperable devices, or otherwise incorporate novel digital health technologies; and
   b. Incorporate appropriate metrics for digital health improvements to monitor, track, analyze and report the results of digital health premarket review timelines.

3. Publish final guidance addressing when to submit a 510(k) for a software modification to an existing device beyond 12 months of receiving a proposed list from Industry. The list will include, among other device classes, Class II implantable and Class III devices.

4. Take the place of a postmarket surveillance requirements to an existing device with regulatory decision-making, in order to advance the use of RWE, including:
   a. Engage with stakeholders, including industry, through roundtables, informal meetings, and teleconferences.
   b. Hold a public workshop; and
   c. Revise existing and/or publish new relevant guidance documents, including publishing a draft revised version of the "Guidance for the Content of Summary Submissions for Software Contained in Medical Devices" (issued in 2005) by the end of FY2019, and within 12 months of the close of the comment period, publish the final revised version.

5. Explore opportunities to establish premarket approval/clearance pathways tailored to SaMD, SiMD, and novel digital health technologies that take into account real world evidence while incorporating principles established through international harmonization. To accomplish this task, the Agency will:
   a. Engage with stakeholders, including industry, through roundtables, informal meetings, and teleconferences.
   b. Hold a public workshop; and
   c. Revise existing and/or publish new relevant guidance documents, including publishing a draft revised version of the "Guidance for the Content of Summary Submissions for Software Contained in Medical Devices" (issued in 2005) by the end of FY2019, and within 12 months of the close of the comment period, publish the final revised version.

6. Participate in international harmonization efforts related to digital health, including work on developing SaMD and other digital health technologies through efforts through the International Medical Device Regulators Forum (IMDRF).
FDA will apply user fee revenues to ensure timely completion of Draft Guidance documents. The Agency will strive to finalize, withdraw, reopen the comment period, or issue a new notice for 80% of draft guidance documents within 3 years of the close of the comment periods as resources permit. The Agency will strive to finalize, withdraw, and not continue to develop draft guidance documents and improve the development process as resources permit, but not to the detriment of meeting substantive review timelines and statutory obligations.

K. Total Product Life Cycle (TPLC)

The establishment of CDRH’s Office of In Vitro Diagnostic Device Evaluation and Safety (now the Office of In Vitro Diagnostics and Radiological Health (OIR)) has led to improved consistency and predictability due to the enhanced integration of premarket, postmarket, and compliance-related activities and staff and improved information sharing among staff. In addition, the successful development and evaluation of medical devices depends on the integration of clinical and engineering personnel. CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Building on the success of the TPLC model building in the other device areas based on the lessons learned from the TPLC experience with OIR and taking into account the Center’s mission, vision, and strategic priorities, and development of a patient-centric benefit-risk framework for regulatory and non-regulatory decision making across the TPLC. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel. Because an essential element for the success of the Center’s benefit-risk decision making framework and approach is the alignment of clinical and engineering personnel, CDRH will continue to develop and enhance the linkages between scientific and engineering personnel.

V. INDEPENDENT ASSESSMENT OF REVIEW PROCESS MANAGEMENT

FDA and the industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry. The assessment shall be conducted in two phases under contract to FDA. The contractor, independent, consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment and described below within the budget provided under this user fee agreement.

PHASE 1

During the first phase, the contractor will complete an evaluation of FDA’s implementation of the corrective action plan developed in response to recommendations from the MDUFA III public meeting. For Phase 1, FDA will award the contract by the end of CY2017. The contractor will evaluate the implementation of MDUFA III recommendations and prepare a written assessment within 1 year of contract award.

PHASE 2

During the second phase, the contractor will:

1. Evaluate FDA’s premarket review program to identify efficiencies that should be realized as a result of the process improvements and investments under MDUFA III and IV;
2. Evaluate premarket review program infrastructure and allocation of PTEs;
3. Assess the alignment of resource needs with the training and expertise of hires;
4. Identify and share best practices across branches in ODE and OIR;
5. Assess the progress of programs targeted for improvement under this agreement, including the:
   a. Quality Management program;
   b. Proportion of deficiencies in which FDA references the basis for the deficiency determination;
   c. Pre-Submission program (assess whether (a) CDRH is providing guidance specific to the questions being asked; (b) CDRH is using Pre-Submissions appropriately; and (c) CDRH and Industry are adhering to the procedural aspects as set forth in this agreement);
6. Third Party Review program (assess efficiency of program and suggest process improvements);
7. Digital Health program;
8. Patient Engagement program, and
9. Real World Evidence program;
10. Analyze conversions of Special 510(k)s to Traditional 510(k)s, and
11. Assess other key areas identified by FDA and industry as resources permit.

For Phase 2 of the independent assessment, FDA will award the contract no later than 3/31/2020. However, the contractor would not begin the audit of deficiency letters and Pre-Submissions before 10/1/2020. The contractor will publish comprehensive findings and recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable.

VI. PERFORMANCE REPORTS

The Agency will report its progress toward meeting the goals described in this letter, as follows. If, throughout the course of MDUFA IV, the Agency and Industry agree that a different format or different metrics would be more useful, FDA and CBER will modify the format as per the agreement of both FDA and Industry.

1. Quarterly reporting at the CDRH Division level/CBER Center level (in recognition of the significantly smaller number of submissions reviewed at CBER).
2. FDA will provide a report that does not go through a 3rd party, reporting will include:
   i. Average and quintiles of the number of calendar days to Substantive Interaction for PMA submissions.
   ii. Average and quintiles of the number of calendar days to Substantive Interaction for IDE submissions.
   iii. Average number of review cycles.
   iv. Rate of submissions not accepted for review.
3. For PMA submissions, reporting will include:
   i. Average and quintiles of the number of calendar days to Substantive Interaction for Original PMA, Panel-Track PMA Supplement, and Premarket Report Submissions.
   ii. Average and quintiles of the number of Days, Industry Days, and Total Days to a MDUFA decision.
4. Rate of submissions not accepted for filing review, and rate of applications not filed.
5. For de novo requests, reporting will include:
   i. Average, and quintiles of the number of FDA Days, Industry Days, and Total Days to a MDUFA decision.
   ii. Average number of review cycles.
   iii. Rate of submissions not accepted for review.
6. For Pre-Submissions, reporting will include:
   i. Number of all qualified Pre-Submissions received.
   ii. Rate of submissions not accepted for review, upon final guidance.
   iii. Average and quintiles of the number of calendar days from submission to written feedback.
   iv. Number of Pre-Submissions that require a meeting.
   v. Percent of submissions with meetings for which industry provided minutes within 15 days.
7. For IDE applications, reporting will include:
   i. Number of original IDEs received.
   ii. Average number of amendments prior to approval or conditional approval of the IDE.
8. CDRH will report quarterly, and CBER will report annually, the following data at the Center level:
9. Rate of NSE decisions for 510(k) submissions.
10. Rate of withdrawals for 510(k), de novo, and PMA submissions.
11. Rate of Not Approvable decisions for PMA submissions.
12. Rate of Denial decisions for de novo requests.
13. Key product areas or other issues that FDA identifies as noteworthy because of a potential effect on performance, including submissions with rates of Additional Information requests.
14. Specific topic or product area as it relates to performance goals, agreed upon at the previous meeting.
15. Number of submissions that missed the goals and the total number of elapsed calendar days broken down into FDA days and industry days.
17. Agency level summary of fee collection.
18. Independent assessment implementation plan status.
19. Results of independent assessment and subsequent periodic audits and progress toward implementation of the recommendations and any corrective action.
20. Number of discretionary fee waivers or reductions granted by type of submission.
21. Additional, the Agency will provide the following information on an annual basis:
22. Qualitative and quantitative update on how funding is being used for the device review process.
23. Percentage of review time devoted to direct review of applications.
24. How funding is being used to enhance scientific review capacity.
3.4. Summary information on training courses available to CDRH and CBER employees, including new reviewers, regarding device review and the percentage of applicable steps for which they have successfully completed each such course. CDRH will provide information concerning any revisions to the new reviewer training curriculum.

3.5. Performance of the shared outcome goal for average Total Time to decision

3.6. For 510(k) submissions, reporting will include:

- i. Number of submissions reviewed by a Third Party
- ii. Number of Special Submissions
- iii. Number of Traditional Submissions
- iv. Average and number of days to Accept/Refuse to Accept
- v. Number of Abbreviated Submissions

3.7. For 510(k) submissions that go through a 3rd party, reporting will include:

- i. Time from FDA receipt of third party report to FDA decision at the 90% percentile
- ii. Once 3rd party program enhancements have been implemented, resources saved as a result of enhancements to the 3rd party review program.

3.8. For PMA submissions, reporting will include the number of the following types of PMA submissions received:

- i. Original PMAs
- ii. Priority PMAs
- iii. Priority PMAs for Reimbursements
- iv. Panel-Track PMA Supplement
- v. PMA Modules
- vi. 180-Day PMA Supplements
- vii. Real-Time PMA Supplements

3.9. For De Novo requests, reporting will include:

- i. Number of submissions received
- ii. Number of submissions to FDA
- iii. Average and number of days to Accept/Refuse to Accept, upon final guidance

3.10. For CLIA waiver applications, reporting will include:

- i. Number of CLIA waiver applications received
- ii. Average and quintiles of the number of calendar days to Substantive Interaction
- iii. Average and quintiles of the number of FDA Days, Industry Days, and Total Days to a MDUFA decision and a discussion of any trends in the data

3.11. Report on the ASCA program

3.12. Data regarding the reduction in reviewer to manager ratio.


3.15. Summary of quality system audits

3.16. Data regarding quarterly data on performance within goals for 510(k), de novo, and PMA MDUFA decisions for devices identified as LDTs by the submitter compared to all non-LDT IVD devices. The following elements will be reported:

- Number and percentage of LDT 510(k)s and non-LDT IVD 510(k)s completed within 90 FDA Days
- Number and percentage of LDT de novos and non-LDT IVD de novos completed within 150 FDA Days
- Number and percentage of LDT PMAs and non-LDT IVD PMAs completed within 180 FDA Days

3.17. FDA permits to treat LDTs no less favorably than other devices to which MDUFA performance goals apply.

On an annual basis, FDA and Industry will discuss FDA's return on investment, which may include process improvements, improved performance, and other enhancements, under MDUFA IV.

VII. DEFINITIONS AND EXPLANATIONS OF TERMS

A. Applicant

Applicant means a person who makes any of the following submissions to FDA: an application for premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); a premarket notification under section 510(k) of the FDCA; an application for investigational device exemption under section 520(g) of the FDCA; a Pre-Submission; a de novo request (evaluation of automatic class III designation) under section 513(f)(2) of the FDCA; a CLIA Waiver by application. An electronic copy is not considered to be an electronic submission.

B. Electronic submission template

An electronic submission template, or eSubmission template, is a guided submission preparation tool for industry. Similar to an online form, the eSubmission template walks industry through the relevant content and context for the respective premarket submission type and device in order to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.

C. Electronic submission template

An electronic submission template, or eSubmission template, is a guided submission preparation tool for industry. Similar to an online form, the eSubmission template walks industry through the relevant content and context for the respective premarket submission type and device in order to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.

D. FDA Days

FDA Days are those calendar days when a submission is considered to be under review at the Agency for submissions that have been accepted (510(k) or de novo acceptance request), filed (PMA) or submitted (CLIA Waiver by application). FDA Days begin on the date of receipt of the submission or the amendment to the submission that enables the submission to be accepted (510(k)) or (PMA).

E. MDUFA Decisions

Original PMAs: Decisions for Original PMAs are Approval, Approvable, Approvable Pending GMP Inspection, Not Approvable, withdrawal, and Denial.


Real-Time PMA Supplements: Decisions for Real-Time PMA supplements include Approval, Approvable, Not Approvable.

510(k)s: Decisions for 510(k)s are substantially equivalent (SE) or not substantially equivalent (NSE).

De Novo Requests: Decisions for De Novo requests are grant, withdrawal, and decline.

CLIA Waiver by Application Submissions: Decisions for CLIA Waiver by Application Submissions are Approval, Withdrawal, and Denial.

Submissions placed on Application Integrity Program Hold will be removed from the MDUFA cohort.

F. Pre-Submission

A Pre-Submission includes a formal written request from an applicant for feedback from FDA which is provided in the form of a substantive interaction, financial disclosure statements); a Pre-Submission is not a request for FDA feedback on a Pre-Submission, unless: a. the feedback is documented in an online form, the eSubmission template is a guided submission preparation tool for industry. Similar to an online form, the eSubmission template walks industry through the relevant content and context for the respective premarket submission type and device in order to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.

G. Substantive Interaction

Substantive Interaction is an email, letter, telephone, facsimile, videoconference, or other form of communication such as a request for Additional Information or Major Deficiency letters by FDA notifying the applicant that a substantial deficiency has been identified in the initial submission review, or a communication stating that FDA has not identified any deficiencies in the initial submission review, but has identified further minor deficiencies which will be communicated through interactive review. An approval or clearance letter issued prior to the Substantive Interaction goal will qualify as a Substantive Interaction.

If substantive issues warranting issuance of an Additional Information or Major Deficiency letter are not satisfied by interactive review, further substantive review should be used to resolve any minor issues and facilitate a FDA decision. In addition, interactive review will be used, when applicable, to ensure that the application is subject to a more efficient review process during the initial review cycle (i.e., prior to a Substantive Interaction) to resolve minor issues such as revisions to administrative items (e.g., 505(c) Summary/Statement, Indications for Use statement, environmental impact assessment, financial disclosure statements); a major deficiency or a major deficiency specifically addressed in the guidance document; requests to use an alternative means to address recommendations specified in a guidance document. A final call or email is sent to reviewers that can be readily answered based on a reviewer's experience and knowledge and do not require the involvement of a broader number of FDA staff beyond the routine involvement of the reviewer's supervisor and more experienced mentors.

If substantive issues warranting issuance of an Additional Information or Major Deficiency letter are not resolved by interactive review, further substantive review should be used to resolve any minor issues and facilitate a FDA decision. In addition, interactive review will be used, when applicable, to ensure that the application is subject to a more efficient review process during the initial review cycle (i.e., prior to a Substantive Interaction) to resolve minor issues such as revisions to administrative items (e.g., 505(c) Summary/Statement, Indications for Use statement, environmental impact assessment, financial disclosure statements); a major deficiency or a major deficiency specifically addressed in the guidance document; requests to use an alternative means to address recommendations specified in a guidance document. A final call or email is sent to reviewers that can be readily answered based on a reviewer's experience and knowledge and do not require the involvement of a broader number of FDA staff beyond the routine involvement of the reviewer's supervisor and more experienced mentors.
substantive issues (e.g., modification of the proposed Indications for Use may lead to revisions in labeling and administrative items), or if they were still unresolved following interactive review attempts. Both interactive review and Substantive Interactions will occur on the review clock except upon the issuance of an Additional Information or Major Deficiency Letter which stops the review clock.

H. Total Time to Decision

Total Time to Decision is the number of calendar days from the date of receipt of an accepted or filed submission to a MDUFMA decision.

The average Total Time to Decision for 510(k) submissions is calculated as the average of all decisions for 510(k) submissions within a closed cohort, excluding the highest 2% and the lowest 2% of values. A cohort is closed when 95% of the accepted submissions have been independently checked to make sure it operates according to international standards.

A conformity assessment scheme is a system for conformity assessment (e.g., medical devices or management processes) to one or more consensus standards. The system specifies the applicable standards, the rules, procedures, and management requirements for carrying out the conformity assessment to meet a regulatory need. Informally, such a scheme may be referred to as an accreditation scheme.

Testing laboratory is an organization that possesses the necessary technical competence and capabilities to conduct testing to make a determination that one or more characteristics of an object are in conformance with a set of predefined requirements.

J. BLA-related Definitions

Review and act on—the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where applicable, the actions necessary to place the application in condition for approval.

Class I resubmitted applications—applications in which the complete response letter includes the following items only (or combinations of these items):

(a) Final printed labeling
(b) Review and
(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes that correct or update deficiencies and, where applicable, the actions necessary to place the application in condition for approval.

VII. Definitions and Explanation of Terms

PDUFMA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022

This document contains the performance goals and procedures for Prescription Drug User Fee Act (PDUFMA) reauthorization for fiscal years (FYs) 2018-2022, known as PDUFMA VI. It is commonly referred to as the “goals letter” or “commitment letter.” The goals letter represents the product of FDA’s discussions with the regulated industry and public stakeholders, as mandated by Congress.

The performance goals and other commitments specified in this letter apply to aspects of the human drug review program that are important for facilitating continued innovation and improving the review time for innovative new medicines for patients. While much of FDA’s work is associated with formal tracked performance goals, the Agency and industry mutually agree that it is appropriate to manage some areas of the human drug review program with internally tracked timeframes. This provides FDA the flexibility needed to respond to a highly diverse workload, including unanticipated public health needs. FDA is committed to meeting the performance goals specified in this letter while continuing to improve its performance regarding other important areas specified in relevant published documents that relate to preapproval drug development and post-approval activities for marketed products. FDA and the regulated industry will periodically and regularly assess the progress of the human drug review program through PDUFMA VI. This will enable FDA and the regulated industry to identify emerging challenges and develop strategies to address these challenges to ensure the efficiency and effectiveness of the human drug review program.

Unless otherwise stated, goals apply to cohorts of each fiscal year (FY).

1. ENSURING THE EFFECTIVENESS OF THE HUMAN DRUG REVIEW PROGRAM

A. Review Performance Goals

1. NDA/BLA Submissions and Resubmissions

a. Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60 day filing date.

b. Review and act on 90 percent of priority NME NDA and original BLA submissions within 5 months of the 60 day filing date.

c. Review and act on 90 percent of standard non-NME original NDA submissions within 18 months of receipt.

Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt.

d. Review and act on 90 percent of Class 1 resubmitted original applications within 2 months of receipt.

f. Review and act on 90 percent of Class 2 resubmitted original applications within 6 months of receipt.

2. Original Efficacy Supplements

a. Review and act on 90 percent of standard efficacy supplements within 10 months of receipt.

b. Review and act on 90 percent of priority efficacy supplement within 6 months of receipt.

3. Resubmitted Efficacy Supplements

a. Review and act on 90 percent of Class 1 resubmitted efficacy supplements within 2 months of receipt.

b. Review and act on 90 percent of Class 2 resubmitted efficacy supplements within 6 months of receipt.

4. Original Manufacturing Supplements

a. Review and act on 90 percent of manufacturing supplements requiring prior approval within 6 months of receipt.
b. Review and act on 90 percent of all other manufacturing supplements within 6 months of receipt.

c. Review Performance Goal Extensions

1. Major Amendments

i. A major amendment to an original application, efficacy supplement, or resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by three months.

ii. A major amendment may include, for example, a major new clinical safety/efficacy study report; major re-analysis of previously submitted studies; submission of a Risk Evaluation and Mitigation Strategy (REMS) with element to assure safe use (ETASU) not included in the original application; or significant amendment to a previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

iii. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by two months.

iv. Only one extension can be given per review cycle.

v. Consistent with the underlying principles outlined in the the program guidance, FDA’s decision to extend the review clock should, except in rare circumstances, be limited to occasions where review of the new information would result in significant deficiencies in the application and lead to approval in the current review cycle.

b. Inspection of Facilities Not Adequately Identified in an Original Application or Supplement

1. All original applications, including those in the program (see Section I.B.2) and supplements are expected to include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with information needed to schedule inspections of manufacturing facilities that may be necessary before approval of the original application or supplement.

2. During FDA’s review of an original application or supplement, the Agency identifies a manufacturing facility that was not included in the comprehensive and readily located list in an original application or efficacy supplement, the goal date may be extended by three months.

3. If FDA identifies the need to inspect a manufacturing facility that is not included in the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by two months.

4. These review goals are summarized in the following tables:

<table>
<thead>
<tr>
<th>Table 1.—Original and Resubmitted Applications and Supplements</th>
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</thead>
<tbody>
<tr>
<td><strong>Submission Cohort</strong></td>
</tr>
<tr>
<td>NME NDAs and original BLAs</td>
</tr>
<tr>
<td>New NMEs</td>
</tr>
<tr>
<td>Class 1 Resubmissions</td>
</tr>
<tr>
<td>Class 2 Resubmissions</td>
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<tr>
<td>Original Efficacy Supplements</td>
</tr>
<tr>
<td>Class 1 Resubmitted Efficacy Supplements</td>
</tr>
<tr>
<td>Class 2 Resubmitted Efficacy Supplements</td>
</tr>
</tbody>
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| Table 2 | Prior Approval | All Other |
|---------------------------------------------------------------|
| Manufacturing Supplements | 90% in 4 months of the receipt date | 90% in 6 months of the receipt date |

B. Program for Enhanced Review Transparency and Communication for NME NDAs and original BLAs

To promote transparency and communication between the FDA review team and the applicant, FDA will apply the following model ("the Program") to the review of all New Molecular Entity New Drug Applications (NME NDAs) and original Biologics License Applications (BLAs), including applications that are resubmitted following a Refuse-to-File decision, received from October 1, 2017, through September 30, 2022. The goal of the Program is to promote the efficiency, effectiveness, and timeliness of the first cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality new drugs and biologics.

Approach to Application Review. The standard approach for the review of NME NDAs and original BLAs is described in this section. However, the FDA review team and the applicant may discuss and reach mutual agreement on an alternative approach to the timing and nature of interactions and information exchange between the applicant and FDA, i.e., a Formal Communication Plan for the review of the NME NDA or original BLA. The Formal Communication Plan may include elements of the standard approach (e.g., a mid-cycle communication or a late-cycle meeting) as well as other interactions that sometimes occur during the review process (e.g., a meeting during the filing period). The elements of the plan are to be discussed and agreed to at the pre-submission meeting (see Section I.B.1) and reflected in the meeting minutes. The Formal Communication Plan may be reviewed and amended at any time during the review and at any time based on the mutual agreement of the review team and the applicant. For example, the review team and the applicant may mutually agree at any time to cancel future specified interactions in the Program (e.g., the late-cycle meeting) that become unnecessary (e.g., because previous communications between the review team and the applicant are sufficient). Any amendments made to the Formal Communication Plan should be consistent with the goal of an efficient and timely first cycle review process and not impede the review team’s ability to conduct its review.

Expeditied Reviews. In certain cases, an application review process will be for a product that the FDA review team identifies as meeting an important public health need. If the FDA review team determines that a first-cycle approval is likely for such an application, the team intends to make every effort to conduct an expedited review and act early on the application. FDA conducts expedited reviews to promote timely access to critically needed therapies for patients without compromising FDA’s high standards for demonstrating the safety, efficacy, and quality of new medicines. Expedited reviews are typically characterized by frequent contact between the applicant and the FDA review team throughout the review process. Any parameters of the Program that are intended to facilitate expedited reviews are noted throughout Section I.B.

If significant application deficiencies are identified by the review team at any time during an expedited review, FDA intends to revert, for the remainder of the review, to the standard approach to the review of priority NME NDAs and original BLAs (as described in this section), and will inform the applicant accordingly.

The following Section I.B describes the parameters that will apply to FDA’s review of applications in the Program.

1. Pre-submission meeting: The applicant is strongly encouraged to discuss the Ombudsmen content of the application with the appropriate FDA review division at a pre-NDA/BLA meeting. This meeting will be attended by the FDA review team, including appropriate senior FDA staff.

a. The pre-NDA/BLA meeting should be held sufficiently in advance of the planned submission of the application to allow for meaningful response to FDA feedback and should generally occur not less than 2 months prior to the planned submission of the application.

b. In addition to FDA’s preliminary responses to the applicant’s questions, other potential discussion topics include preliminary discussions on the appropriate FDA review division for the application or other risk management actions, and, where applicable, the development of a Formal Communication Plan and a timeline for review activities associated with a scheduling recommendation under the Controlled Substances Act for drugs with abuse potential. These discussions will be summarized at the conclusion of the meeting and reflected in the FDA meeting minutes.

c. The FDA and the applicant will agree on the content of a comprehensive plan for the proposed indication(s) at the pre-submission meeting. The FDA and the applicant may also reach agreement on submission of a limited number of application components not later than 30 calendar days after the submission of the original application. These submissions must be of a type that would not be expected to materially impact the ability of the review team to begin its review. These agreements will be summarized at the conclusion of the meeting and reflected in the FDA meeting minutes.

1. Examples of application components that may be appropriate for delayed submission include updated stability data (e.g., 15-month data to update a previously submitted with the original submission) or the final audited report of a preclinical study.

2. The following items may be considered for timely submission: (1) regulatory authorities concerning the application, (2) the 505(b)(2) application, (3) the Investigational New Drug Application (IND), (4) the Investigational New Drug Application (IND) supplement (IR), (5) any documents prepared for the IND, (6) the IND and IND supplements, (7) the IND supplement, (8) the IND and IND supplements, (9) the IND supplement, (10) the IND and IND supplements, (11) the IND supplement, (12) the IND and IND supplements, and (13) the IND supplement.

3. The following items may be considered for timely submission: (1) regulatory authorities concerning the application, (2) the 505(b)(2) application, (3) the Investigational New Drug Application (IND), (4) the Investigational New Drug Application (IND) supplement (IR), (5) any documents prepared for the IND, (6) the IND and IND supplements, (7) the IND supplement, (8) the IND and IND supplements, (9) the IND supplement, (10) the IND and IND supplements, (11) the IND supplement, (12) the IND and IND supplements, and (13) the IND supplement.

4. The following items may be considered for timely submission: (1) regulatory authorities concerning the application, (2) the 505(b)(2) application, (3) the Investigational New Drug Application (IND), (4) the Investigational New Drug Application (IND) supplement (IR), (5) any documents prepared for the IND, (6) the IND and IND supplements, (7) the IND supplement, (8) the IND and IND supplements, (9) the IND supplement, (10) the IND and IND supplements, (11) the IND supplement, (12) the IND and IND supplements, and (13) the IND supplement.
ii. Major components of the application (e.g., clinical trial or the full study report of required long-term safety data) are expected to be submitted with the original application and not subject to agreement for late submission.

2. Original application submission: Applications are expected to be complete, as agreed between the FDA review team and the applicant at the pre-NDA/BLA meeting, at the time of original submission of the application. If the applicant does not have a pre-NDA/BLA meeting with FDA, and no agreement exists between FDA and the applicant on the contents of a complete application or delayed submission of certain components of the application, the applicant’s submission is expected to be complete at the time of original submission.

a. All applications are expected to include a comprehensive and readily located list of all clinical sites and manufacturing facilities included or referenced in the application.

b. Any applications that FDA agreed at the pre-submission meeting could be submitted after the original application are expected to be received not later than 15 calendar days after receipt of the original application.

c. Incomplete applications, including applications with components that are not received within 15 calendar days after receipt of the original submission, will be subject to a Refuse-to-File decision.

d. The following parameters will be applied to applications that are subject to a Refuse-to-File decision and are subsequently filed over protest:

   i. The original submission of the application will be subject to the review performance goals as described in Section I.B.4.

   ii. The application will not be eligible for the goals of the Program (e.g., mid-cycle communication, late-cycle meeting).

   iii. FDA generally will not review amendments to the application during any review cycle. FDA also generally will not issue information requests to the applicant during the agency’s review.

   iv. Review and resubmission goals described in Section I.A.1.e and I.A.1.f will not apply to any resubmission of the application following an FDA complete response action. Any review will be reviewed at available resources permit.

e. Since applications are expected to be complete at original submission, submitted amendments are expected to be rare and not to contain major new information or analyses. Review of unsolicited amendments, including those submitted in response to an FDA communication of deficiencies, will be handled in accordance with the GRMP guidance. This guidance includes the underlying principle that FDA will consider the most efficient path toward completion of a comprehensive review that addresses application deficiencies and leads toward a first cycle approval when possible.

3. Day 74 Letter: FDA will follow existing procedures regarding identification and communication of filing review issues in the “Day 74 letter.” For applications subject to the Program, the timeline for this communication will be within 74 calendar days from the date of FDA receipt of the original submission. FDA will include in the Day 74 letter for applications in the Program will include the planned date for the internal mid-cycle review meeting.

The Day 74 letter will generally not be distributed before the mid-cycle meeting date included in the Day 74 letter for applications in the Program will include the planned date for the internal mid-cycle review meeting. The letter will also include preliminary information of the date of FDA receipt of the original submission. The review performance goals for these applications are as follows:

i. Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60 day filing date.

ii. Review and act on 80 percent of priority NME NDA and original BLA submissions within 6 months of the 60 day filing date.

3. Mid-Cycle Communication: The FDA Regulatory Project Manager (RPM) and other appropriate members of the FDA review team (e.g., Cross Discipline Team Leader (CDTL)), will call the applicant, generally within 2 weeks following the Agency’s internal mid-cycle review meeting, to provide the applicant with an update on the status of the review of their application. An agenda will be provided to the mid-cycle communication. Scheduling of the internal mid-cycle review meeting will be handled in accordance with the GRMP guidance. The specific date and time of the telephone call with the applicant.

a. The update should identify any significant issues identified by the review team to date, any information requests, information regarding major safety concerns and preliminary review team thinking regarding risk management recommendations for the mid-cycle meeting, updates regarding plans for the AC meeting (if an AC meeting is anticipated), an update regarding FDA review activities associated with scheduling recommendation under the Controlled Substances Act (if applicable), and other projected milestone dates for the remainder of the review cycle.

b. In the case of an expedited review, FDA will communicate the timelines for the Late-Cycle Meeting and the Late-Cycle Meeting background package (see Section I.B.6) which may occur earlier with more condensed timeframes compared to a review that is not expedited.

6. Late-Cycle and Advisory Committee Meetings: A meeting will be held between the FDA review team and the applicant to discuss the status of the application late in the review cycle. Late-cycle meetings will generally be face-to-face meetings; however, the meeting may be held by teleconference if FDA and the applicant agree. Since the application is expected to be complete at the time of submission, FDA intends to complete primary and secondary reviews of the application in advance of the planned late-cycle meeting.

a. FDA representatives at the late-cycle meeting are expected to include the signatories of the audit validation, review team members from appropriate disciplines, and appropriate team leaders and/or supervisors from disciplines for which substantive issues have been identified in the review to date.

b. For applications that will be discussed at an AC meeting, the following parameters apply:

   i. FDA intends to convene AC meetings no later than 2 months (standard review) or no later than 6 weeks (priority review) prior to the PDUGA goal date. The late-cycle meeting will occur not less than 12 calendar days before the date of the AC meeting.

   ii. The FDA will prepare and post questions for the AC to the sponsor and the AC not less than 2 calendar days before the AC meeting.

iii. Following an AC Meeting, FDA and the applicant may agree on the need to discuss feedback from the AC for the purpose of facilitating the remainder of the review. Such discussions will generally be held by teleconference without a commitment for formal meeting minutes issued by the agency.

iv. For applications that will not be discussed at an AC meeting, the late-cycle meeting will generally occur not later than 3 months (standard review) or two months (priority review) prior to the PDUGA goal date.

d. Late-Cycle Meeting Background Packages: The Agency background package for the late-cycle meeting will be sent to the applicant not less than 10 calendar days (or 2 calendar days for an AC meeting) before the late-cycle meeting. The package will consist of a brief memorandum from the review team outlining substantive application issues (e.g., deficiencies identified by primary and secondary reviews), the Agency’s background package for the AC meeting (incorporated by reference if previously sent to the applicant), potential questions and/or points for discussion for the AC meeting (if planned) and the current assessment of the need for REMS or other risk management actions. If the application is subject to an expedited review, the background package may be streamlined and brief using a bulleted list to identify issues to be discussed.

e. Late-Cycle Meeting Discussion Topics: Potential topics for discussion at the late-cycle meeting include major deficiencies identified to date; issues to be discussed at the AC meeting (if planned); current assessment of the need for REMS or other risk management actions; status update of FDA’s activities associated with scheduling recommendation under the Controlled Substances Act, if applicable; Information requests from the review team to the applicant; and additional data or analyses the applicant may wish to submit.

f. With regard to submission of additional data or analyses, the FDA review team and the applicant will discuss whether such data will be reviewed by the Agency in the current review cycle and, if so, whether the submission will be considered a major amendment and trigger an extension of the PDUGA goal date.

7. Inspections: FDA’s goal is to complete all GCP, GLP, and GMP inspections for applications in the Program within 90 calendar days of the date of original receipt for priority applications and within 10 months of the date of original receipt for standard applications. This will allow 2 months at the end of the review cycle to attempt to address any deficiencies identified by the inspections.

C. First Cycle Review Management

FDA and industry share a commitment to ensuring an efficient and effective first cycle performance for all applications subject to the PDUGA program. This commitment was first articulated in the GRMP guidance finalized in 2005. FDA will update this guidance (PDUGA VII) to incorporate various activities (e.g., the NME Program, REMS) that have been added to the human drug review program since the guidance was finalized, and the importance of internal review timelines that govern aspects of the human drug review program that are not part of the PDUGA program. FDA will publish a revised draft guidance for public comment no later than the end of FY 2018.
D. Review of Proprietary Names to Reduce Medication Errors

To enhance patient safety, FDA is committed to various measures to reduce medication errors related to look-alike and sound-alike proprietary names and such factors as unclear label abbreviations, acronyms, dose designations, and error prone label and packaging design. The following performance goals established by FDA are reviewed in drug and biological product proprietory names during development (as early as end-of-phase 2) and during FDA’s review of a marketing application:

1. Proprietary Name Review Performance Goals During Drug Development
   a. Review 90% of proprietary name submissions filed within 180 days of receipt. Notify sponsor of tentative acceptance or non-acceptance.
   b. If the proprietary name is found to be unacceptable, the sponsor can request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision (meeting package required).
   c. If the proprietary name is found to be unacceptable, the above review performance goals also apply to the written request for reconsideration with supporting data or the submission of a new proprietary name.
   d. A complete submission is required to begin the review clock.

2. Proprietary Name Review Performance Goals During Application Review
   a. Review 90% of NDA/BLA proprietary name submissions filed within 60 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.
   b. A supplemental review will be done meeting requests for new review performance goals if the proprietary name has been submitted previously (IND phase after end-of-phase 2) and has received tentative acceptance.
   c. If the name is found to be unacceptable, the sponsor can request reconsideration by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision (meeting package required).
   d. If the proprietary name is found to be unacceptable, the above review performance goals apply to the written request for reconsideration with supporting data or the submission of a new proprietary name.
   e. A complete submission is required to begin the review clock.

E. Major Dispute Resolution

1. Procedure:
   For procedural or scientific matters involving the review of human drug applications and supplements (as defined in PDUFA) that cannot be resolved at the signatory authority level (including a request for reconsideration by the signatory authority after reviewing any materials that are planned to be forwarded with an appeal to the next level), the response to appeals of decisions will be within 30 calendar days of the Center’s receipt of the written appeal.

2. Performance goal: 90% of such answers are provided within 30 calendar days of the Center’s receipt of the written appeal.

3. Conditions:
   a. Sponsors should first try to resolve the procedural or scientific issue at the signatory authority level (including a request for reconsideration by the signatory authority following a previous written notification) or written and should ordinarily be to either grant or deny the appeal.
   b. If the decision is to deny the appeal, the response should include reasons for the denial and any actions the sponsor might take to persuade the Agency to reverse its decision.
   c. In cases, further data or further input from others might be needed to reach a decision on the appeal. In these cases, the Agency will respond to the request to obtain that information (e.g., requesting further information from the sponsor, scheduling a meeting with the sponsor, scheduling the review division for consideration of the next scheduled available advisory committee (AC)).
   d. In these cases, once the required information is received by the Agency (including any required input from whom the appeal was made), again has 30 calendar days from the receipt of the required information in which to either grant or deny the appeal.
   e. Again, if the decision is to deny the appeal, the response should include the reasons for the denial and any actions the sponsor might take to persuade the Agency to reverse its decision.
   f. If the Agency decides to present the issue to an AC for consideration, the Agency will provide a written response to the sponsor’s request.
   g. N.B. If the Agency decides to present the issue to an AC for consideration, the Agency will provide a written response to the initial decision made by the Agency.

H. Meeting Management Goals

Type A meetings are those meetings that are necessary for an otherwise stalled drug development program to proceed (i.e., a “critical path” meeting) or to address an important safety issue. Post-action meetings requested within three months after FDA regulatory action other than approval (i.e., issuance of a complete response letter) will generally be considered Type A meetings.

Type B meetings include pre-IND meetings and pre-NDA/BLA meetings, while Type B (RPO) meetings are reserved for certain End-of-Phase 1 meetings (i.e., for 21 CFR Part 312 Subpart E or 21 CFR Part 314 Subpart H or similar products) and End-of-Phase 2/Phase 3 meetings. Type C meetings. Meetings regarding REMS or postmarketing requirements that occur outside the context of the review of a marketing application will also generally be considered Type B meetings.

Type C meetings are any other type of meeting.

1. Responses to Meeting Requests
   a. Procedure: FDA will notify the requester in writing of the date, time, and place for the meeting, as well as expected Center participants following receipt of a formal meeting request. Table 3 below indicates the timeframes for FDA’s response to a meeting request.

   **Table 3**

<table>
<thead>
<tr>
<th>Meeting Type</th>
<th>Response Time (calendar days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>14</td>
</tr>
<tr>
<td>B</td>
<td>21</td>
</tr>
<tr>
<td>B(EOP)</td>
<td>21</td>
</tr>
<tr>
<td>C</td>
<td>21</td>
</tr>
</tbody>
</table>

1. For any type of meeting, the sponsor may request a written response to its questions rather than a face-to-face meeting, videoconference or teleconference. FDA will review the request and make a determination on whether a written response is appropriate or whether a face-to-face meeting, videoconference, or teleconference is necessary. If FDA determines a written response is appropriate, FDA will notify the requester of the date it intends to send the written response in the
Agency’s response to the meeting request. This date will be consistent with the timeframes specified in Table 4 below for the specific meeting type.

2. Scheduling Meetings

a. Procedure: FDA will schedule the meeting on the next available date at which all applicable Center personnel are available to attend, consistent with the component’s other business; however, the meeting should be scheduled consistent with the type of meeting. The timeframes for the Agency to send the written response if the requested date for any meeting type is greater than the specified timeframe, the meeting date should be within 14 calendar days of the requested date.

b. Performance goal: 90% of meetings are held within the timeframe for each meeting type, and 90% of written responses are sent within the timeframe for each meeting type.

3. Meeting Background Packages

The timing of the Agency’s receipt of the sponsor background package for each meeting type (including those meetings for which a written response is not provided) is specified in Table 5 below.

### Table 4

<table>
<thead>
<tr>
<th>Meeting Type</th>
<th>Meeting Scheduling or Written Response Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>30 calendar days from receipt of meeting request</td>
</tr>
<tr>
<td>B(EOP)</td>
<td>60 calendar days from receipt of meeting request</td>
</tr>
<tr>
<td>C</td>
<td>70 calendar days from receipt of meeting request</td>
</tr>
</tbody>
</table>

### Table 5

<table>
<thead>
<tr>
<th>Meeting Type</th>
<th>Receipt of Background Package</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At the time of the meeting request</td>
</tr>
<tr>
<td>B(EOP)</td>
<td>30 calendar days before the date of the meeting requested (written response only)</td>
</tr>
<tr>
<td>C</td>
<td>47 calendar days before the date of the meeting requested (written response only)</td>
</tr>
</tbody>
</table>

*If the scheduled date of a Type B(EOP) or C meeting is earlier than the timeframes specified in Table 4, the meeting background package will be due no sooner than 6 calendar days and 7 calendar days following the response time for Type B(EOP) and C, respectively.

4. Preliminary Responses to Sponsor Questions

a. Procedure: The Agency will send preliminary responses to the sponsor’s questions contained in the background package no later than five calendar days before the meeting date for Type B(EOP) and C meetings.

b. Performance goal: 90% of preliminary responses to questions for Type B(EOP) meetings are issued by FDA no later than five calendar days before the meeting date.

5. Sponsor Notification to FDA

Not later than three calendar days following the sponsor’s receipt of FDA’s preliminary responses for a Type B(EOP) or C meeting, the sponsor will notify FDA of whether the meeting is still needed, and if it is, the anticipated agenda of the meeting given the sponsor’s review of the preliminary responses.

6. Meeting Minutes

a. Procedure: The Agency will prepare minutes that will be available to the sponsor 30 calendar days after the meeting. Calendar days of the minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting, and must not need be in great detail. Meeting minutes are not required if the Agency transmits a written response for any meeting type.

b. Performance goal: 90% of minutes are issued within 30 calendar days of the date of the meeting.

7. Conditions

For a meeting to qualify for these performance goals:

- A written request must be submitted to the review division.
- The written request must provide:
  1. A brief statement of the purpose of the meeting and the sponsor’s proposal for either a face-to-face meeting or a written response from the Agency.
  2. A listing of the specific objectives/outcomes the requester expects from the meeting.
  3. A proposed agenda, including estimated times needed for each agenda item.
  4. A listing of planned external attendees.
  5. A listing of participants/disciplines representative(s) from the Center with an explanation for the request as appropriate, and the date the meeting is requested.
  6. The date that the meeting background package will be sent to the Center. Refer to Table 5 for timeframes for the Agency’s receipt of background packages.

The Agency concurs that the meeting will serve a useful purpose (i.e., it is not premature or clearly unnecessary). However, requests for a Type B or B(EOP) meeting will generally be considered in the most unusual circumstances.

8. Guidance

FDA will publish revised draft guidance on formal meetings between FDA and sponsors no later than September 30, 2018.

**I. Enhancing Regulatory Science and Expediting Drug Development**

To ensure that new and innovative products are available to patients in a timely manner, FDA will build on the success of the FDA’s regulatory science program that included advancing the science of meta-analysis methodologies, advancing the use of biomarkers and pharmacogenomics, enhancing communications between FDA and sponsors during drug development, and advancing the science of rare diseases. The extension and continuation of this work will encompass additional evaluation of the breakthrough therapy program established early consultations between FDA and sponsors on the use of new surrogate endpoints in the primary basis for product approval, advancing rare disease drug development, advancing the development of combination products, and exploring the use of real world evidence for use in regulatory decision-making.

1. Promoting Innovation Through Enhanced Communication Between FDA and Sponsors

FDA’s philosophy is that timely interactive communication with sponsors during drug development is a core Agency activity to help achieve the Agency’s mission to facilitate the conduct of efficient and effective drug development programs, which can enhance public health by increasing the speed and effectiveness of drugs available to the American public in a timely manner. Accordingly, FDA will maintain dedicated drug development collaborative and task forces (e.g., CBER and CDER), focused on enhancing communication between FDA and sponsors during drug development.

One function of the staff is to serve as a liaison that will facilitate general and, in some cases, specific interactions between sponsors and each Center, which will serve as a point of contact for sponsors who have general questions about drug development or who need clarification on which regulatory division to contact with their questions. The liaison will also serve as a secondary point of contact in each Center for sponsors who are encountering challenges in communication with the review team for their IND (e.g., in instances when they have not received a response from the review team to a simple or clarifying question or referral to another meeting after the initial meeting [i.e., the days of the sponsor’s initial request]). In such cases, the liaison will work with the review team and the sponsor to facilitate resolution of issues.

The second function of the staff is to provide ongoing training to the review organization on best practices for communication with sponsors. The content of training includes, but is not limited to, FDA’s philosophy regarding timely interactive communication with sponsors during drug development as a core Agency activity, best practices for addressing sponsor requests for advice and timely communication of responses through appropriate methods (e.g., teleconferences, secure email, or when questions are best addressed through the formal meetings process), and the role of the liaison staff in each Center in facilitating communication between the review staff and sponsor community, including the staff’s role in facilitating resolution of individual communication requests. The staff will also collaborate with sponsor stakeholders (e.g., through participation in workshops, webinars, and other meetings) to communicate FDA’s philosophy and best practices for communication with sponsors during drug development.

To continue to enhance timely interactive communication with sponsors during drug development in PDUFA VI, FDA will do the following:

a. Independent Assessment. FDA will conduct an independent third party to assess current practices of FDA and sponsors in communicating during drug development. The statement of work for this project will be published for public comment prior to beginning the assessment. The third party will be expected to separately engage both FDA and sponsor IND holders for their IND (e.g., in instances when they have questions or general questions about drug development programs identified by IND number. The third party will identify best practices and areas for improvement in communication by FDA review staff and sponsors. FDA will publish the final report of the assessment on FDA’s website no later than the end of FY 2020.

The Public Workshop. FDA will convene a public workshop by the end of March 2021 to discuss the findings of the independent assessment, including anonymized, aggregated data from sponsor and review teams resulting from the contractor interviews.
c. Guidance. FDA will consider the third party’s recommendations for best practices in communication and update the current draft or final guidance on “Best Practices for Communicating with IND Sponsors and FDA During Drug Development” if appropriate. If FDA determines that the guidance should be updated, based on the recommendations of the third party and feedback received from the public workshop, FDA will update the guidance no later than one year following the public workshop.

2. Ensuring Sustained Success of Breakthrough Therapy Program

Breakthrough therapy designation is intended to facilitate drug development and review of drug and biological products, alone or in combination, for serious or life-threatening diseases or conditions when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies. A breakthrough therapy designation includes the features of the fast track program, intensive FDA guidance on an efficient drug development program, and an organizational commitment by FDA involving senior managers. Additionally, FDA will continue to work closely with sponsors throughout the breakthrough therapy designation, development, and review processes. Both FDA and the regulated industry are committed to ensuring the expedited development and review of innovative therapies for serious or life-threatening diseases or conditions that may offer important therapeutic advantages over existing therapies.

3. Early Consultation on the Use of New Surrogate Endpoints

FDA and industry believe that early consultation between review teams and sponsors is important for development programs where the sponsor intends to use a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. Early consultation in the drug development program allows the review team to consult with FDA senior management to evaluate the sponsor’s proposal before providing advice regarding the proposed biomarker as a new surrogate endpoint to support accelerated or traditional approval. Requests to engage with FDA on this topic will be handled as Type C meetings. The purpose of this meeting is to discuss the feasibility of the surrogate as a primary endpoint, and identify any gaps in knowledge and best practices related to the surrogate’s use. The outcome of this meeting may require further investigation by the sponsor and discussion and agreement with the agency before the surrogate endpoint could be used as the primary basis for product approval. To qualify for this consultation, these Type C meeting requests must be accompanied by the complete human factors protocol and specific questions, the Agency will evaluate human factors protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

4. Advancing Development of Drugs for Rare Diseases

FDA will build on the success of the Rare Disease Program (RDP) in CDER and CBER by continuing to advance and accelerate development and timely approval of drugs and biologics for rare diseases, including rare diseases in children. The Rare Disease Program in CBER will continue to host meetings and public workshops to facilitate and accelerate the development and approval of drugs for children with rare diseases. The RDP will continue to provide training to all CDER and CBER review staff related to development, review, and approval of drugs for rare diseases as part of the RDP Training Program. The objective of the training will be to familiarize review staff with the challenges associated with rare disease applications and strategies to address these challenges; to promote best practices for review and regulation of rare disease applications; and to encourage flexibility and scientific judgment among reviewers in the review of rare disease drug development and application review. The training will also emphasize the importance of the RDP staff as members of the core review team to help ensure consistency of scientific and regulatory approaches across applications and review teams.

RDP staff will continue to engage in outreach to industry, patient groups, and other stakeholders to provide training on FDA’s RDP Training Program and to foster collaborations in the development of tools (e.g., patient reported outcome measures) and data (e.g., natural history studies) to support review of drugs for rare diseases. In addition, the staff will also facilitate interactions between stakeholders and FDA review divisions to ensure appropriate use of FDA’s regulatory programs and engagement of patients in FDA’s regulatory decision-making. FDA will also include updates on the activities and success of the PDUFA annual performance report to include, for example, the number of training courses offered and staff trained, the number of review team members participating as core team members, and metrics related to engagement with external stakeholders. FDA will also continue to include information on the status of annual reports on innovative drug approvals, including utilization of expedited programs and regulatory flexibility and appropriate comparative metrics to non-rare disease innovative approvals.

5. Advancing Development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER

a. FDA will develop staff capacity and capability across the medical product centers and the Office of Combination Products (OCP) to more efficiently, effectively, and consistently review and respond to submissions that include combination products. These staff will advance the development of combination products by providing combination product expertise as part of the core review team throughout the review process and promoting best practices for review of combination products. The additional capacity will include staff who will focus on review of cGMP, engineering aspects, human factors protocol design and scientific and regulatory requirements identified by the sponsor.

b. FDA will streamline the process for combination product review and improve the Agency’s ability to assess workload and allocate resources to the review of combination products.

By no later than December 31, 2017, FDA will complete a lean process mapping for review of combination products and adopt changes to review work flow to improve the inter-center consultation process.

ii. By no later than December 31, 2017, FDA will begin tracking workload and timelines for cross-center consultations to enable appropriate allocation of resources and regulatory flexibility for review of combination product review throughout PDUFA VI.

iii. By no later than September 30, 2018, for each component within FDA that is committed to ensure the expedited development and review of combination products, FDA will outline in appropriate internal documents, the Agency’s process for resolving internally any scientific or regulatory issues and consult with the Office of the Commissioner to set forth the criteria for conducting cross-center consultations outside the reviewing Center. FDA will describe the responsibilities of staff in each Center and Office, expectations for core review division members and staff in activities and meetings related to the combination product development program and application review. FDA will describe key terms to be used in review of combination products to foster clear communication within FDA and to regulated industry. The topic areas and expected completion dates of these specifications are as follows:

1. Human Factors Assessments (March 31, 2019)

2. Quality assessment of combination products, including coordination of facility inspections (September 30, 2019)

3. Patient-oriented labeling, including instructions-for-use materials for those drug-device and biologic-device combination products regulated by CBER and CDER (September 30, 2019)

4. By no later than December 31, 2018, FDA will make available on FDA’s website key points of contact in OCP and the medical product centers for device conducting product review. FDA agrees to maintain and update this information periodically.

5. FDA will establish submission procedure timelines for combination products by no later than September 30, 2018. Beginning in FY 2019, FDA will establish timelines to review and provide comment on the protocols for Human Factors studies of combination drug-device and biologic-device products within 60 days.

6. Procedure for review of human factors protocols for combination products. Upon specific request by a sponsor (including specific questions that the sponsor desires to be answered) consistent with the steps below, FDA will evaluate these protocols and issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

7. The sponsor should submit a limited number of specific questions about the human factors protocol design, scientific and regulatory requirements for which the sponsor seeks agreement (e.g., are the study participant groups appropriate to represent intended users, is the study endpoint adequate, are the critical tests that should be evaluated appropriately identified).

8. Within 60 days of Agency receipt of the protocol and specific questions, FDA will provide a written response to the sponsor that includes a succinct assessment of
the protocol and answers to the questions posed by the sponsor. If the Agency does not agree that the protocol design, execution plans, and data analyses are adequate to achieve the sponsor’s objectives, the reasons for the disagreement will be explained in the response.

(iii) Performance goals for FDA will be phased in to calculating in FY 2019 as follows:
   a. By FY 2019, review 50% of human factors protocol submissions within 60 days and provide written comments.
   b. By FY 2020, review 70% of human factors protocol submissions within 60 days and provide written comments.
   c. By no later than December 31, 2018, FDA will begin staff training related to development, review, and approval of drug-device and biologic-device combination products reviewed in CDER and CBER. The training will be provided to all CDER, CBER, Center for Devices and Radiological Health (CDRH), and Office of Combination Products (OCP) staff, and will be part of the reviewer training core curriculum. The key purposes of this training include familiarizing review staff with the regulatory requirements and challenges associated with combination product applications and strategies to address these challenges; promoting best practices for review and regulation of combination products by CDER and CBER, and helping ensure coordination and consistent approaches within the Centers in the review and regulation of combination product applications. The training will also emphasize the role of various experts in the Centers as members of the review team and OCP’s roles and responsibilities in order to help ensure consistent scientific and regulatory approaches across applications and review teams.
   d. FDA will contract with an independent third party to assess current practices for combination drug product review. This study will focus on areas where the needs for intercenter coordination and consistent approaches are greatest, including such areas as the Request-for-Designation, cGMP/facility topics, human factors and bridging studies, and labeling. The contractor will be expected to work closely with FDA staff and individual sponsors as part of the assessment.
   e. The assessment will be based on a randomly selected subset of combination products in various phases of development. The assessment will identify best practices and areas for improvement by FDA review staff and sponsors in the submission and review of combination products for consideration by both FDA and sponsors. FDA will publish the final report of the assessment on FDA’s website no later than the end of FY 2020. FDA will consider the assessment findings regarding best practices on the part of FDA review staff and sponsors in any updates to relevant documents such as MAPPs, SOPPs, and standardized or harmonized protocols, and in the review and submission of Combination Product applications.

b. By no later than December 31, 2019, FDA will publish draft guidance or update previously published guidance issued by the medical product centers and OCP for review staff and industry to facilitate and encourage the development of drug-device and biologic-device combination product on the topics noted below. The draft guidance(s) will be finalized by the end of FY 2022.

1. Bridging studies, including the bridging of data from combination products that employ different device components for the same drug or biologic and the same device component across different drugs and biologics.

ii. Patient-oriented labeling (e.g., instructions-for-use).

6. Enhancing Use of Real World Evidence for Use in Regulatory Decision-Making

As we participate in the current data revolution, it is important that FDA consider the possibilities of using so-called “real world” data as an important tool in evaluating not only the efficacy but also the effectiveness. To accomplish this will require an understanding of what questions to ask, including how such data can be generated and used to inform evaluation, what the challenges are to appropriate generation and use of these data, and how to address such challenges. Towards this end, FDA will do the following:

a. By no later than the end of FY 2018, FDA will complete one or more public workshops(s) with key stakeholders, including patients, biopharmaceutical companies, and academia, to gather input into issues related to Real World Evidence (RWE) use in regulatory decision-making. The workshop(s) should address, among other things, the following topics:
   - Benefits to patients, regulators, and biopharmaceutical companies of RWE in regulatory decision-making;
   - RWE availability, quality, and access challenges, and approaches to mitigate these;
   - Methodological approaches for the collection, analysis, and communication of RWE; and
   - Appropriate contexts of use of RWE in regulatory decision-making regarding effectiveness.

b. By no later than the end of FY 2019, FDA will initiate (or fund by contract), appropriate and methodologically sound (e.g., methodologically sound data generation) projects to collect meaningful patient-oriented labeling (e.g., instructions-for-use).

J. Enhancing Regulatory Decision Tools to Support Drug Development and Review

1. Enhancing the Incorporation of the Patient’s Voice in Drug Development and Decision-Making

To facilitate the advancement and use of systematic approaches to collect and utilize robust and meaningful patient and caregiver input that can more consistently inform drug development and, as appropriate, regulatory decision making, FDA will conduct a public workshop to gather input from the wider community of patients, patient advocates, academic researchers, expert practitioners, industry, and other stakeholders.

i. By the end of FY 2018, FDA will publish a draft guidance describing approaches to incorporate comprehensive patient and caregiver input on burden of disease and current therapy. The guidance will address topics including: standardized nomenclature and terminologies, methods to collect meaningful patient input throughout the drug development process, and methodological considerations for data collection, processing, management, and analysis.

ii. By the end of FY 2019, FDA will publish a draft guidance describing processes and methodological approaches to development of patient-focused assessments that are most important to patients. The guidance will address topics including: methods for sponsors, patient organizations, academic researchers, and expert practitioners to identify what are most important to patients in terms of burden of disease, burden of treatment, and other critical aspects. The guidance should address technologies that may be used for the collection, capture, storage, and analysis of patient perspective information. The guidance will also address methods to better incorporate clinical outcome assessments into endpoints that are considered significantly robust for regulatory decision-making.

iii. By the end of FY 2020, FDA will publish a draft guidance describing approaches to identifying and developing measures for an identified set of impacts (e.g., burden of disease and treatment), which may facilitate collection of meaningful patient input in clinical trials. The guidance will address methods to measure impacts in a meaningful way, and identify an appropriate set of measures that matter most to patients.

iv. By the end of FY 2021, FDA will publish a draft guidance on clinical outcome assessments, which, when final, will, as appropriate, revise or supplement the 2009 Guidance to Industry on Patient-Reported Outcomes Measures. The draft guidance will also address technologies that may be used for the collection, capture, storage, and analysis of patient perspective information. The guidance will also address methods to better incorporate clinical outcome assessments into endpoints that are considered significantly robust for regulatory decision-making.

v. By the end of FY 2022, FDA will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of the public comment period on the draft guidance.

vi. FDA will create and maintain a repository of publicly available tools on FDA’s website as a resource for stakeholders. The repository will also include FDA’s clinical outcome assessment compendium, patient-focused drug development meeting resources, and ongoing efforts on patient-focused drug development.

vii. As appropriate, FDA will revise existing MAPPs and SOPPs to include suggested approaches for incorporating patient input across all phases of the drug development process.
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e. By the end of FY 2019, FDA will conduct a public workshop, through a qualified third party, with the primary purpose of gathering ideas and experiences of the patient and caregiver community and their recommendations on approaches and best practices that would enhance patient engagement in clinical trials. The meeting will also gather input from academic researchers and expert practitioners. The meeting will result in a published report on proceedings and recommendations from discussions at the meeting.

2. Enhancing Benefit-Risk Assessment in Regulatory Decision-Making

FDA will further advance its implementation of the benefit-risk assessment framework into the human drug review program through the following commitments to be accomplished during PDUFA VI:

a. FDA will develop its regulatory science and review expertise and capacity in MIDD approaches. This staff will support the highly-specialized evaluation of model-based strategies used in the approval of novel approaches to the agency.

b. FDA will convene a series of workshops to identify best practices for MIDD. Topics will include: (1) physiologically-based pharmacokinetic (PBPK) modeling and analysis and inferences from dose-exposure-response studies; (2) disease progression model development, including natural history and trial simulators, and correlates of protection for evaluating biological products, including vaccines and blood products. Each workshop will focus on current and emerging methodologies, including methodological limitations. FDA will produce a written summary of the topics discussed in each workshop.

c. Starting in FY 2018, FDA will conduct a pilot program for MIDD approaches. For sponsors participating in the pilot program, FDA will grant a pair of meetings specifically designed for this pilot program, consisting of an initial and a follow-up meeting on the same drug development issue, to occur within a span of approximately 120 days. These meetings will be led by the clinical pharmacology or biostatistical review teams for new drugs and biologics. This guidance will:

i. Articulate FDA’s decision-making context and framework for benefit-risk assessment, illustrating the application of the benefit-risk framework throughout the human drug lifecycle, using a case study approach, if appropriate.

ii. Discuss appropriate interactions between a sponsor and FDA during drug development and evaluation to understand the therapeutic context (i.e., the severity of disease that represents the targeted indication and the extent to which medical need in the target population) regarding regulatory decisions for the product at the various stages of drug development and evaluation.

iii. Identify appropriate approaches to communicate to the public FDA’s thinking on a product’s benefit-risk assessment, such as through product-specific discussions using the benefit-risk framework at AC meetings.

iv. By beginning in FY 2021, FDA will conduct an evaluation of the implementation of the benefit-risk framework in the human drug review program. FDA will evaluate how reviewers across the organization apply the benefit-risk framework and identify best practices in use of the benefit-risk framework. A staff will be dedicated to the benefit-risk framework implementation conducted in PDUFA V and a plan for continued implementation during FYs 2018–2022.

v. By the end of FY 2021, FDA will convene and/or hold meetings in, at their request, with a variety of stakeholder groups, including the incorporation of the patient’s voice in drug development and decision-making, in the human drug review program through the following commitments to be accomplished during PDUFA VI:

a. By March 31, 2018, FDA will publish an update to the implementation plan titled “Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making.” The update will include a report on the progress made during PDUFA V and a plan for continued implementation during FYs 2018–2022.

b. By the end of FY 2019, FDA will establish and triage pilot program eligibility, in the human drug review program, using a case study approach. This would also establish a benefit-risk framework throughout the human drug lifecycle, including best approaches to communicating FDA’s benefit-risk assessment.

c. By the end of FY 2020, FDA will publish a draft guidance on benefit-risk assessments for new drugs and biologics. This guidance will:

i. Update FDA’s decision-making context and framework for benefit-risk assessment, illustrating the application of the benefit-risk framework throughout the human drug lifecycle, using a case study approach, if appropriate.

ii. Discuss appropriate interactions between a sponsor and FDA during drug development and evaluation to understand the therapeutic context (i.e., the severity of disease that represents the targeted indication and the extent to which medical need in the target population) regarding regulatory decisions for the product at the various stages of drug development and evaluation.

iii. Identify appropriate approaches to communicate to the public FDA’s thinking on a product’s benefit-risk assessment, such as through product-specific discussions using the benefit-risk framework at AC meetings.

iv. By beginning in FY 2021, FDA will conduct an evaluation of the implementation of the benefit-risk framework in the human drug review program. FDA will evaluate how reviewers across the organization apply the benefit-risk framework and identify best practices in use of the benefit-risk framework. A staff will be dedicated to the benefit-risk framework implementation conducted in PDUFA V and a plan for continued implementation during FYs 2018–2022.

v. By the end of FY 2021, FDA will develop or revise, as appropriate, relevant MAPPs or SOPPs, and/or review templates and training, to incorporate guidelines for the evaluation of MIDD approaches.

3. Enhancing Capacity to Support Analysis

To facilitate the advancement and use of complex adaptive, Bayesian, and other novel clinical trial designs, FDA will conduct the following activities during PDUFA VI:

a. FDA will develop the staff capacity to enable processes to facilitate appropriate use of these types of methods. This staff will support the computationally intensive reorientation of the model-based review effort. Bayesian, and other novel clinical trial designs, with a particular focus on clinically complex clinical trial designs that rely on computer simulations to determine operating characteristics.

b. Starting in FY 2018, FDA will conduct a pilot program for highly innovative trial designs. This staff will support the computationally intensive reorientation of the model-based review effort. Bayesian, and other novel clinical trial designs, with a particular focus on clinical trial designs for which simulations are necessary to evaluate the operating characteristics.

c. By the end of 2nd quarter FY 2018, FDA will convene a public workshop to discuss various complex adaptive, Bayesian, and other novel clinical trial designs, with a particular focus on clinically complex clinical trial designs. Simulations are necessary to evaluate the operating characteristics, and the acceptability of these designs in regulatory decision-making.

d. By the end of FY 2019, FDA will publish draft guidance, or revise, as appropriate, relevant MAPPs or SOPPs, and/or review templates and training, to incorporate guidelines for the evaluation of MIDD approaches.

4. Enhancing Capacity to Review Complex Innovative Designs

To facilitate the advancement and use of complex adaptive, Bayesian, and other novel clinical trial designs, FDA will conduct the following activities during PDUFA VI:

a. FDA will develop the staff capacity to enable processes to facilitate appropriate use of these types of methods. This staff will support the computationally intensive reorientation of the model-based review effort. Bayesian, and other novel clinical trial designs, with a particular focus on complex clinical trial designs for which simulations are necessary to evaluate the operating characteristics.

b. Starting in FY 2018, FDA will conduct a pilot program for highly innovative trial designs. This staff will support the computationally intensive reorientation of the model-based review effort. Bayesian, and other novel clinical trial designs, with a particular focus on complex clinical trial designs for which simulations are necessary to evaluate the operating characteristics.

c. By the end of 2nd quarter FY 2018, FDA will convene a public workshop to discuss various complex adaptive, Bayesian, and other novel clinical trial designs, with a particular focus on clinically complex clinical trial designs. Simulations are necessary to evaluate the operating characteristics, and the acceptability of these designs in regulatory decision-making.

d. By the end of FY 2019, FDA will publish draft guidance, or revise, as appropriate, relevant MAPPs, SOPPs, and/or review templates and training, to incorporate guidelines for evaluating complex clinical trial designs that rely on computer simulations to determine operating characteristics.

5. Enhancing Capacity to Support Analysis

To support the enhancement of analysis data standards for product development and review

To support the enhancement of analysis data standards for product development and review, the opportunity for post-submission discussion of standardized datasets and programs, and maintain the knowledge of and engage in collaborations with the Design and Development of Design, analysis and review of clinical and non-clinical studies. Examples of these standards
models could include the Standard for Exchange of Nonclinical Data (SEND), Clinical Data Acquisition Standards Harmonization (CDASH), Study Data Tabulation Model (SDTM), and Analytical Data Model (ADaM).

b. In parallel, FDA will improve staff capacity to assist with FDA development and updating of therapeutic area user guides (TAUGs), including appropriate content for the analysis data standards used in submission and review.

c. By end of FY 2019, FDA will convene a public workshop to enhance drug development and application of analysis data standards.

d. FDA will collaborate with external stakeholders and participate in public workshops and meetings such as standards development organizations, on development of data standards, processes, documentation and continuous improvement of clinical trials and regulatory science.

e. By end of FY 2020, FDA will develop or revise, as appropriate, relevant guidelines, MAPPs, SOPs and training associated with submission and utilization of standardized analysis datasets and programs used in review, and on the processes, procedures, and responsibilities related to the receipt, handling, and recollection of submitted analysis data and programs.

6. Enhancing Drug Development Tools Qualification for Biomarkers

To facilitate the enhancement of the drug development tools qualification pathway for biomarkers, FDA will conduct the following activities under PDUFA VI:

a. FDA will develop the staff capacity to enhance biomarker qualification review by increasing base capacity. FDA will also pilot processes to engage external experts to support review of biomarker qualification submissions.

b. By the end of FY 2018, FDA will convene a public workshop to focus on 1) the appropriate use of biomarkers in drug development, and 2) a framework with appropriate standards and scientific approaches to support biomarkers under the taxonomy, including scientific criteria to determine acceptance of a biomarker qualification submission and essential elements of a formal biomarker qualification plan.

c. By the end of FY 2018, FDA will publish draft guidance on proposed taxonomy of biomarker usage and related contexts of use.

d. By end of FY 2020, FDA will publish draft guidance on general evidentiary standards for biomarker qualification to be supplemented with focused guidance on specific biomarker contexts.

e. FDA will develop or revise, as appropriate and necessary, relevant MAPPs and SOPPs on the biomarker qualification process.

f. FDA will list biomarker qualification submissions that are in the qualification process on a public website, to be updated quarterly. The submission of a submission on this list will be based on the consent of the submittor for FDA to publish information about the submission, including stage and current status, and the proposed use or the biomarker. Following qualification of a biomarker FDA will post reviews and summary documents that outline the qualification process and the appropriate scientiﬁc decision.

g. Sponsors who do not use this qualiﬁcation pathway will have an opportunity to interact with the Agency through additional channels.

K. Enhancement and Modernization of the FDA Drug Safety System

FDA will continue to use user fees to enhance the current drug safety system, including adoption of new scientiﬁc approaches, improving the utility of existing tools for the detection, evaluation, prevention, and mitigation of adverse events, standardization and integration of REMS into the healthcare system, enhancing communication and integration between post-marketing and pre-marketing review staff, and improving tracking, communication and oversight of postmarketing safety issues. Enhancements to the Sentinel System will improve public health by increasing patient protection while continuing to enable access to needed medications.

User fees will provide support for A) advancing postmarketing drug safety evaluation through expansion of the Sentinel System, B) FDA pharmacovigilance activities, and B) timely and effective evaluation and communication of postmarketing safety ﬁndings related to human drugs.

1. Advancing Postmarketing Drug Safety Evaluation Through Expansion of the Sentinel System and Integration into FDA Pharmacovigilance Activities

FDA will use user fees to conduct a series of activities to systematically implement projects and seek stakeholder feedback in FDA pharmacovigilance practices. These activities will involve augmenting the quality and quantity of data available through the Sentinel System, developing tools for determining when and how that data is utilized, and comprehensive training of review staff on the use of Sentinel.

a. By the end of FY 2018, FDA will hold or fund by contract, an assessment of how its current and emerging Sentinel systems, FDA will implement robust mechanisms to improve management of PDUFA program funding. FDA is committed to enhancing management of PDUFA resources and improving PDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct a series of resource capacity planning and financial transparency activities to enhance management of PDUFA resources in PDUFA VI.

II. ENHANCING MANAGEMENT OF USER FEE RESOURCES

A. Resource Capacity Planning and Modernized Time Reporting

FDA is committed to enhancing management of PDUFA resources in PDUFA VI. FDA will conduct activities to develop a resource capacity planning function and modernized time reporting approach in PDUFA VI.

1. Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs

FDA will use user fee funds to continue to support review, oversight, tracking, and communication of postmarketing drug safety issues.

a. FDA will make improvements to its current processes that capture and track information, including enhancements to its information technology systems, as needed, in order to support the management and oversight of postmarketing drug safety issues.

b. By the end of FY 2019, FDA will update existing policies and procedures (MAPPs and SOPPs) concerning tracking postmarketing safety signals to include consistent and timely notification to a sponsor (1) when a serious safety signal involving a product is identified and (2) to the extent practicable, not less than 72 hours before public posting of a safety notice under section 921 of the Food and Drug Administration Amendments Act of 2007.

c. By the end of FY 2022, FDA will conduct, or fund by contract, an assessment of how its data systems and processes, as described in MAPPs and SOPPs, and reporting, oversight, and communication of postmarketing drug safety issues.

2. Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs

FDA will modernize the user fee structure to improve the predictability of FDA funding and sponsor invoices, improve efficiency by simplifying the administration of user fees, and ensure fair treatment of sponsors. These activities could include what the Agency has learned regarding the current processes that capture and track information, including enhancements to its information technology systems, as needed, in order to support the management and oversight of postmarketing drug safety issues.
capacity adjustment will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability. FDA will conduct activities to develop and implement an annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized.

**B. Financial Transparency and Efficiency**

The contractor will perform an evaluation of the PDUFA program resource planning during FY 2018 to ensure that PDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct activities to enhance transparency of the PDUFA program resources.

1. FDA will contract with an independent third party to conduct an evaluation of the PDUFA program resource planning during FY 2018 to ensure that PDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner in PDUFA VI. The study will include, but is not limited to, the following areas:

a. Evaluate all components of the PDUFA program resource planning, request, and allocation. Provide FDA resource planners with a plan to utilize fee funds through when funds are spent. The contractor will recommend options to improve the process and data needed to enhance resource management decisions.

b. Assess how FDA administers PDUFA user fees organizationally, including, but not limited to, billing, user fee collection, and expenditures. The contractor will recommend options to enhance the efficiency of user fee administration.

c. Evaluate FDA's existing PDUFA program financial and administrative oversight and governance functions. Assess alternative governance models including roles and responsibilities, organizational location, and personnel skill sets required. The contractor will recommend options on the most effective governance model to support the human drug review program.

d. Assess FDA's technical capabilities to conduct effective financial management and planning in the context of generally accepted government-wide resource management and planning practices. The contractor will recommend options for the technical capabilities needed by financial personnel involved in PDUFA program resource management to enhance financial management and planning.

e. Evaluate how FDA estimates fee paying units for annual fee setting. The contractor will recommend options to enhance the accuracy of FDA's PDUFA user fee estimation methods.

2. FDA will publish a PDUFA 5-year financial plan no later than the 2nd quarter of FY 2018. FDA will publish updates to the plan no later than the 2nd quarter of each subsequent fiscal year.

3. FDA will convene a public meeting no later than the third quarter of each fiscal year in FY 2018 to discuss the PDUFA 5-year financial plan, along with the Agency's progress in implementing modernized time reporting, resource capacity planning, and the modernized user fee structure. FDA will publish updates to the 5-year financial plan no later than the 2nd quarter of FY 2019 to discuss the planning in the context of generally accepted financial management and planning practices.

**III. IMPROVING FDA HIRING AND RETENTION OF REVIEW STAFF**

To speed and improve development of safe and effective new therapies for patients, enhancing human drug review capacity and capability is essential. The contractor will recommend options for the technical capabilities and effective new therapies for patients, enhancing human drug review capacity and capability is essential. The contractor will recommend options for the technical capabilities and effective new therapies for patients, enhancing human drug review capacity and capability is essential. The contractor will recommend options for the technical capabilities and effective new therapies for patients, enhancing human drug review capacity and capability is essential.

**A. Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity**

1. Complete implementation of FTE-based position management system capability.

   a. FDA will complete development of Position Management baseline accounting of all current positions and FTE counts engaged in the human drug review program. In addition, the FDA will complete the transition from the Established Center and Office including filled and vacant positions, a governance structure for on-going position management that will accommodate PDUFA funding, FTE management, and Position Management policy and guidance ratified by FDA senior management, outlining processes for adding new positions, deleting positions, and changing established positions.

   b. FDA will complete implementation of the new Position-Based Management System.

2. Complete implementation of an online position classification system.

   a. FDA will finalize the establishment of an online Position Description (PD) library. The library will include all current well-classified PDs and current standardized PDs. Once operational, any new PDs classified using the on-line classification tools, and any newly created standardized PDs, will be stored and accessible within FDA's PD library and available for FDA-wide use as appropriate.

   b. Complete implementation of corporate recruiting.

   a. Post key scientific and technical disciplines commonly needed across offices engaged in the human drug review program. FDA will complete the transition from the use of individual vacancy announcements for individual offices to expanded use of a common vacancy announcement and certificate of eligible job applicants that can be used by multiple offices. As a part of this effort, FDA will complete the transition from use of individual vacancy announcements that are posted for a limited period to common vacancy announcements with open continuous posting to maximize the opportunity for qualified applicants to apply for these positions.

**B. Augmentation of Hiring Staff Capacity and Capability**

In recognition of the chronic and continuing difficulties of recruiting and retaining sufficient numbers of qualified Human Resources (HR) staff, FDA will engage a qualified contractor to provide continuous support throughout PDUFA VI to augment the existing FDA HR staff capacity and capabilities. The utilization of a qualified contractor will assist FDA in successfully accomplishing PDUFA goals for recruitment and retention of human drug review program staff.

**C. Complete Establishment of a Dedicated Function to Ensure Needed Science and Matchmaking**

1. Rapid advances in the science and technology of human drug development and manufacturing require FDA’s human drug review program staff to keep pace with science and learn innovative methods and techniques for review of new therapies. FDA will complete the transition from the use of individual vacancy announcements for individual offices to expanded use of a common vacancy announcement and certificate of eligible job applicants that can be used by multiple offices. As a part of this effort, FDA will complete the transition from use of individual vacancy announcements that are posted for a limited period to common vacancy announcements with open continuous posting to maximize the opportunity for qualified applicants to apply for these positions.

2. FDA will confirm progress in the hiring of PDUFA V FTEs. FDA will report on progress against the hiring goals for FY 2018–2022 on a quarterly basis posting updates to the FDA’s PDUFA Performance webpage.

**E. Comprehensive and Continuous Assessment of Hiring and Retention**

FDA hiring and retention of staff for the human drug review program will be evaluated by a qualified, independent contractor with expertise in assessing HR operations and transformation. This will include continuous assessments throughout the course of implementation of initiatives identified in sections III.A–D, and metrics including, but not limited to, those related to recruitment and retention in the human drug review program including, but not limited to, specifically targeted scientific disciplines and levels of experience.

The contractor will conduct a comprehensive review of current hiring processes and hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in human drug review program staffing. This includes the entire hiring function and related capabilities. FDA and regulated industry leadership will periodically and regularly assess the progress of hiring and retention throughout PDUFA VI.
1. Initial Assessment: The assessment will include an initial baseline assessment to be conducted and completed no later than December 31, 2017. The initial baseline study will be an evaluation of the current state and provide recommended options to address any identified gaps or areas identified as priorities for improvement, and a study plan published no later than December 31, 2017. FDA will hold a public meeting no later than December 31, 2017, to present and discuss report findings, and present and specific plans, including agency senior management oversight, and timeline for implementing recommended enhancements to be fully operational by no later than December 31, 2018.

2. Interim Assessment: An interim assessment will be published by March 31, 2020, for public comment. By June 30, 2020, FDA will hold a public meeting during which the public may present their views. FDA will discuss the findings of the interim assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment. FDA will also address any issues identified to date including actions proposed to improve the likelihood of success of the program.

3. Final Assessment: A final assessment will be published by December 31, 2021, for public comment. FDA will hold a public meeting by no later than March 30, 2022, during which the public may present their views. FDA will discuss the findings of the final assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment. FDA will also address any issues identified and plans for addressing these issues.

IV. INFORMATION TECHNOLOGY GOALS

A. Objective

FDA is committed to achieving the long-term goal of improving the predictability and consistency of the electronic submission process (Section IV.B), and enhancing transparency and accountability of FDA information technology related activities (Section IV.C). FDA is pursuing these objectives through IT investments that support the PDUFA program.

B. Improve the Predictability and Consistency of PDUFA Electronic Submission Processes

1. Electronic Submission Documentation: By December 31, 2017, FDA will publish and maintain up-to-date documentation for the following:
   a. The electronic submission process, including key electronic submission milestones and associated sponsor notifications.
   b. The rejection process for electronic submissions.
   c. The electronic submission validation criteria.
   d. Software names and versions for Electronic Technical Document (eCTD) validation and data validation tools.

2. Electronic Submission and System Status:

By September 30, 2018, FDA will:
   a. Publish targets for and measure ESG availability overall (including scheduled downtime) and during business hours (8am to 8pm). ESG availability is defined in Section I.A.1.
   b. Publish submission instructions to use the event of an ESG service disruption.
   c. By December 31, 2017, FDA will publish target submission upload duration(s) and timeframes between key milestones.
   d. Publish ESG scheduled unavailability and user interface changes.

3. Enhance Transparency and Accountability of PDUFA Submission and Data Standards Activities:

   a. FDA staff and industry will jointly plan and hold quarterly meetings and will share performance updates prior to each meeting.
   b. The meeting will address current challenges and emerging needs.

4. By September 30, 2018, FDA will implement the ability to communicate electronic submission milestone notifications, including final submission upload status (e.g., successfully processed or rejected), to sender designated contact.

5. FDA will provide expert technical support for electronic submissions to FDA reviewers and stakeholders.

6. For those systems that sponsors interact with directly, FDA will invite industry to participate in public comment. To advance testing in advance of implementing significant changes that impact industry’s interaction with the system.

7. By December 31, 2017, FDA will document and implement a process to provide advance notification of systems and process changes commensurate with the complexity of the change.

8. Comprehensive and continuous assessment of hiring and retention as described in Section I.K.

B. FDA will include in the annual PDUFA Performance Report information on the Agency’s progress in meeting the specific commitments identified in Sections I.I–K of this document.

C. Safety updates submitted in the same fiscal year.

D. FDA will post, at least annually, historic and current metrics on ESG performance in relation to published targets, characterized by volume of submissions, and standards adoption and consequence.

E. By December 31, 2017, FDA will incorporate milestones in support of PDUFA goals into the IT Strategic Plan. Milestones and metrics for PDUFA initiatives will be included in the plan. The plan will be updated and discussed annually during a meeting described in Section IV.C.1.

F. FDA will:
   a. Collaborate with Standards Development Organizations to enhance the predictability and long-term sustainability of supported data standards.
   b. Publish a data standards action plan updated at least annually for each PDUFA review program.
   c. Publish and maintain a current FDA Data Standards Catalog.

V. IMPROVING FDA PERFORMANCE MANAGEMENT

A. The Studies Conducted Under This Initiative are Intended to

1. Development of programs to improve access to internal and external expertise.

2. Reviewer development programs, particularly as they relate to the human drug review programs.

3. Advancing science and use of information management tools.

4. Improving both inter- and intra-Center consistency, efficiency, and effectiveness.

5. Improved reporting of management objectives.

6. Increased accountability for use of user fee revenues.

7. Focused investments on improvements in the process for the review of human drug applications.

8. Improved communication between the FDA and industry.

B. Studies Will Include

1. Assessment of current practices of FDA and sponsors in characterization of drug development as described in Section I.I.1.

2. Assessment of the current practices for combination drug product review as described in Section I.I.1.

3. Evaluation of how reviewers across the organization apply the benefit-risk framework and identify best practices in use of the benefit-risk framework as described in Section I.I.2.

4. Analysis of the impact of the Sentinel expansion and use for regulatory purposes as described in Section I.I.2.

5. Assessment of how FDA data systems and processes, as described in MAPPs and SOPPs, support review, oversight, and compliance in the hiring of new staff to support the new initiatives as identified in Sections I.K.1.

6. Evaluation of options and recommendations for a new methodology to accurately assess changes in the budgetary needs of the human drug review program as described in Section I.I.2.

7. Evaluation of PDUFA program resource management to ensure that PDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner in PDUFA VI as described in Section III.

8. Comprehensive and continuous assessment of hiring and retention as described in Section III.E.

VI. PROGRAM REPORTING FOR PDUFA VI AND CONTINUING PDUFA V INITIATIVES

A. FDA will include in the annual PDUFA Performance Report information on the Agency’s progress in meeting the specific commitments identified in Sections I.I–K of this document.

B. FDA will include in the annual PDUFA Financial Report information on the Agency’s progress in the hiring of new staff to support the new initiatives as identified in Section III.

VII. DEFINITIONS AND EXPLANATION OF TERMS

1. “Human drug applications” refers to new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act and biologics license applications submitted under section 351(a) of the Public Health Service Act, as defined in the Prescription Drug User Fee Act.

2. “Human drug review program” refers to the activities to conduct “the process for the review of human drug applications,” as defined in the Prescription Drug User Fee Act.

3. The term “review and act on” means the issuance of a complete action letter after the commissioner review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.

4. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

5. Class 1 resubmitted applications are applications resubmitted after a complete response letter (or a not approvable or approval letter) that includes the following items only (or combinations of these items):

   a. Final printed labeling
   b. Draft labeling
   c. Summary updates submitted in the same format, including tabulations, as the original safety submission with new data and features

8. Comprehensive and continuous assessment of hiring and retention as described in Section III.E.
changes highlighted (except when large amounts of new information including important new adverse experiences not previously reported with the product are presented in the resubmission)

d. Status updates to support provisional or final dating periods

8. Other minor clarifying information (determined by the Agency as fitting the Class 1 category)

j. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry

Class 2 resubmissions are resubmissions that include any other items, including any items that would require presentation to an advisory committee.

7. The performance goals and procedures also apply to original applications and supplements for human drugs initially marketed for over-the-counter (OTC) uses through an NDA or switched from prescription to OTC status through an NDA or supplement.

As used in this commitment letter, “regulatory decision making” may include, for example, FDA’s process for making a regulatory decision on a drug or biological product throughout the product lifecycle, such as during drug development, following FDA’s review of a marketing application, including review of proposed labeling for the product, or in the post-approval period (e.g., FDA’s decision regarding a supplement to an approved application).

Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD, as follows:

BIOSIMILAR BIOLOGICAL PRODUCT AUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022

I. Ensuring the Effectiveness of the Biosimilar Biological Product Review Program
A. Review Performance Goals
B. Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs
C. First Cycle Review Management for Supplements with Clinical Data
D. Guidance

<table>
<thead>
<tr>
<th>Performance Goal</th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
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<td>Prior approval</td>
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<td>75% in 4 months of receipt</td>
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<td>All other</td>
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<td>90% in 6 months of receipt</td>
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5. Review Performance Goal Extensions
a. Major Amendments
i. Amendments submitted to an original application, supplement with clinical data, or resubmission of any of these applications, submitted at any time during the review cycle, may extend the goal date by three months.

ii. A major amendment may include, for example, a major new clinical study report; major protocol changes; and any newly submitted study(ies); submission of a risk evaluation and mitigation strategy (REMS) with elements to assure safe use (ETASU) not included in the original application; or significant new information previously submitted REMS with ETASU. Generally, changes to REMS that do not include ETASU and minor changes to REMS with ETASU will not be considered major amendments.

iii. A major amendment to a manufacturing supplement submitted at any time during the review cycle may extend the goal date by two months.

iv. Only one extension can be given per review cycle.

v. Consistent with the underlying principles articulated in the GRMP guidance, FDA’s decision to extend the review cycle should, except in rare circumstances, be limited to occasions where review of the new information could address outstanding deficiencies in the application and lead to approval in the current review cycle.
b. Inspection of Facilities Not Adequately Identified in an Original Application or Supplement
   i. All original applications and supplements include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement. This list provides FDA with the information necessary to inspect the facilities that may be necessary before approval of the original application or supplement.
   ii. In the event of an original application or supplement, the Agency identifies a manufacturing facility that was not included as part of the comprehensive and readily located list in an original application or supplement with clinical data, the goal date may be extended by three months.

2. If FDA requests the applicant inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in a manufacturing supplement, the goal date may be extended by two months.

B. Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs

The Program for Enhanced Review Transparency and Communication between the FDA review team and the applicant, FDA will apply the following model ("the Program") to the review of all original Biologics License Applications (BLAs) submitted under section 351(k) of the Public Health Service Act ("351(k) BLAs"), including applications that are resubmitted following a Refuse-to-File decision, received from October 1, 2017, through September 30, 2022. The goal of the Program is to promote the efficiency and effectiveness of the first cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality biosimilar and biologic products.

The approach for the review of original 351(k) BLAs is described in section 1. However, the FDA review team and the applicant will agree on an alternative approach to the timing and nature of interactions and information exchange between the applicant and FDA, as described in this Guide and Instructions For Use) and, where applicable, the development of a Formal Communication Plan. These discussions will be summarized in the minutes of the meeting and reflected in the FDA meeting minutes.

The FDA and the applicant will agree on the content of a complete application for the proposed indication(s) at the pre-submission meeting. The pre-submission meeting will be subject to the review performance goal as described in Section I.A.1.a. The pre-submission meeting goal is not indicative of deficiencies that may be identified later in the review cycle.

1. Pre-submission meeting:
   a. The pre-submission meeting will be held 30 calendar days from the date of FDA receipt of the original submission. The timeline for this communication will be subject to the review performance goal as described in Section I.A.1.a. The pre-submission meeting goal is not indicative of deficiencies that may be identified later in the review cycle.
   b. Applications are expected to be complete, as agreed between the FDA review team and the applicant at the pre-submission meeting. The pre-submission meeting will be subject to the review performance goal as described in Section I.A.1.a. The pre-submission meeting goal is not indicative of deficiencies that may be identified later in the review cycle.
   c. Applications are expected to be complete at the time of submission. Applications that are incomplete within 30 calendar days after receipt of the original submission, will be subject to a Refuse-to-File decision.
   d. The following parameters will apply to applications that are subject to a Refuse-to-File decision and are subsequently filed over protest:
   i. The original submission of the application will be subject to the review performance goal as described in Section I.A.1.a.
   ii. The application will be handled in accordance with the GRMP guidance including the underlying principle that FDA will consider the most efficient path toward completion of a comprehensive review that addresses application deficiencies and issues identified during the initial filing review.
   iii. Day 74 letter: FDA will follow existing procedures regarding identification and communication of substantive review issues identified during the initial filing review to the applicant in the "Day 74 letter." If no substantive review issues were identified during the filing review, FDA will so notify the applicant. FDA’s filing review represents a preliminary review of the application and is not indicative of deficiencies that may be identified later in the review cycle.
   iv. For applications subject to the Program, the timeline for this communication will be within 74 calendar days from the date of FDA receipt of the original submission.

2. Original mid-cycle submission:
   a. The following mid-cycle review meetings will be subject to the review performance goal as described in Section I.A.1.a. The mid-cycle review meeting goal is not indicative of deficiencies that may be identified later in the review cycle.
   b. Applications are expected to be complete, as agreed between the FDA review team and the applicant at the mid-cycle review meeting. The mid-cycle review meeting will be subject to the review performance goal as described in Section I.A.1.a. The mid-cycle review meeting goal is not indicative of deficiencies that may be identified later in the review cycle.
   c. In the event of an original application or supplement, the Agency identifies a manufacturing facility that was not included as part of the comprehensive and readily located list in the application or supplement, the goal date may be extended by three months.

3. Mid-cycle communication:
   a. All original applications and supplements include a comprehensive and readily located list of all manufacturing facilities included or referenced in the application or supplement.
   b. Any components of the application that FDA identifies as needing to be submitted for review following a mid-cycle communication meeting could be submitted after the original application are expected to be received not later than 30 calendar days after receipt of the original application. Applications, including applications with components that are not received within 30 calendar days after receipt of the original submission, will be subject to a Refuse-to-File decision.

   i. The mid-cycle review meeting goal is not indicative of deficiencies that may be identified later in the review cycle.
applicant with an update on the status of the review of their application. An agenda will be sent to the applicant prior to the mid-cycle communication. Scheduling of the inter- nal review team meeting will be handled in accordance with the GRMP guidance. The RPM will coordinate the specific date and time of the telephone call with the applicant.

The update should include any significant issues identified by the review team to date, any information requests, and information regarding any planned late-cycle meeting with the following: 

a. The analytical similarity data, including the potential relevance of any issues (e.g. data analysis issues or potential clinical impact). Any critical differences intended to support a demonstration that the proposed biosimilar biological product is highly similar to the reference product.

b. The data intended to support a demonstration of no clinically meaningful differences, including discussion of any immunogenicity issues.

c. The data intended to support a demonstration of interchangeability.

d. CMC issues.

In addition, the update should include preliminary review team thinking regarding the content of the proposed REMS, where applicable, proposed date(s) for the late-cycle meeting and other projected milestone dates for the remainder of the review cycle.

4. Late-Cycle Advisory Committee Meetings: A meeting will be held between the FDA review team and the applicant to discuss the timeline of the review of the application late in the review cycle. Late-cycle meetings will generally be face-to-face meetings; however, the meeting may be held by teleconference if FDA and the applicant agree. Since the application is expected to be complete at the time of submission, FDA intends to complete primary and secondary reviews of the application in advance of the planned late-cycle meeting.

a. FDA representatives at the late-cycle meeting are expected to include the signatory authority for the application, review team members from appropriate disciplines, and appropriate team leaders and/or supervisors from disciplines for which substantive issues have been identified in the review to date.

b. For applications that will be discussed at an Advisory Committee (AC) meeting, the following apply:

i. FDA intends to convene AC meetings no later than 2 months prior to the Biologics License Application (BLA) goal date. The late-cycle meeting will occur not less than 12 calendar days before the date of the AC meeting.

ii. FDA intends to provide final questions for the AC to the sponsor and the AC not less than 2 weeks prior to the AC meeting.

iii. Following an AC meeting, FDA and the applicant may agree on the need to discuss feedback from the committee for the purpose of facilitating the remainder of the review. Such a meeting will generally be held by teleconference without a commitment for formal meeting minutes issued by the agency.

c. For applications that will not be discussed at an AC meeting, the late-cycle meeting will generally occur not later than 3 months prior to the BLA goal date.

d. Late-Cycle Meeting Background Packages: The Agency background package for the late-cycle meeting will be sent to the applicant not less than 10 calendar days before the late-cycle meeting. The package will consist of any discipline review (DR) letters issued, a preliminary report from the review team outlining substantive application issues (e.g., deficiencies identified by primary and secondary reviews), the Agency’s background package for the AC meeting (incorporated by reference if previously sent to the applicant), potential questions and/or potential agenda items for the meeting (or minutes, if planned) and the current assessment of the content of proposed REMS or other risk management actions, where applicable.

5. Late-Cycle Topics: Potential topics for discussion at the late-cycle meeting include:

i. Major deficiencies identified to date;

ii. Interchangeability data, including the potential relevance of any issues (e.g. data analysis issues or potential clinical impact) or potential critical differences intended to support a demonstration that the proposed biosimilar biological product is highly similar to the reference product;

iii. All data intended to support a demonstration of no clinically meaningful differences, including discussion of any immunogenicity issues.

iv. Issues intended to support a demonstration of interchangeability.

v. CMC issues.

vi. Inspectional findings identified to date.

vii. Issues to be discussed at the AC meeting (if planned).

viii. Current assessment of the content of proposed REMS or other risk management actions, where applicable.

ix. Information requests from the review team to the applicant; and additional data or analyses the applicant may wish to submit.

With respect to any additional data or analyses, the FDA review team and the applicant will discuss whether such data will be reviewed by the Agency in the current review cycle and, if so, whether the submission will be considered a major amendment and trigger an extension of the BLUF.

7. Inspections: FDA’s goal is to complete all GCP, GLP, and GMP inspections for applications in the Program within 10 months of the date of original receipt of the application. This will allow 2 months at the end of the review cycle to attempt to address any deficiencies identified by the inspections.

8. Assessment of the Program: The Program described in this Section I.B shall be evaluated to determine its impact on the efficiency and effectiveness of the first review cycle for biosimilar products. The assessment shall be conducted by an independent contractor with expertise in assessing quality and efficiency of biopharmaceutical development and regulatory review programs. The statement of work for this effort will be published for public comment prior to beginning the assessment. The assessment will occur continuously throughout the course of the Program.

Aspects and other measures of the Program that will be assessed by the independent contractor include, but are not limited to:

a. Adherence by the applicant and FDA to the current GRMP guidance or the GRMP guidance as updated in accordance with Section I.D, as applicable.

b. Completeness and quality of the submitted application.

c. Number of unanticipated amendments submitted by the applicant.

d. Timing and adequacy of Day 74 letters conducted for the mid-cycle communication of any DR letters.

9. Late-cycle meeting background package conduct of the late-cycle meeting time to approval.

Percentage of applications that are approved during the first review cycle:

a. Percentage of applications that are extended beyond the first review cycle.

b. Number of review cycles for applications that are ultimately approved time to resubmission for applications that receive a complete response in the first review cycle.

This assessment will also include a demonstration of the issues typically discussed during the mid-cycle communication and the late-cycle meeting and the ability of the additional FDA-applicant commitments with Clinical Data
FDA will inform the applicant of the planned review timeline for 90% of all supplements with clinical data.

In the event FDA determines that significant deficiencies exist, the applicant may request a meeting with FDA to discuss the proposal and any actions the sponsor might take to persuade the Agency to reverse its decision.

If the Agency decides to present the issue to an advisory committee and there are not 30 days before the next scheduled advisory committee meeting, this will be presented at the next scheduled advisory committee meeting to allow conformance with advisory committee administrative procedures.

Clinical Hold

1. Procedure: The Center should respond to a sponsor’s complete response to a clinical hold within 30 days of the Agency’s receipt of the submission of such sponsor response. The Center will provide written notice to the Agency that the responses are provided within 30 calendar days of the Agency’s receipt of the sponsor’s response.

H. Special Protocol Question Assessment and Agreement

1. Procedure: Upon specific request by a sponsor (including specific questions that the sponsor desires to be answered), the Agency will evaluate certain protocols and request issues to assess whether the design is adequate to meet scientific and regulatory requirements identified by the sponsor.

a. The sponsor should submit a limited number of specific questions about the protocol design and scientific and regulatory requirements for which the sponsor seeks agreement (e.g., are the clinical endpoints adequate to assess whether the clinically meaningful differences between the proposed biosimilar biological product and the reference product).

b. Within 45 days of Agency receipt of the protocol and specific questions, the Agency will provide a written response to the sponsor that includes a succinct assessment of the protocol design and any answers to the specific questions proposed by the sponsor. If the Agency does not agree that the protocol design, execution plans, and data analyses are adequate to meet scientific and regulatory requirements, the Agency will provide written notice to the Agency that the responses for the disagreement will be explained in the response.

2. Performance goal: 90% of such responses are provided within 30 calendar days of the Center’s receipt of the written appeal.

3. Conditions:

a. Sponsors should first try to resolve the procedural or scientific issue at the signatory authority level. If it cannot be resolved at that level, it should be appealed to the next higher organizational level (with a copy to the signatory authority) and then, if necessary, to the next higher organizational level.

b. Responses should be either verbal (followed by a written confirmation within 14 calendar days of the verbal notification) or written and should ordinarily be to either grant or deny the appeal.

c. If the decision is to deny the appeal, the response should include reasons for the denial and any actions the sponsor might take to persuade the Agency to reverse its decision.

d. In some cases, further data or further input from others might be needed to reach a decision. In such cases, the “response” should be the plan for obtaining that information (e.g., requesting further information from the sponsor, scheduling a meeting with the sponsor, or scheduling the issue for discussion at the next scheduled available advisory committee).

e. In these cases, once the required information is received by the Agency (including any advice from an advisory committee), the person to whom the appeal was made, again with the review division so that the division is aware of the developmental context in which the protocol is being reviewed and the questions being answered.
protocols reviewed under this process, the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

2. Performance goal: 90% of special protocol assessments and agreement requests completed and returned to sponsor within 45 days.

3. Reporting: The Agency will track and report the number of original special protocol assessments and resubmissions per original special protocol assessment.

I. Meeting Management Goals

Formal BioUFA meetings between sponsors and FDA consist of Biosimilar Initial Advisory and BPD Type 1–4 meetings. These meetings are further described below.

A Biosimilar Initial Advisory Meeting is an in-depth data review and advice meeting regarding an ongoing trial, affecting the proposed biosimilar biologic product and the reference product. Such a meeting will include substantive review of summary data or full biosimilar product.

A BPD Type 1 Meeting is a meeting which is necessary for an otherwise stalled drug development program to proceed (e.g., meeting to discuss or confirm assay selection meeting), a special protocol assessment meeting, or a meeting to address an important safety issue.

A BPD Type 2 Meeting is a meeting to discuss a specific issue (e.g., proposed study design or endpoints) or questions where FDA may provide targeted advice related to the decision to continue, discontinue, or proceed with the development program. Such term may include an initial substantive review of summary data, but does not include review of full study reports.

A BPD Type 3 Meeting is an in-depth data review and advice meeting regarding an ongoing biosimilar biological product development program. Such term includes substantive review of full study reports, FDA advice regarding any potential regulatory issues identified by the sponsor, and discussion of the proposed biosimilar biological product and the reference product, and FDA advice regarding additional studies, including design and analysis.

A BPD Type 4 Meeting is a pre-submission meeting to discuss the format and content of a complete application for an original biosimilar biological product application under the Program or supplement submitted under §313(k) of the PHS Act. The purpose of this meeting is to discuss the format and content of the planned submission and other items, including identification of any potential issues identified based on the information provided, identification of the status of ongoing or needed studies to adequately address the Food and Drug Administration Act (PREA), accounting FDA reviewers with the general information to be submitted in the marketing application (including technical information), and discussion of the best approach to the presentation and formatting of data in the marketing application.

1. Response to Meeting Requests

a. Procedure: FDA will notify the requester of the date, time, and place for the meeting, as well as expected Center participants following receipt of a formal meeting request and background package. Table 1 below indicates the timeframes for FDA’s response to a meeting request.

<table>
<thead>
<tr>
<th>Meeting type</th>
<th>Response time (calendar days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biosimilar Initial Advisory</td>
<td>21</td>
</tr>
<tr>
<td>BPD Type 1</td>
<td>14</td>
</tr>
<tr>
<td>BPD Type 2–4</td>
<td>21</td>
</tr>
</tbody>
</table>

For Biosimilar Initial Advisory and BPD Type 2 meetings, the sponsor may request a written response to its questions, rather than a face-to-face meeting, videoconference or teleconference. If a written response is deemed appropriate, FDA will notify the requester of the date it intends to send the written response. This date will be consistent with the timeframes specified in Table 2 below for the specific meeting type.

b. Performance Goal: FDA will respond to meeting requests and provide notification within the response times noted in Table 1 for 90 percent of each meeting type.

2. Scheduling Meetings

a. Procedure: FDA will schedule the meeting on the next available date at which all applicable Center personnel are available to attend, consistent with the component’s other business; however, the meeting should be scheduled consistent with the type of meeting requested. Table 2 below indicates the timeframes for FDA to schedule the meeting following receipt of a formal meeting request and background package, or in the case of a written response for Biosimilar Initial Advisory and BPD Type 2 meetings, the timeframes for the Agency to send the written response. If the requested date for any meeting type is greater than the specified timeframe, the meeting date should be within 14 calendar days of the requested date.

<table>
<thead>
<tr>
<th>Meeting type</th>
<th>Meeting scheduling or written response time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biosimilar Initial Advisory</td>
<td>75 calendar days from receipt of meeting request and background package.</td>
</tr>
<tr>
<td>BPD 2</td>
<td>90 calendar days from receipt of meeting request and background package.</td>
</tr>
</tbody>
</table>

b. Performance Goal: 90% of minutes are consistent with the timeframes specified in Table 2 for each meeting type and the meeting should be within or beyond the appropriate time frame of the meeting type being requested.

3. Preliminary Responses

a. Procedure: The Agency will send preliminary responses to the sponsor’s questions contained in the background package no later than five calendar days before the face-to-face, videoconference or teleconference meeting date for BPD Type 2 and Type 3 meetings.

b. Performance goal:

<table>
<thead>
<tr>
<th>Meeting type</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPD Type 2</td>
<td>2018–2019: 80% of responses are sent within the timeframe.</td>
</tr>
<tr>
<td></td>
<td>2020–2021: 80% of responses are sent within the timeframe.</td>
</tr>
</tbody>
</table>

4. Meeting Minutes

a. Procedure: The Agency will prepare minutes which will be available to the sponsor 30 calendar days after the meeting. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and agenda items from the meeting in bulleted form and need not be in great detail. Meeting minutes are not necessary if the Agency transmits a written response for Biosimilar Initial Advisory and BPD Type 2 meetings.

b. Performance Goal: 90% of minutes are issued within 30 calendar days of the date of the meeting.

5. Conditions

For a meeting to qualify for the following performance goals:

a. A written request and supporting documentation (i.e., the background package) must be submitted to the appropriate review division or office.

b. The request must provide:

1. A brief statement of the purpose of the meeting, the sponsor’s proposal for the type of meeting, and the sponsor’s proposal for a meeting, teleconference, or a written response (Biosimilar Initial Advisory and BPD Type 2 meetings only);

2. A listing of the specific objectives/outcomes the requester expects from the meeting;

3. A proposed agenda, including estimated times needed for each agenda item;

4. A list of questions, grouped by discipline. For each question there should be a brief explanation of the context and purpose of the question;

5. A listing of planned external attendees; and

6. A listing of requested participants/diagnosis representatives from the Center with an explanation for the request as appropriate.

a. Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or beyond the appropriate time frame of the meeting type being requested.

b. The Agency concurs that the meeting will serve a useful purpose (i.e., it is not premature or clearly unnecessary). However, requests for BPD Type 2, 3, and 4 Meetings will be reviewed except in the most unusual circumstances.

The Center may determine that a different type of meeting (i.e., Biosimilar Initial Advisory, or BPD Type 1–4) is more appropriate and it may grant a meeting of a different type than requested, which may require the payment of a biosimilar biological product development fee as described in section 744H of the Federal Food, Drug, and Cosmetic Act before the meeting will be provided. If a biosimilar biological product development fee is required, the sponsor must pay the fee within the time frame required under section 744H, the meeting will be cancelled. If the sponsor pays the biosimilar biological product development fee after the meeting has been cancelled due to non-payment, the time frame described in
section I.I.1.a will be calculated from the date on which FDA received the payment, not the date on which the sponsor originally submitted the meeting request.

Sponsors are encouraged to consult available FDA guidance to obtain further information on recommended meeting procedures.

6. Guidance

a. FDA will publish revised draft guidance on Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants no later than September 30, 2018.

b. FDA will update the current draft or final guidance on Best Practices for Interac-
tion Between IND Sponsors and FDA During Drug Development, as appropriate, to apply to communications between IND spon-
sors and biosimilar biological product development. FDA will publish a re-
vised draft or final guidance by December 31, 2018.

II. ADVANCING DEVELOPMENT OF BIOSIMILAR BIO-
LOGICAL PRODUCTS THROUGH FURTHER CLARIFICATION OF THE 351(k) REGULATORY PATHWAY

A. On or before December 31, 2017, FDA will publish revised draft guidance describing consider-
ations in demonstrating interchangeability with a reference product. FDA will work to-
toward the goal of publishing a revised draft or final guidance within 24 months after the close of the public comment period.

B. On or before December 31, 2017, FDA will publish draft guidance describing statistical consideration analysis of analytical similarity data intended to support a dem-
onstration of “highly similar” for biosimilar biological products. FDA will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of the public comment period.

C. On or before March 1, 2018, FDA will publish draft guidance describing processes and further considerations related to post-
approval manufacturing changes for bio-
similar biological products. FDA will work toward the goal of publishing a revised draft or final guidance within 18 months after the close of the public comment period.

D. FDA will work towards the goal of pub-
lishing revised draft guidance or final guid-
dance documents on or before May 31, 2019 for draft guidances published between January 1, 2017 and March 30, 2017, otherwise as those described in (II-A.2). These draft guid-
ances will include:

1. Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Refer-
ence Product (draft guidance published in May 2014)

2. Nonproprietary Naming of Biological Products (draft guidance published in August 2015)

3. Labeling for Biosimilar Biological Prod-
ucts (draft guidance published in March 2016)

III. ENHANCEMENT OF CAPACITY FOR BIOSIMILAR REGU-
LATIONS AND GUIDANCE DEVELOPMENT, RE-
VIEW TRAINING, AND TIMELY COMMUNICA-
TIONS

A. FDA will strengthen the staff capacity to develop new regulations and guidance to clarify scientific criteria for biosimilar de-
velopment and approval to provide certainty to industry and other stakeholders related to key regulatory issues including the scope of eligible biosimilar biological products.

B. FDA will strengthen staff capacity to develop or revise MaPPs, SOPPs, and review templates to facilitate rapid update and ap-
plication of new policies and guidance by re-
view staff, and to develop and deliver timely comprehensive training to all CDER and CBER review staff and special government employees involved in the review of 351(k) BLAs.

C. FDA will strengthen staff capacity to deliver timely information to the public to improve public understanding of biosimil-
arity and interchangeability.

D. FDA will strengthen staff capacity to deliver information concerning the date of first licensure and product exclu-
sivity expiry date, to be included in the Purple Book.

FDA will update the Purple Book to in-
clude the following information: the BLA number, product name, proprietary name, date of licensure, interchangeable or bio-
similar determination, and whether the BLA has been withdrawn. FDA will update this information in the Purple Book within 30 days after approval or withdrawal. In ad-
dition, within 30 days after FDA determines the date of first licensure, the date of first li-
censure and the reference product exclu-
sivity expiry date will be included in the Purple Book.

IV. ENHANCING MANAGEMENT OF USER FEE RESOURCES

FDA will establish an independent user fee structure and fee amounts to ensure stable and sustainable fee collections, improve the predictability of FDA funding and sponsor invoices, improve efficiency by simplifying the administration of user fees, and enhance transparency and accountability of the fee.

FDA is committed to enhancing man-
agement of BsUFA resources and ensuring the efficient administration and alloca-
tion of BsUFA user fees. FDA will admin-
for patients, enhancements to the biosimilar biological review program require that FDA hire and retain sufficient numbers and types of technical and scientific experts to efficiently and effectively review new biologics. In order to strengthen this core function and increase public access to biosimilar biological products, the FDA will commit to do the following:

A. Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity

1. Complete implementation of FTE-based position system capability.
   a. FDA will complete development of position management baseline accounting of all current positions and FTE counts engaged in the biosimilar biological product review program for each applicable Center and Office including filled and vacant positions, a governance structure for on-going position management that will be accountable to FDA senior management, and position management policy and guidelines ratified by FDA senior management, outlining processes for adding new positions, deleting positions, and changing established positions.
   b. FDA will complete implementation of the new position-based management system.

2. Completion of an online position classification system.
   a. FDA will finalize the establishment of an online Position Description (PD) library. The library will include all current classified PDs and current standardized PDs. Once operational, any new PDs classified using the online classification tools, and any updated standardized PDs will be stored and accessible within FDA’s PD library and available for FDA-wide use as appropriate.
   b. Complete implementation of corporate recruiting.
      a. For key scientific and technical disciplines commonly needed across offices engaged in the biosimilar biological product review process, FDA will complete the transition from the use of individual vacancy announcements for individual positions to expanded use of a common vacancy announcement and certificate of eligible job applicants that can be used by multiple offices.
      b. The contractor will assist FDA in successfully addressing all identified deficiencies throughout the course of implementation of the metric goals for targeted hires within the biosimilar biological product review program staff for BsUFA II. In particular, FDA will complete implementation of corporate recruiting, conduct outreach to a targeted list of source qualified candidates, and conduct competitive recruiting to fill vacancies that require top scientific, technical, and professional talent.
      c. The contractor will conduct analyses, no less than monthly, of compensation and other factors affecting retention of key staff in targeted disciplines and provide leadership and support for agency compensation oversight boards that currently exist or may be established as needed to ensure retention of key scientific, technical, and professional staff.
   c. Set Clear Goals for Biosimilar Biological Product Review Program Hiring
      1. FDA will establish priorities for management of the metric goals for targeted hires within the biosimilar biological product review program staff for BsUFA II. In particular, the contractor will assist FDA in successfully completing the transition from the use of individual vacancy announcements for individual positions to expanded use of a common vacancy announcement and certificate of eligible job applicants that can be used by multiple offices. As a result, FDA will complete the transition from the use of individual vacancy announcements that are posted for a limited period to common vacancy announcements with open continuous posting to maximize the opportunity for qualified applicants to apply for these positions.

B. Augmentation of Hiring Staff Capacity and Capability

In recognition of the chronic and continuing difficulties of recruiting and retaining sufficient numbers of qualified human Resources (HR) staff, FDA will engage a qualified contractor to provide continuous support throughout BsUFA II to augment the existing FDA HR staff capacity and capabilities. The utilization of a qualified contractor will assist FDA in successfully accomplishing the goals outlined above for augmentation of hiring and retention of biosimilar biological product review program staff.

C. Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Including for Review of Biosimilar Biological Products

1. Rapid advances in the science and technology of biosimilar biological product development and manufacturing require FDA’s biosimilar biological product review program staff to keep pace with science and learn innovative methods and techniques for review of new products. FDA will complete establishment of a new dedicated unit within the Office of Medical Products and Tobacco charged with the continuous recruiting, staffing, and retention of scientific, technical, and professional staff for the PDUFA and BsUFA review programs.

2. Interim Assessment: An interim assessment will be published by March 31, 2020, for public comment. By June 30, 2020, FDA will also address any issues identified to date including actions proposed to improve the likelihood of success of the program. FDA will also address any issues identified to date including actions proposed to improve the likelihood of success of the program.

3. Final Assessment: A final assessment will be published by December 31, 2021, for public comment. FDA will hold a public meeting by no later than March 30, 2022, during which the public may present their views. FDA will discuss the findings of the final assessment, including progress relative to program milestones and metrics, and other aggregated feedback from internal customers and participants in HR services that may be included in the continuous assessment.

V. DEFINITIONS AND EXPLANATION OF TERMS

A. The term “review and act on” means the issuance of a complete action letter after the complete review of a filed complete application. The action letter is available to the full Senate, I ask unanimous consent to have in the RECORD the notifications which have been received. If the cover letter references a classified annex, then such annex is available to all Senators in the office of the Foreign Relations Committee.

In keeping with the committee’s intention to see that relevant information is available to the full Senate, I ask unanimous consent to have in the RECORD the notifications which have been received. If the cover letter references a classified annex, then such annex is available to all Senators in the office of the Foreign Relations Committee.

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

DEFENSE SECURITY
COOPERATION AGENCY,
Arlington, VA.

HON. BOB CORRER, Chairman, Committee on Foreign Relations, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 38, concerning the Notification of Offer and Acceptance to the Government of Australia for defense articles and
services estimated to cost $108.7 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

GREGORY M. KAUSNER,
Acting Director.

Enclosures.

TRANSMITTAL NO. 17–38
Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex Item No. vii
(vii) Sensitivity of technology:
1. The ALE-70 is a towed radio frequency countermeasure designed for deployment from the F-35 aircraft and is comprised of electronic and mechanical sub-assemblies to accomplish the intended purpose. The ALE-70 consists of three major components: the reel-launcher assembly, the tow line, and the T-1687 countermeasure transmitter. Upon deployment from the aircraft, the countermeasure transmitter is reeled out to a prescribed distance, held in tow behind the jet by the tow line. The aircraft responds in response to commands from the countermeasure controller located in the jet. The waveforms are utilized to confuse or deceive adversary radars or radar guided weapons.

2. The ALE-70 generates, amplifies, and transmits signals in response to commands from the countermeasure controller; the electronics keep the towed unit from remaining where the jet. Neither the countermeasure transmitter nor the reel/launcher assembly contains stored information or software representing critical program information.

As the ALE-70 contains no software or stored waveforms/techniques, Anti-Tampering security measures are not required. ALE-70 hardware is classified SECRET to protect specific data elements associated with the performance of the countermeasure.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software details, the information could be used to develop countermeasures or equivalent systems which might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Australia can provide substantially the same degree of protection for the sensitive technology as being released as the U.S. Government.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Australia.

DEFENSE SECURITY
COOPERATION AGENCY
Arlington, VA.

Hon. BOB CORKER
Chairman, Committee on Foreign Relations U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-55, concerning the Department of the Air Force’s proposed Letter(s) of Offer and Acceptance to the Federal Republic of Nigeria, for defense articles and services estimated to cost $593 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

GREGORY M. KAUSNER,
Acting Director.

TRANSMITTAL NO. 16–55
Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

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4. A determination has been made that Australia can provide substantially the same degree of protection for the sensitive technology as being released as the U.S. Government.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Australia.

DEFENSE SECURITY
COOPERATION AGENCY
Arlington, VA.

Hon. BOB CORKER
Chairman, Committee on Foreign Relations U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 16-55, concerning the Department of the Air Force’s proposed Letter(s) of Offer and Acceptance to the Federal Republic of Nigeria, for defense articles and services estimated to cost $593 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

GREGORY M. KAUSNER,
Acting Director.
The proposed sale of this equipment and support does not alter the basic military balance in the region.

The prime contractor is the Sierra Nevada Corporation, headquartered in Centennial, Colorado. There are no known offsets agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of U.S. Government or contractor representatives to Nigeria for mobile training teams and contract logistic support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

CONFIRMATION OF CHRISTOPHER WRAY

Mr. VAN HOLLEN. Mr. President, I wish to voice my support for Christopher Wray’s confirmation to be the next Director of the FBI. After meeting with Mr. Wray and reviewing his record, I believe he embodies the independence and integrity necessary to lead the Bureau through this tumultuous period.

This vacancy arose because President Trump abruptly fired then-Director James Comey. The circumstances surrounding Mr. Comey’s firing are alarming and suspicious. Mr. Comey testified under oath that the President not only demanded his personal loyalty on numerous occasions but also intimated that Mr. Comey should investigate then-National Security Advisor Michael Flynn and Russian interference in the 2016 elections.

Mr. Wray will face numerous challenges as the new Director of the FBI. He will have to deal with a President who has shown a complete disregard for traditional protocols designed to ensure the agency’s independence. During our meeting, Mr. Wray assured me that he would remain independent from the President and would reject any attempts by President Trump to inappropriately intervene in the work of the FBI.

During our meeting, I also impressed upon Mr. Wray the importance of consolidating the FBI’s staff in one building to ensure that it grows with its current space and the building is deteriorating, which compromises the agency’s mission. I look forward to working with him to give FBI personnel the facilities they deserve.

As Mr. Wray takes his position, he will need to work immediately to affirm the FBI’s independence and restore the confidence of an agency shaken by the President’s inappropriate conduct with respect to Mr. Comey and other matters. This Congress must conduct vigorous oversight to ensure that Mr. Wray maintains the high standard of integrity that he has promised and to respond to any attempts by the President or his political advisors to exert undue influence at the FBI. I pledge to do everything I can to support his important mission and the vital work of the FBI.

U.S.-CUBA TRADE ACT OF 2017

Mr. WYDEN. Mr. President, today I wish to propose a new day in U.S. relations with Cuba. With his recent imposition of new restrictions, the President presented one vision of that relationship—one that looks backwards and reverts to a failed policy of isolation that has done nothing to improve the lives of the Cuban people and has harmed the American economy. I would like to present an alternative vision—one that looks to the future and at fostering a new exchange of ideas and commerce between the two countries.

It is often noted that Cuba is less than 100 miles away, but decades between the United States. In no small part because of the U.S. embargo. Decades of the same, tired, failing economic policies left the Cuban Government in place and only hurt the Cuban people and American farmers and manufacturers.

As Cuban-American relations thaw under Presidents Bush and Obama, the Cuban Government decided to try something different. Private entrepreneurs are operating an increasing number of businesses. In Cuba, taxi drivers and tourist-related businesses are opening up their homes for visitors to stay in and selling products directly to visiting Americans. In addition, the government’s grip on information and communication is necessarily weakening as technology and the Internet inevitably permeate the country.

The U.S. has come a long way since the 1990s and hardly resembles the world of the 1960s. Our policies toward Cuba should reflect that change. The U.S.-Cuba Trade Act of 2017 would completely remove the architecture of sanctions against Cuba and establish normal trade relations with that country.

I want to be clear that this is not a free pass for the Cuban Government. I continue to have grave concerns about its suppression of pro-democracy movements, but I reject the view that continued sanctions will bring positive change. The past five decades provide empirical evidence that it will not. I also reject the cynical argument that the U.S. must choose between engagement with Cuba or support for human rights and political freedom. Indeed, if the past half century has shown us anything, it is that smart, principled engagement is the way to bring about greater economic and political freedom for the Cuban people.

Just as important as what the embargo means for the Cuban people is what it means for U.S. farmers and businesses. Even with the changes under the Obama administration, it remains almost impossible to do business in Cuba. Cuba is a natural customer of the United States, but restrictions on credit and travel, among other things, have severely hampered the ability of U.S. exporters to enter the Cuban market. The question is: What are we getting by surrendering a market that should be ours to the EU, China, Brazil, and others? I am afraid that the answer is nothing.

That is why I introduced the U.S.-Cuba Trade Act of 2017, to finally put an end to the ineffective embargo against Cuba.
HONORING CORPSMAN FIRST CLASS RYAN LOHREY

Mr. DONNELLY. Mr. President, today I wish to recognize and honor the extraordinary service and sacrifice of U.S. Navy Hospital Corpsman First Class Ryan Lohrey of Middletown, IN. Dedication to his country, loyalty to his fellow service members, and a deep love for his family were the qualities that defined Ryan’s life.

A native of Middletown, IN, Ryan graduated from Shenandoah High School in 2005. Two years after graduation, he joined the U.S. Navy, where he served as a special amphibious reconnaissance corpsman, providing medical care to his fellow service members.

On Monday, July 10, 2017, Ryan and 15 other service members died tragically when the KC-130J aircraft they were on crashed in Mississippi. The plane was carrying service members from Marine Aerial Refueler Transport Squadron 452 and the 2d Marine Raider Battalion, a special operations unit. Hundreds gathered on July 27 as a military honor guard carried Ryan’s body from Indianapolis International Airport to New Castle, IN. He received military honors during his funeral in Middletown on July 31, 2017.

Ryan is remembered for his selfless sacrifice, humility, patience, and infectious smile. He distinguished himself through his service in the U.S. Navy, where he deployed with the 2d Marine Reconnaissance Battalion and later with the 2d Marine Raider Battalion. He was a veteran of Operation Enduring Freedom in Afghanistan and Operation Inherent Resolve in Iraq. Ryan had qualification as an enlisted fleet marine force warfare specialist, marine combatant diver, and Navy and Marine Corps parachutist. He rose to become a special amphibious reconnaissance corpsman. For his service, among the awards he earned were a Purple Heart, Navy and Marine Corps Commendation Medal, Combat Action Ribbon with Gold Star in lieu of second award, and Good Conduct Medal with two Bronze Stars in lieu of second and third award.

Ryan was a devoted patriot, son, husband, and father, who loved football and making others laugh. He is survived and will be deeply missed by his wife, Cassie; his two children, Gavin and Allie; his parents, Michael and Teresa Lohrey of Middletown; and his grandparents, Barbara Lohrey of Middletown, and George Lohrey, of Sulphur Springs; as well as friends, the U.S. Navy family, and Hoosiers across the State of Indiana.

As Ryan’s grandmother said, “Ryan was my hero. He’s everybody’s hero.” Ryan set an example for others and will be remembered for his strong character. Let us always remember and emulate the shining example this brave man set.

May God welcome Ryan home and give comfort to his family and friends.

HONORING LIEUTENANT AARON ALLAN

Mr. DONNELLY. Today I wish to recognize and honor the extraordinary service and sacrifice of Lt. Aaron Allan of the Southport Police Department. Dedication, loyalty, and compassion for those in need are the qualities that defined Lt. Allan’s life.

Lt. Aaron Allan was a 6-year veteran with the Southport Police Department, who began his career in law enforcement in 2001. A kind and caring person, Lt. Allan was someone who devoted his life to serving his community. Lt. Allan earned the nickname “Teddy Bear” because of his kind heart and willingness to help anyone in need. Lt. Allan led and was well-liked by his fellow police officer since he was 5 years old. Before he joined the Southport Police Department in 2011 as a volunteer officer, he previously worked as an officer at the Indiana School for the Deaf and for Franklin Township.

In 2015, he was named Southport Police Department’s “Officer of the Year,” after saving two lives. Among his efforts, he performed CPR to save a man at the Indiana School for the Deaf. Furthermore, before backup officers arrived with a defibrillator, in recognition of his work, he became the only full-time paid officer in an all-volunteer force of reserve officers. He was a devout volunteer in the National Guard. In Southport, who believed in community policing and prided himself on stopping to talk with residents and getting to know them. Lt. Allan made a difference in the community and always put the safety and well-being of his fellow citizens first. When he encountered a family whose car would not start and the husband had been diagnosed with a brain tumor and the wife cared for her husband and young daughter. Allan went to an auto parts store and bought them a new car battery with his own money. It went beyond that. He participated in “Shop with a Deputy,” volunteering to take underprivileged children shopping. He also excelled responding to difficult calls, whether a citizen had overdosed and needed Narcan or he encountered a drunk driver. He enriched and touched so many lives through his service, and he was the ultimate sacrifice while responding to fellow citizens in need.

On Thursday, July 27, 2017, Lt. Allan was doing his job, responding to an incident involving an overturned vehicle at 30th and Tropicana in Southport, when he was shot. Hours before Lt. Allan was killed, he walked his 5-year-old son, Aaron, Jr., to the bus for his first day of kindergarten. He put his life on the line so that Hoosiers could have the chance to live in safety, and he was deeply grateful. He died doing what he loved, and his legacy will live on.

Lt. Allan was a devoted citizen, son, husband, father, and friend, who loved his children and his fellow brothers and sisters in blue. He loved his job as a Southport Police Officer, and no amount of gratitude can repay Lt. Allan or his loved ones for his sacrifice.
abstention in the irregular voting stations admitted for this election, the President of the National Electoral Council announced a false call participation of eight million and eighty thousand three hundred and twenty (8,089,320) electors, making the committed fraud even more evident;

CONSIDERING

The Venezuelan people, in exercise of their right to resistance, made various peaceful protests during the day of July 30th, 2017, with the deplorable balance of 16 people killed, hundreds injured and many arrested in an arbitrary manner, with the repression which the regime of Nicolas Maduro has attended for trying to impose its fraudulent and illegitimate National Constituent Assembly;

CONSIDERING

That the international community, like countries such as Argentina, Colombia, Spain, United States of America and Mexico, as well as international demarcations such as the Organization of American States (OAS) and the European Parliament, expressed their rejection on the fraudulent constituent process of Nicolas Maduro’s regime;

CONSIDERING

That the fraudulent election of the illegitimate National Constituent Assembly of July 30th, 2017, involved a major change in the political and constitutional Venezuelan scene, having to represent the definitive at- tempt of restoring the dictatorship of totalis- m, having to represent the definitive at- tempt of restoring the dictatorship of totalis- m, and actively contribute to re-establish the effective validity of the Constitution of the Bolivarian Republic of Venezuela.

Fifth: Urge the citizen Luisa Ortega Diaz, in her position as General Attorney of the Republic, to investigate at great length the criminal acts against the protesters, as well as the committed crimes that took place during the electoral process on July 30th, 2017, and to exercise the relevant actions against the of- ficers and people that ordered and executed such crimes, so as to be effective the punitive, administrative, and disci- plinary responsibilities of those who order and executed the repressive acts against the people and of those who participated in the constitutional fraud of the National Con- stituent Assembly.

Sixth: Urge to the Public Minister to over- take investigations and formalities directed to establish the penal responsibility of all public officers and people evolved in the fraudulent National Constituent Assembly that aims to impose a change that violates the constitution and changes the republican foundation of the Na- tion.

Seventh: Grateful for the solidarity expres- sed by the International Community with regard to the people of Venezuela and in rejection of the fraudulent National Con- stituent Assembly, and for arranging neces- sary meetings to execute common actions of states committed to the universal defense of human rights and relevant Inter- national Entities, so that through the admit- ted mechanisms of Public International rights and thus contribute to depose the fraudulent National Constituent Assembly and to reestablish the effective va- lidity of the Constitution of 1999.

Eighth: Support to who participated in Venezuela in the exercise of the right to resist the des- potism that the National Constituent As- sembly aims to impose. We support both the organized and planned actions that con- tribute to depose such illegal Constituent Assembly, and the execution of necessary ac- tions to reestablish the validity of the Con- stitution of Venezuela that obeys the mandate of the Popu- lar Consultation that took place on July 16th, 2017.

Ninth: Ratify the people of Venezuela, faithful to its republican tradition, to im- pugn all forms of despotic government that derived from the National Constituent Assembly, while the country is linked to the duty of obedience to such constituent and those who contribute to its installation oper- ation. The recognized authorities will be the only ones arising from free and democratic elections.

Tenth: Forward a copy of this agreement to the Secretary-General and the Permanent Council of the Organization of American States (OAS), the Organization of United Na- tions (UN) to the Inter-American Commiss- ion on human rights (IACHR) and the mem- bers of the diplomatic corps, specially to the representatives of those States that have spoken out without knowing about the elec- tion of the National Constituent Assembly.

Tenth first: Give publicity to this agree- ment.

Given, signed and sealed in the Federal Legislative Palace, seat of the National As- sembly of the Bolivarian Republic of Ven- ezuela, in Caracas, the first day of August of two thousand seventeen, Year 207 of inde- pendence and of fact to establish effectively the validity of the constitutional mandate of the people stated in the Popular Consultation on July 16th, 2017, by which, this National Assembly, as a legal and exclusive representative of the Venezuelan people will take all the measures and actions directed to depose the National Constituent Assembly as a power that ill- egitimately and arbitrarily tries to establish effective the validity of the constitution of the Bolivarian Republic of Venezuela.

JULIO ANDRES BORGES

President of the Na- tional Assembly.

FREDDY GUEVARA CIORTEZ;

First Vice President.

DENNIS PEREIRA;

Second Vice President.

JOSÉ IGNACIO GUEDE;

President of the National Constituent Assembly.

JOSE LUIS CARTAYA;

Subsecretary.

THE GREAT AMERICAN ECLIPSE

Mr. WYDEN. Mr. President, today I wish to recognize the historic event of the Great American Eclipse that will cross the continental United States on August 21. That morning, the eclipse will first pass over my home State of Oregon, then sweep across the U.S., ending in South Carolina. Millions of people across Oregon and the country are planning on watching those few moments when the moon will cover the sun and everything will go dark.

It has been 99 years since a total solar eclipse has occurred across the entire country, and whether someone is 5 or 95, this may be the only time they will ever see a total eclipse. It is truly a once-in-a-lifetime event.

This solar eclipse is a rare occurrence where the wonders of science will come right to the front doors of millions of people. That fact hasn’t been lost on schools and science organizations throughout Oregon. Educators from the coastal areas of the State to the mountains of eastern Oregon have been working hard to use this eclipse as an opportunity to engage students in the areas of science, technology, engineer- ing, and mathematics, commonly called STEM.

One of the best science museums in the country, the Oregon Museum of Science Industry, OMSI, has planned an amazing viewing party, with the help of the Oregon Science Board. They have committed massive numbers of students and community members get the ex- perience of viewing eclipses from the International Space Station. Over the years, OMSI has been a leader in getting students excited about STEM fields. I am so glad the museum is using this eclipse as yet another oppor- tunity to get communities involved in science.

Universities throughout the State are also doing their part to ensure stu- dents and community members get the most out of the event. In Corvallis, Or- egon State University is hosting a 3- day eclipse event, with astronomy ex- hibits and a series of science lectures. I also understand that Portland State University, with the help of NASA, will launch video cameras attached to high- altitude balloons, giving anyone the ability to tune in and watch a live stream of the eclipse. Programs like these are so important because they make scientific knowledge more accessible to the younger generations.

I also want to take a few moments today to recognize the local leaders,
first responders, and the National Guard who are working tirelessly to ensure that communities throughout the State enjoy the eclipse festivities safely. These public servants have been a shining light in making sure Oregons and visitors alike have the best experience while viewing the solar eclipse.

As the eclipse arcs across the country and folks from the West Coast to the East Coast don their eclipse glasses to look up at the darkened sun, it is my hope that it ignites a passion in students throughout the country to explore STEM fields more deeply.

THE USS “WEST VIRGINIA”

Mrs. CAPITO. Mr. President, I would like to recognize the service of the first ship named for our Nation’s 35th State—our only State born of war—the armed cruiser USS West Virginia. She was commissioned on February 23, 1905, and served in both the Atlantic and Pacific fleets. On two occasions, she deployed to Mexico to enforce U.S. diplomacy. In 1916, she was renamed the USS Huntington, in order to permit the assignment of her old name to a new battleship.

That new battleship—the second USS West Virginia—was commissioned in December 1923 and affectionately nicknamed the “Wee Vee.” In 1940, she moved to Hawaii and became part of the U.S. Pacific Fleet. She was the youngest of all the battleships at Pearl Harbor. During the attack on Pearl Harbor on December 7, 1941, the USS West Virginia was moored outboard the USS Tennessee; as a result, the Tennessee was not hit by a single torpedo, while the West Virginia was hit by nine torpedoes.

Despite being mortally wounded by shrapnel, the ship’s captain, Mervyn S. Bennion, remained on the bridge ordering counterflooding of starboard compartments to prevent capsizing; for his actions, Captain Bennion posthumously received the Congressional Medal of Honor. Captain Bennion’s actions are regularly cited as the epitome of proper command under fire.

Displaying a resilience befitting the people of her namesake, the USS West Virginia refused to stay sunk. She was pumped out and refloated on May 17, 1942, and sailed to Puget Sound Naval Yard for repairs. After being fully modernized, she saw action in the invasion of the Philippines, the Battle of Iwo Jima, and the Battle of Okinawa, among others. She was present in Tokyo Bay on September 2, 1945, for the formal Japanese surrender.

The USS West Virginia was decommissioned on January 9, 1947; her awards included the American Defense Service Medal with “Fleet” clasp; the Asiatic-Pacific Campaign Medal with five battle stars; the World War II Victory Medal; and the Navy Occupation Medal with “Asia” clasp. An antiaircraft gun remains at City Park in Parkersburg, WV; the ship’s wheel and binacle are on display at the Hampton Roads Naval Museum. Her mast sits in front of Oglebay Hall at West Virginia University, and Interstate 470 in West Virginia is named the “USS West Virginia Memorial Highway.”

The U.S. Navy resurrected the proud history of the 35th State’s moniker with a 1983 contract to build a Ship, Submarine, Ballistic, Nuclear, SSBN, the 11th of an eventual 18 Ohio-class submarines, otherwise to be known as the USS West Virginia. She was launched on October 14, 1989, sponsored by Mrs. Erma Byrd, wife—and high school sweetheart—of the late U.S. Senator Robert C. Byrd, of West Virginia—the longest serving Senator and the longest serving Member in the history of the U.S. Congress—and commissioned on October 20, 1990.

The USS West Virginia, SSBN 736 conducts a sacred mission. It has often been said that the U.S. Navy could only send one platform to sea, it is the SSBN that executes the most important mission: the mission of strategic deterrence.

Always at the tip of the spear, the USS West Virginia conducts operations in order to exploit the advantages of undersea operation. It can be deployed up to 15 months at a time. As the submariner identity states: “We are elite, selective, and high performing. We operate for who have the tip of the spear.” This is the only survivable nuclear deterrent. Last bastion of master and commander.”

West Virginia is proud of the honor, courage, and commitment of the brave sailors who crew and have crewed the USS West Virginia, and we are eternally grateful for the sacrifices that you and your families make in service to the United States of America. “Montani Semper Liberi.”

TRIBUTE TO ALAN BAKER AND EARL BRECHLIN

Ms. COLLINS. Mr. President, in 2001, Maine’s legendary Ellsworth American newspaper celebrated its 150th year by launching a new enterprise, the Mount Desert Islander. This dedication starts with community connections, and the Sunbeam Mission. As the author of nine books that reflect Maine’s history, and character. The Maine Seacoast Mission is a non-denominational, nonprofit organization founded in 1905 to support island and coastal communities in Downeast Maine, and its boat, the Sunbeam V, helps to connect people in those communities with essential services and with each other. Through their dedication to the craft of journalism, Alan Baker and Earl Brechlin have strengthened that support and those community connections, and the Sunbeam Award is a fitting recognition of their many contributions.

150TH ANNIVERSARY OF THE JACOB LEINENKUGEL BREWING COMPANY

Mr. JOHNSON. Mr. President, today I wish to honor a true original, the Jacob Leinenkugel Brewing Company, on 150 years of brewing great beer in Wisconsin’s North Woods. The Leinenkugels were fairly typical Wisconsinites in the mid-1800s—German immigrants, and lovers of beer. Jacob Leinenkugel started in the business in 1867 after he and three brothers learned the craft from their father, a brewer and distiller. Together, the Leinenkugel family started four breweries, including the Spring Brewery, which eventually became Jacob Leinenkugel Brewing.

While the Leinenkugel family was typical, the brewer’s business started further from ordinary. For a century and a half, the Jacob Leinenkugel Brewing Company has put Chippewa Falls, WI, on the map and excellent beer in the hands of people throughout Wisconsin and the rest of the U.S.

Walk into most any bar in the State and there will be “Leinie’s” on tap. Go to a backyard cookout or a Milwaukee
Brewers tailgate on a hot summer’s day and there will Summer Shandy in the cooler. Stop by a Wisconsin supper club for dinner and odds are you or someone at the table next to you will be enjoying their fish fry with a Honey Weizen.

Leinenkugel Brewing is the seventh oldest continuously operating brewery in the country. This lengthy heritage did endure trying moments. Leinenkugel’s survived Prohibition by producing soda, ginger ale, and a non-alcoholic cereal beverage to stay in business. Afterward, the brewer eventually grew into the fourth largest craft brewer in the United States.

The original brewery is still operating, and its Leinenkugel Lodge visitor center in Chippewa Falls welcomes 125,000 visitors annually, making it a top tourist destination in northern Wisconsin. Along with its original lager, Leinenkugel’s new brews 21 other beers, with offerings for every taste and style, including a special German Marzen-style lager to celebrate the family’s roots and the brewery’s 150th anniversary.

Leinenkugel Brewing is more than beer. Leinenkugel’s is a Wisconsin institution, and a home for the lives of people across the State—even those who have never lifted a pint. The brewery’s Canoes for a Cause outreach program has provided education and resources to help improve and protect Wisconsin springs and waterways. Generations of the Leinenkugel family have served our country in the military and other civic capacities. That tradition continues today as former Marine Corps captain and Leinenkugel Brewing president Jake Leinenkugel serves as a senior White House adviser for the Department of Veterans Affairs.

Six generations have taken a family from the North Woods of Wisconsin to the refrigerators of beer lovers in all 50 States and around the world, maintaining its Wisconsin roots and cherishing its German heritage. I join my fellow Wisconsinites in raising a glass in appreciation for the last 150 years and hoping for many more to come.

MS. BALDWIN. Mr. President, today I rise to recognize the Jacob Leinenkugel Brewing Company on their 150th anniversary. I am so pleased to honor this great Wisconsin company.

Throughout its history, family has always been at the core of the Leinenkugel business. The family’s brewing tradition began well before they came to America. Jacob’s father, Mathias, was a brewer and brandymaker from Meckenheim, Germany, and waterways. Generations of the Leinenkugel family have served our country in the military and other civic capacities. That tradition continues today as former Marine Corps captain and Leinenkugel Brewing president Jake Leinenkugel serves as a senior White House adviser for the Department of Veterans Affairs.

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participate in many community fundraisers, such as the Annual Hancock Relay for Life for the American Cancer Society. The bank also hosts an annual charity golf tournament that raises money for a local organization. This year, the tournament raised $25,000 that was donated to the Acadia Family Center to sponsor a year’s worth of treatment for two individuals battling substance abuse. Additionally, Bar Harbor Bank & Trust employees teach local children lessons about saving money through the ABA’s Teach Children to Save Day and explain how to use credit wisely to teenagers in the community. In 2016 alone, this bank provided over 450 children with lessons in savings education.

I wish to join the communities all around Maine, New Hampshire, and Vermont in congratulating Bar Harbor Bank & Trust for this remarkable achievement on its 130th anniversary. I look forward to following its continued growth and success, and I applaud the bank for its dedication to its employees, customers, and local communities.

70th Anniversary of the Maine Lobster Festival

Mr. KING. Mr. President, today I wish to recognize the Maine Lobster Festival on its 70th anniversary. On this date, the people of Maine celebrate our rich history in the valuable lobster trade, as well as the continuous commitment by our coastal communities to support and perpetuate our great maritime heritage.

Since 1947, The Maine Lobster Festival has provided the people of Maine and tourists with exciting events, entertainment, and Maine seafood. The festival emerged out of a community-based effort at reviving summer activities that Camden, ME, established prior to World War II. A small group of citizens and their visitors came together to revel in their coastal marine community. Their small gathering, which lost money in its first year, moved to Rockland the following year and immediately became an annual staple of the coastal area’s summer schedule, creating the Maine Lobster Festival to operate as a nonprofit corporation that is responsible for the festival to this day.

This nearly weeklong engagement in August, attended by both internationally recognized as well as local musicians and entertainers, who fill the concert stage with enthralling performances. A midway provides excitement for children of all ages. King Neptune and his court attend the event every year and a highlight is the crowning of the Maine Sea Goddess. The festival also boasts a wide range of Maine artistry, from craftsmen to painters, as well as one of the region’s largest and most popular parades. In addition, there are fresh lobster dinners prepared in the world’s largest lobster cooker for the thousands of hungry attendees. While you may no longer be able to get “all the lobster you can eat for $1,” the festival promises to have more than enough lobster to go around.

Year-in and year-out, the combined effort of more than a thousand volunteers generously donate their time makes the festival possible. Volunteers are committed to improving and showcasing their communities to the thousands of festival-goers that come from different parts of Maine, from across the country and around the world. Not only do they donate their time and effort, but they also donate all proceeds to the communities to provide needed support to local institutions such as food pantries, community service groups, emergency services, and college scholarships.

The Maine Lobster Festival is recognized nationwide as one of the best events in the country, and this distinction could not be bestowed on a more deserving enterprise. I wish to join the greater Rockland community, as well as the State of Maine, in congratulating the Maine Lobster Festival on its 70th year of being an historic and cherished Maine institution.

Marion contributed to CBO’s work in ways that went well beyond her administrative responsibilities. She routinely took the lead to make sure that key life events of staff—such as birthdays, weddings, and births—were celebrated, and she was often the first person other employees turned to when they needed assistance with planning and organizing events. In addition, her contributions to the charitable works of the agency were well-known and appreciated. Marion is extremely warm, generous, and giving—she was always there to provide support, encouragement, and someone to talk to. Her contribution to the working environment at CBO was beyond measure, and she will be greatly missed.

TRIBUTE TO JEFFREY HOLLAND

Mr. ENZI. Mr. President, the Senate Budget Committee wishes to honor and recognize Jeffrey Holland on his retirement after 26 years of distinguished service to the Congress with the Congressional Budget Office. Jeff is highly regarded by Republicans and Democrats on both sides of the Capitol for his deep knowledge of the budget process and his commitment to the nonpartisan role that CBO plays in the budget process.

Jeff arrived at CBO in 1991 soon after graduation from Carnegie Mellon University’s Heinz School of Public Policy. He earned his master’s degree in public policy and management. He joined the projections unit in the budget analysis division, which is responsible for preparing projections of Federal spending, deficits, debt, and other data related to the Federal budget, as well as providing ongoing support to Congress.

In 1999, Jeff became chief of the projections unit, and for the past 18 years, he has successfully overseen the production of multiple reports on the Budget and Economic Outlook, annual analyses of the President’s budget request, and also several reports on sequestration, the debt ceiling, national income, and product accounts, and the Troubled Asset Relief Program. Through all of these tasks, he has been the steady hand of the projections unit, generous with his time and knowledge, and highly responsive to questions and requests for data or information from the staff of the Budget Committee. His patience, attention to detail, and reliably clear thinking have been vital to the smooth functioning of the budget analysis division.

In addition, Jeff has often lent his expertise to legislative branches of other countries as they seek to develop their own capacity for nonpartisan budget analysis. He is a sought-after explainer of the Federal budget process to students of our Nation’s Capital. In short, Jeff’s expertise, knowledge, and generosity of time and spirit will be sorely missed. We wish him well as he
moves on after years of outstanding service to the Congress. We are grateful for that service, and we wish him the best in the years to come.

ADDITIONAL STATEMENTS

REMEMBERING BELLE LIKOVER

Mr. BROWN. Mr. President, this week, the city I call home lost a great Ohioan, and Connie and I lost a friend, Belle Likover of Shaker Heights. Belle passed away at age 97, and over her extraordinary life, she saw the creation of our country's greatest social insurance programs: Social Security, Medicare, and Medicaid—and fought to protect those lifelines for American seniors.

Ms. Likover was born the same year as my mother and grew up in Beaver Falls, PA. She remembered her childhood as a happy one, with one big exception: the Great Depression. In an interview several years ago, she talked about the lasting effects those memories had on her, saying, "We saw everybody else suffer. I remember the shantytowns, families living in what used to be packing crates. There was a constant stream of people who came to our backdoor for food. My mother never turned anybody away."

Those experiences would shape her activism throughout her life. In high school and later in college, at the Ohio State University, she said she was "never bashful about speaking out." She joined the high school varsity debate team as a sophomore, as the only girl on the team, and learned how to marshal an argument. She told an interviewer that, "Every position of marshaling I've had, I owe to that debate coach."

In college, she put that training to use, first getting involved in political causes in 1937, when she and a friend helped organize an antifascist group at Ohio State. They saw what was happening in Germany and across Europe and how dangerous that was for the world.

Growing up in that time of turmoil and as a woman at a time when her abilities would be constantly questioned, Belle faced setbacks. As a child, she asked for chemistry sets instead of dolls, but in college, a chemistry professor asked her if she wanted a PhD. She was told she was growing up—"They didn't have Medicare, they ended up in poorhouses," she told me. And she added, "Do you know how many people can't wait until they're 65 to get covered by Medicare?"

Just last fall, she joined us on a call with Ohio reporters to talk about how devastating it would be to raise the retirement age. That was Belle Likover—an activist and advocate, full of compassion but never bashful, all the way through age 97. Our family's thoughts and prayers are with Belle's loved ones. We will miss her, and we will strive to carry on her advocacy for Ohio seniors.

TRIBUTE TO ERNEST "ERNIE" GRECCO

Mr. CARDIN. Mr. President, today I would like to congratulate a dear friend of mine, Ernie Grecco, for 55 years of dedicated service to the labor movement and to working men and women and their families in the Baltimore–Washington metropolitan area and across the Nation. Ernie recently retired after serving for 20 years as president of the Metropolitan Baltimore AFL–CIO Council, which covers Baltimore City and Anne Arundel, Baltimore, Carroll, Cecil, Harford, and Howard Counties. For the last 15 years, he also served as secretary on the board of directors of the United Way of Central Maryland. Ernie's vocation and his avocation have been to make life better for other people. There is an old saying, "You make a living by what you get; you make a life by what you give." Ernie has given so much to so many for so long. It is why I feel privileged and proud to call him my friend.

Ernie became involved in the labor movement in 1962 while he was working at Calvert Distilleries. He was a member of Distillery Workers Union Local 34 and was elected shop steward. He served as shop steward until 1970, when he was elected secretary-treasurer of Local 34-D. He also served as trustee of the Distillery Workers International Union.

In 1973, then-President Nick Fornaro of the Baltimore Central Labor Council hired Ernie as a job placement officer for the Institutional Training Project. In this capacity, Ernie was responsible for helping find jobs for hundreds of men and women housed at the Jessup and Hagerstown Penal Institutions who were qualified for work-release status. In 1976, he became the director of the Metropolitan Baltimore AFL–CIO Council's Committee on Political Education, COPE. He served in this position until 1983 when he became the COP director for the Maryland State and District of Columbia AFL–CIO. He was elected to serve as president of the Metropolitan Baltimore AFL–CIO Council in 1987, and he also served as first vice president of the Maryland State and DC AFL–CIO.

Ernie has held many other leadership positions over the course of his illustrious career. For instance, he chaired the Young Trade Unionists, which was created to bring younger people into the labor movement. He served as president of the Union Label & Service Trades Council, which promoted the purchase of union services and products. Ernie has also served on the Baltimore Workforce Investment Board, the Maryland Transportation Commission, the Maryland Workers Compensation Commission, and the Maryland Racing Commission.

As president of the Metropolitan Baltimore AFL–CIO Council, Ernie established monthly meetings with the mayor of Baltimore City to encourage better communications and collaboration between the city and the unions. The committee consists of all city unions and a representative from the building trades. Ernie also championed the council's community services division. The community services division provides assistance to working people through information and referral advocacy to help them solve personal and family crises. The services include education and training for union peer counselors; Baltimore Works, a job placement program for disconnected workers; and Project LEAP, an adult education literacy program.

It should come as no surprise that Ernie has received numerous awards for his indefatigable service to people. He has the distinction of receiving not one, but two, national awards for community service. The American Red Cross in 1991 and the Joseph A. Beirne Award from United Way of America in 1999. Last year, United Way of Central Maryland gave Ernie its Philip H. Van Grecco Award for Outstanding Service. In 1995, the Baltimore City Fire Fighters Local 734 and Baltimore City Fire Officers Local 964 created the Grecco Labor Award to be given to a firefighter who "best exemplifies the continuing and complex efforts of the local union membership to build the relationship between labor and management."

During Ernie's career, he has been loved and respected not just in Baltimore, but in Annapolis and across the State of Maryland for his steadfast commitment to the labor movement and working people. He is, understandably, an avid Orioles, Ravens, and Maryland fan, but bittersweet because his beloved wife Dorothy—"Dot"—recently passed away, but I know Ernie will spend much of his time with his daughter, Nina Grecco Dukes, and his son, Gary, and Gary's wife Kelly, and his grandchildren, Ashley, Adam, Katy, and Ben.

I have relied on Ernie's sage counsel on labor matters and other issues over
the years, and I treasure our friendship. I have been a better and more effective legislator because of Ernie’s friendship and advice for which I am truly grateful. On behalf of the entire U.S. Senate, I congratulate Ernie on his accomplishments and his work observing, leading, and, remembering Ernie as I do, he will find new ways to be of service to others; it is simply at the core of who he is.

TRIBUTE TO BETTY JENEL OLSEN CARR

• Mr. CRAPO. Mr. President, today I wish to mark a wonderful occasion, a birthday that many do not live to celebrate. Today we honor the 95th birthday and wonderful life of Betty Jenel Olsen Carr, born in Kimberly, ID, on August 2, 1922. Her early life was very much what you would expect from rural Idaho in the 1920s, and in many ways, there now still has some of these echoes of a strong work ethic and family values.

Betty grew up with seven siblings in a family that learned self-sufficiency and self-reliance on an 80-acre farm. Edith, Melba, Vera, Nina, and Betty lived cozily together with their parents, Hannah Marie Sandberg and Neils Albert Olsen, in a small, white wooden farmhouse that had no electricity or running water. When Betty was a child. However, the dream of a black pot-belly iron stove that kept everyone warm and fed.

Education figured prominently in Betty’s goals, as she graduated at the top of her Kimberly High School class, even though she skipped her final year of high school to start college. She fostered her love of reading through editing the school newspaper. She also played flute in the marching band and, improbably, at just 5 feet, 4 inches tall, played forward on the girls basketball team. She headed off to college at what was then called the Southern Branch of the University of Idaho—now Idaho State University—and studied journalism, but most importantly, she followed through on something she said in high school. She had been looking through her older sister’s college yearbook and spotted the photo of a handsome young man. She declared, “When I get to college, I am going to go out with that guy.” She did indeed—she met and married Taylor Henry Carr a couple of years into college. Taylor served 3 years in World War II, and a family treasure is the love letters the two sent to each other during that difficult time that they were separated by his wartime service.

When Taylor returned home, he completed his education at the medical school at the University of Utah with the help of the GI bill and became a surgeon. Betty and he raised their seven children in Idaho Falls, ID. Each of those children has become remarkable in their own right, contributing to their communities, States, and country.

—Katherine Ann, Taylor Douglas, Philip Olsen, Jan Elizabeth, Kenneth Wright, Steven Edward, and Gregory Curtis. Their home was filled with love, education, and adventure.

From a personal perspective, there has never been a better child psychologist or wiser parent than Aunt Betty. Betty is my mother Melba’s youngest sister—my beloved Aunt Betty, who was a second mother to me. She understood teenagers in a unique manner and knew just when to encourage me at these times. She was also blessed to hear advice from someone who loves them and is not a parent. Growing up, I always knew I would find welcoming arms and a warm shoulder just a few blocks from my home. Aunt Betty understood that, ultimately, love and the relationship with our loved ones was more important than anything else, and she epitomized that with her acceptance and encouragement of even the craziest ideas. A few years ago, I was delighted to find her in the U.S. Capitol when she made the long trip from Idaho to Washington, DC. A treasured item on display in my personal office is a photo with her from that trip.

Today Betty, the lifelong lover of reading, is as sharp as ever. At 95, she remains active, interested, and involved. She races through the crossword puzzle, tends her garden and great-grandkids, and never misses exercising class or bridge club. She recently went underwater in a diving bell in Florida. I am privileged to claim her as part of my family and honored to recognize her longevity as an Idahoan. Happy, happy birthday.

REMEMBERING DAN FAUSKE

• Ms. MURKOWSKI. Mr. President, Alaskans will gather on August 9 to celebrate the life of Dan Fauske, a public servant who lost his battle with cancer in April. Upon learning of Dan’s passing, Representative Mike Chennault, four-term Speaker of the Alaska House of Representatives described Dan as “Superman.” In Mike’s words, “Dan Fauske leaped tall buildings in a single bound. Like Superman, there was not a challenge he couldn’t take on.”

Dan was a dear friend of mine, and his family is part of our extended family. Dan’s son, D.J., who now serves as director of government and external affairs for the North Slope Borough, helped open my Washington office in 2003 as a staff assistant. D.J. subsequently married Gretchen Wieman, a legislative correspondent in my office during that period.

I counted on Dan for advice and counsel on important public policy issues affecting Alaska, as did many others in the State. His integrity and wisdom were unsurpassed, but Dan’s greatest attribute was perhaps his humility. He was known as a straight shooter; one who was about getting the job done and doing it right. Although he waded into many a difficult political problem, he resisted the urge to become a politician. If there was an ounce of self-promotion in Dan Fauske, I never saw it. Dan was one of the most grounded people I have ever met, and that was the key to his influence and effectiveness.

Dan Fauske, like so many builders of Alaska in the half century after Statehood, adopted our State as his home. Dan was born in Fairbanks on December 13, 1950. He relocated to Alaska in 1974 after serving in the Army—not to the big city, but to Barrow, now called Utqiagvik, the northernmost American city. A place where the first language was then and remains today Inupiaq. His older brother, Dave, was a teacher in the village. Dan worked construction and delivered fresh water, and he made himself part of the community. Elise Patkotak remembers him as one who approached the world as if everyone were a potential friend. She still has a dog ramp to help Elise get her handicapped dog into the house. This is just one example of the many random acts of kindness for which Dan was known. Bridging the cross-cultural divide, his kindness was reciprocated in the community.

Dan left Alaska to study for an MBA at Gonzaga University in Spokane, WA, but it was a temporary absence. Utqiagvik was Dan’s home, and upon returning, Dan worked for the North Slope Borough. He was chief financial officer and chief administrative officer. During his tenure, he pursued a vigorous capital construction program which brought water and sewer to many of the North Slope villages.

In 1995, Dan moved his family to Anchorage. He was named chief executive officer of the Alaska Housing Finance Corporation, AHFC. John Bitney, then a legislative staffer, remembers the day that he and the legislative auditor presented a bill in committee to liquidate AHFC. Just when the committee was about to move the bill, a man ventures forward from the audience, announces that he is the CEO of AHFC, and it is his second day on the job. He asked the committee to allow him to pursue a turnaround of the agency—and, boy, were we lucky that the committee agreed.

For 18 years, Dan would not only rescue AHFC from its financial difficulties, but mold it into one of the most respected State housing agencies in the Nation. During his tenure, AHFC pioneered its weatherization and energy rebate program, which helped Alaskan families survive the challenge of high energy costs in the frozen North. He issued more than $1.9 billion back to the State of Alaska through cash payments. The AHFC building has been renamed the “Daniel R.
Fauske Building” by the Alaska Legislature in honor of his many accomplishments.

Dan was so successful at AHFC, the Alaska Legislature asked him to take on a second duty, that of exploring the feasibility of constructing a small diameter, bringing natural gas from the North Slope to serve Alaskans. In 2013, he left his job at AHFC to pursue this “second job” full time as executive director of the Alaska Gasline Development Corporation, AGDC. He served in that role until November 2015.

At AGDC, Dan brought the same focus to the position he had to every other one he had held in his distinguished career: serving Alaskans. For Dan, AGDC’s mission wasn’t so much about commercializing Alaska’s gas as it was delivering energy to Alaskans. His focus on delivering energy relieved and security drove the State’s efforts and resulted in AGDC joining the integrated effort to build Alaska LNG as the entity focused on delivering gas to Alaskans.

Whether it was building water systems on the North Slope, developing housing across the State, or delivering energy efforts for Alaskans first. That was what we loved about him, he saw policy not at the 50,000-foot level but in the face, life, and experience of every person he worked with and served.

Dependable, trusted, respected—the consummate “go to” guy—all of these phrases are used to describe Dan Fauske. He believed in Alaskans. Like all great Alaskans. Dependable, trusted, respected, the consummate “go to” guy—all of these phrases are used to describe Dan Fauske. He believed in Alaskans. Like all great Alaskans, he believed anything could be achieved if they put their minds to it. Whether it was building water systems on the North Slope, developing housing across the State, or delivering energy efforts for Alaskans first. That was what we loved about him, he saw policy not at the 50,000-foot level but in the face, life, and experience of every person he worked with and served.

Dan Fauske will long be remembered in executive director of the Alaska Gasline Development Corporation, AGDC. He served in that role until November 2015. At AGDC, Dan brought the same focus to the position he had to every other one he had held in his distinguished career: serving Alaskans. For Dan, AGDC’s mission wasn’t so much about commercializing Alaska’s gas as it was delivering energy to Alaskans.

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Dan Fauske will long be remembered as a true leader who walked with the people and a key figure in Alaska history of the post-Statehood era.

RECOGNIZING HILLCREST AIRCRAFT COMPANY

Mr. RISCH. Mr. President, today I would like to recognize an outstanding small business located in my home State of Idaho. As many of my colleagues in the Western Caucus can tell you, catastrophic wildfires are a cause for major concern and costs for large swaths of the West, particularly in the summer months. This month’s small business has found their specialty in helping to control these large wildfires in a safe and efficient manner. As chairman of the Senate Committee on Small Business and Entrepreneurship, I am pleased to honor Hillcrest Aircraft Company as the U.S. Senate Small Business of the Month for August 2017.

Hillcrest Aircraft Company is based out of Lewiston, Idaho and is a family helicopter company with a national spectrum of work. Hillcrest Aircraft Company was founded by local pilots in 1946. Jerry Wilson partnered with the company in 1969, eventually becoming the sole owner in 1972. Jerry’s son, Gale Wilson, is the current president of the company, and his son, Keith White, serves as vice president. The Wilson’s legacy of promoting a strong work ethic coupled with strict safety requirements led them into a premier helicopter business. In 1968, Hillcrest became the first certified Bell customer service facility in Idaho, and 1 year later, in 1969, they became an approved FAA repair station. Their commitment to safety and firefighting. Whether they are transporting firefighters to remote areas or dropping hundreds of gallons of water on a raging fire, Hillcrest prides itself on protecting communities from dangerous wildfires. In fact, they have fought fires in all of the lower 48 States during their 60-plus years of experience. On top of aerial firefighting, Hillcrest flies for power and timber companies, photographers, videographers, and even fish planters. Their comprehensive background in the industry, dedication to operational safety, and commitment to strict ethical standards continue to keep this family-owned business busy around the clock.

Hillcrest has always put safety first, and in 2015 and 2016, they were rewarded for their efforts. Hillcrest achieved the necessary requirements for the International Standard for Business Aircraft Operations, IS-BAO, Stage I registration by implementing a new safety management system, SMS in 2015 and Stage II registration in 2016. This safety standard acknowledges the company’s efforts to improve their safety risk profile and operating efficiency. Hillcrest was one of the first rotary-wing-only operators to achieve the IS-BAO Stage II.

The future is bright for Hillcrest Aircraft Company as they continue to expand their business. Just a couple of months ago in June, Hillcrest opened their very own fixed base operation, FBO, at the Lewiston-Nez Perce County Airport. I would like to congratulate Gale Wilson and his family, along with all of the employees at Hillcrest, for the hard work they do in trying conditions while still keeping their commitment to safety. I wish the best for Hillcrest Aircraft Company, and I am confident that they will continue to keep Idahoans and Americans safe.

REMEMBERING HERBERT NEEDLEMAN

Mr. WHITEHOUSE. Mr. President, I recently received the sad news that Dr. Herbert L. Needleman has passed away. With Herbert’s passing, we lost a great man—and the scientific community lost one of its best.

In the 1970s, Herb undertook groundbreaking studies that revealed the dangers of lead exposure in children. According to the Pittsburgh Gazette, Herb “had been thinking about the impact lead had on children’s cognitive abilities for nearly two decades before he finally came up with a way to test historic lead levels.” He made powerful adversaries in the lead industry, but true to his research, Dr. Needleman found new and inventive ways to prove the toxic effects of lead exposure.

As a researcher at Temple University, he developed the “Tooth Fairy” approach: a method to test children’s baby teeth for lead exposure levels. This method led to pioneering research that found that Black children living in cities had lead levels five times higher than suburban, White children. In the words of Herb’s son, “He just couldn’t tolerate injustice and could not stop seeking the truth.” The results of Herb’s hard work and his dedication to seeking the truth today reach from the halls of science to the apartments of inner cities.

I got to see his determination first hand, working alongside him in fighting the lead paint industry in Rhode Island. When I was confronting the lead industry, over 35,000 Rhode Island children under the age of 6 had elevated levels of lead in their systems. His research was instrumental in the fight for the health of Rhode Island’s children. I am deeply grateful for Herbert’s help in my home State, and I know Rhode Island families are grateful as well.

America has lost a beloved pediatrician, psychiatrist, and brilliant scientist. I offer my condolences to the Needleman family and to the many people he taught and mentored through the years. He lives on as a lasting lesson in the power of science to help others.

MESSAGES FROM THE PRESIDENT

Messages from the President of the United States were communicated to the Senate by Ms. Ridgway, one of his secretaries.

EXECUTIVE MESSAGES REFERRED

In executive session the Presiding Officer laid before the Senate messages from the President of the United States submitting sundry nominations and a withdrawal which were referred to the appropriate committees.

MESSAGE FROM THE HOUSE

At 3:31 p.m., a message from the House of Representatives, delivered by Mr. Novotny, one of its reading clerks, announced that pursuant to 10 U.S.C. 4355(a), and the order of the House of January 3, 2017, the Speaker appoints the following Member on the part of the House to the Board of Visitors to the United States Military Academy: Mr. WOMACK of Arkansas.

The message also announced that pursuant to 44 U.S.C. 2702 and the order
of the House of January 3, 2017, the Speaker appoints the following individual on the part of the House of Representatives to the Advisory Committee on the Records of Congress: Ms. Lori Schwartz of Omaha, Nebraska.

The message further announced that pursuant to section 114(b) of the John C. Stennis Center for Public Service Training and Development Act (2 U.S.C. 1103), and the order of the House of January 3, 2017, the Speaker appoints the following individual on the part of the House of Representatives to the Board of Trustees for the John C. Stennis Center for Public Service Training and Development for a term of 6 years: Mrs. MARTHA ROBY of Montgomery, Alabama.

The message also announced that pursuant to section 214(a) of the Help America Vote Act of 2002 (52 U.S.C. 20044), and the order of the House of January 3, 2017, the Speaker appoints the following individual on the part of the House of Representatives to the Election Assistance Commission: Mr. Elliot Berke of Arlington, Virginia.

EXECUTIVE AND OTHER COMMUNICATIONS

The following communications were laid before the Senate, together with accompanying papers, reports, and documents, and were referred or ordered to lie on the table as indicated:

EC–2460. A communication from the Acting Assistant Attorney General, Office of Legislative Affairs, Department of Justice, transmitting, pursuant to law, a report entitled "Unemployment and Re-employment Rights Act of 1994 (USERRA) Quarterly Report to Congress; Third Quarter of Fiscal Year 2017"; to the Committee on Veterans' Affairs.

EC–2461. A communication from the Secretary of the Commission, Bureau of Consumer Protection, Federal Trade Commission, transmitting, pursuant to law, the report of a rule entitled "Energy Labeling Rule" (RIN3084–AB15) received during adjournment of the Senate in the Office of the President of the Senate on July 31, 2017; to the Committee on Commerce, Science, and Transportation.

PETITIONS AND MEMORIALS

The following petitions and memorials were laid before the Senate and were referred or ordered to lie on the table as indicated:

POM–79. A resolution adopted by the Legislature of the State of Hawaii submitting an application to the United States Congress to restore free and fair elections; to the Committee on Agriculture, Nutrition, and Forestry.

POM–80. A resolution adopted by the City Commission of the City of Sunrise, Florida urging the United States Congress to oppose the proposed elimination of the Community Development Block Grant and Home Investment Partnerships Programs and supporting full funding in the Fiscal Year 2018 budget for the United States Department of Housing and Urban Development; to Committee on Banking, Housing, and Urban Affairs.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. BARRASSO, from the Committee on Appropriations and the Committee on Foreign Relations, with an amendment in the nature of a substitute:

S. 690. A bill to extend the eligibility of recipients of Social Security Disability Insurance Trust Fund; to the Committee on Finance.

S. 810. A bill to facilitate construction of a bridge on certain property in Christian County, Missouri, and for other purposes (Rept. No. 115–143).

By Mr. HOEVEN, from the Committee on Indian Affairs, without amendment:

S. 699. A bill to authorize the Secretary of the Interior to assess sanitation and safety conditions at Bureau of Indian Affairs facilities, that were completely or partially affected Columbia River Treaty tribes access to traditional fishing grounds and expend funds on construction of facilities and structures to improve those conditions, and for other purposes (Rept. No. 115–143).

By Mr. RISCH, from the Committee on Small Business and Entrepreneurship, without amendment:

S. 154. A bill to amend the Small Business Act to ensure small businesses affected by the outbreak of transmissible diseases are eligible for disaster relief.

S. 650. A bill to amend the Small Business Act to expand tax credits and training for small businesses that engage in research and development, and for other purposes.

S. 769. A bill to extend the eligibility of re-designated areas as HUB Zones from 3 years to 7 years.

Whereas, the Twenty-ninth Legislature intends that this continuing application shall be considered with the applications that have been adopted by the 2013–2014 Vermont Legislature, the 2015–2016 Rhode Island Legislature, the Ninety-eighth Illinois General Assembly, the 2014–2015 New Jersey Legislature, and the 2015–2016 Hawaii Legislature, as well as all applications that are subsequently adopted until two-thirds of the several states have applied for, and Congress has approved, a continuing amendment to restore free and fair elections: Now, therefore, be it

Resolved, By the House of Representatives of the Twenty-ninth Legislature of the State of Hawaii, Regular Session of 2017, the Senate concurring, that the people of the State of Hawaii, speaking through its Legislature, hereby submit an application to the United States Congress to restore free and fair elections as described herein; and be it further

Resolved, By the House of Representatives of the Twenty-ninth Legislature of the State of Hawaii, Regular Session of 2017, the Senate concurring, that the people of the State of Hawaii, speaking through its Legislature, hereby submit an application to the United States Congress to restore free and fair elections as described herein; and be it further
By Mr. RISCH, from the Committee on Small Business and Entrepreneurship, with amendments:

A. 929. A bill to improve the HUBZone program.

By Mr. RISCH, from the Committee on Small Business and Entrepreneurship, with an amendment in the nature of a substitute:

S. 1996. A bill to amend title 38, United States Code, to make certain improvements in the laws administered by the Secretary of Veterans Affairs, and for other purposes.

EXECUTIVE REPORTS OF COMMITTEES

The following executive reports of nominations were submitted:

By Mr. ROBERTS for the Committee on Agriculture, Nutrition, and Forestry:

*Brian D. Quintenz, of Ohio, to be a Commissioner of the Commodity Futures Trading Commission for a term expiring April 13, 2022.

By Mr. McCURDY for the Committee on Armed Services:

Army nomination of Brig. Gen. Mark D. Camerer, to be Major General.

Army nominations of Rear Adm. DeWolfe H. Miller III, to be Vice Admiral.

Navy nomination of Rear Adm. John D. Alexander, to be Vice Admiral.

Navy nomination of Vice Adm. John C. Aquilina, to be Vice Admiral.

Army nomination of Lt. Gen. Robert P. Ashley, Jr., to be Lieutenant General.

Army nomination of Brig. Gen. Darrell J. Guth, to be a Member of the Small Business Administration.

Army nomination of Col. Brian E. Miller, to be Brigadier General.

Mr. MCCAIN, Mr. President, for the Committee on Armed Services I report favorably on the following nominations which were printed in the RECORD on the dates indicated and ask unanimous consent, to save the expense of reprinting on the Executive Calendar that these nominations lie at the Secretary’s desk for the information of Senators.

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

Army nomination of Damian R. Tong, to be Major.

Army nominations beginning with Danny Arroyo and ending with Brian P. Weber, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Murray E. Carlock and ending with Carlos V. Silva, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Alon S. Aharon and ending with Edwin A. Wymer, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Julia R. Pietsch and ending with Hal E. Vineyard, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Tressa D. Cochran and ending with Karen F. Wiggins, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Scott R. Cheever and ending with Diana E. Zechaschel, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Edward J. Alexander and ending with Bridget C. Wolfe, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Robin Crear and ending with Neil P. Woods, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Eric W. Bullock and ending with Crystal R. Romay, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Betty S. Alexander and ending with James S. Zmijeksi, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Dominic J. Antenucci and ending with Matthew J. Wooten, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Brian S. Anderson and ending with Michael A. Zundel, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Erin C. Bann and ending with Evan R. Whitleck, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Thomas B. Ableman and ending with Bruce A. Yee, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Eric W. Haas and ending with Gail M. Mulleavy, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Christopher L. Almond and ending with Daniel W. Wall, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Army nominations beginning with Robert E. Shaw and ending with Zachary S. Young, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Army nominations beginning with Thomas E. Arnold and ending with Michael P. Yunker, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Army nominations beginning with Andrew B. Bridforth and ending with Ronald J. Mitchell, which nominations were received by the Senate and appeared in the Congressional Record on July 25, 2017.

By Mr. THUMS for the Committee on Commerce, Science, and Transportation:

*Ajit Varadaraj Pai, of Kansas, to be a Member of the Federal Communications Commission for a term of five years from July 1, 2016.

*Karen Dunn Kelley, of Pennsylvania, to be Under Secretary of Commerce for Economic Affairs.

*Elizabeth Erin Walsh, of the District of Columbia, to be Assistant Secretary of Commerce and Director General of the United States and Foreign Commercial Service.

*Steven Gill Brubady, of Virginia, to be General Counsel of the Department of Transportation.

*Jessica Rosenworcel, of Connecticut, to be a Member of the Federal Communications Commission for a term of five years from July 1, 2016.

*Mark H. Busby, of Virginia, to be Administrator of the Maritime Administration.

*Peter B. Davidson, of Virginia, to be General Counsel of the Department of Commerce.

*Robert L. Sumwalt III, of South Carolina, to be a Member of the Federal Communications Commission for the remainder of the term expiring June 30, 2018.

*Brendan Carr, of Virginia, to be a Member of the Federal Communications Commission for a term of five years from July 1, 2018.

*Ronald L. Batory, of New Jersey, to be Administrator of the Federal Railroad Administration.

*ALAXANDER for the Committee on Health, Education, Labor, and Pensions:

*James J. Sulivan, Jr., of Pennsylvania, to be a Member of the Occupational Safety and Health Review Commission for a term expiring April 27, 2021.

*Brett Giroir, of Texas, to be Medical Director in the Regular Corps of the Public Health Service, subject to the qualifications therefor as provided by law and regulations, and to be an Assistant Secretary of Health and Human Services.

*Heather L. MacDougal, of Florida, to be a Member of the Occupational Safety and Health Review Commission for a term expiring April 27, 2021.

*Elnore F. McCance-Katz, of Rhode Island, to be Assistant Secretary for Mental Health and Substance Use, Department of Health and Human Services.

*Lance Allen Robertson, of Oklahoma, to be Assistant Secretary for Aging, Department of Health and Human Services.

*Jerome M. Adams, of Indiana, to be Medical Director in the Regular Corps of the Public Health Service, subject to qualifications therefor as provided by law and regulations, and to be Surgeon General of the Public Health Service for a term of four years.
INTRODUCTION OF BILLS AND JOINT RESOLUTIONS

The following bills and joint resolutions were introduced, read the first and second times by unanimous consent, and referred as indicated:

By Mr. UDALL (for himself, Mr. PORTMAN, Mr. PETERS, Mr. WYDEN, Mr. GRAHAM, Mr. GARDNER, Mr. BERNSTEIN, Mr. FRANKEN, Ms. BALDWIN, and Mr. ALEXANDER):

S. 760. A bill to amend the Energy Policy and Conservation Act to establish a Water Engagement Office within the Environmental Protection Agency, and for other purposes; to the Committee on Environment and Public Works.

By Mr. CORNYN (for himself and Mr. WYDEN):

S. 761. A bill to provide for Federal agencies to develop public access policies relating to research data, by employees of that agency or from funds administered by that agency; to the Committee on Homeland Security and Governmental Affairs.

By Mr. RISCH:

S. 762. A bill to amend the Marine Mammal Protection Act of 1972 to reduce predation by sea lions on endangered Columbia River salmon and other species not listed under the Endangered Species Act of 1973, and for other purposes; to the Committee on Commerce, Science, and Transportation.

By Mr. DUCKWORTH:

S. 763. A bill to amend section 212(d)(5) of the Immigration and Nationality Act to allow parole of aliens into the United States to receive health care furnished by the Secretary of Veterans Affairs; to the Committee on the Judiciary.

By Mr. DUCKWORTH:

S. 764. A bill to require the Secretary of Homeland Security to establish a veterans visa program to permit veterans who have been detained in the United States to return as immigrants, and for other purposes; to the Committee on the Judiciary.

By Mr. BENNET (for himself and Mr. COONS):

S. 765. A bill to provide for the Secretary of Agriculture the ability to enter into a lease agreement for administrative sites on National Forest System land, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. MENENDEZ (for himself, Mr. GRAHAM, Mr. WHITEHOUSE, Ms. COLLINS, Mrs. SHAHEEN, Ms. WARNEN, and Mr. COONS):

S. 766. A bill to provide for human health threats, consumption, and trade of equines raised in the United States; to the Committee on Health, Education, Labor, and Pensions.

By Mrs. GILLIBRAND:

S. 767. A bill to amend the Food and Nutrition Act of 2008 to provide for a standard medical expense deduction under the supplemental nutrition assistance program, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. MENENDEZ (for himself, Mrs. BLUMENTHAL, Mr. LEAHY, Mr. WHITEHOUSE, Mr. SCHUMER, Mr. NELSON, Mr. FRANKEN, Mrs. SHAHEEN, Mr. PETERS, Ms. HASSAN, Mr. CARDIN, Mr. REED, Mrs. MURRAY, Mr. DURBIN, Ms. STABENOW, Mr. FEINSTEIN, Mr. MERKLEY, Mr. MARKSY, Ms. HIRONO, Ms. HARRIS, and Mr. BOOKER):

S. 760. A bill to amend the Internal Revenue Code of 1986 to provide that the provisions shall apply to legally married same-sex couples in the same manner as other married couples for other purposes; to the Committee on Finance.

By Mr. MENENDEZ (for himself, Mr. BLUMENTHAL, Mr. LEAHY, Mr. WHITEHOUSE, Mr. SCHUMER, Mr. NELSON, Mr. FRANKEN, Mrs. SHAHEEN, Mr. PETERS, Ms. HASSAN, Mr. CARDIN, Mr. REED, Mrs. MURRAY, Mr. DURBIN, Ms. STABENOW, Mr. FEINSTEIN, Mr. MERKLEY, Mr. MARKSY, Ms. HIRONO, Ms. HARRIS, and Mr. BOOKER):

S. 761. A bill to amend the Public Utility Regulatory Policies Act of 1978 to assist States in adopting updated interconnection procedures and tariff schedules and standards for supplemental, backup, and standby power for projects for combined heat and power, for electricity to heat to power technology, and for other purposes; to the Committee on Energy and Natural Resources.

By Mrs. SHAHEEN:

S. 762. A bill to amend the Higher Education Act of 1965 to provide for the automatic recertification of income for income-driven repayment plans, and for other purposes; to the Committee on Health, Education, Labor, and Pensions.

By Mrs. SHAHEEN (for herself, Mr. CARDIN, Mrs. LANDRY, Mr. KENNEDY, and Mr. REED):

S. 763. A bill to require certain financial assistance under the State energy program and the Weatherization Assistance Program to be distributed without undue delay to supplement energy assistance under the State energy program and the Weatherization Assistance Program; to the Committee on Energy and Natural Resources.

By Mr. WYDEN:

S. 764. A bill to amend the Immigration and Nationality Act to provide for the conduct of certain economic activities in Malheur County, Oregon, to provide for the conduct of a study on the need for a regional economic development center in Malheur County, and to allocate funds to Oregon State University to conduct the study; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. WYDEN (for himself and Mr. MERKLEY):

S. 765. A bill to provide for the conduct of certain economic activities in Malheur County, Oregon, to provide for the conduct of a study on the need for a regional economic development center in Malheur County, and to allocate funds to Oregon State University to conduct the study; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. WYDEN (for himself and Mr. MERKLEY):

S. 766. A bill to provide for the conduct of certain economic activities in Malheur County, Oregon, to provide for the conduct of a study on the need for a regional economic development center in Malheur County, and to allocate funds to Oregon State University to conduct the study; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. WYDEN (for himself and Mr. MENENDEZ, Ms. HIRONO, Ms. BALDWIN, Mr. SCHUMER, Mr. WHITEHOUSE, Mrs. FEINSTEIN, Mr. BENNET, Mr. BOOKER, Mr. DURBIN, Mr. KAIN, Mr. BROWN, Mr. LEAHY, Mr. FRANKEN, Mr. HEINRICH, Mr. MASTO, Mr. CARID, Ms. HASSAN, Mr. CARPER, Mr. VAN HOLLEN, Mr. COONS, Mrs. MCCASKILL, Mrs. MURRAY, Ms. HARRIS, Ms. STABENOW, Mr. REED, Ms. KLOBUCHAR, Mr. SANDERS, Mr. SCHUMER, Mr. BLUMENTHAL, Ms. CANTWELL, Mr. PERDUE, Ms. DUCKWORTH, Mr. PETERS, Mr. UDALL, Mr. MARKSY, Mr. MURPHY, Ms. HEITKAMP, Mrs. SHAHEEN, Mrs. GILLIBRAND, Mr. BERNSTEIN, Mr. KING, Mr. SCHATZ, Mr. WARNER, Mr. TISCHER, and Mr. MANCHIN):

S. 767. A bill to amend the Internal Revenue Code of 1986 to require a credit to employers who provide paid family and medical leave, and for other purposes; to the Committee on Finance.

By Mrs. FISCHER (for herself and Mr. KING):

S. 768. A bill to amend the Internal Revenue Code of 1986 to provide a credit to employers who provide paid family and medical leave, and for other purposes; to the Committee on Finance.

By Mr. WYDEN (for himself and Mr. RUHO):

S. 769. A bill to amend title 31, United States Code, to ensure that persons who form corporations or limited liability companies in the United States disclose the beneficial owners of those limited liability companies, in order to prevent wrongdoers from exploiting United States corporations and limited liability companies for criminal gain, to focus law enforcement in detecting, preventing, and punishing terrorism, money laundering, and other misconduct involving United States corporations and limited liability companies, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. KENNEDY (for himself, Mr. NELSON, Mr. INHOFE, Mr. RUHO, Mr. CASSIDY, and Ms. WARNEN):

S. 770. A bill to authorize the mooting of a postage stamp in honor of the 75th anniversary of the end of World War II, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. BLUNT (for himself and Ms. CANTWELL):

S. 771. A bill to eliminate duties on imports of recreational performance outerwear, to establish the Sustainable Textile and Apparel Research Fund, and for other purposes; to the Committee on Finance.

By Mr. COTTON (for himself and Mr. PERDUE):

S. 772. A bill to amend the Immigration and Nationality Act to establish a skill-based immigration policy that focuses family-sponsored immigration on spouses and minor children, to eliminate the Diversity Visa Program, to set a limit on the number of refugees admitted annually to the United States, and for other purposes; to the Committee on the Judiciary.

By Mr. UDALL (for himself, Mr. ROUNDS, Mr. BOOZMAN, Mrs. MURRAY, and Mr. HEINRICH):

S. 773. A bill to amend titles 10 and 37, United States Code, to authorize the reciprocal investment and credit for retired pay purposes for maternity leave taken by members of the reserve components, and for other purposes; to the Committee on Armed Services.

By Mr. SULLIVAN:

S. 774. A bill to require the Committee on Foreign Investment in the United States to authorize the reciprocal investment and, for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. SANDERS:

S. 775. A bill to appropriate amounts to the Department of Veterans Affairs to improve health care for veterans, and for other purposes; to the Committee on Veterans’ Affairs.
By Mr. WARNER (for himself, Mr. Moran, Mrs. Capito, and Mr. Casey):
S. 1724. A bill to amend the Internal Revenue Code of 1986 to establish a new tax credit and grant program to stimulate investment and healthy nutrition options in food deserts, and for other purposes; to the Committee on Finance.

By Ms. DUCKWORTH (for herself and Mrs. Cortez Masto):
S. 1725. A bill to require the Secretary of Homeland Security to identify each alien who has entered, or is serving in, the Armed Forces of the United States when any alien applies for an immigration benefit or is placed in an immigration enforcement proceeding, and for other purposes; to the Committee on the Judiciary.

By Mr. MENENDEZ (for himself, Mr. Blumenthal, Mr. Markey, Mrs. Feinstein, Ms. Hirono, Mr. Frank, Mrs. Shaheen, Ms. Warren, Mr. Whitehouse, Mr. Durbin, Mr. Merkley, Mr. Van Hollen, Mr. Udall, Mr. Booker, Mr. Leahy, and Mrs. Gillibrand):
S. 1726. A bill to amend the Securities Exchange Act of 1934 to require shareholder authorizations before a public company may make certain political expenditures, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. DUCKWORTH (for herself and Mrs. Cortez Masto):
S. 1727. A bill to establish a naturalization office at every initial military training site; to the Committee on Armed Services.

By Mr. CARDIN:
S. 1728. A bill to require non-Federal prisons, correctional, and detention facilities holding Federal prisoners or detainees under a contract with the Federal Government to make the same information available to the public that Federal prisons and correctional facilities are required to make available; to the Committee on the Judiciary.

By Mr. ROBERTS (for himself, Mr. Warner, Mr. Crapo, Mr. Cardin, and Mr. Young):
S. 1729. A bill to amend title XVIII of the Social Security Act to provide for independent accreditation for dialysis facilities and assurances of high quality surveys; to the Committee on Finance.

By Ms. COLLINS (for herself, Mr. Moran, Mrs. Shaheen, Mr. Rubio, Mr. Blumenthal, Mr. Enzi, Mr. Isakson, Mr. Durbin, and Mr. Murphy):
S. 1730. A bill to implement policies to end preventable maternal, newborn, and child deaths globally; to the Committee on Foreign Relations.

By Mr. THUNE:
S. 1731. A bill to address the forest health crisis on National Forest System land, and for other purposes; to the Committee on Environment and Public Works.

SUBMISSION OF CONCURRENT AND SENATE RESOLUTIONS

The following concurrent resolutions and Senate resolutions were read, and referred to the appropriate committees, as indicated:

By Mr. WICKER (for himself, Mr. Schatz, Mr. Gardner, Ms. Hassan, Mr. Moran, and Mr. Peters):
S. Res. 242. A resolution expressing the sense of the Senate about a strategy to deploy fifth generation mobile networks (5G networks) and next-generation wireless and wired technologies to promote economic development, innovation, and infrastructure development, and to provide critical services, including public safety, throughout the United States; to the Committee on Commerce, Science, and Transportation.

By Mr. FLAKE (for himself, Mr. Gardner, Mr. Lee, Mr. Cotton, Mrs. McCaskill, and Mr. Bennet):
S. Res. 243. A resolution expressing the sense of the Senate that Joseph Leon George should be honored for heroism at Pearl Harbor, Hawaii, on December 7, 1941; to the Committee on Armed Services.

By Mr. McCONNELL (for himself and Mr. Schumer):
S. Res. 244. A resolution to authorize testimony, document production, and representation in United States of America v. Robert Menendez, et al; considered and agreed to.

ADDITIONAL COSPONSORS

S. 58
At the request of Mr. HELLER, the names of the Senator from South Carolina (Mr. Scott), the Senator from Michigan (Ms. Stabenow), the Senator from Alaska (Mr. Sullivan) and the Senator from Michigan (Mr. Peters) were added as cosponsors of S. 58, a bill to amend the Internal Revenue Code of 1986 to repeal the excise tax on high cost employer-sponsored health coverage.

S. 139
At the request of Mr. WICKER, the name of the Senator from South Carolina (Mr. Scott) was added as a cosponsor of S. 168, a bill to amend and enhance certain maritime programs of the Department of Transportation.

S. 253
At the request of Mr. CARDIN, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 253, a bill to amend title XVIII of the Social Security Act to repeal the Medicare outpatient rehabilitation therapy caps.

S. 256
At the request of Ms. HEITKAMP, the name of the Senator from Massachusetts (Ms. Warren) was added as a cosponsor of S. 256, a bill to establish the Stop, Observe, Ask, and Respond to Health and Wellness Training pilot program to address human trafficking in the health care setting.

S. 261
At the request of Mr. BLUNT, the name of the Senator from Mississippi (Mr. Wicker) was added as a cosponsor of S. 261, a bill to amend the Federal Food, Drug, and Cosmetic Act to improve requirements for restaurants and similar retail food establishments, and to amend the authority to bring proceedings under section 403A.

S. 266
At the request of Mr. HATCH, the name of the Senator from North Dakota (Mr. Hoeven) was added as a cosponsor of S. 266, a bill to award the Congressional Gold Medal to Anwar Sadat in recognition of his heroic achievements and courageous contributions to peace in the Middle East.

S. 283
At the request of Mr. FRANKEN, the name of the Senator from Ohio (Mr. Brown) was added as a cosponsor of S. 283, a bill to amend title 38, United States Code, to provide for the treatment of veterans who participated in the cleanup of Eniwetak Atoll as radiation exposed veterans for purposes of the presumption of service-connection of certain disabilities by the Secretary of Veterans Affairs, and for other purposes.

S. 322
At the request of Mr. PETERS, the name of the Senator from Maryland (Mr. Van Hollen) was added as a cosponsor of S. 322, a bill to protect victims of domestic violence, sexual assault, stalking, and dating violence from emotional and psychological trauma caused by acts of violence or threats of violence against their pets.

S. 372
At the request of Mr. PORTMAN, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 372, a bill to amend the Tariff Act of 1930 to ensure that merchandise arriving through the mail shall be subject to review by U.S. Customs and Border Protection and to require the provision of advance electronic information on shipments of mail to U.S. Customs and Border Protection and for other purposes.

S. 394
At the request of Mr. ROUNDS, the name of the Senator from Texas (Mr. Cruz) was added as a cosponsor of S. 394, a bill to amend title 18, United States Code, to provide that a member of the Armed Forces and the spouse of that member shall have the same rights regarding the receipt of firearms at the location of any duty station of the member.

S. 436
At the request of Mr. GRASSLEY, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 428, a bill to amend titles XIX and XXI of the Social Security Act to authorize States to provide coordinated care for children with complex medical conditions through enhanced pediatric health homes, and for other purposes.

S. 497
At the request of Mr. BENNET, the name of the Senator from Maine (Mr. King) was added as a cosponsor of S. 456, a bill to amend the Federal Food, Drug, and Cosmetic Act to establish a program to increase the development of new drugs to treat pediatric cancers, and for other purposes.

S. 497
At the request of Ms. CANTWELL, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 497, a bill to amend title XVIII of the Social Security Act to provide for Medicare coverage of certain lymphedema compression treatment items as items of durable medical equipment.

S. 581
At the request of Mr. MANCHIN, the names of the Senator from New Hampshire (Mrs. Shaheen) and the Senator from Maine (Mr. King) were added as
cosponsors of S. 591, a bill to include information concerning a patient's opioid addiction in certain medical records.

S. 593  
At the request of Mrs. Capito, the name of the Senator from Alabama (Mr. Strange) was added as a cosponsor of S. 593, a bill to amend the Pittman-Robertson Wildlife Restoration Act to facilitate the establishment of additional or expanded public target ranges in certain States.

S. 655  
At the request of Mrs. Shaheen, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 635, a bill to amend title 28, United States Code, to prohibit the exclusion of individuals from service on a Federal jury on account of sexual orientation or gender identity.

S. 902  
At the request of Mr. Moran, the names of the Senator from Colorado (Mr. Bennet) and the Senator from Nevada (Mr. Heller) were added as cosponsors of S. 1002, a bill to enhance the ability of community financial institutions to foster economic growth and serve their communities, boost small businesses, increase individual savings, and for other purposes.

S. 1044  
At the request of Mrs. Capito, the name of the Senator from Mississippi (Mr. Wicker) was added as a cosponsor of S. 1044, a bill to amend title XVIII of the Social Security Act to ensure equal access of Medicare beneficiaries to community pharmacies in underserved areas as network pharmacies under Medicare prescription drug coverage, and for other purposes.

S. 1113  
At the request of Mrs. Feinstein, the name of the Senator from Hawaii (Ms. Hirono) was added as a cosponsor of S. 1113, a bill to amend the Federal Food, Drug, and Cosmetic Act to ensure the safety of cosmetics.

S. 1139  
At the request of Mr. Tester, the name of the Senator from Missouri (Mrs. McCaskill) was added as a cosponsor of S. 1139, a bill to amend the Financial Stability Act of 2010 to modify the requirements of stress tests.

S. 1182  
At the request of Mr. Young, the names of the Senator from New Mexico (Mr. Udall) and the Senator from Maryland (Mr. Cardin) were added as cosponsors of S. 1182, a bill to require the Secretary of the Treasury to mint commemorative coins in recognition of the 100th anniversary of The American Legion.

S. 1254  
At the request of Ms. Stabenow, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 1254, a bill to amend the Internal Revenue Code of 1986 to expand the small employer health insurance credit.

S. 1301  
At the request of Mr. Cornyn, the name of the Senator from Louisiana (Mr. Kennedy) was added as a cosponsor of S. 1311, a bill to provide assistance in abolishing human trafficking in the United States.

S. 1323  
At the request of Mr. Grassley, the name of the Senator from Massachusetts (Ms. Warren) was added as a cosponsor of S. 1312, a bill to prioritize the fight against human trafficking in the United States.

S. 1348  
At the request of Mr. Wyden, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 1348, a bill to amend title XI of the Social Security Act to require drug manufacturers to publicly justify unnecessary price increases.

S. 1394  
At the request of Mr. Carper, the name of the Senator from Delaware (Mr. Coons) was added as a cosponsor of S. 1354, a bill to establish an Individual Market Reinsurance fund to provide funding for State individual market stabilization reinsurance programs.

S. 1462  
At the request of Mrs. Shaheen, the name of the Senator from Illinois (Ms. Duckworth) was added as a cosponsor of S. 1428, a bill to amend section 21 of the Small Business Act to require cyber certification for small business development center counselors, and for other purposes.

S. 1505  
At the request of Mr. Warner, the name of the Senator from Nevada (Mr. Heller) was added as a cosponsor of S. 1500, a bill to amend the Federal Deposit Insurance Act to ensure that the reciprocal deposits of an insured deposit institution are not considered to be funds obtained by or through a deposit broker, and for other purposes.

S. 1524  
At the request of Mr. Hatch, the names of the Senator from South Carolina (Mr. Scott) and the Senator from Florida (Mr. Nelson) were added as cosponsors of S. 1509, a bill to amend the Federal Food, Drug, and Cosmetic Act to authorize an exclusivity period for certain drugs that are approved for a new indication for a rare disease or condition, and for other purposes.

S. 1512  
At the request of Mr. Lankford, the name of the Senator from Alabama (Mr. Strange) was added as a cosponsor of S. 1512, a bill to prohibit the Secretary of Energy, the Administrator of the Environmental Protection Agency, the Secretary of the Interior, the Secretary of Transportation, and the Chair of the Council on Environmental Quality from considering, in taking any action, the social cost of carbon, the social cost of methane, the social cost of nitrous oxide, or the social cost of any other greenhouse gas, unless compliant with Office of Management and Budget guidance, and for other purposes.

S. 1532  
At the request of Mr. Thune, the name of the Senator from Nevada (Mr. Heller) was added as a cosponsor of S. 1532, a bill to disqualify from operating a commercial motor vehicle for life an individual who uses a commercial motor vehicle in committing a felony involving human trafficking.
At the request of Ms. KLOBUCHAR, the name of the Senator from North Dakota (Mr. HECK) was added as a cosponsor of S. 1536, a bill to designate a site for a veterans medical care center in the State of North Dakota.

At the request of Mr. Risch, the name of the Senator from Idaho (Mr. CRUZ) was added as a cosponsor of S. 1598, a bill to amend section 203 of Public Law 94–339 to ensure proper authority for the Office of Advocacy of the Small Business Administration, and for other purposes.

At the request of Mr. MARKEY, the name of the Senator from Massachusetts (Ms. WARREN) was added as a cosponsor of S. 1613, a bill to require the Secretary of the Treasury to mint coins in commemoration of President John F. Kennedy.

At the request of Mr. TESTER, the names of the Senator from New York (Mr. SCHUMER) and the Senator from Nevada (Ms. CORTEZ MASTO) were added as cosponsors of S. 1598, a bill to amend title 10, United States Code, to make certain improvements in the laws administered by the Secretary of Veterans Affairs, and for other purposes.

At the request of Mr. GRAHAM, the names of the Senator from California (Mrs. FEINSTEIN) and the Senator from Colorado (Ms. HARRIS) were added as cosponsors of S. 1615, a bill to authorize the cancellation of removal and adjustment of status of certain individuals who are long-term United States residents and who entered the United States as children, and for other purposes.

At the request of Mr. DURBIN, the name of the Senator from Wisconsin (Ms. BERNSTEIN) was added as a cosponsor of S. 1636, a bill to amend the Internal Revenue Code of 1986 to modify the rules relating to inverted corporations.

At the request of Mr. SCOTT, the name of the Senator from Virginia (Mr. RICHARDSON) was added as a cosponsor of S. 1685, a bill to require Fannie Mae and Freddie Mac to establish procedures for considering certain credit scores in making a determination whether to purchase a residential mortgage, and for other purposes.

At the request of Ms. KLOBUCHAR, the name of the Senator from Rhode Island (Mr. REED) was added as a cosponsor of S. 1688, a bill to amend title XVIII of the Social Security Act to allow the Secretary of Health and Human Services to negotiate fair prescription drug prices under part D of the Medicare program.

At the request of Mr. PORTMAN, the names of the Senator from Alaska (Mr. SULLIVAN) and the Senator from Louisiana (Mr. READ) were added as cosponsors of S. 1693, a bill to amend the Communications Act of 1934 to clarify that section 230 of that Act does not prohibit the enforcement against providers and users of interactive computer services of Federal and State criminal and civil law relating to sex trafficking.

At the request of Mr. ROBERTS, the name of the Senator from South Carolina (Mr. SCOTT) was added as a cosponsor of S. Con. Res. 7, a concurrent resolution expressing the sense of Congress that tax-exempt fraternal benefit societies have historically provided and continue to provide critical benefits to the people and communities of the United States.

At the request of Mr. DURBIN, the name of the Senator from the District of Columbia (Mr. DUVALL) was added as a cosponsor of S. 1701, a bill to provide for Federal agencies to develop public access policies relating to research conducted by employees of agencies that are administrated by that agency, to the Committee on Homeland Security and Governmental Affairs.

Mr. CORNYN. Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

BE IT ENACTED BY THE SENATE AND HOUSE OF REPRESENTATIVES OF THE UNITED STATES OF AMERICA IN CONGRESS ASSEMBLED,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Fair Access to Science and Technology Research Act of 2017".

SEC. 2. FINDINGS.

Congress finds that—

(1) the Federal Government funds basic and applied research with the expectation that new ideas and discoveries that result from the research, if shared and effectively disseminated, will advance science and improve the lives and welfare of people of the United States and around the world;

(2) in many cases, it makes it possible for this information to be promptly available to every scientist, physician, educator, and citizen at home, in school, or in a library;

(3) the United States has a substantial interest in maximizing the impact and utility of the research it funds by enabling a wide range of uses of the peer-reviewed literature that reports such research, including by enabling computational analysis by state-of-the-art technologies;

(4) the Office of Science and Technology Policy issued a policy memorandum dated February 22, 2013, which established the commitment of the executive branch of the Federal Government to ensuring that "the results of federally funded scientific research are made available to and useful for the public, industry, and the scientific community"; and

(5) the executive branch advises that such public access should be implemented "with the fewest constraints possible".

SEC. 3. DEFINITION OF FEDERAL AGENCY.

In this Act, the term "Federal agency" means an Executive agency, as defined under section 105 of title 5, United States Code.

SEC. 4. FEDERAL RESEARCH PUBLIC ACCESS POLICY.

(a) Requirement To Develop Policy.—

(1) In General.—Not later than 1 year after the date of enactment of this Act, each Federal agency with annual research expenditures of over $100,000,000 shall develop a Federal research public access policy that is consistent with and advances the purposes of the Federal agency.

(2) Common Procedures.—To the extent practicable, Federal agencies required to develop a policy under paragraph (1) shall follow common procedures for the collection and depositing of research papers.

(b) Content.—Each Federal research public access policy shall provide for—

(1) submission to a digital repository designated or maintained by the Federal agency of an electronic version of the author’s final manuscript of original research papers that have been accepted for publication in peer-reviewed journals and that result from research supported, in whole or in part, from funding by the Federal Government;

(2) the incorporation of all changes resulting from the peer review publication process in the manuscript described under paragraph (1); and

(3) the replacement of the final manuscript with the final published version if—

(A) the publisher consents to the replacement; and

(B) the goals of the Federal agency for functionality and interoperability are retained;
(4) free online public access to such final peer-reviewed manuscripts or published versions within a time period that is appropriate for each type of research conducted or sponsored by the Federal agency, not later than 12 months after publication in peer-reviewed journals, preferably sooner, or as adjusted under established mechanisms;

(5) using established mechanisms for making requests to the applicable Federal agency, for members of the public and other stakeholders to request to adjust the period before a final peer-reviewed manuscript or published version is made publicly available by presenting evidence demonstrating that the period is inconsistent with the purposes of the Federal research public access policy or the needs of the public, industry, or the scientific community;

(6) providing research papers as described in paragraph (4) in formats and under terms that enable productive reuse of the research and computational analysis by state-of-the-art technologies;

(7) improving the ability of the public to locate and access research papers made accessible under the Federal research public access policy;

(8) long-term preservation of, and free public access to, research papers made accessible under the Federal research public access policy—

(A) in a stable digital repository maintained by the Federal agency;

(B) if consistent with the purposes of the Federal agency, in any repository meeting conditions determined favorable by the Federal agency for free public access, interoperability, and long-term preservation.

(c) Application of Policy.—Each Federal research public access policy shall—

(1) apply to—

(A) researchers employed by the Federal agency whose works remain in the public domain; and

(B) researchers funded by the Federal agency;

(2) provide that works described under paragraph (1)(A) shall be—

(A) marked as being public domain material when published; and

(B) made available at the same time such works are made available under subsection (b)(4); and

(3) make effective use of any law or guidance relating to the creation and reservation of a Government license that provides for the reutilization, reuse, or other use of a final manuscript for Federal purposes.

(d) INCLUSIONS.—Each Federal research public access policy shall not apply to—

(1) research progress reports presented at professional meetings or conferences;

(2) laboratory notes, preliminary data analyses, notes of the author, phone logs, or other information used to produce final manuscripts;

(3) classified research, research resulting in works that generate revenue or royalties for authors (such as books) or patentable discoveries, to the extent necessary to protect a copyright or patent;

(4) authors who do not submit their work to a journal or works that are rejected by journals;

(e) PATENT OR COPYRIGHT LAW.—Nothing in this Act shall be construed to affect any right under the provisions of title 17 or 35, United States Code.

(f) GAO REPORT.—Not later than 3 years after the date of enactment of this Act, and every 5 years thereafter, the Comptroller General of the United States shall submit to Congress a report that—

(1) includes an analysis of the period between the date on which each paper becomes publicly available in a journal and the date on which the paper is in the online repository of the applicable Federal agency; and

(2) examines the effectiveness of the Federal research public access policy in providing the public with free online access to papers on research funded by each Federal agency required to develop a policy under section 11(a), including—

(A) whether the terms of use applicable to such research papers in effect are effective in enabling the research and computational analysis by state-of-the-art technologies; and

(B) whether such research papers should be granted a copyright license that is available to the public and that permits the reuse of those research papers, on the condition that attribution is given to the author or authors of the research and any others designated by the copyright owner.

By Mr. WYDEN (for himself and Mr. RUBIO):

S. 1717. A bill to amend title 31, United States Code, to ensure that persons who form corporations or limited liability companies in the United States disclose the beneficial owners of those corporations or limited liability companies, in order to prevent wrongdoers from exploiting United States corporations and limited liability companies; to authorize Federal law enforcement in detecting, preventing, and punishing terrorism, money laundering, and other misconduct involving United States corporations and limited liability companies, and for other purposes; to the extent authorized by law, including the terms and conditions necessary to promote privacy and other interests of the United States; and for other purposes.

Mr. WYDEN. Mr. President, today I am, along with Senator RUBIO, introducing the Corporate Transparency Act of 2017. This bill ends the abuse of anonymous shell companies by criminals who use these entities to launder money, finance terrorism, promote sex trafficking, and evade taxes.

Each year criminals use anonymous shell companies to carry out their illicit schemes. Viktor Bout, the so-called "merchant of death," utilized a vast network of shell corporations, several of which were in the United States, including one suspected of having provided Iran with nuclear technology. Another anonymous U.S. company owned a large share of a Manhattan skyscraper and its apartments. The Panama Papers leaked in 2016 contained information on which the paper is in the online repository of the applicable Federal agency; and

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The Corporate Transparency Act of 2017 is a much needed step in stopping financial crimes and the abuse of anonymous shell companies. I thank Senator RUBIO for joining me in introducing this bill, and I ask my colleagues to join me in supporting this bipartisan bill.

Mr. President, I ask unanimous consent that the text of the bill be printed in the RECORD.

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

S. 1717

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Corporate Transparency Act of 2017."

SEC. 2. FINDINGS.

Congress finds the following:
(1) Nearly 2,000,000 corporations and limited liability companies are being formed under the laws of the States each year.

(2) Very few States obtain meaningful information about the beneficial owners of the corporations and limited liability companies formed under their laws.

(3) A person forming a corporation or limited liability company within the United States typically provides less information to the State of incorporation than is needed to obtain a bank account or driver’s license and typically does not name a single beneficial owner.

(4) Criminals have exploited the weaknesses in State formation processes to conceal their activities forming corporations or limited liability companies in the United States, and have then used the newly created entities to commit crimes affecting interstate and international commerce such as terrorism, drug trafficking, money laundering, tax evasion, securities fraud, financial fraud, and acts of foreign corruption.

(5) Law enforcement efforts to investigate corporations and limited liability companies suspected of committing crimes have been impeded by the lack of available beneficial ownership information, as documented in reports and testimonies by officials from the Department of Justice, the Department of Homeland Security, the Financial Crimes Enforcement Network, the Department of the Treasury, the Internal Revenue Service, and the Government Accountability Office, and others.

(b) In July 2006, a leading international anti-money laundering organization, the Financial Action Task Force on Money Laundering (in this section referred to as the "FATF"), of which the United States is a member, issued a report that criticizes the United States for failing to comply with a FATF standard on the need to collect beneficial ownership information and urged the United States to correct this deficiency by July 2008. In December 2016, FATF issued another evaluation of the U.S., which found that little progress has been made over the last ten years to address this problem. It identified the “lack of timely access to adequate, accurate and current beneficial ownership information” as one of the fundamental U.S. efforts to combat money laundering and terrorist finance.

(7) In response to the 2006 FATF report, the United States repeatedly urged the States to strengthen their incorporation practices by obtaining beneficial ownership information for the corporations and limited liability companies formed under the laws of such States.

(8) Many States have established automated procedures that allow a person to form a corporation or limited liability company within the State 24 hours after filing an online application, without any prior review of the application by a State official or a substantial fee. In these States, 2 States will form a corporation within 1 hour of a request.

(9) Dozens of Internet Web sites highlight the ability of corporations and limited liability companies formed under the incorporation practices of some States, to point to those practices as a reason to incorporate in those States, and list those States as preferred locations for the formation of new corporations, essentially providing an open invitation to criminals and other wrongdoers to form entities within the United States.

(10) In contrast to practices in the United States, all 26 countries in the European Union have formation laws that identify the beneficial owners of the corporations formed under the laws of the country.

(11) To reduce the vulnerability of the United States to wrongdoing by United States corporations and limited liability companies with hidden owners, to protect in corporate entities from criminals misusing United States corporations and limited liability companies, to strengthen law enforcement investigations of suspicious entities, and to meet international anti-money laundering standards, Federal legislation is needed to require the collection of beneficial ownership information for the corporations and limited liability companies formed under the laws of such States.

SEC. 3. TRANSPARENT INCORPORATION PRACTICES.

(a) Transparent Incorporation Practices.

(1) In General.—Chapter 53 of title 31, United States Code, is amended by inserting after section 5332 the following new section: *§ 5333. Transparent Incorporation Practices*

"(a) Reporting Requirements.—

"(1) In general.—Not later than the beginning of fiscal year 2019, the Secretary of the Treasury shall issue regulations requiring each corporation formed in a State that does not have a formation system described in subsection (b) to file with the Financial Crimes Enforcement Network described under subsection (a) a list of the beneficial owners of the corporation or limited liability company formed under the laws of the State.

"(b) Forming System.—Each State shall maintain a system to obtain information from corporations and limited liability companies formed under the laws of such States, and each State shall require the corporations and limited liability companies to provide the beneficial ownership information relating to each corporation or limited liability company formed under the laws of such States to strengthen law enforcement investigations of suspicious entities, to meet international anti-money laundering standards, and to meet Federal banking laws.

"(c) Collection of Information.—The Secretary of the Treasury shall have the authority to require the Secretary of a State to disclose information to the Financial Crimes Enforcement Network described under subsection (a) if the Secretary determines that such information is necessary to uncover beneficial owners that are hidden from law enforcement or other entities described in subsection (a) or necessary to prevent a corporation or limited liability company formed under the laws of the State from being used to launder money or finance international terrorism or drug trafficking.

"(d) Procedures for Collection of Information.—The Secretary of the Treasury shall establish procedures for the collection of information described in subsection (a) in a manner that prevents the disclosure of the information to any person that is not authorized to receive the information under subsection (a).

"(e) Confidentiality.—Any person who provides information to the Financial Crimes Enforcement Network described under subsection (a) on behalf of another country under an international treaty, agreement, or convention, or an order under section 3512 of title 28, shall be protected from any civil or criminal liability associated with the disclosure of information under subsection (a) if the Secretary of the Treasury determines that the transfer of such information will not result in the closure of the account or entity described in subsection (a).

(2) States That License Formation Agent.—

"(A) In general.—Each State shall require the corporation or limited liability company formed under the laws of the State to register with the Financial Crimes Enforcement Network upon receipt of—

"(i) a request for registration made by a Federal or State agency on behalf of another country under an international treaty, agreement, or convention; or

"(ii) a written request made by a Federal or State agency on behalf of another country under an international treaty, agreement, or convention, or section 1703(d) of title 18, in response to a request for assistance from a foreign country;

"(B) updated information.—For each corporation or limited liability company formed under the laws of the State by a person described in paragraph (A), the Secretary of the Treasury shall require the corporation or limited liability company to provide the Secretary of the Treasury with an updated list of the beneficial owners and the information described in subparagraph (A) for each such beneficial owner.

(3) Information Requests.—The Secretary of the Treasury shall have the authority to require each corporation or limited liability company formed under the laws of the State to disclose information relating to the corporation or limited liability company formed under the laws of the State, if the Secretary determines that such information is necessary to uncover beneficial owners that are hidden from law enforcement or other entities described in subsection (a) or necessary to prevent a corporation or limited liability company formed under the laws of the State from being used to launder money or finance international terrorism or drug trafficking.

(4) Notice.—The State discloses clearly and conspicuously that the beneficial ownership information collected under the formation system may be provided to the entities described in subsection (a) if the Secretary determines that such information is necessary to uncover beneficial owners that are hidden from law enforcement or other entities described in subsection (a) or necessary to prevent a corporation or limited liability company formed under the laws of the State from being used to launder money or finance international terrorism or drug trafficking.

(5) No bearer share corporations or limited liability companies.—A corporation or limited liability company formed under the laws of the State may not issue a certificate in bearer form evidencing either a whole or fractional interest in the corporation or limited liability company formed under the laws of the State that is not identified at the time of issuance.

(6) States that license formation agents.—
(A) IN GENERAL.—Notwithstanding paragraph (1), a State described in subparagraph (B) may permit an applicant to form a corporation or limited liability company under the laws of the State, to provide the required information to a licensed formation agent residing in the State, and to enter into an agreement directly, if the application under paragraph (1)(A) or the update under paragraph (1)(B) contains—

(i) the name, current business address, contact information, and licensing number of the licensed formation agent that has agreed to maintain the information required under this subsection; and

(ii) a certification by the licensed formation agent that the licensed formation agent has furnished the information required under this subsection and will maintain the information in the State licensing the licensed formation agent in accordance with State law.

(B) STATES DESCRIBED.—A State described in this subparagraph is a State that maintains a formal licensing system for formation agents and provides a corporate entity formed under the laws of the State, to provide the required information to a licensed formation agent residing in the State, and to enter into an agreement directly, if the application under paragraph (1)(A) or the update under paragraph (1)(B) contains—

(i) the name, current business address, contact information, and licensing number of the licensed formation agent that has agreed to maintain the information required under this subsection; and

(ii) a certification by the licensed formation agent that the licensed formation agent has furnished the information required under this subsection and will maintain the information in the State licensing the licensed formation agent in accordance with State law.

(C) LICENSED FORMATION AGENT DUTIES.—A licensed formation agent that receives beneficial ownership information under State law in accordance with this paragraph shall—

(i) maintain the information in the State in which the corporation or limited liability company is being or has been formed in the same manner as required for States under paragraph (1)(D); and

(ii) provide the information under the same circumstances as required for States under paragraph (1)(D); and

(iii) perform the duties of a formation agent under paragraph (3).

(D) TERMINATION OF RELATIONSHIP.—(i) In General.—Except as provided in clause (ii), a licensed formation agent that receives beneficial ownership information relating to a corporation or limited liability company under State law in accordance with this paragraph shall—

(I) notify the State in writing that the licensed formation agent has resigned or ended the relationship; and

(II) maintain all beneficial ownership information relating to the corporation or limited liability company in the possession of the licensed formation agent to the licensing State.

(ii) Exception.—If a licensed formation agent receives written instructions from a corporation or limited liability company, the licensed formation agent may provide the beneficial ownership information relating to the corporation or limited liability company to another licensed formation agent that is within the same State and has agreed to maintain the information in accordance with this section.

(iii) NOTICE TO STATE.—If a licensed formation agent providing beneficial ownership information to another licensed formation agent under clause (ii), the licensed formation agent providing the information shall promptly notify the State under the laws of which the corporation or limited liability company is formed of the identity of the licensed formation agent receiving the information.

(3) CERTAIN BENEFICIAL OWNERS.—If an applicant to form a corporation or limited liability company or a beneficial owner, officer, director, or similar agent of a corporation or limited liability company who is required to provide identification information under State law in accordance with this section:

(i) knowingly providing, or attempting to provide, false or fraudulent beneficial ownership information, including a false or fraudulent identification photograph, to a State or licensed formation agent under State law in accordance with this section;

(ii) willfully failing to provide complete or updated beneficial ownership information to a State or licensed formation agent under State law in accordance with this section; or

(iii) knowingly disclosing the existence of a subpoena, summons, or other request for beneficial ownership information, including any required identifying photograph.

(D) CIVIL AND CRIMINAL PENALTIES.—In addition to any civil or criminal penalty that may be imposed by a State, any person who violates paragraph (1)—

(A) shall be liable to the United States for a civil penalty of not more than $10,000; and

(B) may be fined under title 18, imprisoned for not more than 3 years, or both.

(E) DEFINITIONS.—For the purposes of this section:

(1) BENEFICIAL OWNER.—The term ‘beneficial owner’ means a natural person who, directly or indirectly—

(i) exercises substantial control over a corporation or limited liability company; or

(ii) a person acting solely as an employee of a corporation or limited liability company and whose control over or economic benefits from the entity are derived solely from the employment status of the person;

(iii) a person who has a substantial interest in, exercises substantial control over, or maintains a financial interest in a corporation or limited liability company; and

(iv) a creditor of a corporation or limited liability company, unless the creditor also has an ownership interest in the corporation or limited liability company formed or to be formed under the laws of a State, the applicant, corporation, or limited liability company in which the entity has or will have an ownership interest in, exercises substantial control over, or receives substantial economic benefits from the entity.

(B) PENALTY.—

(i) IN GENERAL.—It shall be unlawful for—

(A) any person to affect interstate or foreign commerce by—

(i) knowingly providing, or attempting to provide, false or fraudulent beneficial ownership information, including a false or fraudulent identification photograph, to a State or licensed formation agent under State law in accordance with this section; or

(ii) willfully failing to provide complete or updated beneficial ownership information to a State or licensed formation agent under State law in accordance with this section; or

(iii) knowingly disclosing the existence of a subpoena, summons, or other request for beneficial ownership information, including any required identifying photograph.

(ii) PENALTIES.—In addition to any civil or criminal penalty that may be imposed by a State, any person who violates paragraph (1)—

(A) shall be liable to the United States for a civil penalty of not more than $10,000; and

(B) may be fined under title 18, imprisoned for not more than 3 years, or both.

(iii) a person acting solely as an employee of a corporation or limited liability company and whose control over or economic benefits from the entity are derived solely from the employment status of the person;

(iv) a person who has a substantial interest in, exercises substantial control over, or maintains a financial interest in a corporation or limited liability company; and

(v) a creditor of a corporation or limited liability company, unless the creditor also has an ownership interest in the corporation or limited liability company formed or to be formed under the laws of a State, the applicant, corporation, or limited liability company in which the entity has or will have an ownership interest in, exercises substantial control over, or receives substantial economic benefits from the entity.

(2) CORPORATION; LIMITED LIABILITY COMPANY.—The terms ‘corporation’ and ‘limited liability company’—

(A) have the meanings given such terms under the laws of the applicable State; and

(B) include any non-United States entity eligible for registration or registered to do business as a corporation or limited liability company
company under the laws of the applicable State;

(‘‘C’’) do not include any entity that is, and discloses in the application by the entity to form or do business in such State, a parent, subsidiary, or other entity whose ownership interests in the entity were formed before the date of the enactment of this section, in a filing with the State under State law;

(‘‘D’’) any business concern that is an issuer of a class of securities registered under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78l) or that is required to file reports under section 15(d) of that Act (15 U.S.C. 78o(d));

(‘‘ii’’) a business concern constituted or sponsored by a State, a subdivision of a State, or a group of States as a voluntary association or interstate compact between 2 or more States, by a department or agency of the United States, or under the laws of the United States;

(‘‘iii’’) a depository institution (as defined in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813));

(‘‘iv’’) a credit union (as defined in section 101 of the Federal Credit Union Act (12 U.S.C. 1752));

(‘‘v’’) a bank holding company (as defined in section 2 of the Bank Holding Company Act of 1956 (12 U.S.C. 1841));


(‘‘vii’’) an exchange or clearing agency (as defined in section 3 of the Securities Exchange Act of 1934 (15 U.S.C. 78c)) that is registered under section 6 or 17A of the Securities Exchange Act of 1934 (15 U.S.C. 78o and 78oo–1);

(‘‘viii’’) an investment company (as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a–3)) or an investment adviser (as defined in section 202 of the Investment Advisers Act of 1940 (15 U.S.C. 80b–2)), if the company or adviser is registered with the Securities and Exchange Commission, or has filed an application for registration which has not been denied, under the Investment Company Act of 1940 (15 U.S.C. 80a–1 et seq.) or the Investment Advisers Act of 1940 (15 U.S.C. 80b–1 et seq.);

(‘‘ix’’) an investment company (as defined in section 2 of the Investment Company Act of 1940 (15 U.S.C. 80a–2));

(‘‘x’’) a registered entity (as defined in section 3 of the Commodity Exchange Act (7 U.S.C. 1a)), or a futures commission merchant, introducing broker, commodity pool operator, or commodity trading adviser (as defined in section 3 of the Commodity Exchange Act (7 U.S.C. 1a)), if the company or adviser is registered with the Commodity Futures Trading Commission;

(‘‘xi’’) a public accounting firm registered in accordance with section 102 of the Sarbanes-Oxley Act (15 U.S.C. 7212);

(‘‘xii’’) a utility that provides telecommunication service, electrical power, natural gas, or water and sewer services, within the United States;

(‘‘xiii’’) a church, charity, or nonprofit entity that has been described in paragraphs (1), (2), or (4)(a)(1) of the Internal Revenue Code of 1986, has not been denied tax exempt status, and has filed the most recently due annual information return with the Internal Revenue Service, if required to file such a return;

(‘‘xiv’’) any business concern that—

(‘‘I’’) employs more than 20 employees on a full-time basis in the United States;

(‘‘II’’) files income tax returns in the United States demonstrating more than $5,000,000 in gross receipts; and

(‘‘III’’) has an operating presence at a physical office within the United States; or

(‘‘xv’’) any corporation or limited liability company formed and owned by an entity described in clause (i), (ii), (iii), (iv), (v), (vi), (vii), (viii), (ix), (x), (xi), (xii), (xiii), (xiv), or (xv); and

(‘‘D’’) do not include any individual business concern or class of business concerns which the Secretary of the Treasury, with the written concurrence of the Attorney General of the United States, has determined in writing should be exempt from the requirements of subsection (a), because requiring beneficial ownership information from the business concern would not serve the public interest and would not assist law enforcement efforts to detect, prevent, or punish terrorism, money laundering, tax evasion, or other misconduct.

(‘‘3’’) FORMATION AGENT.—The term ‘‘formation agent’’ means a person who, for compensation—

(‘‘A’’) acts on behalf of another person to assist in the formation of a corporation or limited liability company under the laws of a State;

(‘‘B’’) purchases, sells, or transfers the public records that form a corporation or limited liability company;

(2) RULEMAKING.—To carry out this Act and the amendments made by this Act, the Secretary of the Treasury, in consultation with the Department of Homeland Security, the Department of Justice, the Secretary of State, and the Attorney General of the United States, may issue guidance or a rule to—

(1) clarify the definitions under section 5333(d) of title 31, United States Code, as added by paragraph (1) and (2);

(2) specify how to verify beneficial ownership information or other identification information for purposes of such section 5333, including whether the verification procedures specified in section 5333(b)(3) should apply to all applicants under section 5333(b)(1) or whether such verification procedures should require the notarization of signatures;

(3) CONFORMING AMENDMENTS.—Title 31, United States Code, is amended—

(A) in section 5321(a),—

(i) in paragraph (1), by striking ‘‘sections 5314 and 5315’’ each place it appears and inserting ‘‘sections 5314, 5315, and 5332’’; and

(ii) in paragraph (6), by inserting ‘‘(except section 5333)’’ after ‘‘subchapter’’ each place it appears; and

(B) in section 5322, by striking ‘‘sections 5314 or 5324’’ each place it appears and inserting ‘‘sections 5315, 5324, or 5333’’.

(4) TABLE OF CONTENTS.—The table of contents of chapter 53 of title 31, United States Code, is amended by adding at the end the following:

‘‘Sec. 5333. Transparent incorporation practices.’’

(5) RESTRICTIONS ON PUBLIC ACCESS.—A State may—

(A) restrict public access to all or any portion of the beneficial ownership information provided to the State under section 5332 of title 31, United States Code, as added by this Act; and

(B) by statute, regulation, order, or other order of the State, in consultation with the Secretary of the Treasury and the Attorney General, require the State to limit access to the beneficial ownership information to such extent as the State determines is appropriate to fulfill the goals of this chapter.

(6) NO DUTY OF VERIFICATION.—This Act and the amendments made by this Act do not impose any obligation on a State to verify the name, address, or identity of a beneficial owner of a corporation or limited liability company under the laws of such State unless the State provides for the verification.

(7) joint rulemaking. — The Secretary of the Treasury, the Secretary of the Department of Homeland Security, and the Attorney General shall, jointly, issue rules to carry out the requirements of this chapter and the amendments made by this Act, and to ensure that the rules developed in accordance with such requirements are consistent with the requirements of such chapter and such amendments.

(8) RIGHTS OF STATES. — States that are not in compliance with the requirements of this chapter and the amendments made by this Act shall not be barred from carrying out the requirements of this chapter or the amendments made by this Act.

(8) AUTHORIZATION. — (A) In general. — The Secretary of the Treasury may accept certain information under section 5333 of title 31, United States Code, during the 3-year period beginning on the date of enactment of this Act, funds shall be made available to each State to pay reasonable costs relating to compliance with the requirements of such section.

(B) reporting. — To protect the United States against the misuse of United States corporations and limited liability companies with hidden owners, funds shall be made available to each State to pay reasonable costs relating to compliance with the requirements of such section.

(C) coordination. — To protect the United States against the misuse of United States corporations and limited liability companies with hidden owners, funds shall be made available to each State to pay reasonable costs relating to compliance with the requirements of such section.
is subject to the requirement to disclose beneficial ownership information under section 5333 of title 31, United States Code, to provide the information required to be disclosed under section 5333 of title 31, United States Code, is amended—

(1) in subsection (Y), by striking “or” at the end;

(2) by redesignating subparagraph (Z) as subparagraph (AAA); and

(C) by inserting after subparagraph (Y) the following:

‘‘(Z) any person who, for compensation—

‘‘(1) acts on behalf of another person to form, or assist in formation of, a corporation or limited liability company under the laws of a State; or

‘‘(ii) any attorney or law firm that uses a paid formation agent operating within the United States to form the corporation or limited liability company; or’’.

(2) DEADLINE FOR ANTI-MONEY LAUNDERING RULES IMPLEMENTATION—

(A) PROPOSED RULE.—Not later than 120 days after the date of enactment of this Act, the Comptroller General of the United States and the Commissioner of the Internal Revenue Service, shall publish a proposed rule in the Federal Register requiring persons described in section 5312(a)(2)(Z) of title 31, United States Code, as amended by this subsection, to establish anti-money laundering programs under subsection (h) of section 5318 of that title.

(B) FINAL RULE.—Not later than 270 days after the date of enactment of this Act, the Secretary of the Treasury shall publish the rule established in subsection (A) in final form in the Federal Register.

(C) EXCLUSIONS.—Any rule promulgated under this subsection shall exclude from the category of persons involved in forming a corporation or limited liability company—

(i) any government agency; and

(ii) any attorney or law firm that uses a paid formation agent operating within the United States to form the corporation or limited liability company.

SEC. 4. STUDIES AND REPORTS.

(a) REQUIREMENTS.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study and submit to Congress a report—

(1) identifying each State that has procedures that enable persons to form or register under the laws of the State partnerships, trusts, or other legal entities, and the nature of those procedures;

(2) identifying each State that requires persons seeking to form or register partnerships, trusts, or other legal entities under the laws of the State to provide information about the beneficial owners (as that term is defined in section 5333(d)(1) of title 31, United States Code, as added by this Act) and beneficiaries of such entities, and the nature of the required information;

(3) evaluating whether the lack of available beneficial ownership information for partnerships, trusts, or other legal entities—

(A) raises concerns about the involvement of such entities in terrorism, money laundering, tax evasion, securities fraud, or other misconduct; and

(B) has impeded investigations into entities suspected of such misconduct; and

(4) determining whether the failure of the United States to require beneficial ownership information for partnerships and trusts formed or registered in the United States has elicited international criticism and what steps, if any, the United States has taken or is planning to take in response.

(b) ENFORCEMENT AND PREVENTION PRACTICES.—Not later than 5 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study and submit to the Congress a report assessing the effectiveness of incorporation practices implemented under this Act and the amendments made by this Act in—

(1) providing law enforcement agencies with prompt access to reliable, useful, and complete beneficial ownership information; and

(2) strengthening the capability of law enforcement agencies to combat incorporation abuses, civil and criminal misconduct, and detect, prevent, or stop money laundering, tax evasion, or other misconduct.

By Ms. COLLINS (for herself, Mr. COONS, Mr. MORAN, Mrs. SHAHEEN, Mr. RUBIO, Mr. BLUMENTHAL, Mr. ENZI, Mr. ISAKSON, Mr. DURBIN, and Mr. MURPHY):

S. 1730. A bill to implement policies to end preventable maternal, newborn, and child deaths globally; to the Committee on Foreign Relations.

Ms. COLLINS. Mr. President, today I am pleased to be joined by my friend and colleague from Delaware, Senator CHRISS COONS, in introducing the Reach Every Mother and Child Act of 2017. Our legislation would make it the policy of the United States to lead an effort to end preventable deaths of mothers, newborns, and young children in the developing world by 2030.

Due in part to American leadership and generosity, many lives have already been saved. Since 1990, the annual number of deaths of children under the age of five has been cut in half. Nevertheless, far too many mothers, newborns, and young children under the age of five still succumb to disease and malnutrition that could easily be prevented, if only we could reach the mothers and children with simple, proven, cost-effective interventions that we know will help them survive.

Every day approximately 800 women will die from preventable causes related to pregnancy and childbirth. In addition, more than 16,000 children under the age of five will die each day of treatable conditions such as premature, pneumonia, and diarrhea—with malnutrition being the underlying cause in nearly half those deaths.

According to USAID, a concentrated effort could end preventable maternal and child deaths worldwide by the year 2030; however, U.S. leadership and support of the international community are critical to success.

To achieve this ambitious goal, our bill would require the implementation of a strategy to scale up the most effective interventions to save as many lives as possible. This idea is central to our bill. We do not have to guess at what interventions work—the reality is that more than 16,000 children under 5 years old die each day of conditions we know today how to treat.

These life-saving interventions include clean birthing practices, vaccines, nutritional supplements, hand-washing with soap, and other basic needs that remain elusive for far too many women and children in developing countries. This must change.

In addition, our bill would establish a Maternal and Child Survival Coordinator at USAID who would focus on implementing the ten-year strategy and verifying that the most effective interventions are being scaled up in target countries.

The bill would also establish an interagency working group to assist the Coordinator in promoting greater collaboration among all the federal agencies involved in this effort.

To promote transparency and greater accountability, our bill requires that detailed reporting be published on the Foreign Assistance Dashboard, where it can be accessed by the public, Congress, and non-governmental organizations to track the implementation of the strategy and the progress being made.

Finally, our bill would encourage USAID to pay for successful programs run by non-governmental entities. The message we want to send to all our partners in the private sector, the nonprofit sector, the faith community, and in local and international civil society groups is this: if you can figure out a way to increase the likelihood that mothers and their children will survive childbirth and the first five years of life, we want to reward you for your contribution.

Improving the health and well-being of mothers and children around the world has far-reaching social and economic benefits as well. An independent group of economists and global health experts from around the world, known as the Lancet Commission, found that for every $1 invested in health initiatives in the developing world, there is a return of $9 to $20 in growing the gross domestic product of the country receiving the investment.

Other bipartisan initiatives, such as the successful President’s Emergency Plan for AIDS Relief, or PEPFAR, which was started by President George W. Bush, demonstrate that results-driven interventions can turn the tide for global health challenges. Applying lessons learned from past initiatives, our bill would provide the focus and the tools necessary to accelerate progress toward ending preventable maternal and child deaths.

I urge my colleagues to join Senator Coons and me in supporting this bill to save the lives of mothers and children around the world.
SENATE RESOLUTION 242—EXPRESSING THE SENSE OF THE SENATE ABOUT A STRATEGY TO DEPLOY FIFTH GENERATION MOBILE NETWORKS (5G NETWORKS) AND NEXT-GENERATION WIRELESS AND WIRED TECHNOLOGIES TO PROMOTE ECONOMIC DEVELOPMENT AND DIGITAL INNOVATION THROUGHOUT THE UNITED STATES

Whereas wireless and wired broadband networks are essential to economic growth, job creation, and the global competitiveness of the United States;

Whereas wireless and wired broadband networks provide connectivity to billions of devices, applications, and services that are increasing productivity and efficiency across every economic sector;

Whereas wireless and wired broadband networks create and support millions of jobs;

Whereas wireless and wired broadband networks are vital to providing community connections, services and access to internet connectivity to people in the United States living in rural and remote geographic areas;

Whereas wireless and wired broadband networks are a platform for innovation and ingenuity, powering advancements in the Internet of Things and other revolutionary technologies;

Whereas 5G networks will have the capacity to deliver enhanced mobile broadband, significantly faster data transmission speeds, low latency, more reliable connections, and greater data capacity, which will provide for seamless internet connectivity throughout all regions across the United States;

Whereas 5G networks are expected to create more than 3,000,000 new jobs in the United States, generate $275,000,000,000 in investments in the telecommunications industry, and add $500,000,000,000 to the economy of the United States over the next decade;

Whereas next-generation, gigabit Wi-Fi solutions, enabled by innovative spectrum bands are poised to unleash a new round of innovation and consumer benefit from an industry that generates an economic surplus of $575,000,000,000 and contributes $50,000,000,000 annually in gross domestic product to the economy of the United States;

Whereas 5G networks will enable innovative consumer and industrial applications that will enhance and maximize the capability, use, and quality of technological developments, including telemedicine, precision agriculture, self-driving cars, virtual and augmented reality, robotics, smart communities, and advancements in public safety;

Whereas the United States is a global leader in developing new technology and fostering digital innovation that has generated significant economic and social advancement and opportunity in the United States and around the world;

Whereas many states and localities are streamlining policies to facilitate siting and small cell deployment in support of 5G networks;

Whereas modernizing the infrastructure policies of the United States and securing adequate spectrum bands will be essential to the deployment of 5G networks and next-generation wireless technologies, and the realization of all its promised economic and social benefits;

Whereas wireless and wired broadband networks, in addition to other technologies, are essential to closing the digital divide, delivering broadband to rural areas, creating jobs, and powering economic development and innovation across the United States: Now, therefore, be it

Resolved, That it is the sense of the Senate that the United States should—

(1) promote the deployment of 5G networks in a manner that encourages robust investment, job creation, economic growth, and continued United States leadership in developing next-generation wireless technologies;

(2) advance 5G networks as a way of closing the digital divide and reducing the disparity in quality communications services available in rural areas;

(3) recognize that 5G networks will facilitate the development of a new generation of technologies that will open opportunities for increased efficiency, mobility, accessibility, economic development, and prosperity in communities throughout the United States;

(4) commit to modernizing the infrastructure policies of the United States and identifying additional spectrum in low, mid, and high bands for use and to support the deployment of 5G networks and meet the increasing demands for wireless broadband service;

(5) recognize that 5G networks will give consumers access to more choices and enable them to derive greater value from mobile connections;

(6) commit to deploying 5G networks that are resilient and secure;

(7) continue to participate in global efforts to create standards for 5G networks that improve network performance in all cases, enable interoperability, sustain multiple, simultaneous connections, increase network capacity through virtualization or other software developments, and adapt to new technologies and future network applications; and

(8) promote the deployment of broadband technologies to expand the availability, affordability, and quality of broadband service throughout the United States.

SENATE RESOLUTION 243—EXPRESSING THE SENSE OF THE SENATE THAT JOSEPH LEON GEORGE SHOULD BE AWARDED THE NAVY CROSS FOR HEROISM AT PEARL HARBOR, HAWAII, ON DECEMBER 7, 1941

Mr. FLAKE. Mr. President, recently, I was fortunate enough to have the opportunity to host several veterans who survived the sinking of the USS Arizona in the attack on Pearl Harbor.

I would like to briefly share an incredible story they told me about a true American hero named Joe George. On December 7, 1941, Joe was a 26-year-old Boatswain’s Mate Second Class aboard the repair ship USS Vestal in Pearl Harbor, HI, moored alongside the USS Arizona. At 7:48 a.m., many sailors, including Joe, had finished their breakfast when the Imperial Japanese Navy Air Service attacked Pearl Harbor. As we know, the Arizona suffered a direct hit by a Japanese bomb that detonated in the ship’s powder magazine. The resulting explosion sank the ship and claimed the lives of 1,177 servicemembers.

During the unimaginable chaos and carnage, Joe George displayed stunning composure and courage. Joe spotted six sailors trapped in the control tower of the sinking Arizona. These men were severely burned, and they were searching for a way to safety. The six wounded sailors were Seaman First Class Harold Kuhn, Seaman First Class Russell Lott, Gunner’s Mate Third Class Earl Riner, Boatswain’s Mate Second Class Alvin Dvorak, Seaman First Class Donald Stratton, and Fire Controlman Third Class Lauren Bruner, were trapped in the control tower main mast after a massive explosion on the ship.

Whereas those 6 sailors suffered severe burns;

Whereas those wounded sailors searched for a way to safety;

Whereas Boatswain’s Mate Second Class George saw the 6 wounded sailors on the U.S.S. Arizona from the U.S.S. Vestal and threw a heaving line and a heavy line;

Whereas all 6 sailors climbed, nearly 40 feet in the air, hand over hand across the heavy line 70 feet to safety onboard the U.S.S. Vestal;

Whereas 2 sailors died shortly after from their injuries, but the remaining 4 survived;

Whereas Boatswain’s Mate Second Class George was commended for his actions, but he was never given a medal for his role in the rescue of the 6 sailors;

Whereas the 2 surviving sailors rescued from the U.S.S. Arizona, Donald Stratton and Lauren Bruner, seek to honor Boatswain’s Mate Second Class George;

Whereas U.S.S. Arizona survivor Donald Stratton stated, ‘‘I never received anything for his bravery. He is no longer with us, but I believe in his memory, should be awarded the Navy Cross.’’;

Whereas U.S.S. Arizona survivor Lauren Bruner stated, ‘‘The six of us would not have survived except for his courage, in spite of being at high risk himself. He fully deserves having his actions recognized. I feel he should be recognized for this courage and presented the Navy Cross.’’ Now, therefore, be it

Resolved, That the Senate—

(1) honors the heroism of Boatswain’s Mate Second Class Joseph Leon George in saving the lives of 6 sailors on December 7, 1941; and

(2) believes the United States Navy, in light of new information, should consider revisiting delicious and honoring the heroism of Boatswain’s Mate Second Class Joseph Leon George in saving the lives of 6 sailors on December 7, 1941.

Mr. FLAKE. Mr. President, recently, I was fortunate enough to have the opportunity to host several veterans who survived the sinking of the USS Arizona in the attack on Pearl Harbor.

I would like to briefly share an incredible story they told me about a true American hero named Joe George. On December 7, 1941, Joe was a 26-year-old Boatswain’s Mate Second Class aboard the repair ship USS Vestal in Pearl Harbor, HI, moored alongside the USS Arizona.

At 7:48 a.m., many sailors, including Joe, had finished their breakfast when the Imperial Japanese Navy Air Service attacked Pearl Harbor. As we know, the Arizona suffered a direct hit by a Japanese bomb that detonated in the ship’s powder magazine. The resulting explosion sank the ship and claimed the lives of 1,177 servicemembers.

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Whereas those 6 sailors suffered severe burns;

Whereas those wounded sailors searched for a way to safety;

Whereas Boatswain’s Mate Second Class George saw the 6 wounded sailors on the U.S.S. Arizona from the U.S.S. Vestal and threw a heaving line and a heavy line;

Whereas all 6 sailors climbed, nearly 40 feet in the air, hand over hand across the heavy line 70 feet to safety onboard the U.S.S. Vestal;

Whereas 2 sailors died shortly after from their injuries, but the remaining 4 survived;

Whereas Boatswain’s Mate Second Class George was commended for his actions, but he was never given a medal for his role in the rescue of the 6 sailors;

Whereas the 2 surviving sailors rescued from the U.S.S. Arizona, Donald Stratton and Lauren Bruner, seek to honor Boatswain’s Mate Second Class George;

Whereas U.S.S. Arizona survivor Donald Stratton stated, ‘‘I never received anything for his bravery. He is no longer with us, but I believe in his memory, should be awarded the Navy Cross.’’;

Whereas U.S.S. Arizona survivor Lauren Bruner stated, ‘‘The six of us would not have survived except for his courage, in spite of being at high risk himself. He fully deserves having his actions recognized. I feel he should be recognized for this courage and presented the Navy Cross.’’ Now, therefore, be it

Resolved, That the Senate—

(1) honors the heroism of Boatswain’s Mate Second Class Joseph Leon George in saving the lives of 6 sailors on December 7, 1941; and

(2) believes the United States Navy, in light of new information, should consider revisiting delicious and honoring the heroism of Boatswain’s Mate Second Class Joseph Leon George in saving the lives of 6 sailors on December 7, 1941.
On seeing the men, Joe threw a heaving line between the Vestal and the Arizona to rescue the wounded sailors from the sinking ship. Suspended 40 feet in the air, the six sailors climbed 70 feet hand over hand across the rope to safety onboard the Vestal. These sailors did all this while enduring inju-
ries so severe that two would succumb to the wounds in the weeks following the attack.

As they struggled across the heavy line, Joe George remained close by, all the while encouraging the men to push on.

The four sailors who survived their injuries each returned to serve with honor during World War II and then went on to live long lives.

I spoke with two of them, and hearing about the injuries they had and that they still were able to return to service in the Second World War was amazing.

Joe George’s legacy of heroism will remain alive forever in the children, grandchildren, and great-grandchildren of the six sailors who survived the infamous day, thanks to Joe George.

Joe George was never awarded a medal for his role in the rescue of the six sailors, although his commanding officer commended his courageous ac-

dions. When I met with one of the Arizona survivors who was rescued by Joe, he told me, “Joe George was never awarded anything for his bravery. He is no longer with us, but I believe in his memory he should be awarded the Navy Cross.”

Lauren Bruner was another survivor whom Joe saved. He said to me:

“The six of us would not have survived except for his courage, in spite of being at high risk himself. He fully deserves high com-

mendations for his actions. I feel he should be recognized in this way,” Lauren Bruner said.

In his own words, during an interview in 1978, Joe said: “I’ll tell you, the only thing I could tell you about that day was my conscience was my guide.”

Well, his conscience was that of a hero. We need more people like Joe George in this world. That is why I am committed to honoring Joe and why I rise today with the honor and privilege to submit a resolution honoring Joseph Leon George.

Joe passed away in 1996, and it is long overdue that the Senate, the U.S. Navy, and a grateful nation honor the heroism of Boatswain’s Mate Second Class Joseph Leon George.

God bless Joe George, whose im-
mense and astounding composure serves as an example of the men and women in uniform who follow in his wake. Let us never forget his heroism and sacrifice.

I would like to also thank my colleagues Senators GARDNER, LEE, COT-
TON, MCCASKILL, and BENNET for joining me on this resolution. I look for-
ward to working with them on its swift adoption.

SENATE RESOLUTION 244—TO AU-
THORIZE TESTIMONY, DOCU-
MENT PRODUCTION, AND REP-
RESENTATION IN UNITED STATES OF AMERICA V. ROBERT MENENDEZ, ET AL

Mr. McCONNELL, for himself and Mr. SCHUMER, submitted the following resolu-
tion; which was considered and agreed to—

S. Res. 244

Whereas, in the case of United States of America v. Robert Menendez, et al., Cr. No. 15-
155, pending in the United States District Court for the District of New Jersey, testi-
momy and the production of documents may be needed from various current and former Members and employees of the Senate, relat-
ing to their official responsibilities;

Whereas, pursuant to sections 703(a) and 704(a)(2) of the Ethics in Government Act of 1978, 2 U.S.C. §§ 2806(a) and 2807(a)(2), the Senate may, by the judicial or administrative proc-
ess, be taken from such control or possession by the Senate with respect to any subpoena, order, or request for testimony relating to their official responsibilities;

Whereas, by the privileges of the Senate of the United States and rule XI of the Stand-


ing Rules of the Senate, no evidence under the control of the Senate may, by the judicial or administrative proc-

ess, be taken from such control or possession by the Senate with respect to any subpoena, order, or request for testimony relating to their official responsibilities;

Whereas, when in the Senate's judgment evidence under the control or in the possession of the Senate may promote the administration of justice, the Senate will take such action as will protect its evidence consistent with the privileges of the Senate: Now, therefore, be it

Resolved, That current and former Mem-

bers and employees of the Senate are author-
ized to testify and produce documents in the case of United States of America v. Robert Menendez, et al., and related proceedings, ex-
cept concerning matters for which a privi-
lege should be asserted.

SEC. 2. The Senate Legal Counsel is author-
ized to represent current and former Mem-
bers and employees of the Senate in connec-
tion with the production of evidence author-
ized in section one of this resolution.

Mr. McCONNELL, Mr. President, on behalf of myself and the Democratic Leader, I send to the desk a resolution authorizing testimony, production of documents, and representation by the Senate Legal Counsel, and ask for its immediate consideration.

Mr. President, this resolution con-

cerns the case pending in the United States District Court for the District of New Jersey against Senator ROBERT MENENDEZ. Both the Department of Justice and Senator MENENDEZ are ex-

pected to seek trial testimony from Members of Congress.

This resolution would authorize Sen-

ate individuals called to appear to test-
ify and produce documents in this case and related proceedings, except concerning matters for which a privi-
lege is asserted. It would also authorize the Senate Legal Counsel to represent individuals called to testify at trial as fact witnesses regarding their performance of official Senate responsibilities.

AMENDMENTS SUBMITTED AND PROPOSED

SA 747. Mr. TESTER submitted an amendment intended to be proposed by him to the bill H.R. 2810, to authorize appropriations for fiscal year 2018 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table.

SA 748. Mr. CARPER (for himself and Mr. GRASSLEY) submitted an amendment in-
tended to be proposed by him to the bill H.R. 2810, supra; which was ordered to lie on the table.

SA 749. Mr. McCONNELL (for Mr. DAINES (for himself and Mr. Tester) proposed an amendment to the bill S. 1282, to redesignate certain clinics of the Department of Veter-

an Affairs located in Montana.

SA 750. Mr. WHITEHOUSE (for himself, Mr. PITTERS, Mr. TESTER, and Ms. WARREN) submitted an amendment intended to be pro-
posed by him to the bill H.R. 2810, to author-
ize appropriations for fiscal year 2018 for military activities of the Department of De-

fense, for military construction, and for defense activities of the Depart-
ment of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 747. Mr. TESTER submitted an amendment intended to be proposed by him to the bill H.R. 2810, to authorize appropriations for fiscal year 2018 for military activities of the Department of Defense, for military construction, and for defense activities of the Dep-
artment of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

SEC. 601. FISCAL YEAR 2018 INCREASE IN MIL-

ITARY BASIC PAY.

(a) WAIVER OF SECTION 1009 ADJUSTMENT.—The adjus-
tment to become effective during fiscal year 2018 required by section 1009 of title 37, United States Code, in the rates of monthly basic pay authorized members of the uniformed services shall be increased by a percentage that is equal to or greater than the percentage by which—

(1) the ECI for the final fiscal quarter of fiscal year 2017, exceeds

(2) the ECI for the final fiscal quarter of fiscal year 2016.

(b) DETERMINATION OF PERCENTAGE.—The Secretary of Defense shall determine the percentage increase in rates of monthly basic pay authorized members of the uniformed services for fiscal year 2018.
SA 748. Mr. CARPER (for himself and Mr. GRASSLEY) submitted an amendment intended to be proposed by him to the bill H.R. 2810, to authorize appropriations for fiscal year 2018 for military activities of the Department of Defense, for military construction, and for activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title X, add the following:

Subtitle H—Government Purchase and Travel Cards

SEC. 1091. SHORT TITLE.
This subtitle may be cited as the “Saving Federal Dollars Through Better Use of Government Purchase and Travel Cards Act of 2017”.

SEC. 1092. DEFINITIONS.
In this subtitle:
(1) IMPROPER PAYMENT.—The term “improper payment” has the meaning given the term in section 2 of the Improper Payments Information Act of 2002 (31 U.S.C. 3221 note).

(2) QUESTIONABLE TRANSACTION.—The term “questionable transaction” means a charge card transaction that from initial card data appears to be high risk and may therefore be improper or non-compliant with applicable law, regulation or policy.

(3) STRATEGIC SOURCING.—The term “strategic sourcing” means analyzing and modifying agency spending habits in order to better leverage its purchasing power, reduce costs, and improve overall performance.

SEC. 1093. EXPANDED USE OF DATA ANALYTICS.
(a) STRATEGY.—Not later than 180 days after enactment of this Act, the Director of the Office of Management and Budget, in consultation with the Administrator for General Services, shall develop a strategy to expand the use of data analytics in managing government purchase and travel charge card programs. These analytics may employ existing General Services Administration capabilities, and may be in conjunction with agencies’ capabilities, for the purpose of—
(1) identifying examples or patterns of questionable transactions and developing enhanced tools and methods for agency use in—
(A) identifying questionable purchase and travel card transactions; and
(B) covering non-travel purchase payments made with purchase and travel cards;
(2) identifying potential opportunities for agencies to further leverage administrative process streamlining and cost reduction from purchase and travel card use, including additional agency opportunities for card-based strategic sourcing;
(3) developing a set of purchase and travel card metrics and benchmarks for high-risk activities, which shall assist agencies in identifying potential emphasis areas for their purchase and travel card management and oversight activities, including those required by the Government Charge Card Abuse Prevention Act of 2012 (Public Law 112-119); and
(4) developing a plan, which may be based on existing capabilities, to create a library of analytics tools and data sources for use by Federal agencies (including inspectors general of those agencies).

SEC. 1094. GUIDANCE ON IMPROVING INFORMATION SHARING TO CURB IMPROPER PAYMENTS.
(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Director of the Office of Management and Budget, in consultation with the Administrator of General Services and the interagency charge card data management group established under section 1095, shall issue guidance on improving information sharing by government agencies for the purposes of section 1096(a).

(b) ELEMENTS.—The guidance issued under subsection (a) shall—
(1) require relevant officials at Federal agencies, including inspectors general, to communicate that information to the appropriate management levels within the agencies;
(2) require that appropriate officials at Federal agencies review the reports issued by charge card-issuing banks on questionable transaction activity (such as purchase and travel card transaction data, suspension reports, delinquency reports, and exception reports), including transactions that occur with high-risk activities, and suspicious timing or amounts of cash withdrawals or advances;
(3) provide for the appropriate sharing of information related to potential questionable transactions, fraud schemes, and high-risk activities with the General Services Administration and the appropriate officials in Federal agencies;
(4) consider the recommendations made by Inspectors General or the best practices Inspectors General have identified; and
(5) include other requirements determined appropriate by the Director for the purposes of carrying out this subtitle.

SEC. 1095. INTERAGENCY CHARGE CARD MANAGEMENT GROUP.
(a) ESTABLISHMENT.—The Administrator of General Services and the Director of the Office of Management and Budget shall establish a purchase and travel charge card data management group to develop and share best practices for the purposes described in section 1093(a).

(b) ELEMENTS.—The best practices developed under subsection (a) shall—
(1) cover rules, edits, and task order or contract modifications related to charge card-issuing banks;
(2) include the review of accounts payable transaction data for agencies for the purpose of identifying potential key strategic sourcing and other activities (such as recurring payments, utility payments, and grant payments) for which the charge cards or related payment products could be used as a payment method;
(3) include other best practices as determined by the Administrator and Director.

(c) MEMBERSHIP.—The purchase and travel charge card data management group shall meet regularly as determined by the co-chairs, for a duration of three years, and in conjunction with agencies’ capabilities, for the purpose of—
(1) identifying examples or patterns of questionable transactions and developing enhanced tools and methods for agency use in—
(A) identifying questionable purchase and travel card transactions; and
(B) covering non-travel purchase payments made with purchase and travel cards;
(2) identifying potential opportunities for agencies to further leverage administrative process streamlining and cost reduction from purchase and travel card use, including additional agency opportunities for card-based strategic sourcing;
(3) developing a set of purchase and travel card metrics and benchmarks for high-risk activities, which shall assist agencies in identifying potential emphasis areas for their purchase and travel card management and oversight activities, including those required by the Government Charge Card Abuse Prevention Act of 2012 (Public Law 112-119); and
(4) developing a plan, which may be based on existing capabilities, to create a library of analytics tools and data sources for use by Federal agencies (including inspectors general of those agencies).

SEC. 1096. REPORTING REQUIREMENTS.
(a) GENERAL SERVICES ADMINISTRATION REPORT.—Not later than one year after the date of the enactment of this Act, the Administrator of General Services shall submit a report to Congress on the implementation of this subtitle, including the metrics used in determining whether the analytic and benchmarking efforts have reduced, or contributed to the reduction of, questionable or improper payments as well as improved utilization of card-based payment products.

(b) AGENCY REPORT AND CONSOLIDATED REPORT TO CONGRESS.—Not later than one year after the date of the enactment of this Act, the head of each Federal agency described in section 11 of the Government Charge Card Abuse Prevention Act of 2012 (Public Law 112-119) shall submit a report to the Director of the Office of Management and Budget on that agency’s activities to implement this subtitle.

(c) OFFICE OF MANAGEMENT AND BUDGET REPORT TO CONGRESS.—The Director of the Office of Management and Budget shall submit to Congress a consolidated report of agency activities to implement this subtitle, which may include references to reports submitted to Congress by the Director.

(d) REPORT ON ADDITIONAL SAVINGS OPPORTUNITIES.—Not later than one year after the date of the enactment of this Act, the Administrator of General Services shall submit a report to Congress identifying and exploring further potential savings opportunities for government agencies under the Federal charge card programs. This report may be combined with the report required under subsection (a).

SA 749. Mr. MCCONNELL (for Mr. DAINES (for himself and Mr. TESTER)) proposed an amendment to the bill S. 2810, to reauthorize a bill of the Department of Veterans Affairs located in Montana; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. REDESIGNATION OF CERTAIN DEPARTMENT OF VETERANS AFFAIRS CLINICS IN MONTANA.

(a) DAVID J. THATCHER VA CLINIC.—
(1) DESIGNATION.—The clinic of the Department of Veterans Affairs located at 1390 Palmer Street in Missoula, Montana, shall be known and designated as the “David J. Thatcher VA Clinic”.

(b) REFERENCES.—Any reference in any law, regulation, map, document, paper, or other record of the United States to the Dr. Joseph Medicine Crow Clinic referred to in paragraph (1) shall be considered to be a reference to the David J. Thatcher VA Clinic.

(b) JOSEPH MEDICINE CROW VA CLINIC.—
(1) DESIGNATION.—The clinic of the Department of Veterans Affairs located at 1775 Spring Creek Lane in Billings, Montana, shall be known and designated as the “Dr. Joseph Medicine Crow VA Clinic”.

(b) REFERENCES.—Any reference in any law, regulation, map, document, paper, or other record of the United States to the Dr. Joseph Medicine Crow Clinic referred to in paragraph (1) shall be considered to be a reference to the Dr. Joseph Medicine Crow VA Clinic.

(b) LOCAL DISPLAY.—For purposes of subsection (a), a local public display of the name of the clinic referred to in paragraph (1) carried out by the United States or through the use of Federal funds shall include the English name, Dr. Joseph Medicine Crow, and the Crow name, Dakaak Baako, of Dr. Joseph Medicine Crow.

(b) LOCAL DISPLAY.—For purposes of subsection (a), a local public display of the name of the clinic referred to in paragraph (1) carried out by the United States or through the use of Federal funds shall include the English name, Dr. Joseph Medicine Crow, and the Crow name, Dakaak Baako, of Dr. Joseph Medicine Crow.

(b) LOCAL DISPLAY.—For purposes of subsection (a), a local public display of the name of the clinic referred to in paragraph (1) carried out by the United States or through the use of Federal funds shall include the English name, Dr. Joseph Medicine Crow, and the Crow name, Dakaak Baako, of Dr. Joseph Medicine Crow.

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SA 750. Mr. WHITEHOUSE (for himself, Mr. Peters, Mr. Tester, and Ms. Warren) submitted an amendment intended to be proposed by him to the bill H.R. 2810, to authorize appropriations for fiscal year 2018 for military activities of the Department of Defense, military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC.

TEMPORARY EXTENSION OF EXTENDED PERIOD OF PROTECTIONS FOR MEMBERS OF UNIFORMED SERVICES RELATING TO MORTGAGES, MORTGAGE FORECLOSURE, AND EVICTION

Section 710(d) of the Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012 (Public Law 112–154; 50 U.S.C. 3993) is amended by—

(1) in paragraph (1), by striking “December 31, 2017” and inserting “December 31, 2019”; and

(2) in paragraph (3), by striking “January 1, 2018” and inserting “January 1, 2020”.

SA 751. Mr. REED submitted an amendment intended to be proposed by him to the bill H.R. 2430, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes; which was ordered to lie on the table; as follows:

On page 97, strike line 20 and all that follows through line 9 on page 98 and insert the following:

“(1) RELATION TO ORPHAN DRUGS.—

“(a) In general: Exemption for orphan indications.—Unless the Secretary requires otherwise by regulation, this section does not apply to any drug for an indication for which orphan designation has been granted under section 526, except as provided in paragraph (2).

“(2) Applicability despite orphan designation of certain indications.—This section shall apply with respect to a drug or biological product for which an indication has been granted orphan designation under section 526—

“(A) if the pediatric cancer investigation described in subsection (a)(3) applies to the drug or biological product as described in subsection (a)(1); or

“(B) if such orphan indication is limited to a pediatric subpopulation and such indication in the adult population does not qualify for orphan designation.

“(3) Effect of application.—Application of this section to drugs and biological products described in paragraph (2)(B) does not limit the applicability of section 526 to such drugs and biological products.”.

AUTHORITY FOR COMMITTEES TO MEET

Mrs. FISHER. Mr. President, I have 9 requests for committees to meet during today’s session of the Senate. They have the approval of the Majority and Minority Leaders.

Pursuant to Rule XXVI, paragraph 5(a), of the Standing Rules of the Senate, the following committees are authorized to meet during today’s session of the Senate:

COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY

The Committee on Agriculture, Nutrition, and Forestry, is authorized to meet during the session of the Senate on August 2, 2017 at 5 p.m. to conduct a business meeting to report nominations.

COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

The Committee on Commerce, Science, and Transportation is authorized to hold an Executive Session during the session of the Senate on Wednesday, August 2, 2017, at 10 a.m. in room 216 of the Hart Senate Office Building.

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

The Committee on Environment and Public Works is authorized to meet during the session of the Senate on Wednesday, August 2, 2017, at 10 a.m., in room 406 of the Dirksen Senate office building, to conduct a hearing entitled, “FBI Headquarters Consolidation Project—What Happened and What’s Next.”

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

The Committee on Health, Education, Labor, and Pensions is authorized to meet in executive session during the session of the Senate on Wednesday, August 2, at 11 a.m. in the President’s Room. We will be considering the nominations.

COMMITTEE ON FOREIGN RELATIONS

The Committee on Foreign Relations is authorized to meet during the session of the Senate on Wednesday, August 2, 2017 at 11 a.m., to hold a hearing entitled “Nominations.”

COMMITTEE ON FOREIGN RELATIONS

The Committee on Foreign Relations is authorized to meet during the session of the Senate on Wednesday, August 2, 2017 at 2 p.m., to hold a briefing entitled “The Authorizations for the Use of Military Force: Administration Perspective.”

COMMITTEE ON SMALL BUSINESS AND ENTREPRENEURSHIP

The Committee on Small Business and Entrepreneurship is authorized to meet during the session of the Senate Wednesday, August 2, 2017 off the floor at the start of the first vote to conduct a business meeting.

COMMITTEE ON ENERGY AND NATURAL RESOURCES SUBCOMMITTEE ON WATER AND POWER

The Senate Committee on Energy and Natural Resources Subcommitteee on Water and Power is authorized to meet during the session of the Senate in order to hold a hearing on Wednesday, August 2, 2017, at 10 a.m. in Room 366 of the Dirksen Senate Office Building, Washington, DC.

SUBCOMMITTEE ON WESTERN HEMISPHERE

The Committee on Foreign Relations Subcommittee on Western Hemisphere is authorized to meet during the session of the Senate on Wednesday, August 2, 2017, at 10 a.m., to hold a hearing entitled “Assessing the Colombia Peace Process: The Way Forward in U.S.-Colombia Relations.”

UNANIMOUS CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. McCONNELL. Mr. President, I ask unanimous consent that at 11:45 a.m. on Thursday, August 3, the Senate proceed to executive session for consideration of Calendar No. 103, the nomination of the Deputy Secretary at the Department of Energy. I further ask that there be 15 minutes of debate on the nomination equally divided in the usual form, and that following the use or yielding back of time, the Senate vote on confirmation with no intervening action or debate, and that, if confirmed, the motion to reconsider be considered made and laid upon the table and the President be immediately notified of the Senate's action.

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

AUTHORIZING TESTIMONY, DOCUMENT PRODUCTION, AND REPRESENTATION

Mr. McCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of S. Res. 244, submitted earlier today.

The PRESIDING OFFICIAL. The clerk will report the resolution by title.

The senior assistant legislative clerk read as follows:

A resolution (S. Res. 244) to authorize testimony, document production, and representation in United States of America v. Robert Menendez, et al.

There being no objection, the Senate proceeded to consider the resolution.

Mr. McCONNELL. Mr. President, I ask unanimous consent that the resolution be agreed to, the preamble be agreed to, and the motions to reconsider be considered made and laid upon the table with no intervening action or debate.

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

The resolution (S. Res. 244) was agreed to.

The preamble was agreed to.

(The resolution, with its preamble, is printed in today’s RECORD under “Submitted Resolutions.”)

APPOINTMENTS

The PRESIDING OFFICIAL. The Chair, on behalf of the majority leader, pursuant to the provisions of Public Law 115–31, appoints the following individuals to serve as president of the Women’s Suffrage Centennial Commission: Marjorie Dannenfelser of Virginia and Cleta Mitchell of North Carolina.

ORDERS FOR THURSDAY, AUGUST 3, 2017

Mr. McCONNELL. Mr. President, I ask unanimous consent that when the
Senate completes its business today, it adjourn until 10 a.m., Thursday, August 3; that following the prayer and pledge, the morning hour be deemed expired, the Journal of proceedings be approved to date, the time for the two leaders be reserved for their use later in the day, and morning business be closed; further, that following leader remarks, the Senate resume consideration of the motion to proceed to H.R. 2430, with the time until 11 a.m. equally divided between the two leaders or their designees.

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

ADJOURNMENT UNTIL 10 A.M. TOMORROW

Mr. McConnell. Mr. President, if there is no further business to come before the Senate, I ask unanimous consent that it stand adjourned under the previous order.

There being no objection, the Senate, at 6:40 p.m., adjourned until Thursday, August 3, 2017, at 10 a.m.

NOMINATIONS

Executive nominations received by the Senate:

DEPARTMENT OF AGRICULTURE
TED MCKINNEY, OF INDIANA, TO BE UNDER SECRETARY OF AGRICULTURE FOR TRADE AND FOREIGN AGRICULTURE AFFAIRS. (NEW POSITION)

DEPARTMENT OF DEFENSE
JOHN HENDRICKSON, OF SOUTH DAKOTA, TO BE AN ASSISTANT SECRETARY OF THE AIR FORCE. VICE MIRANDA A. A. BALLENTINE, RESIGNED.

DEPARTMENT OF THE INTERIOR
RYAN DOUGLAS NELSON, OF IDAHO, TO BE SOLICITOR OF THE DEPARTMENT OF THE INTERIOR. VICE RILAYNE CHANDLER TOMPKINS.

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
DANIEL M. GADE, OF NORTH DAKOTA, TO BE A MEMBER OF THE EQUAL EMPLOYMENT OPPORTUNITY COMMISSION FOR A TERM EXPIRING JULY 1, 2025. VICE STANLEY S. BARKER, TERM EXPIRED.

DEPARTMENT OF HOMELAND SECURITY
JOHN MARSHALL MITNICK, OF VIRGINIA, TO BE GENERAL COUNSEL, DEPARTMENT OF HOMELAND SECURITY. VICE STEVAN EATON RUSSELL.

DEPARTMENT OF JUSTICE
ROBERT J. HIGDON, JR., OF NORTH CAROLINA, TO BE UNITED STATES ATTORNEY FOR THE EASTERN DISTRICT OF NORTH CAROLINA FOR THE TERM OF FOUR YEARS. VICE THOMAS GRAY WALKER, RESIGNED.

DEPARTMENT OF VETERANS AFFAIRS
MELISSA SUE GLYNN, OF THE DISTRICT OF COLUMBIA, TO BE AN ASSISTANT SECRETARY OF VETERANS AFFAIRS (ENTERPRISE INTEGRATION). VICE LINDA A. SCHWARTZ.

DEPARTMENT OF STATE
JAMIE MCCOURT, OF CALIFORNIA, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE FRENCH REPUBLIC, AND TO SERVE CONCURRENTLY AND WITHOUT ADDITIONAL COMPENSATION AS AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE PRINCIPALITY OF MONACO.

CONFIRMATION

Executive nomination confirmed by the Senate August 2, 2017:

NATIONAL LABOR RELATIONS BOARD

WITHDRAWALS

Executive Message transmitted by the President to the Senate on August 2, 2017 withdrawing from further Senate consideration the following nominations:

GEORGE NESTERCZUK, OF VIRGINIA, TO BE DIRECTOR OF THE OFFICE OF PERSONNEL MANAGEMENT FOR A TERM OF FOUR YEARS. VICE KATHERINE ARCHULETA, RESIGNED, WHICH WAS SENT TO THE SENATE ON MAY 25, 2017.

JAMIE MCCOURT, OF CALIFORNIA, TO BE AMBASSADOR EXTRAORDINARY AND PLENIPOTENTIARY OF THE UNITED STATES OF AMERICA TO THE KINGDOM OF BELGIUM, WHICH WAS SENT TO THE SENATE ON JUNE 26, 2017.