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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.

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.

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.

● This "bullet" symbol identifies statements or insertions which are not spoken by a Member of the Senate on the floor.

TAX REFORM

Mr. MCCONNELL. Mr. President, during the 8 years of the Obama administration, our economy failed to live up to its full potential—meager growth rates, wages that failed to keep pace, and a decline in opportunities. Middle-class families were hurting, and they needed policies that would allow the economy to begin to grow again. Unfortunately, the last administration often gave them exactly the opposite. Some were sins of commission, such as making things worse with an aggressive regulatory rampage. Others were sins of omission, such as failing to address an outdated tax code that has made American companies increasingly uncompetitive in a global economy and, as a result, has moved investment and jobs offshore.

Then, in November Americans chose to go in a different direction. They elected a pro-growth President who would sign legislation from a pro-growth Congress. Ever since, we have been working to turn the tide back in favor of the middle class. We have undertaken what has been described as the ''most ambitious regulatory rollbacks since Reagan.'' We have pursued policies that can once again encourage job growth and American investment.

Just last week, the administration and congressional leaders and, most importantly, the chairmen of the Senate Finance and the House Ways and Means Committees issued a joint statement outlining shared principles for unleashing the American economy through comprehensive tax reform. Comprehensive tax reform represents the single most important action 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, fairer, 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 companies and succeed. We want a tax system that encourages American companies to bring jobs home again.

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 both 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 American 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 just the opposite. Americans deserve true comprehensive tax reform.

I appreciate the good work of our colleagues in the administration and by Members in both Chambers already to get us there, particularly Finance Committee Chairman ORRIN HATCH. Chairman HATCH has been working hard with his fellow Finance Committee members—Senators from both sides of the aisle—literally for years, on this issue, and he continues to lead the way today. Under his leadership and the leadership of Chairman BRADY in the House, Congress's tax-writing committees will advance these principles through regular order, so that Members on both sides of the aisle will have an opportunity to participate in this historic effort, if that is what they choose to do.

This will not be an easy process, but the people we represent are depending on us for help. Now is the time to deliver tax reform, and I look forward to working with my colleagues to accomplish it.

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

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

RECOGNITION OF THE MINORITY LEADER

The PRESIDING OFFICER. The Democratic leader is recognized.

HEALTHCARE

Mr. SCHUMER. Mr. President, first, on the topic of healthcare: I was very happy to hear the statement from Chairman ALEXANDER and Ranking Member MURRAY yesterday in which they pledged the HELP Committee to the task of restabilizing and strengthening the markets, particularly by guaranteeing the cost-sharing reduction program. As Chairman ALEXANDER said: ''Without the payment of these cost-sharing reductions, Americans will be hurt.'' That is clear. Everyone has said it, even the insurance industry, and yet President Trump continues to treat this critical program as if it is some kind of political hostage. The President treats the critical program as if it is some kind of hostage.

Insurers in three States—North Carolina, Pennsylvania, Iowa—have each released separate rates for 2018: one if the payments are made, and one that is 20 percent higher if they are not. In these three States, premiums will be 20 percent higher if President Trump refuses to carry out the law. Every American will see that increase in their monthly bill and know it is a Trump premium tax.

Insurers from coast to coast have said that uncertainty surrounding the cost-sharing reductions are the No. 1 threat to the stability of our markets. State insurance commissioners—many of them Republican—are announcing higher rates for next year and directly blaming the President's failure to guarantee these payments, as the insurance commissioner of Idaho did yesterday.

We have enough problems in the world right now without President Trump creating entirely new ones out of political spite and a petty vindictiveness. When you lose politically, you don't take it out on the American people. That is not Presidential; that is just small.

So we would say to the President: Stop holding this critical program as if it is some kind of political hostage, stop the sabotage, make the payments this month so Chairman ALEXANDER and Ranking Member MURRAY can get to work in a bipartisan way on a longer stabilization package.

Let me salute a large number of my Republican colleagues who agree we have to do cost sharing. They have realized that just sticking with President Trump—particularly when his motivations are not Presidential but are sort of nasty, vindictive—is a bad idea. I salute you because, for the good of America, we have to work together.

TAX REFORM

Mr. SCHUMER. Mr. President, now, on taxes, another matter. Yesterday, my friend the majority leader brought down the curtain on bipartisan tax reform before a discussion between our two parties could even start, dismissing the prospect of Democratic

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 sent him 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 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 this 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 because he so dearly wants 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 just to make ends meet. 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—on the Republican side get up on the floor 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 Democrats—when we sent him 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 Democrats hoped 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 to, it arrives at a result acceptable to people all along the political spectrum. But if it's an assembly line for one party's partisan legislative agenda, [it creates] instability and strife rather than good, stable law.

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 ask—haven't 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 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, I would ask 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 problem is, we don't need another investigation to know what China is up to. That is what the President called for: Let's investigate—another investigation.

It is clear what China is up to. By dumping counterfeit and artificially cheap goods into our markets, denying U.S. companies fair access to its markets, and relentlessly stealing and exporting intellectual property of U.S. companies, China, as I said, has robbed the U.S. economy of trillions of dollars and caused the loss of millions of good-paying U.S. jobs.

Estimates by our own government—already made estimates; we don't need a study, President Trump—pin the cost of cyber espionage alone at $400 billion a year to the U.S. economy—$400 billion a year, and 90 percent of it comes from China's Government. This is not a benign process. This is not some rogue company. This is the Chinese Government.

Here is what our four-star general, Keith Alexander, the former Director of the National Security Agency and commander of the U.S. Cyber Command said. He called the loss of industrial information and IP through cyber theft ''the greatest transfer of wealth in history''—the greatest transfer of wealth in history.

That pains me—this country, with its entrepreneurial vigor, with its acceptance of people from all corners of the globe for centuries to go work hard and create good things, China is stealing it. They are not doing it on their own. Every American, when they hear that statement, it should make them cringe. It makes me cringe almost every day.

Those are the facts. So I would say to President Trump: We don't need another study that takes months and months to complete while no action is taken. We need a plan of action now.

Unfortunately, this is what the Trump administration is doing on all issues of trade. They really talked tough on the issue of steel and aluminum dumping. As someone who has aluminum plants in the State up there in Massena—Alcoa—and all along Lake Ontario—what used to be called Alcan is now called Novelis—I know the issue of aluminum dumping. It hurts jobs in my State. The President early on talked tough, tweeted tough on illegal steel dumping, illegal aluminum dumping, but it is 7 months into this administration, and we are still reviewing its effects on our economy.

The administration failed to secure any deal with China in a number of forums, and they continue to delay on action that was promised in June. Tough talk and tweets are cheap, but strong and decisive action on trade is

required. American workers have waited 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 includes, among other things, an independent trade prosecutor to combat trade cheating, not one of these endless WTO processes that China takes advantage 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 contractors that outsource jobs; stronger ''Buy American'' rules; and an outsourcing tax on companies that leave the United States.

On the issue of NAFTA negotiations, we are laying out a set of tough principles that must be a bottom line for any new NAFTA text. I voted against NAFTA in 1994. That was 23 years ago. We have seen how it has hurt us in so many ways. There have been some benefits, 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 his views than I was to either President 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, create good-paying jobs. But I say to the President: We don't need another investigation, another study that languishes for months and maybe even years. We need strong, bold action on trade, and Democrats will offer those strong bold ideas later this morning.

Thank you.

I yield the floor.

RESERVATION OF LEADER TIME

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

CONCLUSION OF MORNING BUSINESS

The PRESIDING OFFICER. Morning business is closed.

EXECUTIVE SESSION

EXECUTIVE CALENDAR

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

The senior assistant legislative clerk read the nomination of Marvin Kaplan, of Kansas, to be a Member of the National Labor Relations Board for the term of five years expiring August 27, 2020.

The PRESIDING OFFICER. Under the previous order, the time until 11 a.m. will be equally divided between the two leaders or their designees.

The assistant Democratic leader.

DACA

Mr. DURBIN. Mr. President, many times over the last 6 months, I have come to the Senate to speak out on 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 gratitude 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, engineers, 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 children. They have to come forward under this Executive action and register with our government. They have to pay a substantial fee for processing. Then they have to submit themselves to a criminal and national security background check. If they are successful, they are given 2 years of temporary relief 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 public 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 have already 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 known.

A recent study by the Center for American Progress finds that ending DACA, President Obama's Executive action, would cost our economy at least $433 billion in gross domestic product over the next 10 years. The Institute on Taxation and Economic Policy 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 immigration in some of the speeches and statements he has made, but I do appreciate—personally appreciate—that this President has kept the DACA Program in place.

I have spoken directly to President Trump only two times—three times, perhaps. The first two times—one on Inauguration Day—I thanked him for the kind words he had said about Dreamers and the DACA students and those protected by the President's Executive action.

President Trump said to me: Don't worry about those kids.

Well, Mr. President, I continue to worry about those kids. I worry about them now more than ever, not because I have heard any change of heart or reversal from you but because of other circumstances that are bringing this issue to a head. The Texas attorney general, Ken Paxton, and nine other States have threatened to sue you, Mr. President, unless by September 5 you rescind the memorandum that established DACA by President Obama and announce that your administration will not renew or issue any new DACA permits. This direct, specific threat to the DACA Program has left hundreds of thousands of these Dreamers anxious, concerned, and worried about their future.

Last week I was joined by Senator CHUCK SCHUMER, our Democratic leader, and 40 other Senate Democratic colleagues in writing a letter to President Trump, asking him to order his Attorney General, Jeff Sessions, to use all legal options to defend DACA so that these young people can continue to contribute to a country they love.

Some of my friends on the other side of the aisle oppose the DACA Program. To them I say: If you don't support DACA, let's immediately pass the bipartisan Dream Act. If you think President Obama went beyond his Presidential authority with this Executive action, then let's take up this matter where it should be taken up, here in the legislative branch of the government in the U.S. Senate.

I recently reintroduced the Dream Act with my friend and colleague, LINDSEY GRAHAM of South Carolina. Now that I am in the mood of thanking Republican leaders, including President Trump, let me thank Senator LINDSEY GRAHAM, as well as Senator JEFF FLAKE and Senator LISA MURKOWSKI. They have stepped forward to join me in cosponsoring this Dream Act.

Our government should give these young people a chance to earn their way to citizenship. They were brought to this country as children. They didn't make the family decision to cross the border. They have been raised in this country. They have created no problems in terms of criminal background.

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 this a major part of my service in the Senate. These stories 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 of his class 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—once my dream school—Georgetown University, and he was accepted. As a college student, Juan has studied international politics, concentrating on security, minoring 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 need you and 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 about this, and I believe 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: Yes, 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.

HEALTHCARE

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—as the Presiding Officer 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 a million Texans paid the 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 paper 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 CSRs.

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 in my State 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 with the correct facts 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. At a time when 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-medicating—with drugs or alcohol 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 close to where they live. 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's, 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 glad we were able to pass this legislation last night to ensure that this program can continue serving veterans. In moving forward, both Chambers should continue to work with the VA to get the agency back on track and right the years of poor 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 that can save lives and improve the quality of lives. These partnerships between the public and private sectors ensure that patients will have access to safe and effective drugs and medical devices while also maintaining America's position as a global leader in medical innovation. Faster approvals mean treatments and cures reach patients sooner. Increased competition leads to lower costs, and that, in turn, means more lives saved. This is another example of what, I believe, will be a bipartisan accomplishment of the current Senate and current Congress.

I heard one of our colleagues last week stand in front of the Nation and say nothing ever gets done. Well, we are doing some important things. The Veterans Choice Program and the FDA reauthorization bill are important, lifesaving bills that are being passed on a bipartisan basis.

Then, of course, there is the backlog of the President's nominees.

I have never seen anything quite like it. We had an election on November 8, but for many of our colleagues, the election remains undecided. They do not accept the verdict of 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, but it is our 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 who were confirmed by almost unanimous votes of the Senate, which tells me we were delaying those votes unnecessarily. If they were truly controversial, I think it would be reflected in the votes for their confirmations, but they are not.

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 used to see a difference between elections and the responsibility of governing. Regardless of who wins the election, we still have the responsibility to govern. Some people seem to have forgotten that.

Again, I hope we have a big, robust package of noncontroversial nominations approved before we leave for the rest of the month of August. I think it is too important to leave town without that. We need our President to succeed so the country can succeed. This is what every American who voted for President Trump hoped for, and they trusted him to choose men and women for his Cabinet to lead and guide our country. I have to say, he has done a remarkably good job in the people whom he has chosen for his Cabinet so let's come together and confirm these appointees so the administration can better serve our Nation and all Americans.

I yield the floor.

The PRESIDING OFFICER. The Senator from Washington.

Mrs. MURRAY. Mr. President, thank you.

I come to the floor today to urge my colleagues to vote no on the nomination that we will vote on shortly.

On the campaign trail, President Trump promised to put workers first. Instead, President Trump's administration has rolled back worker protections and prioritized corporate interests at the expense of workers.

It is critical, now more than ever, that the NLRB remain independent and committed to advocating for workers and their right to organize, but I am deeply concerned that President Trump's nominee, Mr. Kaplan, does not have a record of supporting the rights of workers and unions.

At his nomination hearing, Mr. Kaplan confused basic labor issues and decisions, further proving he lacks the knowledge and experience to serve on this important board. NLRB members should be committed to standing up for workers, and it is clear Mr. Kaplan does not make the cut.

I urge my colleagues to join me in doing what President Trump has failed to do, and that is to put workers first. Vote against this nomination.

Thank you.

I yield the floor.

CLOTURE MOTION

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

The legislative clerk read as follows:

CLOTURE MOTION

We, the undersigned Senators, in accordance with the provisions of rule XXII of the Standing Rules of the Senate, do hereby move to bring to a close debate on the nomination of Marvin Kaplan, of Kansas, to be a Member of the National Labor Relations Board for the term of five years expiring August 27, 2020.

Mitch McConnell, Chuck Grassley, Marco Rubio, Deb Fischer, John Cornyn, Susan M. Collins, Lamar Alexander, Roy Blunt, Luther Strange, Pat Roberts, James Lankford, Bob Corker, Richard C. Shelby, John Barrasso, Joni Ernst, Orrin G. Hatch.

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

The question is, Is it the sense of the Senate that debate on the nomination of 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:

[Rollcall Vote No. 183 Leg.]

YEAS—50

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

NAYS—48

Baldwin	Gillibrand	Murray
Bennet	Harris	Nelson
Blumenthal	Hassan	Peters
Booker	Heinrich	Reed
Brown	Heitkamp	Sanders
Cantwell	Hirono	Schatz
Cardin	Kaine	Schumer
Carper	King	Shaheen
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. I have to say that he has refused to allow even his own hotel workers to organize or join a union, preventing them from having the opportunity to better advocate for safer working conditions and better pay.

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 few decades, 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 billionaires like him to take advantage 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 his own businesses have had complaints filed numerous times. That is precisely why it is so important that the Board is independent and is committed to advocating for workers and their right to organize.

The preamble of the National Labor Relations Act clearly states that it is the policy of the United States to encourage collective bargaining and to give workers a voice, allowing them to speak up for fair wages and safe working conditions. It is the responsibility of the NLRB to ensure that workers are being treated fairly and to resolve disputes between corporate management and workers.

So it is clear to me that Board members should believe in the core mission that I just stated of the NLRB and should be committed to standing up for workers and their right to collective bargaining, which is exactly why I have very serious concerns about Mr. Marvin Kaplan's record, which has largely been in opposition to the work and mission of the NLRB.

As a labor staffer in the House of Representatives, Mr. Kaplan prepared and staffed hearings where Republicans consistently attacked the NLRB. In fact, I would be hard-pressed to name a single example of Mr. Kaplan supporting the rights of workers and unions.

In addition to Mr. Kaplan's opposition to the core mission of the Board, I also have deep reservations about Mr. Kaplan's lack of legal experience practicing before the NLRB. When I asked Mr. Kaplan about his lack of practical qualifications, his responses were telling: Have you ever represented a party, employer, or a union in an unfair labor practice case or representation case before the Board? No. Have you ever represented a worker in an employment matter? No.

What is more, when asked to speak on the pressing questions facing the Board at his confirmation hearing, he actually confused basic labor issues and decisions, further calling into question whether he has the experience and knowledge to serve on this critically important Board.

This is not a difficult concept for workers across the country to grasp. If you are not qualified for a job that is this important or if you want to undermine the basic goals of the law, you shouldn't get the job.

So I will be voting no on Mr. Kaplan's confirmation. I urge my colleagues to do the same.

I know my colleagues on both sides of the aisle want to strengthen our economy and rebuild our middle class. So I hope we can stand with working families across the country who today are simply asking for a fair shot.

Thank you, Mr. President.

I yield the floor.

The PRESIDING OFFICER. The Senator from Hawaii.

Mr. SCHATZ. Mr. President, there are two reasons why every Member of the Senate should vote against confirming Marvin Kaplan to the NLRB. The first is that he is just not qualified.

The NLRB is the Federal agency that enforces our labor laws. It protects the rights of workers and the private sector to organize for better wages and better working conditions. It is up to them to make sure that their employers follow the law and that when there is an issue between employers and employees, everyone acts reasonably.

Democrats and Republicans who have served on the NLRB have been the top labor and employment attorneys in their fields. They have had 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.

The 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.

This 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 employees . . . and employers . . . substantially burdens and affects the flow of commerce, and tends to aggravate recurrent business depressions, by depressing wage rates 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 and affect 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 plays 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 their incomes and that 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 are 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 vacations, paid sick leave, and 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 2.8 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 1950s 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 or undermine the National Labor Relations Act or undermine the National Labor Relations Board should not be confirmed to a position where they are supposed to act as an arbiter to protect the rights of workers to form a union and to bargain collectively. So I urge my colleagues to oppose the nomination of Marvin Kaplan 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 made a lot of big promises to workers 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 with me 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 this latest nominee to the National Labor Relations Board, Marvin Kaplan. Mr. Kaplan has devoted his career—imagine such a thing—to working to strip workers of their rights and trying to undermine the workers' watchdog he is now seeking to join. I never question people's motives in this body. I just don't quite understand why somebody would devote his work life to trying to take away workers' rights and 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' rights.

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. We see executive salaries and CEO compensation going up and 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 workers' rights, 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 deprive workers of 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 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—and it 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, whether he works in a call center or in a bank or on a factory floor.

I went to my high school reunion in Mansfield, OH, about a year and a half ago. I sat across from a bank teller who works for one of the largest banks in the United States. She has worked at that bank for 30 years. She makes $30,000 a year, and she has worked at a bank, as a bank teller, for most of the last 30 years. That is not respecting the dignity of work. That is simply undermining the value of work.

Pope Francis said:

> The person thrives in work. Labour is the most common form of cooperation that humanity has generated in its history.
>
> Work is a form of civil love . . . that makes the world live and carry on.

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 is up, and 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? The 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 the cars they make. The work was not 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 our economy and in our 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 . . . unmasks 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:

> . . . unmasks the powerful who trample on the rights of the most vulnerable workers, defends the cause of the foreigner, the least, the discarded.
>
> The capitalism 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 labor 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, autoworkers 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 Clinton years 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, a 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 roll back their retirement benefits. They undercut their 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 benefits, including 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—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 demeans 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 corporate lobbyists, 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' Galleries.)

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.

The senior assistant legislative clerk proceeded to call the roll.

Mrs. FISCHER. Madam President, I ask unanimous consent that the order for the quorum call 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 Nebraska'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 Gretna, 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 Gretna 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 Gretna 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 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 next deployment cycle to go 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.

From 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 their very short engagement, 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 Baqubah. The Battle of Baqubah 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 burning 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 machine gun 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 Gretna and Elkhorn, NE. Hundreds of Patriot Guard riders led the funeral procession and over 1,500 people filled Gretna High School to say their final goodbyes. Staff Sergeant Grover traveled to Gretna 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.

ORDER OF PROCEDURE

Mr. MCCONNELL. Madam President, I ask unanimous consent that all postcloture time on the Kaplan nomination expire at 5 p.m. today; that if the nomination is confirmed, the motion to reconsider be considered made and laid upon the table; that the President be immediately notified of the Senate's action, and the Senate then resume legislative session and be in a period of morning business, with Senators permitted to speak therein for up to 10 minutes each.

The PRESIDING OFFICER. Is there objection?

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. TILLIS). Without objection, it is so ordered.

TRIBUTE TO FALLEN SOLDIERS' MOTORCYCLE BRIGADE

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 of America.

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. MERKLEY. 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 not to repeat 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 one group after another—for women, for Africa Americans, for indigenous peoples, 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 right to be treated, in every part of our national life, as a person equal in dignity and promise to all others.'' It has not been easy.

It was Martin Luther King who saw how challenging it was to progress toward that vision, and he noted that ''human progress is neither automatic nor inevitable. . . . Every step towards the goal of justice requires sacrifice, suffering, and struggle; the tireless exertions 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 a Volunteer military, who have gone through significant training—and I am not just referring to boot camp but the ongoing training in specialty after specialty—so 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. Well, 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, 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 Nation—that in 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 1964 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 opposite 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 you in that 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 he said 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 on both counts, 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 single 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 the Commission does matter. 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 are important, 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 access 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 the same apartment 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 equal 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 rural counties 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 necessary to attract and retain business for banks, factories, distribution centers, and small businesses. It is necessary to start and maintain a business, large or small. If business is going to compete outside the local marketplace, there has to be that connectivity. Frankly, in order to compete in the local marketplace and to have the ability to buy at the best price and to get the kind of products needed, the internet really matters.

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 all the time. It actually 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, resetting 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 healthcare. 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 100 miles away can be 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 phone 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 with its own money. There is a big difference between unserved and any level of underserved. If you are unserved, like 69 percent of rural Missourians, the idea that somebody else doesn't have enough competition in the place they live doesn't seem to make very much sense to you. If there is a competitive marketplace and somebody wants to go in there and compete and get the prices down, that is all fine, but I think the government focus should be just like it was with telephones 100 years ago—to see that people had the opportunity to have that phone the same as their neighbors in more densely populated areas.

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.

Tomorrow 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. They are launching a 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, where you and I live. They will make a difference.

I look forward to continuing to work with the Chairman and others on the Commission on this issue. I think rural broadband is particularly leveling in creating the opportunities that we would like to see. The Commission will now be back up to its five-member intention of how many people are supposed to be there, making those decisions.

There is still work to be done. We need to reduce the digital divide. Connectivity is critical. We also need policies that support efficient network structures that allow people to not just connect to a network but to connect with a network that really works.

Let me talk about one other Missouri issue that relates here.

I said earlier that Kansas City is now our biggest city, our most populous city. Still, St. Louis, I think, by region, is the bigger region, but the city of St. Louis is not as big as Kansas City. In Kansas City, they have an internet exchange called KCIX. It is a peering center that offers tremendous benefits to secondary educational institutions, to high schools, to vocational programs, and to others so they really maximize how they communicate with each other and have the availability of resources in one place much more equally available in others, and large amounts of bandwidth can be diverted by using this peering infrastructure.

Frankly, what is happening in Kansas City this fall is that the North Kansas City School District will establish connections to KCIX. It is estimated that it may save the district almost $500,000 a year in bandwidth just by looking at peering. If peering helps there, maybe peering is one of the other things we can look at that will help solve the rural broadband challenge as well.

We are going to be working on this. There will be legislation. There will be continuing efforts to urge the FCC to stay on point. We need to do what we can to make communities in rural America productive and competitive and as healthy as they can be.

By the way, there are a lot of stories here to be told. I hope the next time I come to the floor on this topic that I will come to the floor with some things that are happening in my State that would not have happened if there had not been the access to broadband in not very big communities that are suddenly doing business all over the United States and all over the world.

How we do that is by not letting any of our country wither away, where we have existing infrastructure and schools and sidewalks and water systems and by being sure the people who want to live there can live there, just like we are being sure now, as we see a revitalization of some of our downtowns and inner cities. People will want to move back to them and will have reasons and desires to want to do that. We are seeing an upswing there.

I think we can see the same 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 clerk will call the roll.

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.

GREAT LAKES ENVIRONMENTAL SENSITIVITY INDEX BILL

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 and goods 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 offer; 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 coastline contains 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 floor 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. Accurate documentation 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 oilspill 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 most recent 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 Water. 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 16, 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 at the same hearing: ''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 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 2014: ''Keeping 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 cloture for two board members and the current general counsel who I then voted against confirming.

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 factions 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 also point out that 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; a 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 20, 2017. We held his 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 10 of them, including 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 day. Committee members were not able to get responses to any QFRs from Kent Hirowzawa or Nancy Schiffer before being forced to vote on them.

I look forward to voting for 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. CRUZ. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

VENEZUELA

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

The numbers, 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 spiking to more than 21 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 their classrooms for hours on end 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 response? 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 and medicine, while Maduro and his cronies spin conspiracies and rail against phantom enemies on state media. The situation is so dire that the regime has begun ''rewarding'' some of its most loyal supporters with toilet paper.

Alongside the disintegration of Venezuela's economy is the specter of Maduro's growing dictatorship. We have just witnessed the sham election of a so-called constituent assembly, which Maduro intends to use to try to rewrite Venezuela's Constitution, to crush what is left of its free political institutions, and to consolidate his grip on power. His electoral commission lied about the turnout and downplayed the number of government workers whom the regime pressured to participate. While Maduro preached dialogue on television, his security forces were busy rounding up political opponents and murdering peaceful demonstrators.

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 regime backtracked only 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 socialistic 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 not continue unchallenged. I support the Treasury Department's sanctions against senior 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 behind Maduro can be found China, with its billions in infrastructure investments, and Russia, with its growing control over Venezuela's energy sector, and Iran, whose Hezbollah proxy launders 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 Socialist repression.

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 were carted 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 on behalf of your husbands and the many others who are held captive by the Chavista government.

I look forward to welcoming Leopoldo and Antonio back to freedom and, I hope, they will play leading roles leading 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 my 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 and 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 with you grow. 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 a glorious past and an even greater future.

Through its words and deeds, the Maduro regime has abandoned what little legitimacy it might have had. When this regime expires, Venezuela will restore its place at the forefront of Latin America and become a good friend and partner to America once again.

We stand with the Venezuelan people as your friend against this socialist oppression, and we tell you that there are brighter days ahead, brighter days of economic cooperation, of energy growth, of abundance of prosperity, of throwing off the shackles of totalitarianism.

Estamos contigo Venezuela, tus mejores dias estan por venir.

Mr. President, I yield the floor.

The PRESIDING OFFICER (Mr. TOOMEY).

The Senator from New Mexico.

PROTECT CHILDREN, FARMERS, AND FARMWORKERS FROM NERVE AGENT PESTICIDES ACT

Mr. UDALL. Mr. President, this May, a spray of pesticide from a nearby orchard drifted over to a field, exposing nearly 50 farmworkers in California. They soon became sick with nausea and vomiting. Several were hospitalized. The workers described it as a living nightmare.

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 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.

A few years ago, Bonnie Wirtz also experienced the effects of chlorpyrifos. Bonnie is a farmer in Minnesota. She was exposed when spray drift came into her home through the air-conditioner. Her heart started racing, almost to the point of cardiac arrest, and she couldn't breathe. At the hospital, her nurse practitioner told her she wasn't surprised. She had seen others with similar reactions.

About 10 years ago, Claudia Angulo—a farmworker in California's San Joaquin Valley—was exposed to chlorpyrifos when she was pregnant. Claudia worked sorting oranges, apples, broccoli, and other produce treated with the chemical. When her son Isaac was born with a mental disability and attention deficit hyperactivity disorder, or ADHD, she suspected the pesticides she was exposed to.

A few years ago, European scientists tested some of Isaac's hair. He had traces of over 50 pesticides in his body, and the highest concentration was chlorpyrifos. 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 from the grocery store or through drinking water. 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 ago.

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 is why 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 has shown his hand. He did not respect the science, not even his own scientific team, and not even when the science is overwhelmingly decisive. If the EPA and this administration will not act to protect the public, to protect children, then Congress must.

I have studied the case for banning chlorpyrifos. There is no question it needs to come off the market. In this situation, I believe Congress must step in to protect children's health. That is why I have introduced the Protect Children, Farmers, and Farmworkers from Nerve Agent Pesticides Act—to do what the EPA Administrator Scott Pruitt refuses to do: ban chlorpyrifos.

Let's look at the reasons for banning chlorpyrifos. There are three 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 November 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 immediate 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 undermined intellectual development by age 7. Exposure to organophosphate pesticides like chlorpyrifos is associated with changes in children's 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-spray buffers around schools, 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 a letter 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 safe.''

'''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 the pesticide is safe with reasonable certainty, nor could he. Instead, he hid behind his claim 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 wants 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 don't know exactly 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 when 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 order not 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 cosponsors and the cosponsors who 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 issue—just to name 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. 2288, 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 the ranking member of 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, irksome, and, in fact, 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 and communication 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 and again about the antiquated delay and burdensome process that exists today. The average wait time on an appeal today is 5 years. Let me repeat that. 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 appeals was the ''bad news'' side of improvements in the process to consider the initial appeal. There were more appeals because more claims were disposed of, but that is no excuse for that kind of delay in appeals.

We worked with the VA and veterans groups to devise a new appeals system that allows veterans to choose an option that is right for them. The bill that passed yesterday will create three separate paths. They can choose among them for veterans seeking redress 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 many individual 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 provided at VA hospitals. Make no 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 health information sharing between VA and 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.

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.

My hope is that 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 their need for prompt appeals 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 unfinished agenda 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 Arkansan 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 Associated Industries of Arkansas, 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. MCCONNELL. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

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

LEGISLATIVE SESSION

Mr. MCCONNELL. 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. MCCONNELL. 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 in lieu thereof 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.

(a) REPEAL OF SUNSET.—Section 33 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229) is amended by striking subsection (r).

(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (q)(1)(B) of such section is amended by striking ''2017'' and inserting ''2023''.

(c) AUTHORIZATION FOR CERTAIN TRAINING UNDER ASSISTANCE TO FIREFIGHTERS GRANTS PROGRAM.—Subsection (c)(3) of such section is amended by adding at the end the following:

''(N) To provide specialized training to firefighters, paramedics, emergency medical service workers, and other first responders to recognize individuals who have mental illness and how to properly intervene with individuals with mental illness, including strategies for verbal de-escalation of crisis.''.

SEC. 3. REAUTHORIZATION OF STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANT PROGRAM.

(a) REPEAL OF SUNSET.—Section 34 of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2229a) is amended by striking subsection (k).

(b) AUTHORIZATION OF APPROPRIATIONS.—Subsection (j)(1)(I) of such section is amended, in the matter before clause (i), by striking ''2017'' and inserting ''2023''.

(c) MODIFICATION OF APPLICATION REQUIREMENTS.—Subsection (b)(3)(B) of such section is amended by striking ''of subsection (a)(1)(B)(ii) and (F)'' and inserting ''of 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 subsection (c)(2)'' and inserting ''subsection (a)(1)(E), (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 ''of crises''.

(g) EXPANSION OF STAFFING FOR ADEQUATE FIRE AND EMERGENCY RESPONSE GRANT PROGRAM.—Subsection (a)(1)(B) of such section, as amended by subsection (f), 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''.

SEC. 4. TRAINING ON ADMINISTRATION OF FIRE GRANT PROGRAMS.

(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) tailored to the financial and time constraints of members of the fire and emergency response community; and

(2) accessible to all individuals in the career, combination, paid-on-call, and volunteer fire and emergency response community.

SEC. 5. FRAMEWORK FOR OVERSIGHT AND MONITORING OF THE ASSISTANCE TO FIREFIGHTERS GRANTS PROGRAM, 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 grants 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 participants in the grant programs described in subsection (a).

(2) Conduct of regular risk assessments.

(3) Conducting desk reviews and site visits.

(4) Enforcement actions to recoup potential questionable costs of grant recipients.

(5) Such other oversight and monitoring tools as the Administrator of the Federal Emergency Management Agency considers necessary to mitigate and minimize fraud, waste, abuse, and mismanagement relating to the grant programs described in subsection (a).

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the committee-reported substitute amendment be considered and agreed to, the bill, as amended, 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 committee-reported amendment in the nature of a substitute was agreed to.

The bill (S. 829), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed.

SENIORS FRAUD PREVENTION ACT OF 2017

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 191, S. 81.

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

The senior assistant legislative clerk read as follows:

A bill (S. 81) to establish an advisory office within the Bureau of Consumer Protection of the Federal Trade Commission to prevent fraud targeting seniors, and for other purposes.

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

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 (S. 81) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 81

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 ''Seniors Fraud Prevention Act of 2017''.

SEC. 2. OFFICE FOR THE PREVENTION OF FRAUD TARGETING SENIORS.

(a) ESTABLISHMENT OF ADVISORY OFFICE.—The Federal Trade Commission shall establish an office within the Bureau of Consumer Protection for the purpose of advising the Commission on the prevention of fraud targeting seniors and to assist the Commission with the following:

(1) OVERSIGHT.—The advisory office shall monitor the market for mail, television, Internet, telemarketing, and recorded message telephone call (hereinafter referred to as ''robocall'') fraud targeting seniors and shall coordinate with other relevant agencies regarding the requirements of this section.

(2) CONSUMER EDUCATION.—The Commission through the advisory office shall, in consultation with the Attorney General, the Secretary of Health and Human Services, the Postmaster General, the Chief Postal Inspector for the United States Postal Inspection Service, and other relevant agencies—

(A) disseminate to seniors and families and caregivers of seniors general information on mail, television, Internet, telemarketing, and robocall fraud targeting seniors, including descriptions of the most common fraud schemes;

(B) disseminate to seniors and families and caregivers of seniors information on reporting complaints of fraud targeting seniors either to the national toll-free telephone number established by the Commission for reporting such complaints, or to the Consumer Sentinel Network, operated by the Commission, where such complaints will become immediately available to appropriate law enforcement agencies, including the Federal Bureau of Investigation and the attorneys general of the States;

(C) in response to a specific request about a particular entity or individual, provide publically available information of enforcement action taken by the Commission for mail, television, Internet, telemarketing, and robocall fraud against such entity; and

(D) maintain a website to serve as a resource for information for seniors and families and caregivers of seniors regarding mail, television, Internet, telemarketing, robocall, and other identified fraud targeting seniors.

(3) COMPLAINTS.—The Commission through the advisory office shall, in consultation with the Attorney General, establish procedures to—

(A) log and acknowledge the receipt of complaints by individuals who believe they have been a victim of mail, television, Internet, telemarketing, and robocall fraud in the Consumer Sentinel Network, and shall make those complaints immediately available to Federal, State, and local law enforcement authorities; and

(B) provide to individuals described in subparagraph (A), and to any other persons, specific and general information on mail, television, Internet, telemarketing, and robocall fraud, including descriptions of the most common schemes using such methods of communication.

(b) COMMENCEMENT.—The Commission shall commence carrying out the requirements of this section not later than one year after the date of the enactment of this Act.

RESOLUTIONS DISCHARGED

Mr. MCCONNELL. Mr. President, I ask unanimous consent that applicable committees be discharged and the Senate proceed to the immediate consideration of the following resolutions en bloc: S. Res. 199, S. Res. 225, S. Res. 227, and S. Res. 238.

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

There being no objection, the Senate proceeded to consider the resolutions en bloc.

Mr. MCCONNELL. Mr. President, I ask unanimous consent that the resolutions be agreed to, the preambles be

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 July 20, 2017, under ''Submitted Resolutions.'')

The resolution (S. Res. 238) 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 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 Senator CARPER who has authored another bill on this topic which I support—veterans 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.

(3) PUBLIC DISPLAY OF NAME.—

(A) IN GENERAL.—Any 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 subparagraph (A), a local public display of the name of the clinic referred to in paragraph (1) includes a display inside the clinic, on the campus of the clinic, and in the community surrounding the clinic, such as signs directing individuals to the clinic.

(c) BENJAMIN CHARLES STEELE VA CLINIC.—

(1) DESIGNATION.—The clinic of the Department of Veterans Affairs located at 1766 Majestic Lane in Billings, Montana, shall after the date of the enactment of this Act be known and designated as the ''Benjamin Charles Steele 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 Benjamin Charles Steele VA Clinic.

The bill (S. 1282), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed.

EXECUTIVE SESSION

EXECUTIVE CALENDAR—Continued

The PRESIDING OFFICER. Under the previous order, the Senate will resume 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 of hardworking Americans.

Just observe what they have done. On December 8, 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. That is right. 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 stood with big bank CEOs to announce an Executive order to make it easier for investment advisers to cheat hard-working Americans out of $17 billion a year in retirement savings. On March 1, the Trump administration delayed the rule protecting workers from lethal cancer-causing beryllium a second time. On March 6, congressional Republicans followed the directive of big business lobbyists and voted to make it easier for government contractors to steal wages from their employees. On March 16, President Trump released his budget blueprint, proposing to slash funding for the Labor Department, whose job is to stand for American workers, by 21 percent. On March 22, congressional Republicans voted to make it easier for employers to hide injuries and deaths that their workers suffer on the job. On March 24, the Trump administration delayed a rule that required mine operators to conduct safety inspections and tell miners about any hazardous conditions they discovered before the workers go into the mines. On March 30, congressional Republicans voted to block cities from offering retirement accounts to more than 2 million employees who don't have access to a retirement account at work. On April 4, President Trump delayed the rule preventing investment advisers from cheating hard-working Americans out of their retirement savings. This 60-day delay alone cost Americans an estimated $3.7 billion. On April 6, the Trump administration delayed a rule protecting construction workers from deadly silica poisonings. On May 3, Republicans in Congress voted to keep State governments from offering retirement accounts to employees who don't have access to accounts at work, yanking access away from 15 million Americans. On May 23, President Trump called for massive budget cuts to 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 23, 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 but consistent. Workers 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 serve on 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 Canton, MS, who, beginning tomorrow, will vote on whether to elect a union to represent them. That is what the NLRB has traditionally done—stood up for workers. Just last week, they filed a complaint against Nissan, alleging that the corporation has violated the law by running a union-busting drive, warning workers that they would lose wages and benefits if they took the step of joining a union.

It is also the NLRB's job to do the routine but important work of overseeing the elections. Just last month, the NLRB conducted a secret ballot election at Cooley Dickinson Hospital in Northampton, MA, where nearly 300 service workers 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 elections 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 some workers ineligible to join unions at their workplaces. He 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 before 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.

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. 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 postcloture 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 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. LEE). Are there any other Senators in the Chamber desiring to vote?

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

[Rollcall Vote No. 184 Ex.]

YEAS—50

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

NAYS—48

Baldwin	Gillibrand	Murray
Bennet	Harris	Nelson
Blumenthal	Hassan	Peters
Booker	Heinrich	Reed
Brown	Heitkamp	Sanders
Cantwell	Hirono	Schatz
Cardin	Kaine	Schumer
Carper	King	Shaheen
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 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.

LEGISLATIVE SESSION

MORNING BUSINESS

The PRESIDING OFFICER. Under the previous order, the Senate will be in a period of morning business, with Senators permitted to speak therein for up to 10 minutes each.

The Senator from Arizona.

(The remarks of Mr. FLAKE pertaining to the submission of S. Res. 243 are printed in today's RECORD under ''Submitted Resolutions.'')

Mr. FLAKE. Mr. President, I yield back.

The PRESIDING OFFICER. The Senator from Virginia.

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 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 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 Kaufmann 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 to 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 work 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.

Too often, our Federal workers are disrespected and demeaned by those who would attempt to use them as scapegoats for all that is allegedly wrong here in Washington. In reality, thousands of our Nation's dedicated civil servants work tirelessly every day to make our government work for and by the people.

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. Many risk their lives far away from the limelight. That is how it should be, for they are sworn to secrecy, even from their families and loved ones.

Over the last decade and a half, our intelligence professionals have increasingly been deployed overseas into war zones and other high-threat environments. Regrettably, some have made the highest sacrifice—laying down their lives for their country.

For their service, the risks they take and the sacrifices they make every day and because they do not hear this nearly enough, let me say ''thank you'' to the intelligence community.

As a Senator from the Commonwealth of Virginia, I am proud to represent thousands of current and former members of the intelligence community who live, work, or retire in our great State. I am also proud to represent these individuals in my current capacity as vice chairman of the Senate Intelligence Committee.

My colleagues and I on the committee have again submitted a resolution that marks July 26 as ''United States Intelligence Professionals Day.'' It was on that day 70 years ago that President Truman signed the National Security Act of 1947, which laid the foundation for today's U.S. intelligence community. It was earlier in my statement that we passed that resolution. In recent years, our committee has had success, as we try to protect our intelligence community, with greater intelligence sharing and interoperability and because of investments in people and systems.

Many challenges remain—from the constant barrage of leaks to the security of the supply chain, to outdated processes for security clearances. I hope that this year's intelligence authorization bill will begin to address some of these issues.

Yet today it is the people in the intelligence community whom I want to acknowledge—their professionalism, their dedication to duty and country, their silent service, their sacrifices.

The men and women of the Nation's intelligence agencies deserve our respect and our thanks. They do not deserve to be belittled, disrespected, or threatened, and certainly not from their Commander in Chief.

To the men and women of the intelligence community—these great Federal employees—I conclude with this: We, simply, do not say it enough, but thank you for your service. Thank you for your dedication, and thank you for the great work you do—often unheralded.

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

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

RACE FOR CHILDREN ACT

Mr. RUBIO. Mr. President, I come to the floor today to voice my support for the FDA Reauthorization Act. Within this legislation is a very important measure that will support the development of innovative and promising cancer drugs—the RACE for Children Act,

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 information 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 good news 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 heart 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 that could work for them. 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; there are few, if any, pediatric 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 suffers from the same condition in 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 now 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 there are a lot of adult advances being 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 on the floor was not easy. 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 has not 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.

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 produced tumors all over his body. His body was literally taken over by tumors. At only 5 months of age, baby Derek lost his battle against cancer.

These are real stories. They are real, heartbreaking stories—stories of our neighbors, friends, and family and what they have endured.

But with the developments in medicine today, there is no reason these children shouldn't have a second chance. Yet the treatment options for children with cancer is much more limited than it is for adults, and some of the reasons why are the issues we are trying to address about this law here today.

Recent advancements in cancer treatment enable oncology drugs to specifically target the genetic structure of the cancer, and that makes it possible to transition certain adult cancer drugs for pediatric use. However, the basic information you need to do that—about dosing and safety—needs to be determined to guide the doctors responsible for treating these children. These treatments, these advances are providing new-found hope for cancer patients, but mostly only for adult cancer patients.

Fortunately, we have a chance and an opportunity to change this, and that is the goal of the RACE for Children Act.

The House recently passed the RACE for Children Act as part of the FDA user fee reauthorization bill that is before us here today. It is now our turn to do so and to send this important and potentially lifesaving legislation to the President for his signature.

In a place where we have had some heated debates over the last 7 years, since I have been here—6½, and more to come—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 vote on laws and legislation that 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 1 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 and I urge my Senate colleagues to 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 FDA reauthorization 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 in its own right, by the way—that this is just this bureaucratic exercise to reauthorize an expiring law. Embedded in that law is a very important law, one that I hope will lead to real life-changing innovation in a way that will impact lives, change and save the lives of children here in our country but ultimately in other parts of the world as well.

That is why I felt it was important to come to the Senate floor and, obviously, urge my colleagues to support this initiative but also to urge my colleagues to be proud of it.

We are about to go home, whether it is tomorrow or next week, and answer to our constituents for all the things we didn't do. There are some significant issues we have not confronted and solved for the country, but this is a significant issue. There aren't going to be a lot of articles written about it; there aren't going to be blaring headlines on the websites about it, mailers and campaign commercials. That doesn't mean it isn't important. We live in a society where oftentimes good news doesn't draw ratings, and good news doesn't drive eyeballs and clicks to a website. It doesn't make it unimportant. It doesn't make it insignificant.

This is significant. This is an opportunity. This is evidence that more often than perhaps people realize, fellow Americans of different points of view, representing diverse States and communities, who approach the political process with very different ideologies and aims, come together to make a difference. I am pleased that while there are many things we have not done, we will leave here tomorrow or next week knowing that at least we did one thing that will matter. It is an important thing because these children whom we are trying to help do not have the time to continue waiting for us to step up and take action.

I thank the Chair.

With that, I yield the floor.

I suggest the absence of a quorum.

The PRESIDING OFFICER (Mr. TILLIS). The clerk will call the roll.

The legislative clerk proceeded to call the roll.

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

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

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.

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 least bit humorous in any of this. In fact, President Trump's comments have undermined the efforts of police departments across our Nation to build trust within their communities at a time when that trust is most needed.

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, writing: ''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 vigilantism.''

It is a viewpoint that is real, told through the eyes of an experienced street cop who works in reality, not reality TV. I ask unanimous consent that Chief del Pozo's full CNN essay be printed in the RECORD.

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

[From CNN, July 31, 2017]

TRUMP ON POLICE BRUTALITY: HAR HAR HAR

(By Brandon del Pozo)

When I was a New York Police Department cop in East Flatbush in 2000, I once rushed into an apartment building with fellow officers on a call of an assault. We found a boy in the hallway under attack. He was crying, and bleeding from stab wounds inflicted by his mother's boyfriend. The boy ran into my arms. Our sergeant confronted his attacker. He could have shot the man. Instead, he fought him into submission.

The boy had been stabbed because he had called the police while the man was attacking his mother. She was lying on the hallway stairs in a pool of blood. That her son had served as a distraction was probably the only reason she survived. ''You saved our lives,'' the boy sobbed. He hugged me. His blood and tears wet my shirt.

As the suspect sat there in handcuffs waiting to be led away, I asked him why he had stabbed a child. ''Boy gotta learn not to get in a man's business,'' he said. ''So now he learned.'' A fury rose within me that nearly caused me to shake. ''We should have shot you,'' I said.

But we didn't shoot him, nor did we lay a hand on him once he'd surrendered. 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 vigilantism.

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 fire or arrest a 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 retirement safely, after a satisfying career, is to lead them through policing's cauldron. Excessive force could get them fired or arrested. Making light of it is a failure of leadership.

It was hard to watch a roomful of officers laugh and applaud in response to Trump's remarks. The only charitable explanation was that it indicated a sense of relief that the President understood how vicious some criminals are and how frustrating the work of bringing them to justice can be. The more

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 wedge between the police and the citizens whose mistrust of them has grown. It will cast doubt on legitimate uses of force.

What troubles me the most about the President's remarks, however, is the way they patronized police officers. He has never held a wounded child in his arms or had to decide whether to punch or shoot a man with a knife. He has never had to race to the scene of a police shooting and choke on his feelings as he hunts for a suspect with precision and restraint. His remarks failed to take police work and its hazards seriously.

When I later served as a precinct commander in the Bronx, a sergeant of mine was suspended because he stood there and did nothing as he watched an officer slam a handcuffed suspect's head into the street. A narcotics detective had been shot during a scuffle with a drug crew, the responding officers were blind with rage, and one exacted revenge. When a video surfaced, the emotions didn't convey. It just looked thuggish, like the cop was a criminal, too. By his own account, it seems the President would also have been inclined to stand there and do nothing. There are thousands of American police chiefs who know what these situations require. They want to protect their officers by leading them in the right direction. We don't need the President joking with them about giving in to their baser instincts.

TRIBUTE TO MARY ALICE McKENZIE

Mr. LEAHY. Mr. President, it is a privilege for each of us to represent our constituents, and it is a great honor to be able to recognize the contributions many of them make to our communities at home. On this occasion, I would like to take this opportunity to recognize Mary Alice McKenzie, a fixture in the Burlington, VT, community. Ms. McKenzie has served as the executive director of the Boys & Girls Club of Burlington since 2007, and during her tenure at the club, she has had a lasting impact on the lives of thousands of Vermont children. The community is grateful for her service.

Ms. McKenzie comes from a business and legal background—a nontraditional path to her current position that provided her with a unique set of skills. Mary Alice began her work at the Boys & Girls Club after serving as the chief executive officer of McKenzie Meats from 1985 to 2000. She then spent several years in the Vermont State college system as general counsel and served with the law firm Paul Frank & Collins before taking over at the Boys & Girls Club of Burlington in 2007.

At the Boys & Girls Club, Mary Alice has focused her efforts on education. When she realized how few club kids were going on to higher education, she enacted the Early Promise program, which targets children at a young age who may need additional academic services and then provides college scholarships to older youth. As of today, the scholarship fund has investments totaling $2.3 million from which to draw. In a short time, the club hopes to be able to help 60 Burlington children achieve their academic goals in high school and beyond.

The Boys & Girls Club plays an important role in the lives of more than 1,000 Burlington children. Aside from the academic services, the club also works to ensure a safe and stable community for its young members. When Ms. McKenzie began hearing reports of suspected drug use occurring in a park across the street from the club, she assembled a task force of local law enforcement officials, social workers, and policymakers to work towards a solution that would ensure the safety of club kids. The Boys & Girls Club expanded activities in the park and eventually took over use of an old storage building which is now an academic center.

Ms. McKenzie has also focused her efforts on children who have experienced trauma. Under her leadership, the club has started a program to help children deal with the issues that stem from trauma at a young age. Their goal is to create stability for children whose home lives may be turbulent due to issues such as homelessness and addiction. These are profoundly difficult situations for youth to handle, and the efforts of the staff at the Boys & Girls Club are surely appreciated.

These efforts have not gone unnoticed. Not only is Ms. McKenzie beloved by members of the club who tell stories of her kindness and generosity, but in 2014, Ms. McKenzie was granted Champlain College's Distinguished Citizen Award for her years of service to the community. This award was well deserved; there are few people who dedicate themselves to service in the way that Mary Alice McKenzie has.

During her tenure at the Boys & Girls Club of Burlington, Mary Alice McKenzie has repeatedly identified significant issues within the community and worked to find creative and lasting solutions. As she concludes her years of service with the club, it is clear that her efforts have paid off. The Boys & Girls Club has more teens moving on to college than ever before, and the club continues to expand, providing an invaluable space for Burlington's youth to spend their free time. I am very grateful for Mary Alice's tireless dedication, and I look forward to seeing what the future of her career brings. Marcelle and I think of her as a dear friend.

CBO ESTIMATE OF H.R. 2430

Mr. ENZI. Mr. President, for the information of my colleagues, the Congressional Budget Office released its estimate of H.R. 2430, the FDA Reauthorization Act of 2017, in July 2017. Information related to this House-passed bill can be found at the Congressional Budget Office's website with the following link: https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/hr2430.pdf

FOOD AND DRUG ADMINISTRATION USER FEE REAUTHORIZATION

Mr. ALEXANDER. 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 Committee on Health, Education, Labor, and Pensions of 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, Generic Drug 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:

DEPARTMENT OF HEALTH & HUMAN SERVICES,
Washington, DC, January 4, 2017.

Hon. LAMAR ALEXANDER,
Chairman, Committee on Health, Education, Labor and Pensions, U.S. Senate, 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], 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 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, to develop reauthorization recommendations for GDUFA that would build upon and enhance the success of the program. In addition, we have complied 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 successes 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 deficiencies to industry throughout rather than at the end of a review cycle, increasing the chances for applicants to remedy deficiencies and obtain approval in fewer cycles. This will allow for improved predictability and transparency and enable industry advanced business planning.

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.

FDA will also make improvements to the facility assessment program in order to increase predictability, transparency and safety. In addition, FDA has committed to accountability and reporting enhancements. FDA will conduct activities to evaluate the financial administration and resource allocations of the GDUFA II program to help identify areas to enhance operational and fiscal efficiency and transparency. FDA will also expand GDUFA program performance reporting to enable the regulated industry, patients and consumer groups, and other stakeholders to better gauge the generic drug program's performance.

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 order to maintain a predictable fee base and to more closely align fee responsibility with program costs and fee-paying ability, FDA and industry have agreed to shift the burden more toward annual program fees. To address specific small business concerns, FDA and industry have proposed three distinct small business considerations. We anticipate that the proposed GDUFA II will increase public access to affordable, generic drug products.

The following five enclosures are provided for your consideration: The proposed GDUFA II statutory language; a redline of current law; the GDUFA Reauthorization Performance Goals and Procedures—Fiscal Years 2018 through 2022; the Background for the Proposed Changes for Reauthorization of GDUFA in Fiscal Years 2018 through 2022; and the summary of public comments.

Thank you for the opportunity to present our recommendations to reauthorize this vital program. 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,
Secretary.

DEPARTMENT OF HEALTH &
HUMAN SERVICES,
Washington, DC, January 4, 2017.

Hon. PATTY MURRAY,
Ranking Member, Committee on Health, Education, Labor and Pensions, U.S. Senate, Washington, DC.

DEAR SENATOR MURRAY: 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], 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 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, to develop reauthorization recommendations for GDUFA that would build upon and enhance the success of the program. In addition, we have complied 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 successes 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 deficiencies to industry throughout rather than at the end of a review cycle, increasing the chances for applicants to remedy deficiencies and obtain approval in fewer cycles. This will allow for improved predictability and transparency and enable industry advanced business planning.

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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 order to maintain a predictable fee base and to more closely align fee responsibility with program costs and fee-paying ability, FDA and industry have agreed to shift the burden more toward annual program fees. To address specific small business concerns, FDA and industry have proposed three distinct small business considerations. We anticipate that the proposed GDUFA II will increase public access to affordable, generic drug products.

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Thank you for the opportunity to present our recommendations to reauthorize this vital program. 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,
Secretary.

DEPARTMENT OF HEALTH &
HUMAN SERVICES,
Washington, DC, January 4, 2017.

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], 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).

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Sincerely,

SYLVIA BURWELL,
Secretary.

DEPARTMENT OF HEALTH &
HUMAN SERVICES,
Washington, DC, January 4, 2017.

Hon. FRANK PALLONE,
Ranking Member, Committee on Energy and Commerce, House of Representatives, Washington, DC.

DEAR REPRESENTATIVE PALLONE: 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], 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).

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Thank you for the opportunity to present our recommendations to reauthorize this vital program. 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,
Secretary.

Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD a copy of the commitment letter for 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 Aspirations
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 Aspirations
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 No Further Comment Letters
E. Guidance on Post-Approval Changes to Type II API DMFs
V. Facilities
A. Guidance on Risk-Based Site Selection Model
B. Outreach to Foreign Regulators on Risk-Based Site Selection Model
C. Export Support and Education of Other Health Authorities
D. Communications to Foreign Regulators
E. Communication Regarding Inspections
F. GDUFA II Facility Compliance Status Database
VI. Enhanced Accountability and Reporting
A. Resource Management Planning and Modernized Time Reporting
B. Financial Transparency and Efficiency

C. Performance Reporting
VII. Definitions

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

This document contains the performance goals and program enhancements for the Generic Drug User Fee Act (GDUFA) reauthorization for Fiscal Years (FYs) 2018–2022, known as GDUFA II. It is commonly referred to as the ''goals letter'' or ''commitment letter''. The goals letter represents the product of the Food and Drug Administration's (FDA's) discussions with the regulated industry and public stakeholders, as mandated by Congress. The performance goals and program enhancements specified in this letter apply to aspects of the generic drug review program that are important for facilitating timely access to quality, affordable generic medicines. FDA is committed to meeting the performance goals specified in this letter and to continuous improvement of its performance.

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

GDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018–2022

The performance goals and procedures of the FDA, as agreed to under the first reauthorization of the generic drug user fee program, are summarized below.

I. SUBMISSION REVIEW PERFORMANCE GOALS

A. Original ANDAs and ANDA Amendments

1. Review and act on 90 percent of standard original Abbreviated New Drug Applications (ANDAs) within 10 months of the date of ANDA submission.

2. Review and act on 90 percent of priority original ANDAs within the applicable review goal.

a. Review and act on priority original ANDAs within 8 months of the date of ANDA submission, if the applicant submits a Pre-Submission Facility Correspondence 2 months prior to the date of ANDA submission and the Pre-Submission Facility Correspondence is found to be complete and accurate and remains unChanged.

b. Review and act on priority original ANDAs within 10 months of the date of ANDA submission if the applicant does not submit a Pre-Submission Facility Correspondence 2 months prior to the date of ANDA submission or facility information changes or is found to be incomplete or inaccurate.

3. Review and act on 90 percent of standard major ANDA amendments within the applicable review goal.

a. Review and act on standard major ANDA amendments within 8 months of the date of amendment submission if preapproval inspection is not required.

b. Review and act on standard major ANDA amendments within 10 months of the date of amendment submission if preapproval inspection is required.

4. Review and act on 90 percent of priority major ANDA amendment submissions within the applicable review goal.

a. Review and act on priority major ANDA amendments within 6 months of the date of amendment submission if preapproval inspection is not required.

b. Review and act on priority major ANDA amendments within 8 months of amendment submission if (i) preapproval inspection is required and (ii) applicant submits a Pre-Submission Facility Correspondence 2 months prior to the date of amendment submission and the Pre-Submission Facility Correspondence is found to be complete and accurate and remains unchanged.

c. Review and act on priority major ANDA amendments within 10 months of amendment submission if (i) preapproval inspection is required and (ii) the applicant does not submit a Pre-Submission Facility Correspondence 2 months prior to amendment submission, or facility information Changes or is found to be incomplete or inaccurate.

5. Review and act on 90 percent of standard and priority minor ANDA amendments within 3 months of the date of amendment submission.

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

Submission Type	Goal
Standard Original ANDAs	90% within 10 months of submission date.
Priority Original ANDAs	90% within 8 months of submission date if applicant meets requirements under I(A)(2)(a). 90% within 10 months of submission date if applicant does not meet requirements as described under I(A)(2)(b).

TABLE FOR SECTION I(A)(3)–(5): ANDA AMENDMENTS

Submission Type	Goal
Standard Major ANDA Amendments.	90% within 8 months of submission date if preapproval inspection not required. 90% within 10 months of submission date if preapproval inspection required.
Priority Major ANDA Amendments.	90% within 6 months of submission date if preapproval inspection not required. 90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(A)(4)(b). 90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(A)(4)(c).
Standard and Priority Minor ANDA Amendments.	90% within 3 months of submission date.

B. PASs and PAS Amendments

1. Review and act on 90 percent of standard Prior Approval Supplements (PASs) within the applicable review goal.

a. Review and act on standard PASs within 6 months of the date of PAS submission if preapproval inspection is not required.

b. Review and act on standard PASs within 10 months of the date of PAS submission if preapproval inspection is required.

2. Review and act on 90 percent of priority PASs within the applicable review goal.

a. Review and act on priority PASs within 4 months of the date of PAS submission if preapproval inspection is not required.

b. Review and act on priority PASs within 8 months of the date of PAS submission if (i) preapproval inspection is required and (ii) the applicant submits a Pre-Submission Facility Correspondence 2 months prior to the date of PAS submission and the Pre-Submission Facility Correspondence is found to be complete and accurate and remains unchanged.

c. Review and act on priority PASs within 10 months of PAS submission if (i) preapproval inspection is required and (ii) the applicant does not submit a Pre-Submission Facility Correspondence 2 months prior to the date of PAS submission, or facility information changes or is found to be incomplete or inaccurate.

3. Review and act on 90 percent of major amendments to standard PASs within the applicable review goal.

a. Review and act on major amendments to standard PASs within 6 months of the date of amendment submission if preapproval inspection is not required.

b. Review and act on major amendments to standard PASs within 10 months of the date of amendment submission if preapproval inspection is required.

4. Review and act on 90 percent of major amendments to priority PASs within the applicable review goal.

a. Review and act on major amendments to priority PASs within 4 months of the date of amendment submission if preapproval inspection is not required.

b. Review and act on major amendments to priority PASs within 8 months of the date of amendment submission if (i) preapproval inspection is required and (ii) the applicant submits a Pre-Submission Facility Correspondence 2 months prior to the date of amendment submission and the Pre-Submission Facility Correspondence is found to be complete and accurate and remains unchanged.

c. Review and act on major amendments to priority PASs within 10 months of amendment submission if (i) preapproval inspection is required and (ii) the applicant does not submit a Pre-Submission Facility Correspondence 2 months prior to the date of amendment submission, or facility information changes or is found to be incomplete or inaccurate.

5. Review and act on 90 percent of minor amendments to standard and priority PASs within 3 months of the date of amendment submission.

TABLE FOR SECTION I(B)(1) AND (2): PASs

Submission Type	Goal
Standard PASs	90% within 6 months of submission date if preapproval inspection not required. 90% within 10 months of submission date if preapproval inspection required.
Priority PASs	90% within 4 months of submission date if preapproval inspection not required. 90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(B)(2)(b). 90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(B)(2)(c).

TABLE FOR SECTION I(B)(3)–(5): PAS AMENDMENTS

Submission Type	Goal
Standard PAS Major Amendments.	90% within 6 months of submission date if preapproval inspection not required. 90% within 10 months of submission date if preapproval inspection required.
Priority PAS Amendments	90% within 4 months of submission date if preapproval inspection not required. 90% within 8 months of submission date if preapproval inspection required and applicant meets requirements under I(B)(4)(b). 90% within 10 months of submission date if preapproval inspection required and applicant does not meet requirements as described under I(B)(4)(c).
Standard and Priority Minor PAS Amendments.	90% within 3 months of submission date.

C. Unsolicited ANDA Amendments and PAS Amendments

1. Review and act on unsolicited ANDA amendments and PAS amendments submitted during the review cycle by the later of the goal date for the original submission/solicited amendment or the goal date assigned in accordance with Sections (I)(A)(3), (4) and (5) and (I)(B)(3), (4) and (5), respectively, for the unsolicited amendment.

2. Review and act on unsolicited ANDA amendments and PAS amendments submitted between review cycles by the later of the goal date for the subsequent solicited amendment or the goal date assigned in accordance with Sections (I)(A)(3), (4) and (5) and (I)(B)(3), (4) and (5), respectively, for the unsolicited amendment.

D. DMFs

1. Complete the initial completeness assessment review for 90 percent of Type II Active Pharmaceutical Ingredient (API) Drug Master Files (DMFs) within 60 days of the later of the date of DMF submission or DMF fee payment.

TABLE FOR SECTION I(D): DMFs

Submission Type	Goal
Type II API DMF	90% of initial completeness assessments within 60 days of the later of the date of DMF submission or DMF fee payment.

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 correspondence within 60 days of the date of submission.

b. Review and respond to Complex controlled correspondence 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 citizen petitions, the 60- or 120-day time period starts on the date FDA responds to the petition (if there is only one petition) or last pending petition.

3. FDA will review and 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.

TABLE FOR SECTION I(E): CONTROLLED CORRESPONDENCE

Submission Type	Goal
Standard Controlled Correspondence.	90% within 60 days of submission date.
Complex Controlled Correspondence.	90% within 120 days of submission date.
FDA will review and respond to 90% of submitter requests to clarify ambiguities in the controlled correspondence request within 14 days of request receipt	

F. GDUFA I Bridging

1. Continue to review and act on ANDAs and ANDA amendments, PASs and PAS amendments and controlled correspondence submitted prior to October 1, 2017 that have been assigned GDUFA I goal dates pursuant to the GDUFA 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 GDUFA II goal date. (Attachment A shows how FDA, until September 30, 2017, assigned TADs to ANDA amendments not subject to GDUFA 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 GDUFA 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 but remain pending in the same review cycle as of October 1, 2017, by GDUFA 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 guidances that address ANDA receipt determinations, FDA will issue a Manual of Policies and Procedures (MAPP) by October 1, 2017 setting forth procedures for filing reviewers on communication of minor technical deficiencies (e.g., 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 a refuse-to-receive decision.

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 review program enhancements below to the review of all ANDAs. The goal of these program enhancements is to improve predictability and transparency, promote the efficiency and effectiveness 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) (IR(s)) and/or Discipline Review Letter(s) (DRL(s)) from each review discipline as soon as the discipline has completed its review, with the first IR(s) and/or DRL(s) at about the mid-point of the review.

2. Following the IR and/or DRL 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 GDUFA 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 (RPM) learns that a major deficiency is likely forthcoming, the RPM will notify the Authorized Representative that a major deficiency is likely forthcoming. If the Authorized Representative raises concerns or seeks additional information regarding the forthcoming major deficiency, the RPM will encourage the Authorized 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 RPM will notify the Authorized Representative of the outstanding discipline(s), the general nature of the delay (when possible), and the estimated timeframe for receiving the response.

10. The Authorized Representative may periodically request a Review Status Update. In response to the Authorized Representative's request, the RPM 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 appropriate 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 such 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

1. If during a review cycle of an ANDA or PAS, the review classification of the ANDA or PAS changes from Standard to Priority, FDA will notify the applicant within 14 days of the date of the change.

2. If a previous ANDA or ANDA amendment was subject to priority review, but a subsequent ANDA amendment is subject to standard review, FDA will notify applicant within 14 days of the date of receipt of the solicited amendment.

3. A request for a change may occur at any time during the review.

4. Once an ANDA or PAS submission is classified as being subject to priority review, the application will retain such priority review classification status until FDA takes an action on the submission.

5. FDA will include an explanation of the reasons for any denial of a review status reclassification request.

6. If an applicant requests a teleconference as part of its request to reclassify a major amendment or standard review status, FDA will schedule and conduct the teleconference and decide 90% of such reclassification requests within 30 days of the date of FDA's receipt of the request for a teleconference. This goal only applies when applicant accepts the first scheduled teleconference date offered by FDA.

D. ANDA Approval and Tentative Approval

If applicants submit and maintain ANDAs consistent with the statutory requirements for approval under 505(j); respond to IRs and DRLs completely and within the time frames requested by FDA and timely submit all required information under 21 CFR parts 314 and 210, including information concerning notice (21 CFR 314.95), litigation status (21 CFR 314.107), and commercial marketing (21 CFR 314.107); then FDA will strive to approve approvable ANDAs in the first review cycle; to approve potential first generics on the earliest lawful ANDA approval date, if known to FDA; and to tentatively approve 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, an applicant may pursue 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 Center for Drug Evaluation and Research's (CDER's) receipt of the written appeal pursuant to the applicable goal.

a. In FY 2018, the goal is 70 percent.

b. In FY 2019, the goal is 80 percent.

c. In FY 2020, 2021, and 2022 the goal is 90 percent.

5. CDER's Formal Dispute Resolution Project Manager (or designee) will track each formal appeal above the Division level through resolution

F. Other ANDA Review Program Aspirations

1. FDA aspires to continually improve the efficiency of the ANDA review program.

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, other program functions include determinations whether listed drugs were voluntarily withdrawn from sale for reasons of safety or effectiveness and ANDA proprietary name reviews.

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

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 review 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, subject to 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 ANDA 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 MAPP.

4. Industry may request that FDA develop product-specific guidance via email to genericdrugs@fda.hhs.gov.

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 concerns:

i. Development of a Complex Product for which FDA has not issued product-specific guidance or

ii. 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,

b. The prospective applicant submits a complete meeting package, including a data package and specific proposals,

c. A controlled correspondence response would not adequately address the prospective applicant's questions, and

d. A Product Development Meeting would significantly improve ANDA review efficiency.

2. Dependent on available resources, FDA may grant a prospective applicant a Product Development Meeting concerning Complex Product development issues other than those described in Section III(D)(1)(a) above if, in FDA's judgment:

a. The prospective applicant submits a complete meeting package, including a data package and specific proposals,

b. A controlled correspondence response would not adequately address the prospective applicant's questions, and

c. 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 FY2019, 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 can meet the 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 before each 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 FY 2020, 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 the applicant 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 each route of administration for which data is available.

2. FDA will update the Inactive Ingredient Database on an ongoing basis, and post quarterly notice of updates made. 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 fulfilment of submission review and pre-ANDA commitments set forth in Sections I and III, respectively.

1. Annually, FDA will conduct a public workshop to solicit input from 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 forms 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 Generic 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.

I. Safety Determination Letters

1. FDA will issue 90% of safety determination letters within 60 days of the date of submission of disclosure authorization.

J. Other Pre-ANDA Program Aspirations

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 submitted to the DMF holder are issued at least in parallel with the issuance of review comments relating to the DMF for

the ANDA. This commitment applies to comments to the applicant issued in any ANDA CRL and comments issued in the first IR letter by the drug product review discipline.

B. Teleconferences to Clarify DMF First Cycle Review Deficiencies

1. FDA will grant and conduct teleconferences when requested to clarify deficiencies in first cycle DMF deficiency letters.

2. DMF holders must request such teleconferences in writing within 20 business days of issuance of the first cycle DMF deficiency letter, identifying specific 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, the DMF holder may submit, and 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 and has no 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 API 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 site 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 help determine which establishments are scheduled to receive a surveillance inspection each year.

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 regarding FDA's surveillance inspection program and the meaning of inspection classifications.

D. Communications to Foreign Regulators—Upon receipt of a 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 regulator, issue 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 exist through an IR, DRL or CRL pursuant to Section II(B)) above.

2. By October 1, 2018, FDA agrees to communicate to the facility owner final inspection classifications that do not negatively impact approvability of any pending application within 90 days of the end of the inspection. FDA agrees to ongoing periodic engagement with industry stakeholders to provide updates on agency activities and seek stakeholder feedback.

F. GDUFA II Facility Compliance Status Database—By January 1, 2019, FDA will update its existing, 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 response to any documented 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

FDA will build internal capacity to enable improved productivity and performance through regular assessment of progress towards GDUFA goals, consistent methodologies for and timely reporting of GDUFA metrics, and transparent and efficient administration; allocation and reporting of user fee resources.

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 these activities and for publishing a GDUFA program resource management planning and modernized time reporting implementation plan no later than fourth quarter FY 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 no later than the end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing 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 resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct activities to evaluate 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.

1. FDA will contract with an independent third party to evaluate and report on how the GDUFA program is resourced and how those resources are utilized, and recommend improvements to the process.

2. FDA will use the results of that evaluation to create an ongoing financial reporting mechanism to enhance the transparency of GDUFA program resource utilization.

3. FDA will publish a GDUFA 5-year financial plan no later than the 2nd quarter of FY 2018. FDA will publish updates to the 5-year plan no later than the 2nd quarter of each subsequent fiscal year.

4. FDA will convene a public meeting no later than the third quarter of each fiscal year starting in FY 2019 to discuss the GDUFA 5-year financial plan, along with the Agency's progress in implementing modernized time reporting and resource management planning.

C. Performance Reporting

1. FDA will publish the following monthly metrics on its website, using a consistent, publicly disclosed reporting methodology:

a. Number of ANDAs and ANDA amendments, DMFs, Changes Being Effected (CBEs) and PASs submitted in the reporting month delineated by type of submission,

b. Number each of ANDAs and PASs FDA refused for receipt in the reporting month,

c. Number of actions taken in the reporting month delineated by the type of action.

For purposes of the metrics, actions shall include final approvals, tentative approvals, complete response letters, information requests, and discipline review letters (or other such nomenclature as FDA determines to reflect the concepts of an information request or complete response letter), and

d. Number of first cycle approvals and tentative approvals in the reporting month.

2. FDA will publish the following quarterly metrics on its website, using a consistent, publicly disclosed reporting methodology:

a. Number of ANDAs and PASs withdrawn in each reporting month,

b. Number of ANDAs awaiting applicant action, and

c. Number of ANDAs awaiting FDA action.

d. Mean and median approval and tentative approval times for the quarterly action cohort.

3. FDA will publish the following metrics annually as part of the GDUFA Performance Report:

a. Mean and median approval and tentative approval times by FY receipt cohort,

b. Mean and median ANDA approval times, including separate reporting of mean and median times for first cycle approvals,

c. Mean and median number of ANDA review cycles to approval and tentative approval by FY receipt cohort,

d. Number of GDUFA related teleconferences requested, granted, denied and conducted, broken down by type of teleconference,

e. Number of applications received, refused to receive, and average time to receipt decision,

f. Number of product development, pre-submission and mid-review cycle meetings requested, granted, denied and conducted, by face to face or in writing,

g. Number of inspections conducted by domestic or foreign establishment location and inspection type (Pre-Approval Inspection (PAI), Good Manufacturing Practices (GMP), Bioequivalence (BE) clinical and BE analytical) and facility type (Finished Dosage Form (FDF), API, etc.),

h. Median time from beginning of inspection to 483 issuance,

i. Median time from 483 issuance to Warning Letter, Import Alert and Regulatory Meeting for inspections with final classification of Official Action Indicated (OAI) (or equivalent),

j. Median time from date of Warning Letter, Import Alert and Regulatory Meeting to resolution of the OAI status (or equivalent),

k. Number of ANDAs accepted for standard review and priority review,

l. Number of suitability petitions pending a substantive response for more than 270 days from the date of receipt,

m. Number of petitions to determine whether a listed drug has been voluntarily withdrawn from sale for reasons of safety or effectiveness pending a substantive response for more than 270 days from the date of receipt,

n. Percentage of ANDA proprietary name requests reviewed within 180 days of receipt,

o. Number of DMF First Adequate Letters issued, and

p. Number of email exchanges requested and conducted in lieu of teleconferences to clarify deficiencies in first cycle DMF deficiency letters.

VII. DEFINITIONS

A. Act on an application—means FDA will either issue a complete response letter, an approval, a tentative approval, or a refuse-to-receive action.

B. Ambiguity in the controlled correspondence response—means the controlled correspondence response or a critical portion of it, in FDA's judgment, merits further clarification.

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 applicant's letter of authorization or Form 356h. An Authorized Representative may designate an alternate to serve in the Authorized Representative's absence.

E. Change, with respect to facility information—means a change to information in the Pre-Submission Facilities Correspondence that causes FDA to re-evaluate its facility 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 operation(s) performed by a facility, addition of a new facility, withdrawal of a facility used to generate data to meet application requirements or intended for commercial production, or a change in inspection readiness (i.e., a facility is no longer ready for inspection).

F. Complete response letter (CRL)—refers to a written communication to an applicant or DMF holder from FDA usually describing all of the deficiencies that the agency has identified in an abbreviated application (including pending amendments) or a DMF that must be satisfactorily addressed before the ANDA can be approved. Complete response letters will reflect a complete review which includes an application-related facilities assessment and will require a complete response from industry to restart the clock. Refer to 21 CFR 314.110 for additional details. When a citizen petition may impact the approvability of the ANDA, FDA will strive to address, where possible, valid issues raised in a relevant citizen petition in the complete response letter. If a citizen petition raises an issue that would delay only part of a complete response, a response that addresses all other issues will be considered a complete response.

G. Complete review—refers to a full division-level review from all relevant review disciplines, including inspections, and includes other matters relating to the ANDAs and associated DMFs as well as consults with other agency components.

H. Complex controlled correspondence—means:

1. Controlled correspondence involving evaluation of clinical content,

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

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

I. 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, colloids); 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)

2. Complex drug-device combination products (e.g., auto injectors, metered dose inhalers); and

3. Other products where complexity or uncertainty concerning the approval pathway or possible alternative approach would benefit from early scientific engagement.

J. Days—unless otherwise specified, means calendar days.

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 lawful 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 DMF holder indicating that the DMF has no open issues related to the review of the referencing ANDA. Issued only at the conclusion of the first DMF review cycle that determines the DMF does not have any open issues.

N. First generic—any received ANDA (1) that is a first-to-file ANDA eligible for 180-day exclusivity or for which there are no blocking patents 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 ANDAs that were the subject of prior Product Development Meetings 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 and accurate Pre-Submission Facility Correspondence—lists all of the following:

1. All facilities involved in manufacturing processes and testing for the ANDA and corresponding Type II API DMF as required by 21 CFR 314.50(d)(1)(i) and (iii). For each manufacturing or testing facility, the correspondence includes facility name, operation(s) performed, facility contact name, address, FEI number (if a required registrant or one has been assigned), DUNS number, registration information (for required registrants), a confirmation that the facility is ready for inspection, a description of the manufacturing process, and a certification by the applicant that any Type II DMF has similarly complete and accurate facility information as required by 21 CFR 314.50(d)(1)(i), including complete facility information (i.e., facility name, operation, facility contact name, address, FEI number and DUNS number). Facility information that is included in a corresponding Type II DMF is not required to be duplicated in the Pre-Submission Facility Correspondence for the ANDA.

2. All sites or organizations involved in bioequivalence and clinical studies used to support the ANDA submission as described in 21 CFR 314.94(a)(7). This information is provided using a standardized electronic format and includes unique identifiers that are current and accurate, including site or organization name, address and website; and study information including a listing of study names, dates of conduct and main investigators.

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 of the ANDA will 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) 5240.3, Prioritization of the Review of Original ANDAs, Amendments and Supplements, as revised (the CDER Prioritization MAPP).

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 response from the RPM to the Authorized Representative to update the Authorized Representative concerning, at a minimum, the categorical status of relevant review disciplines with respect to the submission 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 protocol contains safety protections 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 controlled correspondence

1. as described in CDER's September 2015 Guidance for Industry, Controlled Correspondence Related to Generic Drug Development, or

2. concerning post-approval submission requirements that are not covered by CDER post-approval changes guidance and are not specific to an ANDA.

AA. Target Action Date (TAD)—Under GDUFA I, FDA's aspirational deadline for action on a pre-GDUFA I Year 3 original ANDA and/or a complete response amendment or equivalent IR to an original ANDA.

GDUFA I TADs become GDUFA II goal dates on enactment of GDUFA II.

BB. Teleconference—means a verbal communication by telephone, and not a written response, unless otherwise agreed to by the applicant.

CC. Unsolicited amendment—an amendment with information not requested by FDA except for those unsolicited amendments considered routine or administrative in nature that do not require scientific review (e.g., requests for final ANDA approval, patent amendments, and general correspondence).

GDUFA II COMMITMENT LETTER, ATTACHMENT A

Category	Pre-cohort Year 3 ANDAs	Pre-cohort Year 3 ANDAs (expedited status)
Major Amendment (Complete Response Letter)	10 months	7 months
Minor Amendment (Complete Response Letter)	5 months	3 months
Easily Correctable Deficiency	3 months.	
Information Request	3 months.	

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

GENERAL

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.

I. 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 as intended, 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 this agreement. FDA and applicants share the responsibility for achieving this objective of reducing the average Total Time to Decision, while maintaining standards for safety and effectiveness. Success of this program will require the cooperation and dedicated efforts of FDA and applicants to reduce their respective portions of the total time to decision.

FDA will be reporting total time performance quarterly as described in Section VI. FDA and industry will participate in the independent assessment of progress toward this outcome, as described in Section V below. As appropriate, key findings and recommendations from this assessment will be implemented by FDA.

A. PMA

FDA will report on an annual basis the average Total Time to Decision as defined in Section VII.H for the three most recent closed receipt cohorts.

For Original PMA and Panel Track Supplement submissions received in Fiscal Years 2016 through 2018, the average Total Time to Decision goal for FDA and industry is 320 calendar days.

For Original PMA and Panel Track Supplement submissions received in Fiscal Years 2017 through 2019, the average Total Time to Decision goal for FDA and industry is 315 calendar days.

For Original PMA and Panel Track Supplement submissions received in Fiscal Years 2018 through 2020, the average Total Time to Decision goal for FDA and industry is 310 calendar days.

For Original PMA and Panel Track Supplement submissions received in Fiscal Years 2019 through 2021, the average Total Time to Decision goal for FDA and industry is 300 calendar days.

For Original PMA and Panel Track Supplement submissions received in Fiscal Years 2020 through 2022, the average Total Time to Decision goal for FDA and industry is 290 calendar days.

B. 510(k)

FDA will report on an annual basis the average Total Time to Decision as defined in Section VII.H for the most recent closed receipt cohort.

For 510(k) submissions received beginning in Fiscal Year 2018, the average Total Time to Decision goal for FDA and industry is 124 calendar days.

For 510(k) submissions received beginning in Fiscal Year 2019, the average Total Time to Decision goal for FDA and industry is 120 calendar days.

For 510(k) submissions received beginning in Fiscal Year 2020, the average Total Time to Decision goal for FDA and industry is 116 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.

II. REVIEW PERFORMANCE GOALS—FISCAL YEARS 2018 THROUGH 2022 AS APPLIED TO RECEIPT COHORTS

The overall objective of the review performance goals stated herein is to assure more timely access to safe and effective medical devices.

A. Pre-Submissions

FDA will continue the Pre-Submission program as described in the Guidance on ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff'' with process improvements and performance goals as noted in this section.

For all Pre-Submissions in which the applicant requests a meeting or teleconference, the applicant will provide a minimum of three proposed meeting dates in the initial submission.

Within 15 calendar days of receipt of a Pre-Submission, FDA will communicate with the applicant regarding whether the application has been accepted and, if applicable, regarding scheduling of the meeting or teleconference. Acceptance will be determined based on the definition of pre-submission in Section VII.F below and an acceptance checklist in published guidance. This communication consists of a fax, email, or other written communication that a) identifies the reviewer assigned to the submission, b) acknowledges acceptance/rejection of the submission, and c) if the submission included a request for a meeting or teleconference and is accepted, either confirms one of the applicant's requested meeting dates or provides two alternative dates prior to day 75 from receipt of accepted submission. A determination that the request does not qualify as a Pre-Submission will require the concurrence of the branch chief and the reason for this determination will be provided to the applicant in the above written communication. FDA intends to reach agreement with the applicant regarding a meeting date within 30 days from receipt of accepted submission. For all requests for meetings or teleconferences that do not have such a meeting or teleconference scheduled by 30 days from receipt of an accepted submission, an FDA manager will contact the applicant to resolve scheduling issues by the 40th day.

FDA will provide written feedback that addresses the issues raised in the pre-submission request within 70 calendar days of receipt date or five calendar days prior to a scheduled meeting, whichever comes sooner, for at least 1,530 Pre-Submissions received in FY 2018, at least 1,645 Pre-Submissions received in FY 2019, at least 1,765 Pre-Submissions received in FY 2020, at least 1,880 Pre-Submissions received in FY 2021, and at least 1,950 Pre-Submissions received in FY 2022. FDA will provide such timely written feedback for additional Pre-Submissions as resources permit, but not to the detriment of meeting the quantitative review timelines and statutory obligations. Written feedback will be provided to the applicant by email or fax and will include: written responses to the applicant's questions; FDA's suggestions for additional topics for the meeting or teleconference, if applicable; or, a combination of both. If all of the applicant's questions are addressed through written responses to the applicant's satisfaction, FDA and the applicant can agree that a meeting or teleconference is no longer necessary, and the written responses provided by email or fax will be considered the final written feedback to the Pre-Submission.

Meetings and teleconferences related to 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.

Applicants 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 of the meeting. At the beginning and end of each meeting, the applicant will affirmatively state that they will draft minutes and provide them to FDA within 15 calendar days. The minutes will summarize the meeting discussions and include agreements and any action items. FDA will provide any edits to the draft minutes to the applicant via email within a timely manner. These minutes will become final 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 that issue with 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 issue remains a point of disagreement.

FDA intends that feedback the Agency provides in a Pre-Submission will not change, provided the information submitted in a future IDE or marketing application is consistent with that provided in the Pre-Submission and documented in the Pre-Submission, and that the data and other information in the future submission do 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 on ''Requests 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 Pre-Submission, an enhanced Pre-Submission acceptance checklist, examples of frequently asked Pre-Submission questions that lend themselves to productive 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 Supplements, 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 to the applicant the specific reasons for rejection 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 statement of the basis for the deficiencies (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 issue and the information to support its position. All deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a determination of safety and effectiveness. Any subsequent deficiencies will be limited to issues raised by the information provided by the applicant in its response, unless FDA concludes that the initial 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. Issues related to post-approval studies, if applicable, and revisions to draft labeling will typically be addressed through interactive review once major deficiencies have been adequately addressed.

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 60 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 form a cohort of 10 or more submissions, upon which the 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, and to incentivize submission of a complete application, submission of an unsolicited major amendment prior to the Substantive Interaction extends the FDA Day review clock by 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 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 party to complete their respective tasks. Issues should be resolved through 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 is not necessary.

For PMA submissions that receive a MDUFA decision of Approvable, FDA will issue a decision within 60 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 checklist to facilitate a more efficient and timely review process.

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 deficiencies (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 issue and the information to support its position. All deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a classification determination. Any subsequent deficiencies will be limited to issues raised by the information provided by the applicant in its response, unless FDA concludes that the initial deficiencies identified do not adequately address important new issues materially relevant to a classification determination. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs. Issues related to revisions to draft labeling will typically be addressed through interactive review once major deficiencies have been adequately addressed.

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 all outstanding issues with the submission preventing FDA from reaching a decision. This discussion 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.

F. 510(k) Submissions

FDA will communicate with the applicant regarding whether the submission has been

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 objective 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, 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 issue and the information to support its position. All deficiency letters will undergo supervisory review prior to issuance to ensure the deficiencies cited are relevant to a determination of substantial equivalence. Any subsequent deficiencies will be limited to issues raised by the information provided by the applicant in its response, unless FDA concludes that the initial deficiencies identified do not adequately address important new issues materially relevant to a determination of substantial equivalence. Such a determination will be supported by the appropriate management concurrence consistent with applicable guidance and SOPs.

FDA will issue a MDUFA decision for 95% of 510(k) submissions within 90 FDA Days. For all 510(k) submissions that do not reach a MDUFA decision within 100 FDA Days, 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 party to complete their respective tasks. Issues should be resolved through 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 is not necessary.

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.

G. CLIA Waiver by Application

FDA will engage in a Substantive Interaction with the applicant within 90 days for 90% of the applications.

Industry will inform FDA that it plans to submit a dual submission (510(k) and CLIA Waiver application) during the Pre-Submission process. FDA will issue a decision for 90% of dual submission applications within 180 FDA days.

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 320 FDA days.

If in any one fiscal year, the number of submissions in any CLIA Waiver 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 of 10 or more 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 party to complete their respective tasks. Issues should be resolved through 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 is not necessary.

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.

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 process in Pre-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 Biologics 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 supplement submissions 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.

III. INFRASTRUCTURE

A. Quality Management

The Agency will establish a dedicated Quality Management (QM) Unit that reports directly to the CDRH Director or Deputy Director and establish a quality management framework for the premarket submission process in CDRH. The Framework will include infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

At least once per year, the Agency will discuss with industry the specific areas it intends to incorporate in its ongoing audit plan. FDA will identify, with industry input, areas to audit, which will include the effectiveness of CDRH's Corrective and Preventive Action (CAPA) process. FDA will expand the scope of its annual audits as it implements and builds up its auditing capability. As part of these ongoing audits, high-performing premarket review processes utilized in one division will be identified and shared accordingly with other divisions to improve efficiencies and effectiveness. At a minimum, FDA audits in the following areas will be completed by the end of FY 2020: Deficiency Letters and Pre-Submissions. Additional audits in the following areas will be completed by the end of FY 2022: Submission Issue Meetings, Interactive Review, Withdrawals and Special 510(k) conversions.

The effectiveness of the QM framework will be evaluated in Phase 2 of the Independent Assessment (see Section V).

B. Scientific and Regulatory Review Capacity

The Agency will apply user fee revenues to reduce the ratio of review staff to front line supervisors in the premarket review program to improve consistency. The Agency will also apply user fee revenues to enhance and supplement scientific review capacity by hiring device application reviewers as well as leveraging external experts needed to assist with the review of device applications.

To ensure such additional positions are filled by qualified experts, the Agency will apply user fee revenues to recruitment and hiring. The Agency will apply user fee revenues to retain high-performing supervisors in the premarket review program.

CDRH intends to enter into an Inter-Agency Agreement (IAA) with the Office of Personnel Management (OPM) to provide supplemental recruitment and staffing support throughout MDUFA IV to augment existing FDA Human Resources services.

C. IT Infrastructure for Submission Management

FDA will enhance IT infrastructure that will allow FDA to perform quality management audits and review consistency.

FDA will implement a new information management system that provides an industry dashboard that displays near real-time submission status.

FDA will develop electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. By FY 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates. FDA will provide an opportunity for public comment on the guidance. No later than 12 months after the close of the public comment period, the Agency will issue a final guidance. FDA will implement the guidance once final. In addition, the Agency will update the Guidance ''eCopy Program for Medical Device Submissions'' to reflect the respective changes to the technical standards and specifications.

FDA will link pre-submissions with subsequent premarket submissions when identified by the applicant.

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 through assessment of work 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 III.A 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 resources needed to meet performance goals given the workload, or in excess of inflation-adjusted statutory revenue targets, FDA and industry will work together to assess how best to utilize those 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 encourage, informal 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 PMAs, PMA Supplements, Original BLAs, and BLA Supplements,'' both FDA and industry believe that an interactive review process for these types of premarket medical device submissions should help facilitate timely completion of the review based on accurate and complete information. Interactive review is intended to facilitate the efficient and timely review 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 the basis for the deficiencies (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 issue and the information to support its position. All deficiency letters will undergo supervisory review prior to issuance to ensure the 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 PMA review if they 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 by an accredited TL, FDA intends to rely on the results from the accredited TL for the purpose of premarket review (i.e., generally accept a 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 will not review reports from accredited TLs 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 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

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

5. 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 directly accredit third party TLs, if FDA has not identified and recognized an AB within 2 years after establishing the tenets of the ASCA program.

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

7. Establish a publicly-accessible website listing TLs accredited by ASCA and 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.

a. By the end of FY 2022: FDA will have piloted, and provided a report on the viability of, an ASCA program which utilizes the schema identified in guidance to include utilization of 5 appropriate cross-cutting/horizontal 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 input on programmatic improvements and/or consideration for expansion.

E. Third Party Review

The Agency will take the following actions to improve the Third Party Review program with a goal of eliminating routine re-review by FDA of Third Party reviews:

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 have access to redacted review memos and other information as appropriate.

b. When FDA's expectations for a particular device type change, FDA will have in place a process to convey this 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 with at least five completed submissions on the web (e.g., rate of NSE, average number of holds, average time to SE).

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 codes 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 willing industry 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. Develop clinical, statistical, and other scientific 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 submission review and early consultation/advice to industry during study planning.

2. By the end of FY 2020, hold one or more public meetings to discuss the topics below and publish the findings and next steps.

a. Discuss approaches for incorporating PPI and PRO as evidence in device submissions, as well as other ways of advancing patient engagement;

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 and case histories for PPIs 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 priority areas in the Federal Register for public comment following the public meeting.

3. FDA will undertake several activities to improve the regulatory predictability and impact of PROs, including:

a. Clarify to device review divisions that use of PROs is voluntary and may be one potential way of demonstrating safety or effectiveness (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. These thresholds may vary depending 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.

4. The existing dispute resolution process should be used in the event of disagreement between the applicant and the Agency on the need for PPI or PRO.

G. Emerging Diagnostics

FDA will work with industry to continue the pilot for emerging diagnostics started under MDUFA III.

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 ACLA), 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 or appointed from a member company. If any of the trade associations elects not to participate on the NEST governing board or for any additional seats allocated to Industry, the participating trade associations will determine how to fill any vacant Industry positions. The governing board also will include, but not be limited to, representation from patient organizations. By the end of FY2019, NEST will implement pilots for at least two product 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) process. 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 and Industry determine 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 advance the use of RWE, 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 described in (H)(1) above.

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 third-party will conduct an assessment to 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 to how RWE can be used to support:

i. Expanded indications for use; and

ii. New clearances/approvals.

If supported by the pilot(s) described in (H)(1) above, the guidance will include discussion of how devices not currently subject to a registry can benefit from RWE.

3. The Agency will establish criteria for streamlining MDR requirements.

a. For most, if not all, device procodes, FDA will permit manufacturers of such devices in those procodes to report malfunctions on a quarterly basis and in a summary MDR format. FDA will publish the list of eligible device procodes within 12 months of receiving a proposed list from Industry. The list will include, among other device procodes, Class II implantable and Class III devices, as appropriate, and will reflect FDA's consideration of Industry's proposed list.

b. FDA may determine that devices under a new procode 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 a 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 procodes for which manufacturers are permitted to report malfunctions on a quarterly basis and in a summary MDR 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 device procodes be added to the list.

f. Nothing in this section precludes the Agency from requiring individual malfunction 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 not eligible for quarterly summary MDR reporting and provide an explanation for that decision and the steps necessary to return to eligibility for quarterly summary MDR reporting.

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 if FDA has access to the information/data in the RWD source and has determined that the information/data in the RWD source is sufficient to take 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 within CDRH's Office of the Center Director to ensure proper coordination and consistency across the Agency. The Agency will not reorganize staff such that existing review staff would be reassigned to the central digital health unit, while retaining and not disrupting the existing digital health talent within the reviewing divisions who have established, long-term therapeutic and device expertise. The digital health unit will perform, at a minimum, the following tasks:

a. Develop software and digital health technical expertise (''Technical Experts'') to provide assistance for premarket submissions that include SaMD, SiMD, interoperable devices, or otherwise incorporate novel digital health technologies.

b. 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; and

c. Incorporate appropriate metrics for digital health improvements to monitor, track, analyze and report the results of digital health premarket review timelines.

2. Publish final guidance addressing when to submit a 510(k) for a software modification to an existing device within 18 months of the close of the comment period.

3. 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 Premarket 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. The Agency will incorporate applicable concepts from its Guidance for ''Off-The-Shelf Software Used in Medical Devices.''

4. Participate in international harmonization efforts related to digital health, including work on developing SaMD and other digital health convergence efforts through the International Medical Device Regulators Forum (IMDRF).

J. Guidance Document Development

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 draft guidance 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, reopen the comment period, or issue a new draft guidance for 100% of draft guidance documents within 5 years of the close of the comment periods as resources permit. The Agency will continue to develop guidance documents and improve the development process as resources permit, but not to the detriment of meeting quantitative 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 with scientific and engineering disciplines. CDRH will explore transitioning to a similar TPLC model building in the other device areas based on the lessons learned from its experience with OIR and taking into account the Center's mission, vision, 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 to device regulation (particularly emerging and innovative technologies) is the incorporation of the clinical context and the impact of a decision on patient health and quality of life, CDRH will take steps to increase and enhance the integration of its clinicians into its TPLC activities, amongst themselves, and with the Center's scientists and engineers. Building on the success of considering and incorporating additional expertise and viewpoints into our decision-making, such as through the use of the Network of Experts and the leveraging of patient perspectives, CDRH will also explore ways in which to better learn from and leverage the expertise of clinicians in other parts of the agency and outside of the agency to inform its decision making, enhance consistency, and assure a more holistic clinical perspective. Clinicians involved in device-related activities will have appropriate training on and make recommendations consistent with applicable device statutory provisions, regulations, guidances, and this Commitment Letter. In addition, CDRH will provide managerial oversight of clinician recommendations and device submission decisions, except for those devices subject to CBER oversight.

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 by a private, independent consulting firm capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment scope 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 independent assessment.

For Phase 1, FDA will award the contract by the end of CY2017. The contractor will evaluate the implementation of MDUFA III recommendations and publish 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 FTEs;

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 effectiveness 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),

d. Third Party Review program (assess efficiency of program and suggest process improvements),

e. Digital Health program,

f. Patient Engagement program, and

g. Real World Evidence program;

6. Analyze conversions of Special 510(k)s to Traditional 510(k)s; and

7. 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 within 1 year. For all recommendations the contractor will provide an estimate of additional resources needed or efficiencies gained, as applicable.

FDA will incorporate findings and recommendations, as appropriate, into its management of the premarket review program. FDA will analyze the recommendations for improvement opportunities identified in the assessment and, as appropriate, develop and implement a corrective action plan, and assure its effectiveness.

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, the reporting will be modified accordingly 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):

1.1. For 510(k) submissions that do not go through a 3rd party, reporting will include:

i. Average and quintiles of the number of calendar days to Substantive Interaction

ii. Average, and quintiles of the number of FDA Days, Industry Days, and Total Days to a MDUFA decision

iii. Average number of review cycles.

iv. Rate of submissions not accepted for review

1.2. 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 FDA Days, Industry Days, and Total Days to a MDUFA decision

iii. Rate of applications not accepted for filing review, and rate of applications not filed

1.3. 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, upon final guidance

1.4. 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

1.5. 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

2. CDRH will report quarterly, and CBER will report annually, the following data at the Center level:

2.1. Rate of NSE decisions for 510(k) submissions

2.2. Rate of withdrawals for 510(k), de novo, and PMA submissions

2.3. Rate of Not Approvable decisions for PMA submissions

2.4. Rate of Denial decisions for de novo requests

2.5. Key product areas or other issues that FDA identifies as noteworthy because of a potential effect on performance, including significant rates of Additional Information requests

2.6. Specific topic or product area as it relates to performance goals, agreed upon at the previous meeting

2.7. Number of submissions that missed the goals and the total number of elapsed calendar days broken down into FDA days and industry days

2.8. Newly released draft and final guidance documents, and status of other priority guidance documents

2.9. Agency level summary of fee collections

2.10. Independent assessment implementation plan status

2.11. Results of independent assessment and subsequent periodic audits and progress toward implementation of the recommendations and any corrective action

2.12. Number of discretionary fee waivers or reductions granted by type of submission

3. In addition, the Agency will provide the following information on an annual basis:

3.1. Qualitative and quantitative update on how funding is being used for the device review process, including the percentage of review time devoted to direct review of applications

3.2. How funding is being used to enhance scientific review capacity

3.3. The number of Premarket Report Submissions received

3.4. Summary information on training courses available to CDRH and CBER employees, including new reviewers, regarding device review and the percentage of applicable staff that have successfully completed each such course. CDRH will provide information concerning any revisions to the new reviewer training program curriculum.

3.5. Performance on 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. Premarket Reports

iv. Panel-Track PMA Supplement

v. PMA Modules

vi. 180-Day PMA Supplements

vii. Real-Time PMA Supplements

viii. Number of submissions FDA classifies as unsolicited major, solicited major, and minor amendments

3.9. For De Novo requests, reporting will include:

i. Number of submissions received

ii. 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.

3.13. Report on implementation of deficiency performance improvements.

3.14. Report on quality management program

3.15. Summary of quality system audits

FDA will report annual and 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

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

On an annual basis, FDA and Industry will discuss the 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.

B. Electronic Copy (e-Copy)

An electronic copy is an exact duplicate of a submission, created and submitted on a CD, DVD, or in another electronic media format that FDA has agreed to accept, accompanied by a copy of the signed cover letter and the complete original paper submission. An electronic copy is not considered to be an electronic submission.

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 contents and components 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 classification request), filed (PMA) or submitted (CLIA Waiver by application). FDA Days begin on the date of receipt of the submission or of the amendment to the submission that enables the submission to be accepted (510(k)) or filed (PMA).

E. MDUFA Decisions

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

180-Day PMA Supplements: Decisions for 180-Day PMA Supplements include Approval, Approvable, and Not Approvable.

Real-Time PMA Supplements: Decisions for Real-Time PMA supplements include Approval, Approvable, and 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 formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission meeting is a meeting or teleconference in which FDA provides its substantive feedback on the Pre-Submission.

A Pre-Submission provides the opportunity for an applicant to obtain FDA feedback prior to intended submission of an investigational device exemption or marketing application. The request must include specific questions regarding review issues relevant to a planned IDE or marketing application (e.g., questions regarding pre-clinical testing protocols or data requirements; design and performance of clinical studies and acceptance criteria). A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation.

The following forms of FDA feedback to applicants are not considered Pre-Submissions.

Interactions requested by either the applicant or FDA during the review of a marketing application (i.e., following submission of a marketing application, but prior to reaching an FDA Decision).

General information requests initiated through the Division of Industry and Consumer Education (DICE).

General questions regarding FDA policy or procedures.

Meetings or teleconferences that are intended to be informational only, including, but not limited to, those intended to educate the review team on new device(s) with significant differences in technology from currently available devices, or to update FDA about ongoing or future product development, without a request for FDA feedback on specific questions related to a planned submission.

Requests for clarification on technical guidance documents, especially where contact is recommended by FDA in the guidance document. However, the following requests will generally need to be submitted as a Pre-Submission in order to ensure appropriate input from multiple reviewers and management: recommendations for device types not specifically addressed in the guidance document; recommendations for nonclinical or clinical studies not addressed in the guidance document; requests to use an alternative means to address recommendations specified in a guidance document.

Phone calls or email messages 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.

G. Substantive Interaction

Substantive Interaction is an email, letter, teleconference, video conference, fax, or other form of communication such as a request for Additional Information or Major Deficiency letters by FDA notifying the applicant of substantive deficiencies identified in initial submission review, or a communication stating that FDA has not identified any deficiencies in the initial submission review and any further minor deficiencies will be communicated through interactive review. An approval or clearance letter issued prior to the Substantive Interaction goal date will qualify as a Substantive Interaction.

If substantive issues warranting issuance of an Additional Information or Major Deficiency letter are not identified, interactive review should be used to resolve any minor issues and facilitate an FDA decision. In addition, interactive review will be used, where, in FDA's estimation, it leads 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., 510(k) Summary/Statement, Indications for Use statement, environmental impact assessment, financial disclosure statements); a more detailed device description; omitted engineering drawings; revisions to labeling; or clarification regarding nonclinical or clinical study methods or data.

Minor issues may still be included in an Additional Information or Major Deficiency letter where related to the resolution of the

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 MDUFA decision.

The average Total Time to Decision for 510(k) submissions is calculated as the average of Total Times to Decision for 510(k) submissions within a closed cohort, excluding the highest 2% and the lowest 2% of values. A cohort is closed when 99% of the accepted submissions have reached a decision.

The average Total Time to Decision for PMA applications is calculated as the three-year rolling average of the annual Total Times to Decision for applications (for example, for FY2018, the average Total Time to Decision for PMA applications would be the average of FY2016 through FY2018) within a closed cohort, excluding the highest 5% and the lowest 5% of values. A cohort is closed when 95% of the applications have reached a decision.

I. Accreditation Scheme for Conformity Assessment

Conformity Assessment is the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

Accreditation is the formal recognition by an independent body, generally known as an accreditation body, that an organization is competent to carry out specific conformity assessment activities. Accreditation is not obligatory but it adds another level of confidence, as 'accredited' means the organization has been independently checked to make sure it operates according to international standards.

A conformity assessment scheme is a system for assessing the conformity of specified objects (e.g., medical devices or management processes) to one or more consensus standards. The system specifies the applicable standards as well as 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 making 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 appropriate, the actions necessary to place the application in condition for approval.

Class 1 resubmitted applications—applications resubmitted after a complete response letter that includes the following items only (or combinations of these items):

(a) Final printed labeling

(b) Draft labeling

(c) Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and 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) Stability updates to support provisional or final dating periods

(e) Commitments to perform Phase 4 studies, including proposals for such studies

(f) Assay validation data

(g) Final release testing on the last 1–2 lots used to support approval

(h) A minor reanalysis of data previously submitted to the application (determined by the Agency as fitting the Class 1 category)

(i) 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 resubmitted applications—resubmissions that include any other items, including any item that would require presentation to an advisory committee.

Mr. ALEXANDER. Mr. President, I ask unanimous consent to have printed in the RECORD a copy of the commitment letter for the Prescription Drug User Fee Act, PDUFA, reauthorization for fiscal years 2018 to 2022, known as PDUFA VI.

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

PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022

PDUFA REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2018 THROUGH 2022

This document contains the performance goals and procedures for the Prescription Drug User Fee Act (PDUFA) reauthorization for fiscal years (FYs) 2018–2022, known as PDUFA 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 and procedural goals and other commitments specified in this letter apply to aspects of the human drug review program that are important for facilitating timely access to safe, effective, and 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 and to continuous improvement of 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 throughout PDUFA VI. This will allow 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).

I. 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 6 months of the 60 day filing date.

c. Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt.

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

e. 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 4 months of receipt

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

5. Review Performance Goal Extensions

a. 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 study(ies); 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 articulated in the GRMP guidance, FDA's decision to extend the review clock 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, 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.

ii. If, 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, the goal date may be extended.

1) If FDA identifies the need to inspect a manufacturing facility that is not included as part of the comprehensive and readily located list in an original application or efficacy supplement, the goal date may be extended by three months.

2) If FDA identifies the need to 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.

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

TABLE 1.—ORIGINAL AND RESUBMITTED APPLICATIONS AND SUPPLEMENTS

Submission Cohort	Standard	Priority
NME NDAs and original BLAs	90% in 10 months of the 60 day filing date	90% in 6 months of the 60 day filing date
Non NME NDAs	90% in 10 months of the receipt date	90% in 6 months of the receipt date
Class 1 Resubmissions	90% in 2 months of the receipt date	90% in 2 months of the receipt date
Class 2 Resubmissions	90% in 6 months of the receipt date	90% in 6 months of the receipt date
Original Efficacy Supplements	90% in 10 months of the receipt date	90% in 6 months of the receipt date
Class 1 Resubmitted Efficacy Supplements	90% in 2 months of the receipt date	90% in 2 months of the receipt date
Class 2 Resubmitted Efficacy Supplements	90% in 6 months of the receipt date	90% in 6 months of the receipt date

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 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 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 to discuss the application, i.e., an ''application orientation meeting''). If appropriate, the Formal Communication Plan should specify those elements of the Program that FDA and the sponsor agree are unnecessary for the application under review. If the review team and the applicant anticipate developing a Formal Communication Plan, the elements of the plan should 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 based on the progress of the review and 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.

Expedited Reviews. In certain cases, an application reviewed in the Program 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 remainder of 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 planned 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 need for REMS 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 complete application 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.

i. Examples of application components that may be appropriate for delayed submission include updated stability data (e.g., 15–month data to update 12–month data submitted with the original submission) or the final audited report of a preclinical study

(e.g., carcinogenicity) where the final draft report is submitted with the original application.

ii. Major components of the application (e.g., the complete study report of a Phase 3 clinical trial or the full study report of required long-term safety data) are expected to be submitted with the original application and are 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 components of the application that FDA agreed at the pre-submission 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.

c. Incomplete 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.

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.B.4.

ii. The application will not be eligible for the other parameters 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. The 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 such resubmission will be reviewed as available resources permit.

e. Since applications are expected to be complete at the time of submission, unsolicited 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. The planned review timeline 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 plans on whether to hold an Advisory Committee (AC) meeting to discuss the application. If applicable, the Day 74 letter will serve as notification to the applicant that the review division intends to conduct an expedited review.

4. Review performance goals: For NME NDA and original BLA submissions that are filed by FDA under the Program, the PDUFA review clock will begin at the conclusion of the 60 calendar day filing review period that begins on the date of FDA receipt of the original submission. The review performance goals for these applications are as follows:

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 6 months of the 60 day filing date.

5. 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 sent to the applicant prior to the mid-cycle communication. Scheduling of the internal mid-cycle review 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.

a. The update should include 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, proposed date(s) for the late-cycle meeting, updates regarding plans for the AC meeting (if an AC meeting is anticipated), an update regarding FDA's review activities associated with a 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 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 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 PDUFA 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 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 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 (standard review) or two months (priority review) prior to the PDUFA 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 expedited review) 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 review activities associated with a 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.

i. 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 PDUFA goal date.

7. Inspections: FDA's goal is to complete all GCP, GLP, and GMP inspections for applications in the Program within 6 months 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 review process for all applications subject to the PDUFA program. This commitment was first articulated in the GRMP guidance finalized in 2005. FDA will update this guidance in PDUFA VI to include review activities (e.g., the NME Program, REMS) that have been added to the human drug review program since the guidance was finalized, principles regarding notification to applicants regarding issues identified during FDA's initial review of the application, principles regarding FDA's notification to applicants regarding planned review timelines, and the importance of internal review timelines that govern aspects of the human drug review program that are not part of PDUFA performance goals. 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 apply to FDA's review of drug and biological product proprietary 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 would 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 90 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.

b. A supplemental review will be done meeting the above 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 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).

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 occur 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. 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 on the appeal. In these 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, scheduling the issue for discussion at the next scheduled available advisory committee (AC).

e. In these cases, once the required information is received by the Agency (including any advice from an AC), the person to 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.

f. 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.

g. N.B. If the Agency decides to present the issue to an AC and there are not 30 days before the next scheduled AC, the issue will be presented at the following scheduled committee meeting to allow conformance with AC administrative procedures.

F. Clinical Holds

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.

2. Performance goal:

90% of such responses are provided within 30 calendar days of the Agency's receipt of the sponsor's response.

G. 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 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., is the dose range in the carcinogenicity study adequate, considering the intended clinical dosage; are the clinical endpoints adequate to support a specific efficacy claim).

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 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 goals of the sponsor, the reasons for the disagreement will be explained in the response.

c. Protocols that qualify for this program include: carcinogenicity protocols, stability protocols, and Phase 3 protocols for clinical trials that will form the primary basis of an efficacy claim. For such Phase 3 protocols to qualify for this comprehensive protocol assessment, the sponsor must have had an end-of-Phase 2/pre-Phase 3 meeting 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.

d. N.B. For products that will be using Subpart E or Subpart H development schemes, the Phase 3 protocols mentioned in this paragraph should be construed to mean those protocols for trials that will form the primary basis of an efficacy claim no matter what phase of drug development in which they happen to be conducted.

e. If a protocol is reviewed under the process outlined above and agreement with the Agency is reached on design, execution, and analyses and if the results of the trial conducted under the protocol substantiate the hypothesis of the protocol, the Agency agrees that the data from the protocol can be used as part of the primary basis for approval of the product. The fundamental agreement here is that having agreed to the design, execution, and analyses proposed in 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 the timeframe.

3. Reporting:

The Agency will track and report the number of original special protocol assessments and resubmissions per original special protocol assessment.

H. Meeting Management Goals

Formal PDUFA meetings between sponsors and FDA consist of Type A, B, B(EOP), and C meetings. These meetings are further described below.

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 an FDA regulatory action other than approval (i.e., issuance of a complete response letter) will also generally be considered Type A meetings.

Type B meetings include pre-IND meetings and pre-NDA/BLA meetings, while Type B (EOP) 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/pre-Phase 3 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.

A Type C meeting is 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

Meeting Type	Response Time (calendar days)
A	14
B	21
B(EOP)	14
C	21

i. 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 a written response is deemed 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.

ii. For pre-IND and Type C meetings, while the sponsor may request a face-to-face meeting, the Agency may determine that a written response to the sponsor's questions would be the most appropriate means for providing feedback and advice to the sponsor. When it is determined that the meeting request can be appropriately addressed through a written response, 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.

b. Performance Goal: FDA will respond to meeting requests and provide notification within the response times noted in Table 3 for 90% 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 4 below indicates the timeframes for the scheduled meeting date following receipt of a formal meeting request, or in the case of a written response, 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 4

Meeting Type	Meeting Scheduling or Written Response Time
A	30 calendar days from receipt of meeting request
B	60 calendar days from receipt of meeting request
B(EOP)	70 calendar days from receipt of meeting request
C	75 calendar days from receipt of meeting request

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 will be provided) is specified in Table 5 below.

TABLE 5

Meeting Type	Receipt of Background Package
A	At the time of the meeting request
B	30 calendar days before the date of the meeting or expected written response
B(EOP)	50 calendar days before the date of the meeting or expected written response*
C6	47 calendar days before the date of the meeting or expected written response*

*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 meetings specified in Table 3, 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. The minutes will clearly outline the important agreements, disagreements, issues for further discussion, and action items from the meeting in bulleted form and need not 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. A written request must be submitted to the review division.

b. The written request must provide:

i. 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;

ii. A listing of the specific objectives/outcomes the requester expects from the meeting;

iii. A proposed agenda, including estimated times needed for each agenda item;

iv. A listing of planned external attendees;

v. A listing of requested participants/disciplines representative(s) from the Center with an explanation for the request as appropriate; and

vi. 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.

c. 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 be honored except 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 developed and 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 development of drugs for rare diseases. The extension and continuation of this work will encompass further evaluation and enhancement of FDA-sponsor communications, ensuring the sustained success of the breakthrough therapy program, establishing early consultations between FDA and sponsors on the use of new surrogate endpoints as 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 During Drug Development

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 making new safe and effective drugs available to the American public in a timely manner. Accordingly, FDA will maintain dedicated drug development communication and training staffs in CDER and CBER, 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. The liaison will serve as a point of contact for sponsors who have general questions about drug development or who need clarification on which review 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 the formal meeting process within 30 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 the issue.

The second function of the staff is to provide ongoing training to the review organizations on best practices in 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 mechanisms (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 regarding 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 contract with an independent third party to assess current practices of FDA and sponsors in communicating during drug development. The statement of work for this effort will be published for public comment prior to beginning the assessment. The third party will be expected to separately engage both FDA staff and individual sponsors through contractor-led interviews as part of the assessment. Due to the significant volume of FDA-sponsor interactions in a given year, the assessment will be based on a random subset of 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.

b. 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 feedback from sponsors and FDA 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 Communication Between 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 the 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 expedite the 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. Additional resources will enable the Agency to 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 by investing additional resources into the breakthrough therapy program.

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 considered a Type C meeting request. The purpose of this meeting is to discuss the feasibility of the surrogate as a primary endpoint, and identify any gaps in knowledge and how they might be addressed. 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 meeting background package at the time the request is made that includes preliminary human data indicating impact of the drug on the biomarker at a dose that appears to be generally tolerable. The remaining meeting procedures as described in Section I.H of this document will apply.

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 facilitate the development and timely approval of drugs and biologics for rare diseases, including rare diseases in children. The Rare Disease Program staff in CDER will be integrated into review teams for rare disease development programs and application review to provide their unique expertise on flexible and feasible approaches to studying and reviewing such drugs to include, for example, innovative use of biomarkers, consideration of non-traditional clinical development programs, use of adaptive study designs, evaluation of novel endpoints, application of new approaches to statistical analysis, and appropriate use of FDA's expedited development and review programs (i.e., Fast Track, Breakthrough, Priority Review, and Accelerated Approval). CBER, through its Rare Disease Program Staff, will also ensure that its review offices consider such flexible and feasible approaches in review.

The RDP staff will also 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 reviewer training core curriculum.μ 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 and regulation of rare disease drug development and application review. The training will also emphasize the important role 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. The staff will continue to foster collaborations in the development of tools (e.g., patient reported outcome measures) and data (e.g., natural history studies) to support development of drugs for rare diseases. In addition, the staff will also facilitate interactions between stakeholders and FDA review divisions to increase awareness of FDA regulatory programs and engagement of patients in FDA's regulatory decision-making.

FDA will include updates on the activities and success of the RDP in the PDUFA annual performance report to include, for example, the number of training courses offered and staff trained, the number of review programs where RDP staff participated as core team members, and metrics related to engagement with external stakeholders. FDA will also continue to include information on rare disease approvals in its 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 as applicable, and through 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 and bridging study protocols and study reports, and labeling, to include instructions-for-use materials.

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.

i. By no later than December 31, 2017, FDA will complete a lean process mapping for combination product review in order to inform 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 regularly assess the progress of combination product review throughout PDUFA VI.

iii. By no later than September 30, 2018, for each component within FDA that is consulted to participate in review of combination products, FDA will outline in appropriate internal documents the Agency's process for resolving internally any scientific or regulatory issues that arise, as well as a commitment for the medical product centers and OCP to coordinate and complete reviews and related activities when consulted in timelines set forth by PDUFA and other published documents (e.g., the GRMP guidance and GRMP MAPP).

c. FDA will establish Manuals of Policies and Procedures (MAPPs) and Standard Operating Policy and Procedures (SOPPs) to promote efficient, effective, and consistent combination product development and review. The documents will describe processes and procedures for conducting review of combination products, including the expectations for consultation of internal experts outside the reviewing Center. FDA will describe the responsibilities of staff in each Center and Office, expectations for core review team members and for other consultant staff in activities and meetings related to the combination product development program and application review. FDA will define the key terms to be used by staff in review of combination products to foster clear communication within FDA and to regulated industry. The topic areas and expected completion dates of these documents are specified below:

i. Human Factors Assessments (March 31, 2019)

ii. Quality assessment of combination products, including coordination of facility inspections (September 30, 2019)

iii. 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)

d. 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 combination product review. FDA agrees to maintain and update this information periodically.

e. FDA will establish submission procedures for Human Factors protocols 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.

i. 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, 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.

(1) The sponsor should submit a limited number of specific questions about the human factors protocol design and 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 tasks that should be evaluated appropriately identified).

(2) Within 60 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 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 goals of the sponsor, the reasons for the disagreement will be explained in the response.

(3) Performance goals for FDA will be phased in, starting in FY 2019 as follows:

a. By FY 2019, review 50% of human factors protocol submissions within 60 days and provide sponsor with written comments.

b. By FY 2020, review 70% of human factors protocol submissions within 60 days and provide sponsor with written comments.

c. By FY 2021, review 90% of human factors protocol submissions within 60 days and provide sponsor with written comments.

f. 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 regulated 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 consistency of scientific and regulatory approaches across applications and review teams.

g. 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, cGMPs/facilities topics, human factors and bridging studies, and labeling. The contractor will be expected to engage both FDA staff and individual sponsors as part of the assessment. 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 submission procedures for human factors protocols, and in the review and submission of Combination Product applications.

h. By the end of FY 2019, FDA will publish draft guidance or update previously published guidance issued by the medical product centers and OCP for review staff and industry describing considerations related to 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.

i. 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 safety of medications but also their effectiveness. To accomplish this will require an understanding of what questions to ask, including how such data can be generated and used appropriately in product 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 workshop(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 activities (e.g., pilot studies or methodology development projects) aimed at addressing key outstanding concerns and considerations in the use of RWE for regulatory decision making.

c. By no later than the end of FY 2021, considering available input, such as from activities noted above, FDA will publish draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions, for example in the approval of new supplemental indications and for the fulfillment of postmarketing commitments and requirements. 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.

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 the following activities during PDUFA VI:

a. FDA will strengthen the staff capacity to facilitate development and use of patient-focused methods to inform drug development and regulatory decisions. This staff, composed primarily of clinical, statistical, psychometric, and health outcomes research expertise, will be integrated into review teams as core members of the team during drug development and application review where the sponsor intends to use patient input or clinical outcome assessment (COAs) such as patient-reported outcomes (PROs) as part of the development program. A core responsibility of the staff will be to engage patient stakeholders and provide timely development-phase consultations to sponsors developing new tools to collect patient and caregiver input. This additional capacity is expected to advance the science of COA development and analysis, and the staff will also support the public qualification activities for COAs.

b. FDA will develop a series of guidance documents to focus on approaches and methods to bridge from initial patient-focused drug development meetings, like those piloted under PDUFA V, to fit-for-purpose tools to collect meaningful patient and caregiver input for ultimate use in regulatory decision making. Prior to the issuance of each guidance, as part of the development, 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 collecting comprehensive and representative 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, reporting, management, and analysis.

ii. By the end of FY 2019, FDA will publish a draft guidance describing processes and methodological approaches to development of holistic sets of impacts that are most important to patients. The guidance will address topics including: methods for sponsors, patient organizations, academic researchers, and expert practitioners to develop and identify what are most important to patients in terms of burden of disease, burden of treatment, and other critical aspects. The guidance will address how patient input can inform drug development and review processes, and, as appropriate, 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 measure(s) 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 Outcome 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. For each of the above, 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.

c. 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.

d. As appropriate, FDA will revise existing MAPPs and SOPPs to include suggested approaches for incorporating an increased patient focus in other on-going or planned FDA public meetings (e.g., FDA scientific workshops). In addition, as appropriate, FDA will develop and implement staff training related to processes, tools, and methodologies described in this section.

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 may also gather input from sponsors, 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 the agency's implementation of structured benefit-risk assessment, 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 convene and/or participate in, at least one meeting, conducted through a qualified third party, to gather industry, patient, researcher, and other stakeholder input on key topics. This would include applying the 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. 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 to understand the therapeutic context (i.e., the severity of disease that represents the targeted indication and the extent of unmet medical need in the target population) regarding regulatory decisions for the product at the various stages of drug development and evaluation.

iii. Discuss 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.

d. Beginning in FY 2021, FDA will conduct an evaluation of the implementation of the benefit-risk framework in the human drug review program. This evaluation will assess how reviewers across the organization apply the benefit-risk framework and identify best practices in use of the benefit-risk framework. The evaluation of the benefit-risk framework implementation conducted in PDUFA V will serve as a baseline for this PDUFA VI assessment.

e. As appropriate, FDA will revise relevant MAPPs and SOPPs to include new approaches that incorporate FDA's benefit-risk framework into the human drug review program.

3. Advancing Model-Informed Drug Development

To facilitate the development and application of exposure-based, biological, and statistical models derived from preclinical and clinical data sources, herein referred to as ''model-informed drug development'' (MIDD) approaches, FDA will conduct the following activities 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 and development efforts.

b. FDA will convene a series of workshops to identify best practices for MIDD. Topics will include: (1) physiologically-based pharmacokinetic modeling; (2) design analysis and inferences from dose-exposure-response studies; (3) disease progression model development, including natural history and trial simulation; and (4) immunogenicity and correlates of protection for evaluating biological products, including vaccines and blood products. Each workshop will focus on current and emerging scientific approaches, 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 issues, to occur within a span of approximately 120 days. These meetings will be led by the clinical pharmacology or biostatistical review components within CDER or CBER.

i. FDA will publish a Federal Register Notice announcing the pilot program and outlining the eligibility criteria and process for submitting to FDA requests to participate in the pilot program.

ii. FDA will select 2–4 proposals (e.g., 1–2 per Center) quarterly each year. FDA will convene an internal review group to review proposals on a quarterly basis and provide recommendations on prioritization and selection of proposals and share knowledge and experience. Program selection will take into account development programs where clinical data are limited such that integration across non-traditional sources may be needed, and for which MIDD can assess uncertainties about issues such as dosing, duration, and patient selection in a way that can inform regulatory decision-making.

iii. Sponsors who do not participate in the pilot will have an opportunity to interact with the Agency through traditional channels.

d. By end of FY 2019, FDA will publish draft guidance, or revise relevant existing guidance, on model-informed drug development.

e. By 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.

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 review work necessary to evaluate complex adaptive, 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.

b. Starting in FY 2018, FDA will conduct a pilot program for highly innovative trial designs for which analytically derived properties (e.g., Type I error) may not be feasible, and simulations are necessary to determine trial operating characteristics. For INDs in the pilot program, FDA will grant a pair of meetings specifically designed for this pilot program, consisting of an initial and follow-up meeting on the same design, to occur within a span of approximately 120 days. These meetings will be led by the biostatistical review components within CDER or CBER. The opportunity for increased interaction with the agency will provide better understanding of the agency's requirements for trial simulations involved in the use of the pilot study design and allow for iteration of design modifications, if needed. In return, FDA's ability to publicly discuss example designs will provide better clarity on the acceptance of different types of trial designs that should facilitate their use in future development programs.

i. FDA will publish a Federal Register Notice announcing the pilot program, clarifying pilot program eligibility, and describing the proposal submission and selection process.

ii. FDA will select up to 2 proposals (e.g., 1 per Center) quarterly each year. FDA will convene an internal review group to review proposals on a quarterly basis and provide recommendations on prioritization and selection of proposals and share knowledge and experience. Program selection will be prioritized based on trial design features and therapeutic areas of high unmet need.

iii. To promote innovation in this area, trial designs developed through the pilot program may be presented by FDA (e.g., in a guidance or public workshop) as case studies, including while the drug studied in the trial has not yet been approved by FDA. Before FDA grants the initial meeting, FDA and the sponsor will agree on the information that FDA may share publicly in these case studies. Participation in the pilot program, including such agreement on information disclosure, will be voluntary and at the discretion of the sponsor.

iv. FDA may periodically review the progress of the pilot program and determine whether it is appropriate to adjust any aspects of the program.

v. Sponsors who do not participate in the pilot will have an opportunity to interact with the Agency through traditional channels. The pilot program will not affect FDA's existing procedures for providing advice on trial designs.

c. By 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 clinical trial designs for which simulations are necessary to evaluate the operating characteristics, and the acceptability of those designs in regulatory decision-making.

d. By end of FY 2018, FDA will publish draft guidance on complex adaptive (including Bayesian adaptive) trial designs.

e. By end of FY 2020, FDA will develop or revise, as appropriate, relevant MAPPs, SOPPs and/or review templates and training to incorporate guidelines on evaluating complex clinical trial designs that rely on computer simulations to determine operating characteristics.

5. Enhancing Capacity to Support Analysis Data Standards for Product Development and Review

To support the enhancement of analysis data standards for product development and review in the human drug review program, FDA will conduct the following activities during PDUFA VI:

a. FDA will develop the staff capacity to efficiently review and provide feedback to sponsors on the readiness of submitted analysis data sets and programs for statistical review. This staff will support pre- and post-submission discussion of standardized datasets and programs, and maintain the knowledge of and engage in collaborations about standards models used in the 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 Analysis Data Model (ADaM).

b. In parallel, FDA will improve staff capacity to assist with FDA development and updating of therapeutic area user guides (TAUGs) to include the 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 advance the development and application of analysis data standards.

d. FDA will collaborate with external stakeholders and participate in public workshops held by third parties 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 guidance, MAPPs, SOPPs 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 documentation of submitted analysis data and programs.

6. Enhancing Drug Development Tools Qualification Pathway for Biomarkers

To facilitate the enhancement of the drug development tools qualification pathway for biomarkers, FDA will conduct the following activities during 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 meeting to discuss 1) taxonomy for biomarkers used 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 the 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 uses and 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. Inclusion of a submission on this list will be based on the consent of the submitter for FDA to publish information about the submission, including stage and current status of qualification and the proposed use of the biomarker. Following qualification of a biomarker FDA will post reviews and summary documents that outline the qualification program and data supporting a qualification decision.

g. Sponsors who do not use this qualification pathway will have an opportunity to interact with the Agency through traditional channels.

K. Enhancement and Modernization of the FDA Drug Safety System

FDA will continue to use user fees to enhance and modernize the current U.S. 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 coordination between postmarketing and pre-market review staff, and improving tracking, communication and oversight of postmarketing safety issues. Enhancements to the drug safety system will improve public health by increasing patient protection while continuing to enable access to needed medical products.

User fees will provide support for A) advancing postmarketing drug safety evaluation through expansion of the Sentinel System and integration into 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 fee funds to conduct a series of activities to systematically implement and integrate Sentinel in FDA pharmacovigilance practices. These activities will involve augmenting the quality and quantity of data available through the Sentinel System, improving methods for determining when and how that data is utilized, and comprehensive training of review staff on the use of Sentinel.

a. FDA will work toward expanding the Sentinel System's sources of data and enhancing the system's core capabilities.

b. FDA will enhance its communication with sponsors and the public regarding general methodologies for Sentinel queries, including what the Agency has learned regarding the most appropriate ways to query and use Sentinel data. This can be done through enhancement of existing mechanisms and/or greater frequency of such mechanisms.

c. FDA will evaluate additional ways to facilitate public and sponsor access to Sentinel's distributed data network to conduct safety surveillance.

d. By the end of FY 2019, FDA will hold or support a public meeting engaging stakeholders to discuss current and emerging Sentinel projects and seek stakeholder feedback and input regarding gaps in the current system to facilitate the further development of Sentinel and its system of Active Risk Identification and Analysis (ARIA).

e. By the end of FY 2020, FDA will establish policies and procedures (MAPPs and SOPPs) to facilitate informing sponsors about the planned use of Sentinel to evaluate a safety signal involving their respective products. These MAPPs and SOPPs will address what types of evaluations and what information about the evaluations will be shared with sponsors, and the timing of such communications.

f. By the end of FY 2020, FDA will facilitate integration of Sentinel into the human drug review program in a systematic, efficient, and consistent way through staff development and by updating existing SOPPs and MAPPs, as needed.

g. By the end of FY 2020, FDA will develop a comprehensive training program for review staff (e.g., epidemiologists, statisticians, medical officers, clinical analysts, project managers, and other review team members) to ensure that staff have a working knowledge of Sentinel, can identify when Sentinel can inform important regulatory questions, and are able to consistently participate in use of Sentinel to evaluate safety issues.

h. By the end of FY 2022, FDA will analyze, and report on the impact of the Sentinel expansion and integration on FDA's use of Sentinel for regulatory purposes, e.g., in the contexts of labeling changes, PMRs, or PMCs.

2. Timely and Effective Evaluation and Communication of Postmarketing Safety Findings Related to Human Drugs

FDA will use user fee funds to continue to support the 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, support review, oversight, and communication of postmarketing drug safety issues.

II. ENHANCING MANAGEMENT OF USER FEE RESOURCES

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 enhance flexibility of financial mechanisms to improve management of PDUFA program funding. FDA is committed to enhancing management of PDUFA resources and ensuring 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.

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. FDA will publish a PDUFA program resource capacity planning and modernized time reporting implementation plan no later than the 2nd quarter of FY 2018. FDA will continue to utilize information and recommendations from a third party assessment of resource capacity planning, financial analytics, and modernized time reporting for PDUFA as part of the implementation plan.

2. FDA will staff a resource capacity planning team that will implement and manage a capacity planning system across the PDUFA program in PDUFA VI.

3. FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program. The report will be published no later than end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing resource needs of the program. This will include the adoption of a new resource capacity adjustment methodology, in place of the current PDUFA workload adjuster, that accounts for sustained increases in PDUFA workload.

4. FDA recognizes that revenue generated by the workload adjuster and the resource

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 document in the annual financial report how the workload adjuster and resource capacity adjustment fee revenues are being utilized.

B. Financial Transparency and Efficiency

FDA is committed to ensuring PDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct activities to evaluate the financial administration of the PDUFA program to help identify areas to enhance efficiency. FDA will also conduct activities to enhance transparency of PDUFA program resources.

1. FDA will contract with an independent third party to conduct an evaluation of PDUFA program resource management 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 process from when FDA receives the user 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 execution. 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 resource management and planning practices. The contractor will recommend options for the technical capabilities needed by financial personnel involved in PDUFA 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 5-year 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 starting in FY 2019 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.

III. IMPROVING FDA HIRING AND RETENTION OF REVIEW STAFF

To speed and improve development of safe and effective new therapies for patients, enhancements to the human drug review program require that FDA hire and retain sufficient numbers and types of technical and scientific experts to efficiently conduct reviews of human drug applications. In order to strengthen this core function and increase the public health impact of new therapies, 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 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 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 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.

3. Complete implementation of corporate recruiting.

a. For 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 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 Scientific Staffing for Human Drug Review Program

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 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 process for the review of human drug applications.

a. The unit will continuously develop and implement scientific staff hiring strategies and plans, working closely with the center review offices and the FDA HR office, to meet discipline-specific hiring commitments and other targeted staffing needs. It will function as a scientific-focused recruiter conducting ongoing proactive outreach to source qualified candidates, and conducting competitive recruiting to fill vacancies that require top scientific, technical and professional talent.

b. The unit will conduct analyses, no less than annually, of compensation and other factors affecting retention of key staff in targeted disciplines, providing 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.

D. Set Clear Goals for Human Drug Review Program Hiring

1. FDA will establish priorities for management of the metric goals for targeted hires within the human drug review program staff for the years of PDUFA VI. These goals for targeted hires are summarized in Table 6 below:

TABLE 6

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
CDER	43	57	45	17	9
CBER	16	8	7	1	0
Other FDA	12	9	6	0	0
Total FTE	71	74	58	18	9

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 website 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 the performance initiatives identified in sections III.A–D, and metrics including, but not limited to, those related to recruiting 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 staff hiring. 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 include 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 report to be 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 its 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 achieve 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. The description should cover the complete process undergone by a submission from the completion of its upload to the Electronic System Gateway (ESG) through the time the submission is made available to the review team.

b. The rejection process for electronic submissions.

c. The electronic submission validation criteria.

d. Software names and versions for Electronic Common 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 Eastern Time). ESG availability is defined for the purposes of this commitment letter as the ability for an external user to complete a submission from each entry point to its delivery to the appropriate FDA Center.

b. Post current ESG operational status on its public website.

c. Publish submission instructions to use in the event of an ESG service disruption.

3. By December 31, 2017, FDA will publish target time frames for the 1) expected submission upload duration(s) and 2) timeframe between key milestones and notifications as defined in 1(a).

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 review staff for submission navigation and troubleshooting.

6. For those systems that sponsors interact with directly, FDA will invite industry to provide feedback and/or participate in user acceptance 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 ample advance notification of systems and process changes commensurate with the complexity of the change and the impact to sponsors for ESG scheduled unavailability and user interface changes.

C. Enhance Transparency and Accountability of FDA Electronic Submission and Data Standards Activities

1. FDA staff and industry will jointly plan and hold quarterly meetings and will share performance updates prior to each meeting. The meeting will address current challenges and emerging needs.

2. Beginning no later than September 30, 2018, FDA will hold annual public meetings to seek stakeholder input related to electronic submission system past performance, future targets, emerging industry needs and technology initiatives to inform the FDA IT Strategic Plan and published targets.

3. By December 31, 2017, FDA will post, at least annually, historic and current metrics on ESG performance in relation to published targets, characterizations and volume of submissions, and standards adoption and conformance.

4. By December 31, 2017, FDA will incorporate strategic initiatives in support of PDUFA goals into the FDA 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.

5. FDA will:

a. Collaborate with Standards Development Organizations and stakeholders to ensure long-term sustainability of supported data standards.

b. Publish a data standards action plan updated at least quarterly.

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 Foster

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 program

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 communicating during 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.5.

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.J.2.

4. Analysis of the impact of the Sentinel expansion and use for regulatory purposes as described in Section I.K.1.

5. Assessment of how FDA data systems and processes, as described in MAPPs and SOPPs, support review, oversight, and communication of postmarketing drug safety issues, as described in Section I.K.2.

6. Evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program as described in Section II.A.3.

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 II.B.1.

8. Comprehensive and continuous assessment of hiring and retention as described in Section III.E.

VI. PROGRESS 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 used 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 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 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 approvable letter) that include the following items only (or combinations of these items):

a. Final printed labeling

b. Draft labeling

c. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and

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. Stability updates to support provisional or final dating periods

e. Commitments to perform Phase 4 studies, including proposals for such studies

f. Assay validation data

g. Final release testing on the last 1–2 lots used to support approval

h. A minor reanalysis of data previously submitted to the application

i. 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

6. 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 on an over-the-counter (OTC) basis through an NDA or switched from prescription to OTC status through an NDA or supplement.

8. As used in this commitment letter, ''regulatory decision making'' may include, for example, FDA's process for making a regulatory decision regarding 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 a copy of the commitment letter for the Biosimilar User Fee Act, BsUFA, reauthorization for fiscal years 2018 to 2022, known as BsUFA II.

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

BIOSIMILAR BIOLOGICAL PRODUCT REAUTHORIZATION 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

E. Review of Proprietary Names to Reduce Medication Errors

F. Major Dispute Resolution

G. Clinical Holds

H. Special Protocol Question Assessment and Agreement

I. Meeting Management Goals

II. Advancing Development of Biosimilar Biological Products Through Further Clarification of the 351(k) Regulatory Pathway

III. Enhancing Capacity for Biosimilar Regulations and Guidance Development, Reviewer Training, and Timely Communication

IV. Enhancing Management of User Fee Resources

A. Resource Capacity Planning and Modernized Time Reporting

B. Financial Transparency and Efficiency

C. Management of Carryover Balance

V. Improving FDA Hiring and Retention of Review Staff

A. Completion of Modernization of the Hiring System Infrastructure and Augmentation of System Capacity

B. Augmentation of Hiring Staff Capacity and Capability

C. Complete Establishment of a Dedicated Function to Ensure Needed Scientific Staffing for Human Drug Review Including for Review of Biosimilar Biological Products

D. Set Clear Goals for Biosimilar Biological Product Review Program Hiring

E. Comprehensive and Continuous Assessment of Hiring and Retention

VI. Definitions and Explanation of Terms

BIOSIMILAR BIOLOGICAL PRODUCT AUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FOR FISCAL YEARS 2018 THROUGH 2022

This document contains the performance goals and procedures for the Biosimilar User Fee Act (BsUFA) reauthorization for fiscal years (FYs) 2018–2022, known as BsUFA II. 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 and procedural goals and other commitments specified in this letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. FDA is committed to meeting the performance goals specified in this letter, enhancing management of BsUFA resources, and ensuring BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner.

Under BsUFA II, FDA is committed to ensuring effective scientific coordination and review consistency, as well as efficient governance and operations across the biosimilar biological product review program. In addition, FDA is committed to the principles articulated in the Good Review Management Principles and Practices (GRMP) guidance,[1] which FDA intends to update and apply to the review of biosimilar and interchangeable products.

FDA and the regulated industry will periodically and regularly assess the progress of the biosimilar biological product review program throughout BsUFA II. This will allow FDA and the regulated industry to identify emerging challenges and develop strategies to address these challenges to ensure the efficiency and effectiveness of the biosimilar biological product review program.

I. ENSURING THE EFFECTIVENESS OF THE BIOSIMILAR BIOLOGICAL PRODUCT REVIEW PROGRAM

A. Review Performance Goals

1. Biosimilar Biological Product Application Submissions and Resubmissions

a. Review and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60 day filing date.

b. Review and act on 90 percent of resubmitted original biosimilar biological product applications within 6 months of receipt.

2. Supplements with Clinical Data

a. Review and act on 90 percent of original supplements with clinical data within 10 months of receipt.

b. Review and act on 90 percent of resubmitted supplements with clinical data within 6 months of receipt.

3. Original Manufacturing Supplements

a. In FY 2018, review and act on 70 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

b. In FY 2019, review and act on 75 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

c. In FY 2020, review and act on 80 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

d. In FY 2021, review and act on 85 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

e. In FY 2022, review and act on 90 percent of manufacturing supplements requiring prior approval within 4 months of receipt.

f. Review and act on 90 percent of all other manufacturing supplements within 6 months of receipt.

4. Goals Summary Tables

TABLE 1.—ORIGINAL AND RESUBMITTED APPLICATIONS AND SUPPLEMENTS

Original Biosimilar Biological Product Application Submissions.	90% in 10 months of the 60 day filing date.
Resubmitted Original Biosimilar Biological Product Applications.	90% in 6 months of the receipt date.
Original Supplements with Clinical Data.	90% in 10 months of the receipt date.
Resubmitted Supplements with Clinical Data.	90% in 6 months of the receipt date.

TABLE 2.—MANUFACTURING SUPPLEMENTS

	Prior approval	All other
Manufacturing Supplements	• FY 2018: 70% in 4 months of the receipt date • FY 2019: 75% in 4 months of the receipt date • FY 2020: 80% in 4 months of the receipt date • FY 2021: 85% in 4 months of the receipt date • FY 2022: 90% in 4 months of the receipt date	90% in 6 months of the receipt date.

5. Review Performance Goal Extensions

a. Major Amendments

i. A major amendment 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 re-analysis of previously 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 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 articulated in the GRMP guidance, FDA's decision to extend the review clock 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 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.

ii. If, 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, the goal date may be extended.

1. If FDA identifies the need to inspect a manufacturing facility that is 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 identifies the need to 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

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 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 interchangeable biological products.

The standard approach for the review of original 351(k) 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 original 351(k) 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 to discuss the application, i.e., an ''application orientation meeting''). If appropriate, the Formal Communication Plan should specify those elements of the Program that FDA and the sponsor agree are unnecessary for the application under review. If the review team and the applicant anticipate developing a Formal Communication Plan, the elements of the plan should 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 based on the progress of the review and 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.

The remainder of this 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 planned content of the application with the appropriate FDA review division at a BPD Type 4 (pre–351(k) BLA) meeting. This meeting will be attended by the FDA review team, including appropriate senior FDA staff.

a. The BPD Type 4 (pre–351(k) 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 regarding the approach to developing the content for REMS, where applicable, patient labeling (e.g., Medication Guide and Instructions For Use) and, where applicable, the development of a Formal Communication Plan. These discussions will be summarized at the conclusion 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 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.

i. Examples of application components that may be appropriate for delayed submission include; stability updates, the final audited report of a preclinical study (e.g., toxicology) where the final draft report is submitted with the original application, or a limited amount of the data from an assessment of a single transition from the reference product to the proposed biosimilar biological product, where applicable.

ii. Major components of the application (e.g., the complete analytical similarity assessment, the complete study report of a comparative clinical study or the full study report of necessary immunogenicity data) are expected to be submitted with the original application and are 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 BPD Type 4 (pre–351(k) BLA) meeting, at the time of original submission of the application. If the applicant does not have a BPD Type 4 (pre–351(k) 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 components of the application that FDA agreed at the pre-submission 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.

c. Incomplete 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.

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 not be eligible for the other parameters 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. The resubmission goal described in Section I.A.1.b will not apply to any resubmission of the application following an FDA complete response action. Any such resubmission will be reviewed as available resources permit.

e. Since applications are expected to be complete at the time of submission, unsolicited 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 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.

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. The planned timeline for review of the application included in the Day 74 letter for applications in the Program will include:

a. the planned date for the internal mid-cycle review meeting,

b. preliminary plans on whether to hold an Advisory Committee (AC) meeting to discuss the application,

c. a target date for communication of feedback from the review division to the applicant regarding proposed labeling and any postmarket requirements or postmarket commitments the Agency will be requesting.

4. Review performance goals: For original 351(k) BLA submissions that are filed by FDA under the Program, the BsUFA review clock will begin at the conclusion of the 60 calendar day filing review period that begins on the date of FDA receipt of the original submission. The review performance goals for these applications are as follows:

a. Review and act on 90 percent of original 351(k) BLA submissions within 10 months of the 60 day filing date.

5. 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 sent to the applicant prior to the mid-cycle communication. Scheduling of the internal mid-cycle review 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 major concerns with the following:

a. The analytical similarity data, including the potential relevance of any issues (e.g. data analysis issues or potential clinical impact of observed analytical 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, updates regarding plans for the AC meeting (if an AC meeting is anticipated), and other projected milestone dates for the remainder of the review cycle.

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 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 parameters apply:

i. FDA intends to convene AC meetings no later than 2 months prior to the BsUFA 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 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 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 BsUFA 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 issues to date, 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 content of proposed REMS or other risk management actions, where applicable.

e. Late-Cycle Meeting Discussion Topics: Potential topics for discussion at the late-cycle meeting include:

i. major deficiencies identified to date;

ii. analytical similarity data, including the potential relevance of any issues (e.g. data analysis issues or potential clinical impact of observed analytical differences), intended to support a demonstration that the proposed biosimilar biological product is highly similar to the reference product;

iii. data intended to support a demonstration of no clinically meaningful differences, including discussion of any immunogenicity issues;

iv. data 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 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 BsUFA goal date.

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 biological products. The assessment shall be conducted by an independent contractor with expertise in assessing the 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 assessments 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 the following:

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

completeness and quality of the submitted application

number of unsolicited amendments submitted by the applicant

timing and adequacy of Day 74 letters

conduct of the mid-cycle communication

any DR letters issued

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

percentage of application reviews that are extended due to a major amendment

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 de-identified analysis of the issues typically discussed during the mid-cycle communication and the late-cycle meeting and the ability of the additional FDA-applicant communications to (a) achieve resolution of these issues during the remainder of the review clock, or (b) allow the applicant to better prepare for a resubmission of the application. Following an FDA regulatory action, the independent contractor will conduct separate interviews of the applicant and the FDA review team to understand each party's perspectives on the review of the application, including whether issues were or should have been identified at the BPD meetings to facilitate application review.

An interim and final assessment of the Program will be published for public comment, with each report followed by a public meeting during which public stakeholders may present their views on the success of the Program to date, including the ability of the Program to help ensure that patients have timely access to safe, effective, and high quality biosimilar biological products. During each public meeting, FDA and the independent contractor will discuss the findings of the interim assessment, including anonymized aggregated feedback from sponsors and FDA review teams resulting from independent contractor interviews. FDA will discuss any issues identified to date including any proposed plans to improve the likelihood of the Program's success.

a. Interim Assessment: An interim assessment of the Program will be published by December 31, 2020, and FDA will hold a public meeting by March 31, 2021.

b. Final Assessment: A final assessment of the Program will be published by June 30, 2022, and FDA will hold a public meeting by September 30, 2022.

C. First Cycle Review Management for Supplements with Clinical Data

1. Notification of Issues Identified during the Filing Review

a. Performance Goal: For supplements with clinical data, FDA will report substantive review issues identified during the initial filing review to the applicant by letter.

b. The timeline for such communication will be within 74 calendar days from the date of FDA receipt of the supplement.

c. If no substantive review issues were identified during the filing review, FDA will so notify the applicant.

d. 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.

e. FDA will notify the applicant of substantive review issues prior to or on the goal date for 90% of applications.

2. Notification of Planned Review Timelines

a. Performance Goal: For supplements with clinical data, FDA will inform the applicant of the planned timeline for review of the application. The information conveyed will include a target date for communication of feedback from the review division to the applicant regarding proposed labeling, post-marketing requirements, and postmarketing commitments the Agency will be requesting.

b. The planned review timeline will be included with the notification of issues identified during the filing review, within 74 calendar days from the date of FDA receipt of the original supplement.

c. The planned review timelines will be consistent with the GRMP guidance.

d. The planned review timeline will be based on the supplement as submitted.

e. FDA will inform the applicant of the planned review timeline for 90% of all supplements with clinical data.

f. In the event FDA determines that significant deficiencies in the supplement preclude discussion of labeling, postmarketing requirements, or postmarketing commitments by the target date identified in the planned review timeline (e.g., significant safety concern(s), need for a new study(ies) or extensive re-analyses of existing data before approval), FDA will communicate this determination to the applicant in accordance with GRMPs and no later than the target date. In such cases the planned review timeline will be considered to have been met. Communication of FDA's determination may occur by letter, teleconference, facsimile, secure e-mail, or other expedient means.

g. To help expedite the development of biosimilar biological products, communication of the deficiencies identified in the supplement may occur through issuance of a DR letter(s) in advance of the planned target date for initiation of discussions regarding labeling, postmarketing requirements, and postmarketing commitments the Agency may request.

f. If the applicant submits a major amendment(s) (refer to Section I.A.5.a for additional information on major amendments) and the review division chooses to review such amendment(s) during that review cycle, the planned review timeline initially communicated (under Section I.C.2.a and b) will generally no longer be applicable. 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 supplement deficiencies and leads toward a first cycle approval when possible.

D. Guidance

FDA and industry share a commitment to ensuring an efficient and effective first cycle review process for all applications subject to the BsUFA program. This commitment is consistent with the principles articulated in the GRMP guidance, which FDA applies to the review of biosimilar and interchangeable products. FDA will update the GRMP guidance during BsUFA II to ensure that it encompasses all review activities for biosimilar and interchangeable products, including principles regarding notification to applicants regarding issues identified during FDA's initial review of the application, principles regarding FDA's notification to applicants regarding planned review timelines, and the importance of internal review timelines that govern aspects of biosimilar and interchangeable product review that are not part of BsUFA performance goals. FDA will publish a revised draft guidance for public comment no later than the end of FY 2018. 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.

E. 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 apply to FDA's review of biosimilar biological product proprietary names during the biosimilar biological product development (BPD) phase and during FDA's review of a marketing application:

1. Proprietary Name Review Performance Goals During The BPD Phase

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 would 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 biosimilar biological product proprietary name submissions filed within 90 days of receipt. Notify sponsor of tentative acceptance/non-acceptance.

b. A supplemental review will be done meeting the above review performance goals if the proprietary name has been submitted previously (during the BPD phase) and has received tentative acceptance.

c. 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).

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.

F. Major Dispute Resolution

1. Procedure: For procedural or scientific matters involving the review of biosimilar biological product applications and supplements (as defined in BsUFA) 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 occur within 30 calendar days of the Center's receipt of the written appeal.

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 on the appeal. In these 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, 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 has 30 calendar days from the receipt of the required information in which to either deny or grant the appeal.

f. 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.

g. Note: If the Agency decides to present the issue to an advisory committee and there are not 30 days before the next scheduled advisory committee, the issue will be presented at the following scheduled committee meeting to allow conformance with advisory committee administrative procedures.

G. Clinical Holds

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.

2. Performance goal: 90% of such 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 related 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 there are 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 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 goals of the sponsor, the reasons for the disagreement will be explained in the response.

c. Protocols that qualify for this program include any necessary clinical study or studies to prove biosimilarity and/or interchangeability (e.g., protocols for pharmacokinetics and pharmacodynamics studies, protocols for comparative clinical studies that will form the primary basis for demonstrating that there are no clinically meaningful differences between the proposed biosimilar biological product and the reference product, and protocols for clinical studies intended to support a demonstration of interchangeability). For such protocols to qualify for this comprehensive protocol assessment, the sponsor must have had a BPD Type 2 or 3 Meeting, as defined in section I.I, below, 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.

d. If a protocol is reviewed under the process outlined above, and agreement with the Agency is reached on design, execution, and analyses, and if the results of the trial conducted under the protocol substantiate the hypothesis of the protocol, the Agency agrees that the data from the protocol can be used as part of the primary basis for approval of the product. The fundamental agreement here is that having agreed to the design, execution, and analyses proposed in

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 protocols 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 BsUFA 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 initial assessment limited to a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product, and, if so, general advice on the expected content of the development program. Such term does not include any meeting that involves substantive review of summary data or full study reports.

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 clinical holds, dispute resolution 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 will provide targeted advice regarding an ongoing biosimilar biological product development program. Such term may include 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 the similarity between 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 351(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 those studies that the sponsor is relying on to support a demonstration of biosimilarity or interchangeability, discussion of any potential review issues identified based on the information provided, identification of the status of ongoing or needed studies to adequately to address the Pediatric Research Equity Act (PREA), acquainting 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 in writing 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 1

Meeting type	Response time (calendar days)
Biosimilar Initial Advisory	21
BPD Type 1	14
BPD Type 2–4	21

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 2

Meeting type	Meeting scheduling or written response time
Biosimilar Initial Advisory.	75 calendar days from receipt of meeting request and background package.
BPD 2	90 calendar days from receipt of meeting request and background package.
Meeting Scheduling Time	
BPD 1	30 calendar days from receipt of meeting request and background package.
BPD 3	120 calendar days from receipt of meeting request and background package.
BPD 4	60 calendar days from receipt of meeting request and background package.

b. Performance goal:

TABLE 3

Meeting type	Goal
BPD Type 2	FY 2018–2019: 80% of meetings are held or written responses are sent within the timeframe. FY 2020–2022: 90% of meetings are held or written responses are sent within the timeframe.
Biosimilar Initial Advisory.	90% of meetings are held or written responses are sent within the timeframe.
BPD Type 1, 3, and 4.	90% of meetings are held within the timeframe for each meeting type.

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 4

Meeting type	
BPD Type 2	• FY 2018: 70% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date. • FY 2019, 75% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date. • FY 2020, 80% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date. • FY 2021, 85% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date. • FY 2022, 90% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date.
BPD Type 3	90% of preliminary responses to questions are issued by FDA no later than five calendar days before the meeting date.

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 action 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 these 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:

i. 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 face-to-face meeting, teleconference, or for a written response (Biosimilar Initial Advisory and BPD Type 2 meetings only);

ii. A listing of the specific objectives/outcomes the requester expects from the meeting;

iii. A proposed agenda, including estimated times needed for each agenda item;

iv. A list of questions, grouped by discipline. For each question there should be a brief explanation of the context and purpose of the question.

v. A listing of planned external attendees; and

vi. A listing of requested participants/disciplines representative(s) from the Center with an explanation for the request as appropriate.

vii. 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.

c. 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 honored 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 under section 744H, and the sponsor does not 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 Communication Between IND Sponsors and FDA During Drug Development, as appropriate, to apply to communications between IND sponsors and FDA during biosimilar biological product development. FDA will publish a revised draft or final guidance by December 31, 2018.

II. ADVANCING DEVELOPMENT OF BIOSIMILAR BIOLOGICAL PRODUCTS THROUGH FURTHER CLARIFICATION OF THE 351(K) REGULATORY PATHWAY

A. On or before December 31, 2017, FDA will publish draft guidance describing considerations in demonstrating interchangeability with a reference product. FDA will work 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 considerations for the analysis of analytic similarity data intended to support a demonstration 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 31, 2019, FDA will publish draft guidance describing processes and further considerations related to postapproval manufacturing changes 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.

D. FDA will work towards the goal of publishing revised draft guidance or final guidance documents on or before May 31, 2019 for draft guidances published between January 1, 2014 and September 30, 2017, other than those described in (II.A–C). These draft guidances will include:

1. Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product (draft guidance published in May 2014)

2. Nonproprietary Naming of Biological Products (draft guidance published in August 2015)

3. Labeling for Biosimilar Biological Products (draft guidance published in March 2016)

III. ENHANCING CAPACITY FOR BIOSIMILAR REGULATIONS AND GUIDANCE DEVELOPMENT, REVIEWER TRAINING, AND TIMELY COMMUNICATION

A. FDA will strengthen the staff capacity to develop new regulations and guidance to clarify scientific criteria for biosimilar development 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 application of new policies and guidance by review 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 biosimilarity and interchangeability.

D. FDA will strengthen staff capacity to deliver information concerning the date of first licensure and the reference product exclusivity expiry date, to be included in the Purple Book.

FDA will update the Purple Book to include the following information: the BLA number, product name, proprietary name, date of licensure, interchangeable or biosimilar 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 addition, within 30 days after FDA determines the date of first licensure, the date of first licensure and the reference product exclusivity 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 predictable user fee funding, improve the predictability of FDA funding and sponsor invoices, improve efficiency by simplifying the administration of user fees, and enhance flexibility of financial mechanisms to improve management of BsUFA program funding. FDA is committed to enhancing management of BsUFA resources and ensuring BsUFA 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 BsUFA resources in BsUFA II.

A. Resource Capacity Planning and Modernized Time Reporting

FDA is committed to enhancing management of BsUFA resources in BsUFA II. FDA will conduct activities to develop a resource capacity planning function and modernized time reporting approach in BsUFA II.

1. FDA will publish a resource capacity planning and modernized time reporting implementation plan that includes BsUFA no later than the 2nd quarter of FY 2018. FDA will continue to utilize information and recommendations from a third party assessment of resource capacity planning, financial analytics, and modernized time reporting for BsUFA as part of the implementation plan.

2. FDA will staff a resource capacity planning team that will implement and manage a capacity planning system across the BsUFA program in BsUFA II.

3. FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the biosimilar biological product review program. The BsUFA evaluation will be conducted under the same contract and by the same independent accounting or consulting firm that will evaluate options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program in PDUFA VI. The report will be published no later than end of FY 2020 for public comment. Upon review of the report and comments, FDA will implement robust methodologies for assessing resource needs of the program. This will include the adoption of a new resource capacity adjustment methodology that accounts for sustained increases in BsUFA workload.

4. FDA recognizes that revenue generated by the 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 document in the annual financial report how the capacity adjustment fee revenues are being utilized.

B. Financial Transparency and Efficiency

FDA is committed to ensuring BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. FDA will conduct activities to evaluate the financial administration of the BsUFA program to help identify areas to enhance efficiency. FDA will also conduct activities to enhance transparency of BsUFA program resources.

1. FDA will contract with an independent third party to conduct an evaluation of BsUFA program resource management during FY 2018 to ensure that BsUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner in BsUFA II. The BsUFA evaluation will be conducted under the same contract and by the same independent third party that will conduct an evaluation of the PDUFA program resource management. The study will include, but is not limited to, the following areas:

a. Evaluate all components of the BsUFA program resource planning, request, and allocation process from when FDA receives the user 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 BsUFA user fees organizationally, including, but not limited to, billing, user fee collection, and execution. The contractor will recommend options to enhance the efficiency of user fee administration.

c. Evaluate FDA's existing BsUFA 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 biosimilar biological product review program.

d. Assess FDA's technical capabilities to conduct effective financial management and planning in the context of generally accepted government resource management and planning practices. The contractor will recommend options for the technical capabilities needed by financial personnel involved in BsUFA resource management to enhance financial management and planning.

2. FDA will publish a BsUFA five-year financial plan no later than the 2nd quarter of FY 2018. FDA will publish updates to the five-year 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 starting in FY 2019 to discuss the BsUFA five-year financial plan, report on the contribution of the BsUFA spending trigger to the BsUFA program, along with the Agency's progress in implementing modernized time reporting, resource capacity planning, and the modernized user fee structure.

C. Management of Carryover Balance

FDA is committed to reducing the carryover balance to no greater than 21 weeks of the FY 2022 target revenue by the end of FY 2022. However, if FDA is unable to reduce the carryover balance to no greater than 21 weeks during the final year (e.g., over collections in FY 2022 that increase the carryover balance beyond 21 weeks), FDA will (1) outline its plan to reduce the carryover balance to no greater than 21 weeks in the FY 2022 BsUFA financial report and (2) update the BsUFA five-year financial plan.

V. IMPROVING FDA HIRING AND RETENTION OF REVIEW STAFF

To speed and improve development of safe and effective biosimilar biological products

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 conduct reviews of 351(k) applications. 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 management 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. 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.

3. Complete implementation of corporate recruiting

a. For key scientific and technical disciplines commonly needed across offices engaged in the biosimilar biological product 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 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 BsUFA II goals for recruitment 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 therapies. FDA will complete the 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.

a. The unit will continuously develop and implement scientific staff hiring strategies and plans, working closely with the center review offices and the FDA HR office, to meet discipline-specific hiring commitments and other targeted staffing needs. It will function as a scientific-focused recruiter conducting ongoing proactive outreach to source qualified candidates, and conducting competitive recruiting to fill vacancies that require top scientific, technical, and professional talent.

b. The unit will conduct analyses, no less than annually, 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.

D. 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, FDA will target hiring 15 FTE in FY 2018, to enhance capacity for biosimilar guidance development, reviewer training, and timely communication.

2. FDA will confirm progress in the hiring of BsUFA I FTEs. FDA will report on progress against the hiring goal for BsUFA II on a quarterly basis posting updates to the FDA website BsUFA Performance webpage.

E. Comprehensive and Continuous Assessment of Hiring and Retention

FDA hiring and retention of staff for the biosimilar biological product review program will be evaluated by a qualified, independent contractor with expertise in assessing HR operations and transformation. The BsUFA II assessment will be conducted under the same contract and by the same independent contractor that will conduct the assessment related to hiring and retention of staff for the human drug review program in PDUFA VI. It will include continuous assessments throughout the course of implementation of the performance initiatives identified in Sections V.A–D, and metrics including, but not limited to, those related to recruiting and retention in the PDUFA and BsUFA review programs 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 PDUFA or BsUFA review program staff hiring. 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 BsUFA II.

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 include 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 report to be 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 its 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.

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, 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.

B. A resubmitted original application is a complete response to an action letter addressing all identified deficiencies.

ARMS SALES NOTIFICATION

Mr. CORKER. Mr. President, section 36(b) of the Arms Export Control Act requires that Congress receive prior notification of certain proposed arms sales as defined by that statute. Upon such notification, the Congress has 30 calendar days during which the sale may be reviewed. The provision stipulates that, in the Senate, the notification of proposed sales shall be sent to the chairman of the Senate 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, room SD–423.

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

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. 17–38, concerning the Navy's proposed Letter(s) 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, as amended

(i) Prospective Purchaser: Government of Australia.

(ii) Total Estimated Value:
Major Defense Equipment *$0.0 million
Other $108.7 million
Total $108.7 million

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:
Major Defense Equipment (MDE): None
Non-MDE includes:
One thousand nine hundred fifty-two (1,952) ALE–70(V)/T–1687A Electronic Towed Decoy Countermeasures, publications and technical documentation, other technical assistance, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support.

(iv) Military Department: Navy (XX–P–AMN Al)

(v) Prior Related Cases, if any: None

(vi) Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid: None

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Attached Annex

(viii) Date Report Delivered to Congress: August 02, 2017.

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Australia—ALE–70 Radio Frequency Countermeasures (RFCM)

The Government of Australia has requested the possible sale of one thousand nine hundred fifty-two (1,952) ALE–70(V)/T–1687A Electronic Towed Decoy Countermeasures, publications and technical documentation, other technical assistance, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support. The total estimated program cost is $108.7 million.

This sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a major non-NATO ally and continues to be an important force for political stability, security, and economic development in the Western Pacific. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability.

The proposed sale will improve Australia's F–35 survivability and will enhance its capability to deter global threats, strengthen its homeland defense, and cooperate in coalition defense initiatives. Australia will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be British Aerospace Enterprise (BAE), Nashua, NH. There are no offsets proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

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 and emits waveforms in response to commands from the countermeasure controller located in the jet. The waveforms are utilized to confuse or decoy adversary radars or radar guided weapons. Designed and produced by BAE Systems of Nashua, New Hampshire, the ALE–70 employs amplifiers based on Gallium Nitride (GaN) technology to meet stringent output requirements.

2. The ALE–70 generates, amplifies, and transmits signals in response to commands from the countermeasures controller which remains aboard 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 elements, the information could be used to develop countermeasures or equivalent system 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 being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

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.

Enclosures.

TRANSMITTAL NO. 16–55

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) Prospective Purchaser: The Federal Republic of Nigeria

(ii) Total Estimated Value:
Major Defense Equipment $29 million
Other $564 million
Total $593 million

(iii) Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:
Major Defense Equipment (MDE):
One hundred (100) GBU–12 (500lb) Paveway II (PW–II) Tailkits
One hundred (100) GBU–58 (250lb) PW–II Tailkits
Four hundred (400) Laser Guided Rockets including Advanced Precision Kill Weapon System (APKWS)
Two thousand (2,000) MK–81 (250lb) bombs
Five thousand (5,000) 2.75 inch Hydra 70 Unguided Rockets (70mm rockets)
One thousand (1,000) 2.75 inch Hydra 70 Unguided Rockets (practice)
Twenty thousand (20,000) Rounds, .50 Caliber Machine Gun Ammo
Non-Major Defense Equipment (MDE): This request also includes the following Non-MDE: Twelve (12) A–29 Super Tucano aircraft, seven (7) AN/AAQ–22F Electro-Optical/Infrared (EO/IR) Sensor and Laser Designators, Initial Spares, Readiness Spares Package, Consumables, Support Equipment, Technical Data, Repair and Return Support, Facilities infrastructure and hangar construction, Night Vision Devices (NVDs), Contract Logistics Services (CLS), Contractor Provided Familiarization and Training, USG Manpower and Services, Field Service Representatives, Training Services (pilot training, USAF training, early A–29 training, flight leader upgrade training, travel and living allowance, maintenance training, specialized training, computer-based training, night vision device training, human rights and international humanitarian law, and munitions training), Training Simulators, Air Worthiness Support, Forward Operating Base Facilities, Forward Operating Location Support, Ferrying, and Non-recurring Engineering. Additionally, all aircraft will include weapons software to support forward looking infrared sensors (FLIRs), ancillary system.

(iv) Military Department: Air Force (X8–D–SAB)

(v) Prior Related Cases, if any: None

(vi) Sales Commission, Fee, etc., Paid, Offered. or Agreed to be Paid: None

(vii) Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold: See Annex attached.

(viii) Date Report Delivered to Congress: Aug 02 2017

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Nigeria—A–29 Super Tucano Aircraft, Weapons and Associated Support

The Government of Nigeria requests twelve (12) A–29 Super Tucano aircraft and weapons, including all associated training, spare parts, aviation and ground support equipment, and hangar, facilities, and infrastructure required to support the program. The estimated total case value is $593 million.

These aircraft will support Nigerian military operations against terrorist organization Boko Haram and to counter illicit trafficking in Nigeria and the Gulf of Guinea. The Super Tucano is a sustainable platform for counterterrorism, counter insurgency, border surveillance, and illicit trade interdiction operations. The proposed sale will support U.S. foreign policy objectives by helping Nigeria to meet shared counterterrorism objectives for the region. This proposed sale will strengthen the U.S. security relationship with Africa's largest democracy. Nigeria will have no difficulty absorbing these aircraft into its armed forces.

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 offset 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.

TRANSMITTAL NO. 16–55

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. This sale involves the release of sensitive weapons software technology information to Nigeria. Software associated with the following weapons will be included in the aircraft operational flight program to support a future weapons capability.

2. Sensitive and/or classified (up to SECRET) elements of the proposed A–29 sale to Nigeria includes the hardware and associated software with: Advanced Precision Kill Weapon System (APKWS) laser guided rockets, Guided Bomb Unit (GBU)–12/58 Paveway II laser guided tail kits, and Mark (MK)–81/82 general purpose bombs.

3. The Hydra 70 Rocket System is a modernized version of the 2.75 inch (70 mm) unguided rocket body with the MK66 Rocket Motor.

4. The APKWS is a low cost semi-active laser guidance kit developed by BAE Systems which is added to current unguided 70 mm rocket motors and warheads similar to and including the Hydra 70 rocket. It is a low collateral damage weapon that can effectively strike both soft and lightly armored targets. APKWS turns a standard unguided 2.75 inch (70 mm) rocket into a precision laser-guided rocket, classification up to SECRET.

5. GBU–12/58 Paveway II (PW–II) Tailkits: 500–lb (GBU–12) and 250–lb (GBU–58) are laser-guided ballistic bombs (LGBs) developed by Raytheon and Lockheed Martin. The LGB is a maneuverable, free-fall weapon that guides to a spot of laser energy reflected off of the target. The LGB is delivered like a normal general purpose (GP) warhead and the semi-active guidance corrects for many of the normal errors inherent in any delivery system. Laser designation for the weapon can be provided by a variety of laser target markers or designators. The tailkit consists of a laser guidance kit, a computer control group (CCG) and a warhead specific Air Foil Group (AFG), that attach to the nose and tail of MK 81 and MK 82 General Purpose (GP) bomb bodies to create an LGB. This sale includes the tailkits to transform Nigeria's existing 500-lb and 250-lb GP bomb bodies into GBU–12s and GBU–58s respectively. Nigeria is also buying additional GBU–58s, 250-lb (MK–81) guided bombs. The overall weapon is CONFIDENTIAL.

6. AN/AAQ–22F Brite Star Electro-Optical/Infrared (EO/IR) Multi-Sensor Targeting System developed by FLIR. The system is a five field-of-view (FOV) large format thermal imager, three FOV color daylight camera with laser designator for terminal guidance of LGBs and IR-guided rockets. The system is classified as UNCLASSIFIED.

7. This sale is necessary in furtherance of U.S. foreign policy and national security objectives outlined in the Policy Justification. Moreover, the benefits to be derived from this sale, as outlined in the Policy Justification, outweigh the potential damage that could result if the sensitive technology were revealed to unauthorized persons.

8. All defense articles and services listed in this transmittal are authorized for release and export to the Government of Nigeria.

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 possesses 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 stop investigating 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. The FBI has long outgrown 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 the country of 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 the exchange of ideas and commerce between the two countries.

It is often noted that Cuba is less than 100 miles away, but decades behind 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 thawed under Presidents Bush and Obama, the Cuban Government decided to try something different. Private entrepreneurs are operating an increasing number of restaurants, taxis, and other tourist-related businesses. Cubans 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 continuing to try and ostracize Cuba 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 and support for basic human rights and dignity. 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 made by 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 others, have severely hampered the ability of U.S. exporters to do business in 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 servicemembers, 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 our country as a special amphibious reconnaissance corpsman, providing medical care to his fellow servicemembers.

On Monday, July 10, 2017, Ryan and 15 other servicemembers died tragically when the KC–130 aircraft they were on crashed in Mississippi. The plane was carrying servicemembers 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 procession honored Ryan 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 Maelyn; 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 for us and honor his commitment to serving his fellow citizens. 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 were 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 a family man 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 had dreamed of being a 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 Schools. 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 State Fairgrounds 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, leader, and role model 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 the family a new car battery with his own money. It went beyond that. He participated in ''Shop with a Deputy,'' volunteering to take underprivileged children Christmas 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 made 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 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 peace and safety, and we are eternally 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.

Lt. Allan is survived and deeply missed by his wife, Stacy, their two sons, his fellow officers in Southport, and citizens across Indiana. Let us strive to remember and emulate the shining example Lt. Allan set for us, and honor his selfless commitment to serving his fellow citizens. May God welcome Lt. Allan home and give comfort to his family and friends.

VENEZUELA

Mr. RUBIO. Mr. President, I ask unanimous consent that a statement by Julio Andres Borges Junyent, President of the National Assembly of the Bolivarian Republic of Venezuela, be printed in the RECORD.

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

THE NATIONAL ASSEMBLY OF THE BOLIVARIAN REPUBLIC OF VENEZUELA—IN RESCUE OF THE CONSTITUTION, DEMOCRACY AND HUMAN RIGHTS: AGREEMENT IN DISREGARD OF THE FRAUDULENTS ELECTORAL RESULTS ON JULY 30TH, 2017 FOR WHICH WAS INTENDED TO IMPOSE AN ILLEGITIMATE NATIONAL CONSTITUENT ASSEMBLY, AND IN CLAIM OF THE 1999 CONSTITUTION AS A DEMOCRATIC BASIS OF THE BOLIVARIAN REPUBLIC OF VENEZUELA

CONSIDERING

On July 30th, 2017 the regime of Nicolas Maduro, with the support of the majority of rectors of the National Electoral Council, judges of the Supreme Court of Justice and the high dome of the National Bolivarian Armed Forces, advanced on the fraudulent constituent process that initiated on May 1, 2017, realizing a supposed illegitimate ''election'' of such illegitimate constituent members;

CONSIDERING

The authorities of the National Bolivarian Armed Forces have assumed the prominence in the announcements concerning the electoral process, investing the constitutional principle of subjection of the military civilian authorities; which is a sample of the militarism they intend to impose, in contravention to the enshrined civic and republican values on the current Constitution of 1999;

CONSIDERING

That this National Assembly has pointed out in various agreements, and it was ratified by the Venezuelan people in the referendum of July 16th, 2017, the National Constituent Assembly is a fraudulent and illegitimate process that only seeks to repeal the Constitution of 1999 by other mechanisms than those provided, in order to establish in Venezuela a dictatorship of totalitarian Court, in reason of which all acts and processes arising from such constituent must be unknown to citizens and government employees, who have the duty to restore the validity of the 1999 Constitution, all this, in accordance with the articles 333 and 350;

CONSIDERING

The fraudulent election of July 30th sought to give legitimacy to the constitutional process, despite the fact that such procedure was initiated with the usurpation of the popular sovereignty, which was never consulted about the convocation of the constituent Assembly, as ordered by the constitutional article 347;

CONSIDERING

In addition, the fraudulent election of July 30th was held on the sidelines of international guarantees and constitutional minimum that must be presented in any democratic election, which shows the high despite

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-nine 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 organizations 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, implies a major change in the political and constitutional Venezuelan scene, having to represent the definitive attempt of restoring the dictatorship of totalitarian court protected on the figure of the National Constituent Assembly, which demands the articulation of effective and immediate action orientated to deposing a despotic form of government, contributing to the effective reestablishment of the Constitution in Venezuela, in context of articles 333 and 350 of the Constitution, with the democratic legitimacy derived from the popular consultation on July 16th and the support of the international community committed on the universal defense of human rights and constitutional democracy.

ACCORDING

First: Confirm that all the acts related to the National Constituent Assembly including the supposed election effected on July 30th, 2017 must be unrecognized because it was a process based on usurpation of the popular sovereignty and of the original Constituent power that belongs exclusively to the people of Venezuela. Likewise, we ratify the right to the resistance of the people of Venezuela against the fraudulent and illegal National Constituent Assembly, as the officials and members of the armed forces must do. Armed forces must disobey all the acts related to the fraudulent Constituent Assembly, and actively contribute to re-establish the effective validity of the Constitution of 1999.

Second: Unrecognized the election effected on July 30th, 2017 of the members of the fraudulent and illegal National Constituent Assembly that was convened without a popular referendum, and against the peoples' will and in contrivance of article number 347 of the Constitution.

Third: Reject the massacre and aberrant crimes against the Venezuelans who in their legal right to freedom of expression, of protesting and resisting were demonstrating their rejection to the fraudulent Constituent Assembly, and who were expressing solidarity to the parliamentarian body with the victims of repression, arrests, and family members of the deceased, and with all the Venezuelan people.

Fourth: Ratify the 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 is illegitimate and of fact to establish effectively the validity of the constitution of the Bolivarian Republic of Venezuela.

Fifth: Urge the citizen Luisa Ortega Diaz, in her responsibility of 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 organization and in the electoral process on July 30th, 2017, and to exercise the relevant actions against the officers and people that ordered and executed such crimes, with the purpose to make effective the punitive, administrative, and disciplinary 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 Constituent Assembly.

Sixth: Urge to the Public Minister to overtake investigations and formalities directed to establish the penal responsibility of all public officers and people evolved in the fraudulent process of the National Constituent Assembly that aims to impose a change that violates the constitution and changes the republican foundation of the Nation.

Seventh: Grateful for the solidarity expressed by the International Community with regard to the people of Venezuela and in rejection of the fraudulent National Constituent Assembly, and for arranging necessary meetings to execute common actions of states committed to the universal defense of human rights and of the relevant International Entities, so that through the admitted mechanisms of Public International rights and thus contribute to depose the fraudulent and illegal National Constituent Assembly and to reestablish the effective validity of the Constitution of 1999.

Eighth: Support to the people of Venezuela in the exercise of the right to resist the despotism that the National Constituent Assembly aims to impose. We support both the organized and planned actions that contribute to depose such illegal Constituent Assembly, and the execution of necessary actions to reestablish the validity of the Constitution of the Bolivarian Republic of Venezuela that obeys the mandate of the Popular Consultation that took place on July 16th, 2017.

Ninth: Ratify the people of Venezuela, faithful to its republican tradition, to impugn 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 operation. 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 Nations (UN) to the Inter-American Commission on human rights (IACHR) and the members of the diplomatic corps, specially to the representatives of those States that have spoken out without knowing about the election of the National Constituent Assembly.

Tenth first: Give publicity to this agreement.

Given, signed and sealed in the Federal Legislative Palace, seat of the National Assembly of the Bolivarian Republic of Venezuela, in Caracas, the first day of August of two thousand seventeen. Year 207 of independence and 158 of the Federation.

JULIO ANDRES BORGES JUNYENT;
President of the National Assembly.
FREDDY GUEVARA CORTEZ;
First Vice President.
DENNIS FERNANDEZ SOLORZANO;
Second Vice President.
JOSE IGNACIO GUÉDEZ;
Secretary.
JOSÉ 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, engineering, 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 hope of engaging folks of all ages in the science behind the eclipse. Oregon native Don Pettit, who is a NASA astronaut, will even be there to share his experience 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 opportunity to get communities involved in science.

Universities throughout the State are also doing their part to ensure students and community members get the most out of the event. In Corvallis, Oregon State University is hosting a 3-day eclipse event, with astronomy exhibits 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 events 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 Oregonians 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 sincere hope that it ignites a ray of 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 armored 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 Navy 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 binnacle 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*, SSBN 736. She was launched on October 14, 1989, sponsored by Mrs. Erma Byrd, wife—and high school sweetheart—of the now 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, if 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 forward at 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, dedicated to covering every aspect of life in a place of extraordinary beauty. It is a pleasure to congratulate the two outstanding journalists who have guided the Islander since its inception, publisher Alan Baker and editor Earl Brechlin, for being recognized with the 2017 Sunbeam Award from the Maine Seacoast Mission.

The recipient of numerous State and national awards for excellence, the Mount Desert Islander is a great example of the value provided by community newspapers. From Acadia National Park, local government, and businesses, to education, sports, and the arts, the Islander's dedicated staff writes the history of their communities as it occurs. They keep people informed and help them be more involved as citizens. They follow State and national issues, always with an eye on how they affect their neighbors.

This dedication starts with committed leadership. After achieving success in journalism and publishing in Philadelphia and New York City, Alan Baker returned home to Maine and, in 1986, joined the Ellsworth American's management team, eventually purchasing the newspaper. In this age of media consolidation, Mr. Baker strongly believes that newspapers should be owned by individuals who are in touch daily with the readers they serve. As a former member of the Maine State Legislature, he is an effective voice for accountability and transparency in all levels of government.

A former ''Maine Journalist of the Year,'' Earl Brechlin has covered Mount Desert Island for more than 35 years, and he has been recognized with more than 100 awards for news, feature writing, and photography. His commitment to journalism is evident in his election as president of both the Maine and New England press associations. A Registered Maine Guide, Mr. Brechlin is the author of nine books that reflect his love for our State's natural beauty, history, and character.

The Maine Seacoast Mission is a nondenominational, 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 brewery they started became far 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 country.

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 Weiss.

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 Leinie 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 now brews 24 other beers, with offerings for every taste and season, 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 that touches 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 while 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, Mathais, was a brewer and brandymaker from Meckenheim, Germany, who settled with his family in Sauk City, WI. Mathais passed his craft on to his four sons who, in turn, opened their own breweries throughout Wisconsin. Their passion for brewing quality beer remains at the heart of the Leinenkugel family 150 years later.

While it is now the fourth-largest craft brewer in the United States, the nascent company had only two employees: Jacob Leinenkugel and his partner, John Miller. Jacob brewed the beer, and John delivered it. Their German brewing methods, combined with excellent grains grown in rich Wisconsin soil and the State's pure water, made Leinenkugel's small brewery an instant success. The hard-working lumberjacks in the logging town of Chippewa Falls were Jacob's first loyal customers. Word of Leinenkugel's beer spread quickly, and its popularity expanded rapidly throughout Northern Wisconsin.

When Jacob passed away in 1899, running the company fell to his son-in-law, Henry Casper, and then to his eldest son, Matt, in 1907. Working alongside his sisters and brothers-in-law, the second generation of Leinenkugel's leadership quickly took the company to new heights.

The brewery experienced its first major test with the passage of Prohibition in 1919. While many American breweries cut their losses and closed shop during this period, Leinenkugel's adapted to the new American reality and began brewing Leino, a non-alcoholic version of their popular beer. Unfortunately, Leino was no match for the real thing and was soon discontinued. Thanks to quick thinking, they pivoted once again and began bottling soda water. By the end of Prohibition, Leinenkugel's was the largest bottler of soda water in the area.

After the repeal of Prohibition, Matt Leinkugel's wife, Katherine, and his sister, Rose, mortgaged their homes to finance updates to the brewery's equipment to save the company. Thanks to the resourcefulness of these women, the Leinenkugel family was able to restore the brewery to its pre-Prohibition glory. Leinenkugel's expanded yet again in the mid-20th century to the greater Midwest area and developed new varieties of beer that would meet the diverse needs of its newest customers.

In 1988, the Miller Brewing Company purchased Leinenkugel's, allowing the brewery to distribute products across the country. Today the brewery is an industry leader that produces 25 different styles of beer. For every 10 shandy-style beers consumed in the United States, nine are produced by Leinenkugel's.

Despite their national success, the Leinenkugels have never forgotten their Wisconsin roots or their commitment to their hometown of Chippewa Falls, WI. Jake Leinenkugel, who led the company until his retirement in 2015, said he and his wife, Peg, will always live in Chippewa Falls. The couple was named ''Chippewa Valley Philanthropists of the Year'' in 2007 for their ongoing contributions of time and money to local causes.

The Leinenkugel family has also maintained a strong commitment to the conservation of natural resources, particularly the freshwater that is a key component in Leinenkugel's products. The family created Canoes for a Cause, a stewardship program aimed at preserving waterways by removing trash, debris, and invasive plant species. They have held Canoes for a Cause events in Milwaukee, Madison, Chicago, Denver, Minneapolis, and Cleveland, often collecting more than 1,000 pounds of trash in a single day.

Today, C.J., Ellie, Matt, and Kirk Leinenkugel carry on the Leinenkugel's legacy. They are the sixth generation of Leinenkugels to continue Jacob's tradition of excellence, taking a small, local brewery and turning it into one of the most successful breweries in the Nation. No matter how many employees or distributors join the team, Leinenkugel's will always remain a family company that, to its core, defines what it means to be kind, hard-working Wisconsinites and genuine Americans.

130TH ANNIVERSARY OF BAR HARBOR BANK & TRUST

Mr. KING. Mr. President, today I wish to commemorate the 130th anniversary of Bar Harbor Bank & Trust. Based in Bar Harbor, ME, Bar Harbor Bank & Trust now has 14 branches in Maine and 35 branches in New Hampshire and Vermont. Known for supporting and understanding the unique people, organizations, and culture of northern New England, Bar Harbor Bank & Trust has not only achieved a strong reputation for providing quality service, but it has also cultivated employees who are dedicated to bettering their communities.

Since its founding in 1887, Bar Harbor Bank & Trust has fostered the personal and professional growth of its employees while serving its customers with the highest level of care and concern. Over the years, Bar Harbor Bank & Trust has expanded to New Hampshire-based subsidiaries: McCrillis & Elredge Insurance, Inc., and Charter Trust Company. It recently acquired Lake Sunapee Bank to make it one of the largest community banks in New England. It been recognized as a leading bank nationwide and ranked among the best places to work in ME.

Bar Harbor Bank & Trust has demonstrated a commitment to supporting the communities it serves. Each year, its employees volunteer thousands of hours to local community organizations. This commitment is sustained by their volunteer pay program that allows employees to get paid time off for volunteering each month to local causes they are passionate about. Furthermore, it allows them to contribute money from their paychecks to the Bank's Community Commitment program each month, and with every donation matched by the bank, the program donates over thousands of dollars annually to local nonprofit organizations, including Maine Veteran's Project, Girls and Boys State, Knox County Homeless Coalition, and dozens more.

In addition to volunteerism, Bar Harbor bank & Trust employees actively

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 money 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 service, 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 continuing 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 summer 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 is 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 is often a U.S. Navy ship that offers unique tour opportunities to festival-goers. As the highlight, 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 midcoast Maine 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 profits of the festival to Maine 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.

TRIBUTE TO MARION CURRY

Mr. ENZI. Mr. President, the Senate Budget Committee wishes to honor and recognize Marion Curry on her retirement from the Congressional Budget Office. Marion has worked in the budget analysis division of the Congressional Budget Office in various capacities for more than 38 years and has been a full-time employee at CBO since 1987. During that time, she served as the administrative assistant for the projections unit, and over the past several years, she expanded her responsibilities to also encompass the health systems and Medicare unit, as well as the low-income health programs and prescription drugs unit.

During her long tenure at CBO, Marion has skillfully carried out a variety of tasks—carefully checking cost estimates as she produced drafts, ensuring that timesheets were done correctly, directing callers to the appropriate person, and in general assuring that administrative matters were taken care of without a hitch. Such duties have undergone many changes over the years—from using telephones as the primary method of contact, typing tables by hand, and sending paper copies of documents, to the current approach of using email as the primary method of contact, transferring spreadsheets to the editorial staff for producing tables, and sending PDFs of documents with supplemental data posted on the web. Through all of those changes, Marion readily adapted to new technology and procedures and carried out her responsibilities with good humor, professionalism, a giving spirit, and a dedication to serving the Congress and the public.

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 others in the organization consulted 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 with a 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, deficit, 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 persistence, attention to detail, and reliably clear thinking have been vital to the smooth functioning of the budget analysis division. Senate staff and CBO colleagues have come to depend on him for his sage advice and deep understanding of the budget laws.

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 visiting 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. I remember people 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 leadership 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 told her, ''If you want a Ph.D., you better marry one.'' Her first husband laid down his life for our country during World War II, leaving Ms. Likover with a newborn daughter to raise.

She published papers without the Ph.D. that her male peers had and worked at the Cleveland Jewish Community Center's senior department, where she saw what a difference Social Security made in the lives of the elderly—and later how Medicaid and Medicare would change their lives. She went to grad school on a JCC scholarship.

Throughout the years, she never ceased in her activism. She joined me at events many times to talk about the importance of Medicare. I interviewed Belle in the summer of 2015, marking the 50th anniversary of the passage of Medicare and Medicaid. She told me she was thrilled when it passed because she remember how poor older people were when 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, Mr. Ernest ''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, and 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 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 dislocated 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 Samuel Gompers Award from 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 Gelder Award for Community Services. 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 much 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 horse-racing fan. His retirement is 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 well-deserved retirement, but knowing 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, rural life 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, Andy, Lamoin, Melba, Phil, 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 home did have a black potbelly cast 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, Phillip 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 and aunt. 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 those times when young people need 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 show her around 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 exercise 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 extraordinaire, 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 in the Murkowski office. 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 Fargo 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. Dan built 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 graduation, Dan went to work 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.

Over the next 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 $7.5 billion in bonds, led AFHC to avoid the subprime mortgage collapse and returned more than $1.9 billion back to the State of Alaska through cash transfers, capital projects, and debt service 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 pipeline to bring 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 relief 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, Dan did it 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 Alaska. He believed in Alaskans. Like all great Alaskans, he believed anything could be done, but what earned him our unwavering respect is that he followed through and got it done.

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 swathes 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, ID, and is a utility helicopter company with a broad spectrum of work. Hillcrest Aircraft Company was founded by local pilots in 1946. Jerry Wilson partnered with the company in 1959, 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 has built the company 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 main focus, however, is aerial 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 a variety of industries, 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 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.

(The messages received today are printed at the end of the Senate proceedings.)

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 of Representatives 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. 20944), 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 Board of Advisors: 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 as indicated:

EC–2454. A communication from the Director of the Regulatory Management Division, Environmental Protection Agency, transmitting, pursuant to law, the report of a rule entitled ''National Priorities List'' (FRL No. 9965–31–OLEM) received during adjournment of the Senate in the Office of the President of the Senate on July 28, 2017; to the Committee on Environment and Public Works.

EC–2455. A communication from the Board of Trustees of the Federal Old-Age and Survivors Insurance and Federal Disability Insurance Trust Funds, transmitting, pursuant to law, a report relative to the Federal Disability Insurance Trust Fund; to the Committee on Finance.

EC–2456. A communication from the Acting Assistant Secretary, Bureau of Political-Military Affairs, Department of State, transmitting, pursuant to law, an addendum to a certification, of the proposed sale or export of defense articles and/or defense services to a Middle East country (OSS–2017–0837); to the Committee on Foreign Relations.

EC–2457. A communication from the Secretary of Education, transmitting, pursuant to law, the report of a rule entitled ''Definitions and Selection Criteria that Apply to Direct Grant Programs'' (RIN1855–AA13) received in the Office of the President pro tempore of the Senate; to the Committee on Health, Education, Labor, and Pensions.

EC–2458. A communication from the Director of Regulations and Policy Management Staff, Food and Drug Administration, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Civil Money Penalty Amounts; Technical Amendment'' (Docket No. FDA–2017–N–0011) received in the Office of the President of the Senate on July 31, 2017; to the Committee on Health, Education, Labor, and Pensions.

EC–2459. A communication from the Director of Regulations and Policy Management Staff, Food and Drug Administration, Department of Health and Human Services, transmitting, pursuant to law, the report of a rule entitled ''Food Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date; Extension of Comment Period; Correction'' ((RIN0910–ZA48) (Docket No. FDA–2011–F–0172)) received in the Office of the President of the Senate on July 31, 2017; to the Committee on Health, Education, Labor, and Pensions.

EC–2460. A communication from the Acting Assistant Attorney General, Office of Legislative Affairs, Department of Justice, transmitting, pursuant to law, a report entitled ''Uniformed Services Employment and Reemployment 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 28, 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 the Judiciary.

HOUSE RESOLUTION NO. 25

Whereas, according to The Federalist No. 52 by James Madison, the framers of the Constitution of the United States intended that the Congress of the United States should be ''dependent on the people alone''; and

Whereas, the ''dependency on the people alone'' has evolved into a dependency on powerful special interests that act through campaigns or third-party groups, thereby creating a fundamental imbalance in our representative democracy; and

Whereas, Americans across the political spectrum agree that elections in the United States should be free from the disproportional influence of special interests and fair enough that any citizen can be elected into office; and

Whereas, Article V of the United States Constitution requires Congress to convene a convention for proposing amendments to the federal Constitution on the application of two-thirds of the legislatures of the several states; and

Whereas, the Twenty-ninth Legislature of the State of Hawaii desires to restore balance and integrity to our elections by proposing a federal constitutional amendment to permanently protect free and fair elections in the United States by addressing issues raised by the decision of the Supreme Court of the United States in *Citizens United v. Federal Election Commission*, 558 U.S. 310 (2010), and related cases and events; and

Whereas, the Twenty-ninth Legislature desires that Hawaii have an equal number of delegates to the Convention as any other state; provided that former or current federal office holders, whether elected or appointed, are not eligible to serve as delegates to the Convention; and

Whereas, the Twenty-ninth Legislature shall retain the ability to restrict or expand the authority of its delegates within the limits expressed herein; and

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 2013–2014 California Legislature, the Ninety-eighth Illinois General Assembly, the 2014–2015 New Jersey Legislature, and the 2015–2016 Rhode Island Legislature, as well as all applications that are subsequently adopted until two-thirds of the several states have applied for, and Congress has convened, a convention for proposing amendments 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, That certified copies of this Concurrent Resolution be transmitted to the President of the United States; Vice President of the United States, as presiding officer of the United States Senate; President Pro Tempore of the United States Senate; the Minority Leader of the United States Senate; the Speaker of the United States House of Representatives; the Minority Leader of the United States House of Representatives; and Hawaii's Congressional delegation.

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 the Committee on Banking, Housing, and Urban Affairs.

POM–81. A resolution adopted by the City Commission of the City of Sunrise, Florida urging the United States Congress to enact legislation modernizing the immigration system during the 115th Congress; to the Committee on the Judiciary.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. BARRASSO, from the Committee on Environment and Public Works, with an amendment in the nature of a substitute:

S. 810. A bill to facilitate construction of a bridge on certain property in Christian County, Missouri, and for other purposes (Rept. No. 115–142).

By Mr. HOEVEN, from the Committee on Indian Affairs, without amendment:

S. 669. A bill to authorize the Secretary of the Interior to assess sanitation and safety conditions at Bureau of Indian Affairs facilities that were constructed to provide 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 onset of transmissible diseases are eligible for disaster relief.

S. 650. A bill to amend the Small Business Act to expand tax credit education and training for small businesses that engage in research and development, and for other purposes.

S. 690. A bill to extend the eligibility of redesignated areas as HUBZones from 3 years to 7 years.

By Mr. RISCH, from the Committee on Small Business and Entrepreneurship, with amendments:

S. 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. 1038. A bill to require the Administrator of the Small Business Administration to submit to Congress a report on the utilization of small businesses with respect to certain Federal contracts.

By Mr. RISCH, from the Committee on Small Business and Entrepreneurship, without amendment:

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.

By Mr. ISAKSON, from the Committee on Veterans' Affairs, without amendment:

S. 1598. 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, 2020.

*Dawn DeBerry Stump, of Texas, to be a Commissioner of the Commodity Futures Trading Commission for a term expiring April 13, 2022.

*Rostin Behnam, of New Jersey, to be a Commissioner of the Commodity Futures Trading Commission for a term expiring June 19, 2021.

By Mr. MCCAIN for the Committee on Armed Services.

Air Force nomination of Brig. Gen. Mark D. Camerer, to be Major General.

Navy nomination 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. Aquilino, to be Vice Admiral.

Army nomination of Lt. Gen. Robert P. Ashley, Jr., to be Lieutenant General.

Army nomination of Brig. Gen. Darrell J. Guthrie, to be Major General.

Army nomination of Col. Brian E. Miller, to be Brigadier General.

Mr. MCCAIN. Mr. President, for the Committee on Armed Services I report favorably the following nomination lists 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 Dennis 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. Plevnia 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 Loren D. Adams and ending with Philip A. Wentz, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Joanne E. Arsenault and ending with Felisha L. Rhodes, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with Michael E. Alvis and ending with Jeffrey P. Wood, which nominations were received by the Senate and appeared in the Congressional Record on July 27, 2017.

Army nominations beginning with John W. Aldridge and ending with Philip E. Zapanta, 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. Zschaschel, 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.

Navy nominations beginning with Betty S. Alexander and ending with James S. Zmijski, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Navy 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 20, 2017.

Navy nominations beginning with Clemia Anderson and ending with Michael A. Zundel, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Navy nominations beginning with Eric F. Bauman and ending with Evan R. Whitbeck, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Navy 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 20, 2017.

Navy nominations beginning with Eric W. Hass and ending with Gail M. Mulleavy, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Navy 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.

Navy nominations beginning with Robert E. Bradshaw and ending with Leroy C. Young, which nominations were received by the Senate and appeared in the Congressional Record on July 20, 2017.

Navy 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.

Navy nomination of Clair E. Smith, to be Lieutenant Commander.

Navy nomination of Morgan E. McClellan, to be Lieutenant Commander.

Navy nominations beginning with Andrew B. Bridgforth 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. THUNE 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 Bradbury, 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, 2015.

*Mark H. Buzby, 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 Chairman of the National Transportation Safety Board for a term of two years.

*Brendan Carr, of Virginia, 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.

By Mr. ALEXANDER for the Committee on Health, Education, Labor, and Pensions.

*James J. Sullivan, 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. MacDougall, of Florida, to be a Member of the Occupational Safety and Health Review Commission for a term expiring April 27, 2023.

*Elinore 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.

*Robert P. Kadlec, of New York, 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 Assistant Secretary for Preparedness and Response, Department of Health and Human Services.

*Nomination was reported with recommendation that it be confirmed subject to the nominee's commitment to respond to requests to appear and testify before any duly constituted committee of the Senate.

(Nominations without an asterisk were reported with the recommendation that they be confirmed.)

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. BROWN, Mr. FRANKEN, Ms. BALDWIN, and Mr. ALEXANDER):

S. 1700. A bill to amend the Energy Policy and Conservation Act to establish a WaterSense program 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. 1701. A bill to provide for Federal agencies to develop public access policies relating to research conducted 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. 1702. 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 Ms. DUCKWORTH:

S. 1703. A bill to amend section 212(d)(5) of the Immigration and Nationality Act to allow certain alien veterans to be paroled into the United States to receive health care furnished by the Secretary of Veterans Affairs; to the Committee on the Judiciary.

By Ms. DUCKWORTH:

S. 1704. A bill to require the Secretary of Homeland Security to establish a veterans visa program to permit veterans who have been removed from the United States to return as immigrants, and for other purposes; to the Committee on the Judiciary.

By Mr. BENNET (for himself and Mr. BOOZMAN):

S. 1705. A bill to provide to 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. WARREN, and Mr. COONS):

S. 1706. A bill to prevent human health threats posed by the consumption of equines raised in the United States; to the Committee on Health, Education, Labor, and Pensions.

By Mrs. GILLIBRAND:

S. 1707. 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 Mrs. GILLIBRAND:

S. 1708. A bill to amend the Food and Nutrition Act of 2008 to provide that certain students who are family caregivers are eligible to participate in the Supplemental Nutrition Assistance Program; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. KENNEDY (for himself, Mr. HATCH, and Mr. CORNYN):

S. 1709. A bill to amend title 18, United States Code, to provide a certification process for the issuance of nondisclosure requirements accompanying certain administrative subpoenas, to provide for judicial review of such nondisclosure requirements, and for other purposes; to the Committee on the Judiciary.

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, Ms. KLOBUCHAR, Mrs. FEINSTEIN, Mr. MERKLEY, Mr. MARKEY, Ms. HIRONO, Ms. HARRIS, and Mr. BOOKER):

S. 1710. A bill to reduce the Federal budget deficit by closing big oil tax loopholes, and for other purposes; to the Committee on Finance.

By Mrs. SHAHEEN:

S. 1711. 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 fees for projects for combined heat and power technology and waste heat to power technology, and for other purposes; to the Committee on Energy and Natural Resources.

By Mr. WYDEN:

S. 1712. 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. COONS, Ms. COLLINS, and Mr. REED):

S. 1713. A bill to require certain financial assistance under the State energy program and the Weatherization Assistance Program to be distributed without undue delay to support State and local high-impact energy efficiency and renewable energy initiatives; to the Committee on Energy and Natural Resources.

By Mr. WYDEN (for himself and Mr. MERKLEY):

S. 1714. 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 commission for certain counties in the State of Oregon, to withdraw certain Federal land located in Malheur County, Oregon, from all forms of entry, appropriation, or disposal under the public land laws, location, entry, and patent under the mining laws, and operation under the mineral leasing laws, and for other purposes; to the Committee on Agriculture, Nutrition, and Forestry.

By Mr. WYDEN (for himself, Mr. MENENDEZ, Ms. HIRONO, Ms. BALDWIN, Ms. WARREN, Mr. WHITEHOUSE, Mrs. FEINSTEIN, Mr. BENNET, Mr. BOOKER, Mr. DURBIN, Mr. KAINE, Mr. BROWN, Mr. LEAHY, Mr. FRANKEN, Mr. HEINRICH, Mr. CASEY, Ms. CORTEZ MASTO, Mr. CARDIN, 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. DONNELLY, Ms. DUCKWORTH, Mr. PETERS, Mr. UDALL, Mr. MARKEY, Mr. MURPHY, Ms. HEITKAMP, Mrs. SHAHEEN, Mrs. GILLIBRAND, Mr. MERKLEY, Mr. NELSON, Mr. KING, Mr. SCHATZ, Mr. WARNER, Mr. TESTER, and Mr. MANCHIN):

S. 1715. A bill to amend the Internal Revenue Code of 1986 to clarify that all provisions shall apply to legally married same-sex couples in the same manner as other married couples, and for other purposes; to the Committee on Finance.

By Mrs. FISCHER (for herself and Mr. KING):

S. 1716. 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. 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 for criminal gain, to assist 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. RUBIO, Mr. CASSIDY, and Ms. WARREN):

S. 1718. A bill to authorize the minting of a coin 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. 1719. 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. 1720. A bill to amend the Immigration and Nationality Act to establish a skills-based immigration points system, to focus 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. 1721. A bill to amend titles 10 and 37, United States Code, to provide compensation 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. 1722. A bill to require the Committee on Foreign Investment in the United States to consider the reciprocity of foreign investment, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Mr. SANDERS:

S. 1723. A bill to appropriate amounts to the Department of Veterans Affairs to improve health care furnished by the Department, 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 Ms. CORTEZ MASTO):

S. 1725. A bill to require the Secretary of Homeland Security to identify each alien who has served, 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. FRANKEN, 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 authorization before a public company may make certain political expenditures, and for other purposes; to the Committee on Banking, Housing, and Urban Affairs.

By Ms. DUCKWORTH (for herself and Ms. 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 prison, 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. 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.

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 (or acted upon), 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 and digital innovation 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. 168

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 system.

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 and clarify certain disclosure 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 Enewetak 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 chapter 44 of 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. 428

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 to children with complex medical conditions through enhanced pediatric health homes, and for other purposes.

S. 456

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. 581, 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. 635

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. 655

At the request of Mr. RISCH, the name of the Senator from Wisconsin (Ms. BALDWIN) was added as a cosponsor of S. 655, a bill to exempt certain 16- and 17-year-old individuals employed in logging operations from child labor laws.

S. 720

At the request of Mr. PORTMAN, the names of the Senator from Arizona (Mr. FLAKE) and the Senator from Alabama (Mr. SHELBY) were added as cosponsors of S. 720, a bill to amend the Export Administration Act of 1979 to include in the prohibitions on boycotts against allies of the United States boycotts fostered by international governmental organizations against Israel and to direct the Export-Import Bank of the United States to oppose boycotts against Israel, and for other purposes.

S. 808

At the request of Mr. THUNE, the name of the Senator from Indiana (Mr. YOUNG) was added as a cosponsor of S. 808, a bill to provide protections for certain sports medicine professionals who provide certain medical services in a secondary State.

S. 828

At the request of Mr. WARNER, the name of the Senator from Michigan (Ms. STABENOW) was added as a cosponsor of S. 828, a bill to amend the Federal Deposit Insurance Act to require the appropriate Federal banking agencies to treat certain municipal obligations as level 2B liquid assets, and for other purposes.

S. 916

At the request of Mr. CASSIDY, the name of the Senator from Minnesota (Ms. KLOBUCHAR) was added as a cosponsor of S. 916, a bill to amend the Controlled Substances Act with regard to the provision of emergency medical services.

S. 976

At the request of Mr. ENZI, the names of the Senator from Hawaii (Ms. HIRONO), the Senator from Missouri (Mrs. MCCASKILL) and the Senator from South Carolina (Mr. GRAHAM) were added as cosponsors of S. 976, a bill to restore States' sovereign rights to enforce State and local sales and use tax laws, and for other purposes.

S. 1002

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.

At the request of Mr. BARRASSO, his name was added as a cosponsor of S. 1182, supra.

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. 1311

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. 1312

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. 1354

At the request of Mr. CARPER, the name of the Senator from Virginia (Mr. WARNER) 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. 1428

At the request of Mr. RISCH, the name of the Senator from Delaware (Mr. COONS) 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. 1462

At the request of Mrs. SHAHEEN, the name of the Senator from Illinois (Ms. DUCKWORTH) was added as a cosponsor of S. 1462, a bill to amend the Patient Protection and Affordable Care Act to improve cost sharing subsidies.

S. 1500

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 depository institution are not considered to be funds obtained by or through a deposit broker, and for other purposes.

S. 1509

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 extension of exclusivity periods 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.

S. 1536

At the request of Ms. KLOBUCHAR, the name of the Senator from Nevada (Mr. HELLER) was added as a cosponsor of S. 1536, a bill to designate a human trafficking prevention coordinator and to expand the scope of activities authorized under the Federal Motor Carrier Safety Administration's outreach and education program to include human trafficking prevention activities, and for other purposes.

S. 1558

At the request of Mr. RISCH, the name of the Senator from Wyoming (Mr. ENZI) was added as a cosponsor of S. 1558, a bill to amend section 203 of Public Law 94–305 to ensure proper authority for the Office of Advocacy of the Small Business Administration, and for other purposes.

S. 1568

At the request of Mr. MARKEY, the name of the Senator from Massachusetts (Ms. WARREN) was added as a cosponsor of S. 1568, a bill to require the Secretary of the Treasury to mint coins in commemoration of President John F. Kennedy.

S. 1598

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 38, United States Code, to make certain improvements in the laws administered by the Secretary of Veterans Affairs, and for other purposes.

S. 1615

At the request of Mr. GRAHAM, the names of the Senator from California (Mrs. FEINSTEIN) and the Senator from California (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.

S. 1636

At the request of Mr. DURBIN, the name of the Senator from Wisconsin (Ms. BALDWIN) 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.

S. 1685

At the request of Mr. SCOTT, the name of the Senator from Virginia (Mr. KAINE) 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.

S. 1688

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.

S. 1693

At the request of Mr. PORTMAN, the names of the Senator from Alaska (Mr. SULLIVAN) and the Senator from Louisiana (Mr. KENNEDY) 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.

S. CON. RES. 7

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.

AMENDMENT NO. 575

At the request of Mr. NELSON, the name of the Senator from Massachusetts (Ms. WARREN) was added as a cosponsor of amendment No. 575 intended to be proposed to 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.

AMENDMENT NO. 592

At the request of Mr. DURBIN, the name of the Senator from California (Mrs. FEINSTEIN) was added as a cosponsor of amendment No. 592 intended to be proposed to 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.

AMENDMENT NO. 680

At the request of Mr. BOOZMAN, the name of the Senator from Arkansas (Mr. COTTON) was added as a cosponsor of amendment No. 680 intended to be proposed to 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.

STATEMENTS ON INTRODUCED BILLS AND JOINT RESOLUTIONS

By Mr. CORNYN (for himself and Mr. WYDEN):

S. 1701. A bill to provide for Federal agencies to develop public access policies relating to research conducted by employees of that agency or from funds administered 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:

S. 1701

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) the Internet 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 reuses of the peer-reviewed literature that reports the results of 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 direct 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 extramural 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);

(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) a means, 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 such a final peer-reviewed manuscript or published version is made publicly available by presenting evidence demonstrating that the period is inconsistent with the objectives 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; and

(8) long-term preservation of, and free public access to, published research findings—

(A) in a stable digital repository maintained by the Federal agency; or

(B) if consistent with the purposes of the Federal agency, in any repository meeting conditions determined favorable by the Federal agency (including 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 reproduction, publication, release, or other uses of a final manuscript for Federal purposes.

(d) EXCLUSIONS.—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; or

(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 subsection (a)(1), including—

(A) whether the terms of use applicable to such research papers in effect are effective in enabling productive reuse of the research and computational analysis by state-of-the-art technologies; and

(B) examines whether such research papers should include a royalty-free 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 for criminal gain, to assist 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.

Mr. WYDEN. Mr. President, today I am, along with Senator RUBIO, introducing the Corporate Transparency Act of 2017. This bill will help us end 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 elicit 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 weapons to the Taliban. Another anonymous U.S. company owned a large share of a Manhattan skyscraper and used its anonymity to facilitate $4.5 million in payments to an Iranian bank that was designated by OFAC as a key financier to Iran's nuclear and ballistic missiles program. Anonymous shell companies have been used to rip off taxpayers as well. In 2010, Michel Huarte was sentenced to 22 years in prison after using a network of 29 shell companies in several States to defraud Medicare, using the entities to submit claims of more than $50 million.

Last year, the release of documents known as the Panama Papers leaked from the Panamanian law firm Mossack Fonseca highlighted the use of American shell companies to carry out potential crimes. Shell company abuse is not just in occurring in offshore tax havens, but right here in the United States, and this bill seeks to put a stop to that.

In the United States, company registrations take place at the State-level. The Corporate Transparency Act of 2017 directs the Treasury Department to issue regulations requiring entities formed in the United States to declare their beneficial owners—the real, natural persons who control each company and benefit from it financially. The bill would do this by setting minimum disclosure standards for States to follow. If individual States choose to collect this information on behalf of businesses formed there, then that's all that a new business would need to do to comply. Participation by the States is completely voluntary. If companies are formed in States that do not collect this information consistent with the new minimum standards, they will need to disclose their beneficial owners directly to the U.S. Treasury Department's Financial Crimes Enforcement Network.

Collecting beneficial ownership information at the time a company is formed will offer the transparency law enforcement needs to investigate these kinds of financial crimes. Under the bill, the new beneficial ownership information would not be available to the public, but available only to appropriate state and federal authorities. Finally, the bill provides civil and criminal penalties for improper disclosure.

The bill is constructed to exempt many legitimate businesses, and the information requested is already provided by most companies in the normal course of business. Collecting beneficial ownership information at the time of incorporation relieves later compliance burdens for legitimate businesses, while at the same time prevents illegitimate businesses from operating in secrecy.

The House companion to this bill, H.R. 3089, was introduced with bipartisan support and efforts to identify the true owners of shell companies have the support of business groups like the Clearing House Association and the B-Team, law enforcement groups like the Fraternal Order of Police, and anti-corruption advocacy groups like the Financial Accountability and Corporate Transparency (FACT) Coalition and Global Witness.

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 procedures to conceal their identities when 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 testimony by officials from the Department of Justice, the Department of Homeland Security, the Financial Crimes Enforcement Network of the Department of the Treasury, the Internal Revenue Service, and the Government Accountability Office, and others.

(6) 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 a fundamental gap in U.S. efforts to combat money laundering and terrorist finance.

(7) In response to the 2006 FATF report, the United States has 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 new corporation or limited liability company within the State within 24 hours of filing an online application, without any prior review of the application by a State official. In exchange for a substantial fee, 2 States will form a corporation within 1 hour of a request.

(9) Dozens of Internet Web sites highlight the anonymity of beneficial owners allowed under the incorporation practices of some States, point to those practices as a reason to incorporate in those States, and list those States together with offshore jurisdictions 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 28 countries in the European Union are required to have formation agents 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 interstate and international commerce from criminals misusing United States corporations and limited liability companies, to strengthen law enforcement investigations of suspect corporations and limited liability companies, to set minimum standards for and level the playing field among State incorporation practices, and to bring the United States into compliance with its 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 and limited liability company formed in a State that does not have a formation system described under subsection (b) to file with the Financial Crimes Enforcement Network such information as the corporation or limited liability company would be required to provide the State if such State had a formation system described under subsection (b).

''(2) DISCLOSURE OF BENEFICIAL OWNERSHIP INFORMATION.—Beneficial ownership information reported to the Financial Crimes Enforcement Network pursuant to paragraph (1) shall be provided by the Financial Crimes Enforcement Network upon receipt of—

''(A) a civil or criminal subpoena or summons from a State agency, Federal agency, or congressional committee or subcommittee requesting such information;

''(B) a written request made by a Federal agency on behalf of another country under an international treaty, agreement, or convention, or an order under section 3512 of title 18 or section 1782 of title 28 issued in response to a request for assistance from a foreign country; or

''(C) a written request made by a financial institution, with customer consent, as part of the institution's compliance with due diligence requirements imposed under the Bank Secrecy Act (Public Law 91508; 84 Stat. 1114), the USA PATRIOT Act (Public Law 10756; 115 Stat. 272), or other applicable Federal or State law.

''(3) LIMITATION.—In issuing regulations pursuant to paragraph (1), the Secretary shall not require such information to be filed with the Internal Revenue Service.

''(b) FORMATION SYSTEM.—

''(1) IN GENERAL.—With respect to a State, a formation system is described under this subsection if it meets the following requirements:

''(A) IDENTIFICATION OF BENEFICIAL OWNERS.—Except as provided in paragraphs (2) and (4), and subject to paragraph (3), each applicant to form a corporation or limited liability company under the laws of the State is required to provide to the State during the formation process a list of the beneficial owners of the corporation or limited liability company that—

''(i) except as provided in subparagraph (F), identifies each beneficial owner by—

''(I) name;

''(II) current residential or business street address; and

''(III) a unique identifying number from a non-expired passport issued by the United States or a non-expired driver's license issued by a State; and

''(ii) if the applicant is not the beneficial owner, provides the identification information described in clause (i) relating to the applicant.

''(B) UPDATED INFORMATION.—For each corporation or limited liability company formed under the laws of the State—

''(i) the corporation or limited liability company is required by the State to update the list of the beneficial owners of the corporation or limited liability company by providing the information described in subparagraph (A) to the State not later than 60 days after the date of any change in the list of beneficial owners or the information required to be provided relating to each beneficial owner;

''(ii) in the case of a corporation or limited liability company formed or acquired by a formation agent and retained by the formation agent as a beneficial owner for transfer to another person, the formation agent is required by the State to submit to the State an updated list of the beneficial owners and the information described in subparagraph (A) for each such beneficial owner not later than 10 days after date on which the formation agent transfers the corporation or limited liability company to another person; and

''(iii) the corporation or limited liability company is required by the State to submit to the State an annual filing containing the list of the beneficial owners of the corporation or limited liability company and the information described in subparagraph (A) for each such beneficial owner.

''(C) RETENTION OF INFORMATION.—Beneficial ownership information relating to each corporation or limited liability company formed under the laws of the State is required to be maintained by the State until the end of the 5-year period beginning on the date that the corporation or limited liability company terminates under the laws of the State.

''(D) INFORMATION REQUESTS.—Beneficial ownership information relating to each corporation or limited liability company formed under the laws of the State shall be provided by the State upon receipt of—

''(i) a civil or criminal subpoena or summons from a State agency, Federal agency, or congressional committee or subcommittee requesting such information;

''(ii) a written request made by a Federal agency on behalf of another country under an international treaty, agreement, or convention, or section 1782 of title 28;

''(iii) a written request made by the Financial Crimes Enforcement Network; or

''(iv) a written request made by a financial institution, with customer consent, as part of the institution's compliance with due diligence requirements imposed under the Bank Secrecy Act (Public Law 91508; 84 Stat. 1114), the USA PATRIOT Act (Public Law 10756; 115 Stat. 272), or other applicable Federal or State law.

''(E) 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 subparagraph (D), pursuant to the requirements of such subparagraph.

''(F) 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.

''(2) 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, or a corporation or limited liability company formed under the laws of the State, to provide the required information to a licensed formation agent residing in the State, instead of to the State 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 possession of 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 that requires a formation agent to register with the State, meet standards for fitness and honesty, maintain a physical office and records within the State, undergo regular monitoring, and be subject to sanctions for noncompliance with State requirements.

''(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)(C);

''(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 and that resigns, dissolves, or otherwise ends a relationship with the corporation or limited liability company shall promptly—

''(I) notify the State in writing that the licensed formation agent has resigned or ended the relationship; and

''(II) transmit 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 transmit 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 provides beneficial ownership information to another licensed formation agent under clause (ii), the licensed formation agent providing the information shall promptly notify in writing 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 this subsection does not have a non-expired passport issued by the United States or a non-expired driver's license or identification card issued by a State, each application described in paragraph (1)(A) and each update described in paragraph (1)(B) shall include a certification by a formation agent residing in the State that the formation agent—

''(A) has obtained for each such person a current residential or business street address and a legible and credible copy of the pages of a non-expired passport issued by the government of a foreign country bearing a photograph, date of birth, and unique identifying information for the person;

''(B) has verified the name, address, and identity of each such person;

''(C) will provide the information described in subparagraph (A) and the proof of verification described in subparagraph (B) upon request under the same circumstances as required for States under paragraph (1)(D); and

''(D) will retain the information and proof of verification under this paragraph in the State in which the corporation or limited liability company is being or has been formed until the end of the 5-year period beginning on the date that the corporation or limited liability company terminates under the laws of the State.

''(4) EXEMPT ENTITIES.—

''(A) IN GENERAL.—A formation system described in paragraph (1) shall require that an application for an entity described in subparagraph (C) or (D) of subsection (d)(2) that is proposed to be formed under the laws of a State and that will be exempt from the beneficial ownership disclosure requirements under this subsection shall include in the application a certification by the applicant, or a prospective officer, director, or similar agent of the entity—

''(i) identifying the specific provision of subsection (d)(2) under which the entity proposed to be formed would be exempt from the beneficial ownership disclosure requirements under paragraphs (1), (2), and (3);

''(ii) stating that the entity proposed to be formed meets the requirements for an entity described under such provision of subsection (d)(2); and

''(iii) providing identification information for the applicant or prospective officer, director, or similar agent making the certification in the same manner as provided under paragraph (1) or (3).

''(B) EXISTING ENTITIES.—On and after the date that is 2 years after the effective date of the amendments to the formation system of a State made to comply with this section, an entity formed under the laws of the State before such effective date shall be considered to be a corporation or limited liability company for purposes of, and shall be subject to the requirements of, this subsection unless an officer, director, or similar agent of the entity submits to the State a certification—

''(i) identifying the specific provision of subsection (d)(2) under which the entity is exempt from the requirements under paragraphs (1), (2), and (3);

''(ii) stating that the entity meets the requirements for an entity described under such provision of subsection (d)(2); and

''(iii) providing identification information for the officer, director, or similar agent making the certification in the same manner as provided under paragraph (1) or (3).

''(C) EXEMPT ENTITIES HAVING OWNERSHIP INTEREST.—If an entity described in subparagraph (C) or (D) of subsection (d)(2) has or will have an ownership interest in a 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 the ownership interest shall provide the information required under this subsection relating to the entity, except that the entity shall not be required to provide information regarding any natural person who has an ownership interest in, exercises substantial control over, or receives substantial economic benefits from the entity.

''(c) PENALTIES.—

''(1) 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 identifying 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, except—

''(I) to the extent necessary to fulfill the authorized request;

''(II) as authorized by the entity that issued the subpoena, summons, or other request; or

''(III) as prescribed by a State; or

''(B) in the case of a formation agent, knowingly failing to obtain or maintain credible, legible, and updated beneficial ownership information, including any required identifying photograph.

''(2) 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.

''(d) DEFINITIONS.—For the purposes of this section:

''(1) BENEFICIAL OWNER.—The term 'beneficial owner'—

''(A) means a natural person who, directly or indirectly—

''(i) exercises substantial control over a corporation or limited liability company; or

''(ii) has a substantial interest in or receives substantial economic benefits from the assets of a corporation or limited liability company; and

''(B) does not include—

''(i) a minor child;

''(ii) a person acting as a nominee, intermediary, custodian, or agent on behalf of another person;

''(iii) a person acting solely as an employee of a corporation or limited liability company and whose control over or economic benefits from the corporation or limited liability company derives solely from the employment status of the person;

''(iv) a person whose only interest in a corporation or limited liability company is through a right of inheritance, unless the person also meets the requirements of subparagraph (A); or

''(v) a creditor of a corporation or limited liability company, unless the creditor also meets the requirements of subparagraph (A).

''(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;

''(B) include any non-United States entity eligible for registration or registered to do business as a corporation or limited liability

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 under the laws of the State or, if the entity was formed before the date of the enactment of this section, in a filing with the State under State law—

''(i) a 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 political subdivision of a State, under an 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));

''(vi) a broker or dealer (as defined in section 3 of the Securities Exchange Act of 1934 (15 U.S.C. 78c)) that is registered under section 15 of the Securities Exchange Act of 1934 (15 U.S.C. 78o);

''(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. 78f and 78q–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 advisor (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 insurance 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 1a of the Commodity Exchange Act (7 U.S.C. 1a)), or a futures commission merchant, introducing broker, commodity pool operator, or commodity trading advisor (as defined in section 1a of the Commodity Exchange Act (7 U.S.C. 1a)) that 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 public utility that provides telecommunications service, electrical power, natural gas, or water and sewer services, within the United States;

''(xiii) a church, charity, or nonprofit entity that is described in section 501(c), 527, or 4947(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 or sales; 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), or (xiv); 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; or

''(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 Secretary of Homeland Security and the Attorney General of the United States, may issue guidance or a rule to—

(A) clarify the definitions under section 5333(d) of title 31, United States Code, as added by paragraph (1); and

(B) 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 process 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 5333''; and

(ii) in paragraph (6), by inserting ''(except section 5333)'' after ''subchapter'' each place it appears; and

(B) in section 5322, by striking ''section 5315 or 5324'' each place it appears and inserting ''section 5315, 5324, or 5333''.

(4) TABLE OF CONTENTS.—The table of contents of chapter 53 of title 31, United States Code, is amended by inserting after the item relating to section 5332 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 as described under section 5332 of title 31, United States Code, as added by this Act; and

(B) by statute, regulation, order, or interpretation adopted or issued by the State after the date of enactment of this Act, provide for public access to all or any portion of such information.

(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 whose information is submitted to such State under section 5333 of title 31, United States Code, as added by this Act.

(b) FUNDING AUTHORIZATION.—

(1) IN GENERAL.—To carry out 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.

(2) FUNDING SOURCES.—To protect the United States against the misuse of United States corporations and limited liability companies with hidden owners, funds shall be provided to each State to carry out the purposes described in paragraph (1) from one or more of the following sources:

(A) Upon application by a State, and without further appropriation, the Secretary of the Treasury shall make available to the State unobligated balances described in section 9703(g)(4)(B) of title 31, United States Code, in the Department of the Treasury Forfeiture Fund established under section 9703(a) of title 31, United States Code.

(B) Upon application by a State, after consultation with the Secretary of the Treasury, and without further appropriation, the Attorney General of the United States shall make available to the State excess unobligated balances (as defined in section 524(c)(8)(D) of title 28, United States Code) in the Department of Justice Assets Forfeiture Fund established under section 524(c) of title 28, United States Code.

(3) MAXIMUM AMOUNTS.—

(A) DEPARTMENT OF THE TREASURY.—The Secretary of the Treasury may not make available to States a total of more than $30,000,000 under paragraph (2)(A).

(B) DEPARTMENT OF JUSTICE.—The Attorney General of the United States may not make available to States a total of more than $10,000,000 under paragraph (2)(B).

(4) RULEMAKING.—Not later than the end of the 180-day period beginning on the date of the enactment of this Act, the Secretary of the Treasury and the Attorney General shall, jointly, issue regulations setting forth the procedures for States to apply for funds under this subsection, including determining which State measures should be funded to assess, plan, develop, test, or implement relevant policies, procedures, or system modifications.

(c) COMPLIANCE REPORT.—Nothing in this section or the amendments made by this section authorizes the Secretary of the Treasury to withhold from a State any funding otherwise available to the State because of a failure by that State to comply with section 5333 of title 31, United States Code. Not later than the end of the 42-month period beginning on the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Financial Services of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate a report—

(1) identifying which States obtain beneficial ownership information as described in such section 5333;

(2) with respect to each State that does not obtain such information, whether corporations and limited liability companies formed under the laws of such State are in compliance with such section 5333 and providing the specified beneficial ownership information to the Financial Crimes Enforcement Network; and

(3) whether the Department of the Treasury is in compliance with such section 5333 and, if not, what steps it must take to come into compliance with this section.

(d) FEDERAL CONTRACTORS.—Not later than the first day of the first full fiscal year beginning at least 1 year after the date of the enactment of this Act, the Administrator for Federal Procurement Policy shall revise the Federal Acquisition Regulation maintained under section 1303(a)(1) of title 41, United States Code, to require any contractor who

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 such section to the Federal Government as part of any bid or proposal for a contract with a value threshold in excess of the simplified acquisition threshold under section 134 of title 41, United States Code.

(e) ANTI-MONEY LAUNDERING OBLIGATIONS OF FORMATION AGENTS.—

(1) IN GENERAL.—Section 5312(a)(2) of title 31, United States Code, is amended—

(A) in subparagraph (Y), by striking ''or'' at the end;

(B) by redesignating subparagraph (Z) as subparagraph (AA); and

(C) by inserting after subparagraph (Y) the following:

''(Z) any person who, for compensation—

''(i) 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) purchases, sells, or transfers the public records that form a corporation or limited liability company; or''.

(2) DEADLINE FOR ANTI-MONEY LAUNDERING RULE FOR FORMATION AGENTS.—

(A) PROPOSED RULE.—Not later than 120 days after the date of enactment of this Act, the Secretary of the Treasury, in consultation with the Attorney 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 described in this subsection 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) OTHER LEGAL ENTITIES.—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) or 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) evaluating 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) EFFECTIVENESS OF INCORPORATION 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 punish terrorism, 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 CHRIS 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 prematurity, 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 will 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, handwashing 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 assessed 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.

SUBMITTED RESOLUTIONS

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

Mr. WICKER (for himself, Mr. SCHATZ, Mr. GARDNER, Ms. HASSAN, Mr. MORAN, and Mr. PETERS) submitted the following resolution; which was referred to the Committee on Commerce, Science, and Transportation:

S. RES. 242

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 industry and economic sector;

Whereas wireless and wired broadband networks create and support millions of jobs;

Whereas wireless and wired broadband networks are vital to providing communications 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 with 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 investment from the wireless 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 that rely on unlicensed spectrum bands are poised to unleash a new round of innovation and consumer benefit from an industry that generates an economic surplus of $547,000,000,000 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, uses, 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 service 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 country;

(4) commit to modernizing the infrastructure policies of the United States and identifying additional spectrum in low, mid, and high bands for licensed and unlicensed uses 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 user experiences, maximize use-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 HONORED FOR HEROISM AT PEARL HARBOR, HAWAII, ON DECEMBER 7, 1941

Mr. FLAKE (for himself, Mr. GARDNER, Mr. LEE, Mr. COTTON, Mrs. MCCASKILL, and Mr. BENNET) submitted the following resolution; which was referred to the Committee on Armed Services:

S. RES. 243

Whereas, on December 7, 1941, Boatswain's Mate Second Class Joseph Leon George was 26 years old;

Whereas Boatswain's Mate Second Class George was a crewmember aboard the U.S.S. Vestal (AR–4), a repair ship, on that day;

Whereas the U.S.S. Vestal was moored next to the U.S.S. Arizona (BB–39);

Whereas the Japanese began the attack on Pearl Harbor, Hawaii, at 7:48 a.m.;

Whereas 6 sailors on the U.S.S. Arizona, Seaman First Class Harold Kuhn, Seaman First Class Russell Lott, Gunner's Mate Third Class Earl Riner, Boatswain's Mate Second Class Alvin Dvork, 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 escape the ship;

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, ''Joe George was never awarded anything for his bravery. He is no longer with us, but I believe in his memory, should be awarded the Navy Cross.''; and

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 high commendations for his actions. 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 decorating 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.

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.

Upon 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 injuries so severe that two would succumb to their 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 four 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 actions. 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 commendations for his actions. I feel he should be recognized for this courage and presented the Navy Cross.

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 . . . 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 immense 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, COTTON, MCCASKILL, and BENNET for joining me on this resolution. I look forward to working with them on its swift adoption.

SENATE RESOLUTION 244—TO AUTHORIZE TESTIMONY, DOCUMENT PRODUCTION, AND REPRESENTATION IN UNITED STATES OF AMERICA V. ROBERT MENENDEZ, ET AL

Mr. MCCONNELL (for himself and Mr. SCHUMER) submitted the following resolution; 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, testimony and the production of documents may be needed from various current and former Members and employees of the Senate, relating 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. §§288b(a) and 288c(a)(2), the Senate may direct its counsel to represent current or former Members and employees of 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 Standing Rules of the Senate, no evidence under the control or in the possession of the Senate may, by the judicial or administrative process, be taken from such control or possession but by permission of the Senate; and

Whereas, when it appears that 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 promote the ends of justice consistent with the privileges of the Senate: Now, therefore, be it

Resolved, That current and former Members and employees of the Senate are authorized to testify and produce documents in the case of *United States of America v. Robert Menendez, et al.*, and related proceedings, except concerning matters for which a privilege should be asserted.

SEC. 2. The Senate Legal Counsel is authorized to represent current and former Members and employees of the Senate in connection with the production of evidence authorized 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 concerns 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 expected to seek trial testimony from Members and Senate staff.

This resolution would authorize Senate individuals called to appear to testify and produce documents in this case and related proceedings, except concerning matters for which a privilege 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 intended 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 Veterans Affairs located in Montana.

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, 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 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.

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 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:

Strike section 601 and the following:

SEC. 601. FISCAL YEAR 2018 INCREASE IN MILITARY BASIC PAY.

(a) WAIVER OF SECTION 1009 ADJUSTMENT.—The adjustment 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 not be made.

(b) INCREASE IN BASIC PAY.—Effective on January 1, 2018, the rates of monthly basic pay for 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.

(c) DETERMINATION OF PERCENTAGE.—The Secretary of Defense shall determine the percentage increase in rates of monthly basic pay provided for by subsection (b) in consultation with the Secretary of Homeland Security, the Secretary of Commerce, and the Secretary of Health and Human Services.

(d) ECI DEFINED.—In this section, the term ''ECI'' has the meaning givern that term in section 1009(a)(3)(A) of title 37, United States Code.

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 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 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. 3321 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 due to non-compliance with applicable law, regulation or policy.

(3) STRATEGIC SOURCING.—The term ''strategic sourcing'' means analyzing and modifying a Federal agency's spending patterns 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 the date of the 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) recovering improper 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 112–194); 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 1093(a)(1).

(b) ELEMENTS.—The guidance issued under subsection (a) shall—

(1) require relevant officials at Federal agencies to identify high-risk activities and 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 pre-suspension and 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 DATA 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 information and purchase and travel card transaction data of agencies for the purpose of identifying potential strategic sourcing and other additional opportunities (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; and

(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 include those agencies as described in section 2 of the Government Charge Card Abuse Prevention Act of 2012 (Public Law 112–194) and others identified by the Administrator and Director.

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 for 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 REPORTS 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 2 of the Government Charge Card Abuse Prevention Act of 2012 (Public Law 112–194) 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 be included as part of another report 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. 1282, to redesignate certain clinics 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 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.

(3) PUBLIC DISPLAY OF NAME.—

(A) IN GENERAL.—Any 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 subparagraph (A), a local public display of the name of the clinic referred to in paragraph (1) includes a display inside the clinic, on the campus of the clinic, and in the community surrounding the clinic, such as signs directing individuals to the clinic.

(c) BENJAMIN CHARLES STEELE VA CLINIC.—

(1) DESIGNATION.—The clinic of the Department of Veterans Affairs located at 1766 Majestic Lane in Billings, Montana, shall after the date of the enactment of this Act be known and designated as the ''Benjamin Charles Steele 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 Benjamin Charles Steele VA Clinic.

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, 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; 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. 3953 note) is amended—

(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:

''(k) RELATION TO ORPHAN DRUGS.—

''(1) 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)(B); 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' Subcommittee 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 OFFICER. 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 OFFICER. 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 OFFICER. 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 OFFICER. The Chair, on behalf of the majority leader, pursuant to the provisions of Public Law 115–31, appoints the following individuals to serve as members 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 HENDERSON, 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 HILARY 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, 2021, VICE CONSTANCE S. BARKER, TERM EXPIRED.

DEPARTMENT OF HOMELAND SECURITY

JOHN MARSHALL MITNICK, OF VIRGINIA, TO BE GENERAL COUNSEL, DEPARTMENT OF HOMELAND SECURITY, VICE STEVAN EATON BUNNELL.

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.

THOMAS L. KIRSCH II, OF INDIANA, TO BE UNITED STATES ATTORNEY FOR THE NORTHERN DISTRICT OF INDIANA FOR THE TERM OF FOUR YEARS, VICE DAVID A. CAPP, 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.

FEDERAL ENERGY REGULATORY COMMISSION

RICHARD GLICK, OF VIRGINIA, TO BE A MEMBER OF THE FEDERAL ENERGY REGULATORY COMMISSION FOR THE TERM EXPIRING JUNE 30, 2022, VICE COLETTE DODSON HONORABLE, TERM EXPIRED.

KEVIN J. MCINTYRE, OF VIRGINIA, TO BE A MEMBER OF THE FEDERAL ENERGY REGULATORY COMMISSION FOR THE REMAINDER OF THE TERM EXPIRING JUNE 30, 2018, VICE NORMAN C. BAY, RESIGNED.

KEVIN J. MCINTYRE, OF VIRGINIA, TO BE A MEMBER OF THE FEDERAL ENERGY REGULATORY COMMISSION FOR THE TERM EXPIRING JUNE 30, 2023. (REAPPOINTMENT)

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

MARVIN KAPLAN, OF KANSAS, TO BE A MEMBER OF THE NATIONAL LABOR RELATIONS BOARD FOR THE TERM OF FIVE YEARS EXPIRING AUGUST 27, 2020.

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.