

There was no objection.

#### PHARMACY DRUG PRICES

The SPEAKER pro tempore. Under the Speaker's announced policy of January 3, 2019, the gentleman from Georgia (Mr. CARTER) is recognized for 60 minutes as the designee of the minority leader.

#### GENERAL LEAVE

Mr. CARTER of Georgia. Madam Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on the subject matter of my Special Order tonight.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Georgia?

There was no objection.

Mr. CARTER of Georgia. Madam Speaker, I am grateful for the time tonight to talk about a very important subject. As many Members know, currently, I am the only pharmacist serving in Congress, and that is something I take very seriously.

Two of the things that I really wanted to concentrate on when I became a Member of Congress, among many things, but two of the main things were, first of all, prescription drug pricing—that is one of the things that we want to talk about here tonight—and the other thing that I wanted to concentrate on was the opioid epidemic. We have been very successful here in Congress in addressing that issue.

Tonight I want to talk about prescription drug pricing because I have witnessed it. I have witnessed what I would describe as truly a crisis.

After 30 years of practicing pharmacy, I have seen families struggle to pay for their medications. I have seen senior citizens at the counter across from me try to make a decision between buying medication and buying groceries. I have seen mothers literally in tears because they couldn't afford the medication for their children.

When I came up to Washington, that was one of the things I wanted to concentrate on. We are very fortunate we have a President and administration who are focused on this issue as well and have done some outstanding things. Two of those things that are being proposed by the administration right now I want to talk about tonight, but the main thing I want to talk about is the prescription drug chain.

Just earlier today, we had a hearing in the Energy and Commerce Committee, in the Health Subcommittee that I serve on, where we had representatives from the pharmaceutical manufacturers and from the PBMs, the pharmacy benefit managers, pointing fingers at each other and blaming each other for the problem.

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I have to tell you, in full disclosure, I am a big fan of the pharmaceutical

manufacturers. What I have seen over my years of pharmacy practice has been nothing short of phenomenal.

When I first started practicing pharmacy in the early 1980s, I can remember a time when, if you needed an antibiotic, you had to take 40 tetracycline. You had to take four a day for 10 days. Now you can take an antibiotic or get a shot in one day and be cured of some of the things that we were treating back there in 1980 with a 10-day supply.

I have seen illnesses such as hepatitis C—and hepatitis C, when I first started practicing pharmacy, was pretty much a death warrant. If you were diagnosed with hepatitis C, you were probably going to die.

Through the research and development of the pharmaceutical manufacturers, I have seen them come up with medication so that we can now treat hepatitis C. That is phenomenal. We can cure it with a pill, and it is because of the research and development that has been done through our pharmaceutical manufacturers and through the National Institutes of Health that we have reached this point.

However, the price of those medications, in many cases, makes it inaccessible for people. If you have to pay \$85,000 for a medication to treat hepatitis C, for many people, that is just simply not accessible. If that medication is not accessible, it does you no good whatsoever.

I have called on the pharmaceutical manufacturers to do their part as well. They are not without responsibility here, and I think they understand that.

Tonight, what I want to concentrate on are the PBMs, the pharmacy benefit managers, the middlemen, if you will. If you look at their mission statement, they will tell you their mission is to lower drug costs.

My questions to you would be: How is that working out? If that is working out, if they are achieving their mission, why are we here? Why are we here tonight talking about this, the high prescription drug costs?

I submit to you that they bring no value whatsoever to the healthcare system.

Madam Speaker, I am very blessed tonight to have a number of speakers here with us to share their expertise, and I want to hear from some of them right now.

I want to begin with the gentleman from Kansas, Representative ROGER MARSHALL, who also is a physician, was a hospital administrator, and knows and understands this system.

Madam Speaker, I yield to the gentleman from Kansas (Mr. MARSHALL).

Mr. MARSHALL. Madam Speaker, I thank my colleague for yielding.

Madam Speaker, I rise today in support of the Trump administration's rule that will modernize Medicare part D and, as a result, lower drug prices, reduce out-of-pocket expenses for America's seniors, and make critical fixes to our systems that will help our local pharmacies.

Across Kansas, there are 506 chain drugstores and 253 independent community pharmacists. These pharmacists are honest, hardworking men and women who often go above and beyond to ensure that patients know how to manage their medications.

I have heard their stories, and they all share the same frustration: direct and indirect remuneration, or DIR, fees.

In many instances in rural America, the only healthcare professionals left standing are my good friends and colleagues from the noble pharmacy profession, and these DIR fees are running them out of town.

The increase of DIR fees over the last several years has raised out-of-pocket costs for our seniors and put our pharmacies at financial risk, often operating in negative margins.

Far too regularly, pharmacy benefit managers, or PBMs, collect DIR fees from pharmacies months and months after claims. It is completely unpredictable and unfair, and the benefits all go into the pockets of the pharmacy benefit managers.

Shame on them for doing this, but not anymore. This proposed rule will guarantee predictability by helping standardize the process and end the disparity between pharmacists, patients, and PBMs.

The Centers for Medicare and Medicaid Services estimated that seniors will save up to \$9 billion—\$9 billion—over the next 10 years, and the Federal Government will save nearly \$17 billion over that same timeframe.

I appreciate President Trump and his administration for addressing this concern and providing commonsense, financially responsible solutions.

It is my hope and the hope of pharmacists across the country that this rule will be finalized quickly so that it can go into effect next year.

I would like to recognize my colleague, pharmacist BUDDY CARTER, who may know this issue better than any of us, as our only pharmacist in Congress.

I thank my colleagues Dr. PHIL ROE, MORGAN GRIFFITH, and PETER WELCH for leading on this issue and bringing it front and center for both the Doctors Caucus and the Energy and Commerce Committee members.

Mr. CARTER of Georgia. Madam Speaker, I thank the gentleman for his keen insight on this subject. It is very important, and I appreciate his expertise.

Madam Speaker, what the gentleman from Kansas was speaking about are two proposals that are before CMS right now.

One proposal would do away with DIR fees. Now, let's make sure we understand that DIR stands for direct and indirect remuneration. This is when the PBMs go back months later—in some cases, years later—and recoup, or claw back, reimbursements for what they have already sent to the pharmacies.

You can imagine what kind of impact this would have on a business. There is

no sustainable business model out there that can absorb that.

I get texts all the time from small pharmacy chains that are telling me: I just got a bill from the PBM. Last year, my total DIR fees were \$500,000, a half million dollars.

That is money they have already paid taxes on, but they are clawing it back. They are taking it back.

CMS has proposed that that end. I am in support of that, and I appreciate CMS doing this.

The other proposed rule that CMS has come out with has to do with the rebates, or discounts, if you will, that are offered to the PBMs by the pharmaceutical manufacturers—not offered to them, but the PBMs demand them from the pharmaceutical manufacturers. What CMS is proposing is that all of those rebates, or discounts, if you will, be given at the point of sale.

What we are trying to achieve here is to make sure that those rebates, that those discounts, are going where they are supposed to be going, and that is to the patients.

Keep in mind, everything we are talking about here is about the patient. We are talking about patient care.

My next guest speaker is also an expert in healthcare. In fact, he is another one of the members of our Doctors Caucus, a urologist from Florida, Representative NEAL DUNN, who, again, has practiced in the healthcare field and who has seen this with his patients.

Madam Speaker, I yield to the gentleman from Florida (Mr. DUNN).

Mr. DUNN. Madam Speaker, I thank Representative CARTER, who is a colleague, a friend, and a neighbor, and who also has genuine expertise on this subject.

The administration recently published two rules that tackle the issues faced by both our Medicare beneficiaries and the pharmacies that serve them.

One rule in particular, the “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses” rule, addresses pharmacy direct and indirect remuneration fee reform by instituting that DIR fees will be negotiated at the point of sale instead of the underhanded and retroactive fashion by which the plans and PBMs currently operate.

Currently, pharmacies can face these clawback fees after they have already filled and sold a prescription for Medicare part D and Medicare Advantage patients.

DIR fees have become a catchall category for pharmacy benefit managers to collect more overhead after prescriptions are sold.

Pharmacies are often unaware of what they will owe, and the standards for these fees can be impossible to meet. As a result, many independent pharmacies in my district are forced to provide the drugs at below cost.

Imagine that for just a moment. DIR fees are causing pharmacies to operate

in the red, all while they are providing lifesaving medication to America’s seniors.

DIR fees have also led to drastic increases in out-of-pocket costs for our patients, which, in turn, forces seniors into the doughnut hole of Medicare part D even sooner.

To protect seniors and pharmacists in my district, and as a medical professional, I urge CMS to finalize the language included in the rule that reflects the negotiated price at the point of sale.

Mr. CARTER of Georgia. Madam Speaker, I thank Dr. DUNN for his keen insight on this very important subject and for his comments.

Madam Speaker, I have a couple other comments about PBMs.

As I mentioned earlier, if you look at their website, if you look at what their mission statement is, it says that they are there to lower drug costs. Well, that is not working out very well.

Let me say this: I am not opposed to anybody making money. I get it. That is capitalism, and that is fine.

But three PBMs control 80 percent of the market—80 percent of the market. Three companies control that, three PBMs. The largest PBM, in 2016, had gross revenues that exceeded that of Ford Motor Company, Pfizer Pharmaceuticals, and McDonald’s added together.

Again, I am not opposed to anybody making money, but tell me how a company can make more than Pfizer Pharmaceuticals, McDonald’s, and Ford Motor Company combined.

To make matters even worse, those companies are worldwide. This PBM is just domestic. They are just here in America.

Again, I am not opposed to anybody making money, but tell me the value they are bringing to the system. They are not bringing any value to the system.

That is why I am in support of what CMS is proposing: doing away with the DIR fees; making sure that the rebates, the discounts, if you will, are given at the point of sale; and increasing transparency.

Madam Speaker, the next speaker is a good friend, a member of the Georgia delegation, Congressman RICK ALLEN from Augusta. RICK is a businessman, a very successful businessman. He understands the challenges in business. Certainly, healthcare costs, I am sure, were challenges for him.

Madam Speaker, I yield to the gentleman from Georgia (Mr. ALLEN).

Mr. ALLEN. Madam Speaker, I thank Congressman CARTER for yielding and for his efforts here this evening to shine a light on an issue that we all know is affecting far too many Americans.

It is a shame to keep doing things when they don’t work. Something has to be done.

Madam Speaker, the rising cost of prescription drugs is causing significant financial burdens for millions of

Americans, patients, seniors, and our businesses. Too often, Americans have to choose between much-needed prescriptions and household expenses.

However, President Trump made it clear to the American people during his State of the Union Address that lowering the cost of prescription drugs was one of his top priorities. As we have seen throughout his Presidency, promises made are promises kept.

Earlier this year, the Trump administration issued a proposal that would create incentives to lower list prices and reduce out-of-pocket spending on prescription drugs, potentially becoming the most sweeping change to how American drugs are priced, a much-needed change.

By delivering discounts directly to patients at the pharmacy counter and bringing long-overdue transparency to a broken system, we are putting patients and seniors first. That is how it should be.

It is high time to end these kickbacks to pharmacy middlemen, referred to as PBMs, in this process of dealing with these DIRs, which are putting many of those in the pharmaceutical business in my district out of business.

I thank the administration, Congressman CARTER, and my fellow colleagues this evening for their commitment to righting this ship and reducing drug prices for all Americans.

Mr. CARTER of Georgia. Madam Speaker, I thank the gentleman for his comments, and I certainly appreciate his leadership here in the House.

Madam Speaker, as you heard earlier from one of our speakers, CMS estimates that this change alone, doing away with the DIR fees—putting the discounts, the rebates, if you will, at the point of sale—will benefit the consumer, benefit the patient, and could save patients \$7.1 to \$9.2 billion.

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Now, let me tell you, that is significant. That is significant for those senior citizens that I was talking about earlier who are trying to make a decision between buying medicine and buying groceries. That is significant to that mother who is trying to buy the medication for her child. Those savings will help. Transparency will help.

The savings are going to go much further than just this estimated seven to \$9 billion, because as we get better transparency we will get lower drug prices. I am convinced of that.

Madam Speaker, my next speaker is a gentleman who certainly understands this issue and has worked closely on it. He has been a champion on this issue. Representative AUSTIN SCOTT, from Georgia, has gone to great lengths to study this issue. He has met with small pharmacies in his district. He has discussed with them the problem, and he understands it; and we are very, very fortunate to have him and his input.

Madam Speaker, I yield to the gentleman from Georgia (Mr. AUSTIN SCOTT).

Mr. AUSTIN SCOTT of Georgia. Madam Speaker, I want to thank my colleague, Representative CARTER, for his work on this. He was a small pharmacy owner before he got here.

Prior to my arrival in Congress, I was actually an insurance broker for many years, a health insurance broker. And it always amazed me, as pharmacy benefit managers tried to explain their business model, that they actually couldn't explain their business model.

So I rise today in support of our local pharmacies and the unique role that they play in serving patients. I stand here to commend the Centers for Medicare and Medicaid Services and the recently-proposed rule aimed at addressing direct and indirect remuneration, DIR, fees and drug rebates; rebates that don't go to the consumer, but rebates that go to multibillion-dollar corporations.

I frequently make stops at local pharmacies when I am back at my home in Georgia, and I appreciate the services that they provide their customers.

I am from a small town, and local pharmacists are a fixture in the community. They are the first line of defense in preventing and treating a customer's needs. They have known most of their customers in their community for many years.

I will give you one brief example. As an insurance broker, we had written a contract on a business and the cards had not come in yet. And there is a small-town pharmacy, and then there is the big chain pharmacy. One of the employee's children had gotten sick.

Guess which pharmacist was going to work with the family to get them the medicine before the insurance card came in? And guess which pharmacist was blocked out of the plan by the pharmacy benefit managers? It was the same one, the local, small-town pharmacist.

I am troubled on many of these visits, because I know how these community pharmacies are finding it more and more difficult to serve their neighbors while remaining competitive in the larger healthcare marketplace.

I hear from my constituents regularly about the financial burden they face as drug prices continue to climb. And the price for a drug today, when they go to get it refilled a month from now may be totally different, and rarely is it lower.

Plain and simple, we pay too much for drugs in this country. I would hope that it is something that we could work together in a bipartisan manner. President Trump has already said that he is willing to sign a piece of legislation to reduce the cost of pharmaceuticals in this country, and it is something that we should be able to come together and pass to help the American citizens and reduce the cost of healthcare for the American family.

Most Americans assume that it is probably a pretty simple transaction for the pharmacist when the phar-

macist purchases the drugs, even though they know it is a very complex transaction for them, never knowing what the drug is going to cost prior to going into the pharmacy.

But the pharmacy transaction is just as complex; and it is anything but clear and simple, and this is because of the pharmacy benefit managers.

They have used direct and indirect remuneration fees, DIR fees, to claw back money from pharmacies on individual claims, long after those claims are believed to have been resolved.

It means that a pharmacy doesn't know how the final reimbursement amount will be received for a claim for weeks or even months. And anyone who runs any business, healthcare business or any other business, knows you can't operate when you don't know what your reimbursement is.

CMS recently proposed drug pricing rules addressing this issue head-on by requiring all pharmacy price concessions, a subset of DIR, to be included in the negotiated price, which is the price the pharmacy will be reimbursed at the point of sale for dispensing the drug.

This directive would move negotiated drug prices much closer to the cost of the drug for the Part D sponsor, essentially eliminating retroactive pharmacy DIR fees.

Patients win when pharmacy price concessions are included in the negotiated price.

I want to commend the administration for making lowering drug prices a priority; and I want to challenge my colleagues in the Democratic Party to work with the administration and the Republicans in this House to push forward legislation that would continue to reduce the cost of healthcare, specifically pharmaceuticals, for the American citizen.

I, along with many of my colleagues on both sides of this aisle, have advocated for these sorts of reforms that bring transparency and accountability to the system.

Now who could be against transparency and accountability?

These are bipartisan issues on which we share broad agreement. I call on the leadership of this House to put the partisan politics aside; follow the lead of the administration; or walk with the administration to address the lack of transparency in the pharmaceutical industry. Give pharmacies a level playing field to compete, and provide Americans access to affordable prescription drugs.

This is something that we should have done for the American citizens long ago and it is something that we can do right now.

Madam Speaker, I thank my good friend and fellow Georgian, Mr. CARTER, for hosting this Special Order this evening. I look forward to continuing to resolve this issue for the American citizens.

Mr. CARTER of Georgia. Madam Speaker, I thank the gentleman for his comments, and I thank him for his

work. He truly has been a champion for his constituents.

His father is a doctor and, certainly, he understands healthcare. As he mentioned, he was an insurance broker, he understands insurance. And a lot of what we talk about here is insurance.

Let me try to articulate, if you will, exactly what I am talking about here. Some of the folks back home who are watching may be thinking, well, I don't really understand why the pharmaceutical manufacturers have to go through the PBMs.

What happens is that insurance companies work on formularies. In other words, they say, if you have got this disease, or if you have got this health problem, these are the drugs that we are going to cover.

The pharmaceutical manufacturer, in order to get their drug on that formulary, has to go to the PBM, the middleman, and has to offer them discounts, rebates, if you will, in order to get their product on that formulary.

That is what we are talking about. That is where they have the pharmaceutical manufacturers by the short hairs, if you will. That is where they really put the pressure on. So that is really what we are talking about.

Look, again, as I have said before, I am not opposed to anybody making money, but show me the value.

I mentioned a hearing that we had earlier today in the Health Subcommittee of the Energy and Commerce Committee. I mentioned that we had some PBMs there. We had two PBMs there. One is one of the major PBMs that requires the pharmaceutical manufacturers to give them rebates in order to have their products listed on the formulary.

And then another PBM was there, and they are just a flat fee. In other words, they just charge an administrative fee. That is all they charge. Again, PBMs, that is the way they evolved. All they were to begin with, when they started way back when, were just simply processors.

But enough about what we have done here in Washington. Let's talk for just a minute about State legislators and what State legislative actions have been taken.

Let me clarify and let me point out that I am not talking about just red States. I am not talking about just blue States. I am not talking about big States. I am not talking about small States. I am talking about all States, all the States in our union;

I am talking about States like Ohio. Ohio's Department of Medicaid published a report in January detailing exactly how PBMs have been gaming the system; that's right; in Ohio.

Ohio found that CVS—CVS is Caremark—that they had been using their role as the PBM for their State Medicaid program to pay CVS pharmacies as much as 46 percent more than competing pharmacies.

Now, this is something else we need to talk about. We need to talk about

what is referred to as vertical integration. That is, right now, where the insurance company owns the PBM and owns the pharmacy.

The top three that I mentioned earlier that control 80 percent of the market, that is the case with all of them. CVS is the pharmacy. Caremark is the PBM. Aetna is the insurance company.

Now, when we were talking to the PBMs today in the committee, we would ask them, what are you doing with these discounts? What are you doing with these rebates that you get? And they would tell us, well, we give them back to the plan sponsors, and the plan sponsors decrease premiums.

Anybody seen their premium decreasing recently? I don't think I have.

But think about it for a moment. If the insurance company owns the PBM, and owns the pharmacy, if the PBM is going to give it back to the insurance company, isn't that just taking money out of one pocket and putting it in the other pocket?

I mean, if CVS—if Caremark is going to give back the money that they are saving in the third party with the PBMs to the insurance company, Aetna, that they also own—and they are not the only one.

What about Express Scripts? Express Scripts just recently bought Cigna. So you have got Cigna as the insurance company. You have got Express Scripts as the PBM. And, oh, by the way, Express Scripts has their own mail order pharmacy and in terms of volume, they are the third largest in America. So, again, we have the situation there.

Same thing goes with United, UnitedHealthcare owns Optum, and they have their own mail order pharmacy.

So, there you have the three top PBMs, controlling 80 percent of the market; that also have their own insurance company, and they also have their own pharmacy.

This is what happened in Ohio. Ohio discovered that Caremark, that third party, the PBM, was paying their pharmacy, CVS, 46 percent more than they were paying competing pharmacies. That is an example of where they were taking money out of one pocket and putting it in another pocket.

What about New York State? Their State Medicaid reported that PBMs were pocketing a 32 percent markup on generic drugs; 32 percent markup on generic drugs; the drugs patients traditionally rely on to be more affordable than their branded alternatives. But New York caught them red-handed.

I can go on and name State after State. The State of Arkansas called a special session to address the situation with PBMs.

Just yesterday, my home State of Georgia, the Governor signed into legislation two bills dealing with PBMs; one of them that would prohibit PBMs from steering their patients to their own pharmacies and steering them away from other pharmacies, independent pharmacies.

So this is just not the Federal Government acting on these issues. We have had States who have acted on these issues as well.

So let's talk about a couple of other things that we have done in Congress. One thing that I want to mention, because I thought it was such an egregious thing that the PBMs were doing in the past—we, thankfully, were able to address this—was called the gag clause.

Thankfully, we had legislation that I was honored to sponsor here in the House that was passed in the House, passed in the Senate, signed into law by the President. It addressed the gag clause.

What is a gag clause?

You want to talk about the audacity of the PBMs? Let me tell you about the audacity of the PBMs.

As I mentioned earlier, about the pharmaceutical manufacturers being under pressure to give the PBMs discounts, rebates, if you will, in order to get their drugs on the formularies; well, independent pharmacies are the same way. They are under pressure.

What the PBMs did is they told—they had a clause in their contract with the pharmacy, and it said that if a drug is cheaper if you buy it out of pocket, if you pay for it out of pocket, if you buy it for cash than the copay, you cannot tell the patient that.

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And if you do tell the patient that, then you run the risk of being kicked out of the network. Well, the reality is you can't afford to be kicked out of the network. If you lose thousands of bodies because that PBM controls that network, then you are out of business.

So pharmacies had no other choice. Patients were paying more with their copay than what they would have paid for it if they would have simply paid out of pocket, just simply paid cash. We did away with that.

Thank you, Mr. President, for signing that legislation.

We addressed that in Congress. We said, no, that is not going to happen anymore. Now pharmacists can do what they were trained to do, and that is take care of their patients and tell them, Look, if you pay for this, you can buy it for \$4 and you don't have to pay a \$20 copay.

You say, Well, how often did that happen?

Well, let me give you just one example that happened in our committee, in the Energy and Commerce Committee. We actually had one of our Members who was the primary caregiver for her husband, who was very ill at the time. We had been talking about the gag clause, so she knew about it. She knew that pharmacists weren't allowed to offer that information.

So she went into the pharmacy, and she was told that her husband's medication, no exaggeration, was going to be \$600. She knew to ask the pharmacist. She said, What if I just pay for

it out of pocket? What if I just pay you cash? How much will it be?

\$40. \$40.

Now, granted, this is an extreme example, but it is an example.

Thank goodness we did away with that. I thank the Senate for passing this. I thank the House for passing it. I especially thank the President for signing this into law.

Madam Speaker, this is a real problem.

I want to conclude by saying that what we are trying to do here is to bring about transparency. Just show us what is happening. That is all we are asking for.

I want to applaud the administration. I want to thank President Donald J. Trump for bringing this issue to light. This has been an issue that he has worked on.

This is a nonpartisan issue. I never in my years of practicing pharmacy asked someone, Are you a Republican or a Democrat? That doesn't matter. This impacts everyone.

I thank the President for his leadership on this and I thank the administration for these two proposed rules: doing away with DIR fees, making the rebates at the point of sale, so that they will truly go to the patient.

These two rules that are being proposed by CMS will help get us to a point where we will have more transparency. That is what we need.

Folks, this is a serious subject, a very serious subject. I have witnessed it firsthand, witnessed it in my practice of pharmacy for over 30 years. It is horrible when you see someone suffering who can't afford a medication.

I call on the pharmaceutical manufacturers to do their part. They have got to do a better job with their pricing. They are not without responsibility here, and I think they understand that.

But, Madam Speaker, we have got to have these two rule proposals passed, and I encourage CMS to follow through on this, do away with DIR fees, put the rebates at the point of sale. This will bring about transparency.

I thank the administration for their support. I thank those who spoke here tonight.

Madam Speaker, thank you for giving me this opportunity to bring to light this extremely important subject.

Madam Speaker, I yield back.

#### THE MUELLER REPORT

The SPEAKER pro tempore. Under the Speaker's announced policy of January 3, 2019, the gentlewoman from Illinois (Ms. SCHAKOWSKY) is recognized for 60 minutes as the designee of the majority leader.

Ms. SCHAKOWSKY. Madam Speaker, the report on the investigation into Russian interference in the 2016 presidential election, more commonly known as the Mueller report, outlines efforts by the Russian Government to manipulate the United States election