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LOWERING THE COST OF PRESCRIPTION DRUGS:

REDUCING BARRIERS TO MARKET COMPETITION

WEDNESDAY, MARCH 13, 2019

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:02 a.m., in Room 2123, Rayburn House Office Building, Hon. Anna G. Eshoo [chairman of the subcommittee] presiding.

Present: Representatives Eshoo, Butterfield, Matsui, Castor, Sarbanes, Lujan, Schrader, Kennedy, Cardenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragan, Blunt Rochester, Rush, Pallone (ex officio), Burgess, Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Staff Present: Jeff Carroll, Staff Director; Luis Domingues, Health Fellow; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Megan Howard,

FDA Detailee; Zach Kahan, Outreach and Member Service Coordinator; Joe Orlando, Staff Assistant; Tim Robinson, Chief Counsel; Samantha Satchell, Professional Staff Member; Kimberlee Trzeciak, Senior Health Policy Advisor; C.J. Young, Press Secretary; Mike Bloomquist, Minority Staff Director; Adam Buckalew, Minority Director of Coalitions and Deputy Chief Counsel, Health; Jordan Davis, Minority Senior Advisor; Margaret Tucker Fogarty, Minority Staff Assistant; Theresa Gambo, Minority Human Resorces/Office Administrator; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; James Paluskiewicz, Minority Chief Counsel, Health; Zack Roday, Minority Communications Director; Kristen Shatynski, Minority Professional Staff Member, Health; and Danielle Steele, Minority Counsel, Health.

Ms. Eshoo. Good morning, everyone. The Subcommittee on Health will now come to order. The chair now recognizes herself for 5 minutes for an opening statement.

First of all, welcome to all of our witnesses. It is a pleasure and an honor to have you here with us today, to everyone that is in the hearing room, and to all of my colleagues. This is the first hearing of the Health Subcommittee on drug pricing -- legislative hearing.

For too long, the American people have been subjected to the abuse of the patent system by pharmaceutical companies, and generic companies entering into agreements and employing tactics that block competition and keep prices high. When brand and generic manufacturers employ these tactics, it is really the American people that lose out by having to pay more for the prescription drugs because there is less competition.

We know that when generics come to market, they can drive prices down exponentially for consumers. The United States has the lowest, generic drug prices in the world. So where there is competition between brand drugs and multiple generics, it works. The bills we are considering today will inject competition in the system sooner, move drugs to the market more quickly, and lower costs. We are examining the CREATES Act, authored by Representatives Cicilline, Sensenbrenner, Nadler, Collins, Welch, McKinley, and the FAST Generics Act, authored by Representatives Welch, McKinley, and Cicilline, which address barriers to generic development.

Both bills take a different approach to address the stalling tactics brand manufacturers use to restrict access to samples of their products. Generic companies rely on samples of the brand product to ensure that the generic is identical to the brand

drug, so that patients can use the products interchangeably.

The second group of bills addresses marketing abuse barriers. The BLOCKING Act, introduced by Representatives Schrader and Carter, target generics that have been granted exclusivity and then block other products from coming to market. This delaying of their exclusivity periods is referred to as parking, and I believe Secretary Azar yesterday referred to it as squatting.

When a company delays the start of the exclusivity period of a product, it not only delays other generics from coming to market, it also delays lower prices reaching patients sooner.

During our hearing on the fiscal year 2020 budget yesterday, Secretary Azar explained that this parking behavior leads to an average delay of 12 months for a generic to come to market. The Protecting Consumer Access to Generic Drugs Act, introduced by Representative Rush, and the FAIR Generic Drugs Act, introduced by Representative Barragan target pay-for-delay agreements. This is brand manufacturers paying generic companies to delay entering the market with generic versions of the drug.

Remember that saying, it takes two to tango, and they have tangoed. And both are wrong. The Protecting Consumer Access to Generic Drugs Act prohibits these pay-for-delay agreements outright. While the FAIR Generics Act sets up a different, legal framework that discourages brand manufacturers and generic companies from entering into these agreements.

The last group of bills make important updates to the Orange and Purple Books at the FDA by amending what information must be included and requiring these resources to be published in a user-friendly way. When manufacturers are considering where to invest their research and development dollars, they use the Orange and Purple Books to

determine what patents are currently active and which patents will be expiring soon.

Representative Kelly and myself introduced the Purple Book, and at any rate, this is a legislative hearing to discuss the bills, to close loopholes, eliminate bad practices in the drug system, all in order to bring the costs down.

I now would like to yield the remainder of my time to Representative Welch.

[The prepared statement of Ms. Eshoo follows:]

******** COMMITTEE INSERT ********

Mr. Welch. Thank you very much. Thank you, first of all, Madam Chair, for your leadership on this incredible issue of drug pricing.

Second, we have got an opportunity, bipartisan, to finally tackle the rip-off pricing in the pharma system. And yesterday we had Secretary Azar here, who said that the administration supports efforts to end pay-for-delay, to have FAST and the CREATES Act passed to help us to ban product-hopping, to crack down on the citizen-petition abuses.

So we have an opportunity, bipartisan, to address something that has been an enormous burden on the American consumer and the American taxpayer. And thank you for your leadership, and I look forward to working with you and our ranking member to make progress. Thank you.

[The prepared statement of Mr. Welch follows:]

******** COMMITTEE INSERT ********

Ms. Eshoo. I thank the gentleman. I now have the pleasure of recognizing the ranking member of the subcommittee, Dr. Burgess, for 5 minutes for his opening statement.

Mr. Burgess. Yes, just prior to doing that, if I could ask to be recognized for a unanimous-consent request for Representative Duncan to be able to participate in today's hearing.

Ms. Eshoo. So ordered.

Mr. Burgess. And also if he is yielded time to make an opening statement, enter a written opening statement in the record, question witnesses during the hearing, and submit additional questions for the record at the end of the hearing.

Ms. Eshoo. So ordered.

Mr. Burgess. So, thank you. We are having a hearing that will touch upon the important topic of drug pricing, and I will admit to being frustrated that we are not considering, perhaps, some additional policies. As the chairman of this subcommittee in December of 2017, I held a drug-supply-chain hearing with a total of ten witnesses. The number of witnesses pushed the limits of how many individuals we could actually fit at one table, and I do recall getting some criticism from the then ranking member of the full committee, but I thought it was critical that we had someone present -- or someone to represent each level of the drug-supply chain.

Now, as evidenced at that hearing, there are a number of conflicting opinions held by the entities along the supply chain, but that does not mean that we should not listen to them. It is likely that legislation to address drug pricing will ruffle some feathers, and that is okay. However, it is not acceptable to intentionally legislate within a black box.

A few of the bills before us today are bipartisan and have been previously introduced, and there are numerous new pieces of legislation. The text of the bills was not shared with the Republicans until last Monday. And that, of course, does not comport with the two-week rule that has been considered sacred for years. Not a Republican rule. This was a rule that both Chairman Waxman and Chairman Dingell held in high regard.

I will reiterate what I said last week. Bipartisanship is asking for my input, not just my vote. There are some of these bills that we might have been able to work and collaborate, and we may still be able to collaborate going forward, but giving a Member less than 24 hours to sign on to a piece of legislation they have never seen is discourteous, especially when we have said at each step along the way, in this Congress, that we are willing to work in a bipartisan fashion. But if we don't have a seat at the table during the drafting process, you can expect it to take longer as we do our due diligence in vetting the policies.

Additionally, no stakeholders had been consulted in the drafting of these bills, including the Association for Accessible Medicines, the generics manufacturers whose bills -- some of these bills are intended to benefit. In fact, the generics manufacturers have either not commented on, or opposed some of the bills that are before us this morning, and we may hear more about that later.

Several of these bills had not seen the light of day outside of the chairman's staff, the Members these bills were assigned to, and House legislative counsel. These bills have received no input from stakeholders, no technical assistance from the agencies, specifically the Food and Drug Administration, and the Federal Trade Commission.

As chairman of the subcommittee, I would have never thought about holding a

hearing on seven bills that were not shared with the other party until 9 days before the hearing, not to mention, without the agency witnesses. It is unthinkable, that the Food and Drug Administration was not invited to testify at this hearing.

And these are not grab-bag, drug-pricing issues. These are seven pieces of complex legislation that all intricately involve the Food and Drug Administration, and not only was the Food and Drug Administration not invited to present us with their thoughts about these bills, but the Food and Drug Administration was not consulted for technical assistance on any of these bills prior to this hearing.

I learned that the staff spoke with the Food and Drug Administration about these bills for the first time yesterday, and the agency had more questions than answers. As the agency that would be largely tasked with implementing these bills, should they be signed into law, it is troubling that agency witnesses were not considered. Ideally, the Republicans could have called the FDA as a Republican witness, but we didn't get the notice for the hearing in time to allow us to do so. As you recall, is it does take some time to get testimony cleared through Office of Management of the Budget.

But I do want to thank the witnesses who are here today, and I want to thank them for agreeing to testify before us this morning. This is a complex problem, and as someone, I think, previously has said, there is no one single solution. So there is no 100 percent solution, but there are probably 101 percent solutions, and if we will get to work on some of them, we can achieve some benefit for the American people.

But I do again thank the witnesses, and I think we can utilize their expertise while we highlight the flaws in some of these bills, we can accentuate what is positive in some of these bills, and use their input to improve upon the bills during the path forward. And I will yield back my time.

[The prepared statement of Mr. Burgess follows:]

******** COMMITTEE INSERT ********

Ms. Eshoo. I thank the gentleman.

I would just like to say a few things about -- a few remarks. First of all, the sky is really not caving in. Half of the bills being considered have been introduced in previous congresses. They are not brand-new. And multiple are bipartisan. We shared language with the minority on March 4th. We included the minority in all witness calls, we are open to having conversations on language. This is a legislative hearing. It is the first step, and to have the FDA -- agencies don't come to legislative hearings to comment on the legislation.

So this is an important -- I believe that this subcommittee is the first to be taking up, with a legislative hearing, seven bills, on drug pricing, and I don't believe any other committee in the House has done that, nor has it occurred in the Senate as yet. So on we go.

Now I would like to call on the -- recognize the chairman of the full committee for his opening statement, 5 minutes. Mr. Pallone?

Mr. Pallone. Thank you, Madam Chair. And let me also add, from a process point of view, you know, the Energy and Commerce Committee is one of the few -- maybe the only one -- that has complete, regular order. Meaning that, you know, we have hearings in the subcommittee; we have markups in the subcommittee; we then have a markup in the full committee. And this has been done on a bipartisan basis.

So I just -- I just want to remind everyone that when you talk about process, you know, we really follow regular order, and I am not trying to disapprove of other committees, but there is very few committees that actually do that entire process.

But in any case, today the committee begins the process of fulfilling our

commitment to provide some much-needed relief to Americans struggling to pay for skyrocketing prescription drugs. I am pleased that we will be examining policies that will help to bring the high cost of prescription drugs down. The American people have justifiably been demanding congressional action to make prescription drugs more affordable, and who can blame them.

Prices are so high that recent data shows that nearly a quarter of Americans didn't fill a prescription in the past year due to the high cost. Nineteen percent say they skipped a dose or cut pills in half because they wanted to make them last longer. These are choices Americans simply should not have to make. It is unacceptable and could, in fact, lead to greater illness and higher medical costs down the road.

And it is time for Congress to help make prescription drugs more affordable. One way to achieve this goal is to facilitate greater competition from generic and biosimilar manufacturers. And I believe reducing barriers to generic drugs and increasing competition in the pharmaceutical market will benefit American families who are struggling to afford their medications.

And let me stress that -- competition. You know, a lot of times Congress is accused of, you know, trying to do things that are not competitive. This is clearly the opposite. This is competition. This is market-driven. This is capitalism. That is what we are about here.

Generic drugs play a critical role in increasing access and reducing costs in our healthcare system. In 2017, the entry of generic drugs to the market saved patients and the public $265 billion, including over $82 billion for Medicare alone, and that is more than $1,900 per enrollee. These numbers alone demonstrate the substantial cost savings to consumers when we ensure generic products can come to market as soon as

possible.

The proposals before us today will close loopholes that some drug companies are exploiting to game the system, unfairly raise drug prices, and take advantage of American families. And more specifically, the bills address three key barriers for generics -- patent listing, drug development and market entry, and market barriers. Two of the bills will be discussing, the Orange Book Transparency Act of 2019, introduced by Representative Kelly, and the Purple Book Care Continuity Act of 2019, introduced by Chairwoman Eshoo, would help to increase accuracy and transparency of the two databases that guide development decisions for generic and biosimilar manufacturers. These bills would help generics overcome the barrier of patent listing.

Two other bills -- the CREATES Act and the FAST Generics Act -- led here on the committee by Representatives Welch and McKinley, would help address the barrier of drug development and market entry. Today the use of restrictive distribution systems, including REMS by certain manufacturers, delays access to samples of branded drug products for development purposes. It also impedes market entry through delays in negotiations on single shared system REMS. And this important legislation would eliminate these barriers.

And, finally, we are considering three policies focused on market barriers -- again, market, I stress market -- the BLOCKING Act, introduced by Representatives Schrader and Carter, would address delays that occur when first-time generics are unable to be approved. This blocks the approval of other generics.

The Protecting Consumer Access to Generic Drugs Act of 2019, introduced by Representative Rush, would discourage use of pay-for-delay agreements that result in generics delaying development or market entry.

And, finally, the FAIR Generics Act, introduced by Representative Barragan, would strengthen incentives for generic first applicants to enter the market on the earliest possible date and disincentive patent settlement agreements that delay generic entry.

These are all commonsense solutions that will remove unnecessary barriers to competition, and again I stress competition. These bills are a strong first step in making prescription drugs more affordable and providing real relief to hardworking Americans that are being price-gouged at the pharmacy counter.

Now, I know there are some people that think that, you know, generics aren't a major factor in bringing drug prices down. Totally disagree. My predecessors -- Congressman Dingell, Congressman Waxman -- very much believed that generics will lower prices and that generic competition is important, and I strongly believe that as well. And that is why we want to bring back the generics as even more a factor in bringing drug prices down, because we believe very strongly in that.

So thank you, Madam Chair. This is a very important hearing.

[The prepared statement of Mr. Pallone follows:]

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Ms. Eshoo. We thank the chairman, and now it is the pleasure to recognize the ranking member of the full committee, Mr. Walden.

Mr. Walden. Well, good morning, Madam Chair, and thanks for having this hearing, and I appreciate the comments of the full committee chair regarding how this committee works with hearings and then subcommittee hearings on legislation, and, of course, full committee markups, and I think that has been a hallmark of this committee, and I am glad to hear it will be that way going forward.

I wasn't going to say this, but given all the other discussion, it is important to note that the majority added a witness to this panel that we didn't find out about until after 5:00 on Friday.

And so, Mr. Davis, we thank you for joining us, because we reached out to you after that, because then we were given an opportunity, and it was sort of short notice, I know. But we appreciate your being here today.

Last Congress, as chairman of this committee, it was a priority of mine to make sure that patients could get streamlined access to more affordable prescription drugs. Working together in a bipartisan manner, the committee advanced the Food and Drug Administration Reauthorization Act, FADARA, to the full House, by unanimous vote, I might add, 54 to zero. The bill then went on to pass the House and, by voice vote, the Senate before being signed into law.

This law helps incentivize the entrance of competitive, generic drugs -- I agree with the chairman, generics really matter -- where there was a lack of competition in the marketplace, resulting in ability to decrease cost to consumers, and as a result, we have already seen generic drugs come to the market through these new pathways and prices

begin to drop for consumers on a variety of medications. So I think the good work of the Energy and Commerce Committee again showing through.

In fact, according to the FDA, roughly 1,275 approvals and approximately 320 tentative approvals for generic drugs have occurred since passage of this law. This includes the approval of the first ever generic EpiPen, and we know what was involved around that. Even more, five competitive generic therapies approvals have taken place thanks to the new pathway granted to the FDA by this committee. And I would also say the work the committee did on the 21st Century Cures, as we heard yesterday from Secretary Azar, also allowed for more drugs to come to market sooner and more competition.

So I thank the former chairman, Mr. Upton, for his leadership, and Ms. DeGette as well.

The bipartisan law has lowered the cost of important medications and devices. It has sped up how medical innovations come to fruition, and this is a win for consumers. The real results are a bipartisan cooperative approach, and we didn't stop there.

We then turned our attention to the complete, drug-supply chain. We put together arguably, I think, one of the best bipartisan Member briefings, as my tenure as chairman. For that briefing, we brought in an academic expert in drug pricing to better educate the members of the committee on the multifaceted problem and creative solutions to drive down the cost of prescription drugs.

Following that, we brought in ten witnesses, into a bipartisan hearing in this very room, where we dug into all aspects of the entire drug-supply chain. That included manufacturing, wholesale and distribution, and payment for drugs, and how each of these stages impacts the cost of medications. And they were all at that table, and they

couldn't point to somebody who wasn't because that person was there, too, and it really helped in our discussion.

Last Congress, our committee made real progress in getting lower-cost generics to market, incentivizing adding competition where it previously did not exist, examining the drug-supply chain, all because we worked together toward a common goal.

Regrettably, while Republicans share the goal of today's hearing -- and we do -- and some of these bills have bipartisan cosponsorship, and we do want to lower the cost of prescription drugs -- we wish it were more inclusive. Today we are considering seven bills. Only three have Republican cosponsors. That is largely because we didn't get a list of these bills until just 8 days ago. And then we were given just 24 hours to help identify potential Republican cosponsors, and by my count, this subcommittee has reviewed 14 bills this Congress. Just four have Republican coauthors, and I know we can do better than that.

Equally concerning, the bills we are examining today each represent complex modifications of the Food, Drug, and Cosmetics Act, and the FDA is not serving as a witness. And I think we would benefit by their input, and certainly Dr. Gottlieb, who is leaving the FDA, was a terrific participant before this committee.

So I hope we will hear from the FDA along the process before the markup. Legislative hearing is the only public opportunity, though, to hear from experts on the policies being advanced, and we will not have the agency responsible for implementing such technical policies present.

So with that, I am going to yield the balance of my time to Mr. Duncan.

[The prepared statement of Mr. Walden follows:]

******** COMMITTEE INSERT ********

Mr. Duncan. I thank the gentleman, and Madam Chairman, thank you for giving me the time and opportunity to be here today. It is an honor to introduce the President and CEO, and owner of Nephron Pharmaceuticals, and my good friend and fellow South Carolinian, Ms. Lou Kennedy.

Nephron Pharmaceuticals moved their headquarters to South Carolina in 2017 and employs over 600 people locally, all with a variety of skill sets. It is important to note that Lou is strongly supportive of our local veterans, all with a variety of skill sets. It is important to note -- excuse me, Nephron hires a significant number of veterans as they are already primed to follow chain-of-command in the work environment. Lou is supportive of the University of South Carolina where Nephron recently established --

Ms. Eshoo. The gentleman's time is expired. I am sorry. Your time is expired. And we are glad that you are joining us today.

Mr. Duncan. I yield back.

[The prepared statement of Mr. Duncan follows:]

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Ms. Eshoo. Once again, welcome to all the witnesses. We have a very full table, and we are anxious to receive your testimony, and thank you for your written testimony. I want to remind Members that pursuant to committee rules, all Members' written, opening statements shall be made part of the record.

So we will start with Ms. Lou Kennedy, the CEO and owner of Nephron Pharmaceuticals. Welcome to you and make sure the mike is on --

Ms. Kennedy. Thank you.

Ms. Eshoo. -- and you have 5 minutes. And you know the lighting system, correct?

STATEMENTS OF LOU KENNEDY, CEO AND OWNER, NEPHRON PHARMACEUTICALS; ANTHONY BARRUETA, SENIOR VICE PRESIDENT, GOVERNMENT RELATIONS, KAISER PERMANENTE; MICHAEL CARRIER, DISTINGUISHED PROFESSOR, RUTGERS LAW SCHOOL; KURT KARST, DIRECTOR, HYMAN, PHELPS, & MCNAMARA, P.C.; JEFF KUSHAN, PARTNER, SIDLEY AUSTIN, LLP; MARC M. BOUTIN, JD, CHIEF EXECUTIVE OFFICER, NATIONAL HEALTH COUNCIL; AND CHESTER "CHIP" DAVIS, JR. PRESIDENT AND CEO, ASSOCIATION FOR ACCESSIBLE MEDICINES (AAM)

STATEMENT OF LOU KENNEDY

Ms. Kennedy. Yes. Five minutes, red button, talk, go. I am a Southerner --

Ms. Eshoo. Yellow is the warning sign.

Ms. Kennedy. Yes.

Ms. Eshoo. Thank you.

Ms. Kennedy. I am a Southerner, but I will speak quickly.

Good morning, Chairwoman Eshoo, Ranking Member Dr. Burgess, Chairman Pallone, and Ranking Member Walden, and distinguished Members of the Energy and Commerce Subcommittee on Health. I want to thank you for this invitation to appear before you today to discuss competition to lower drug prices in the United States.

I am Lou Kennedy. I am CEO and owner of Nephron Pharmaceuticals Corporation. I am headquartered in West Columbia, South Carolina, and we have added more employees and have now reached a thousand employees. We are a leading manufacturer of sterile, genetic -- generic medications, and we are sterile compounders

of drugs on the FDA shortage list for all U.S. hospitals and surgery centers. High quality and affordable products for patients is our company focus.

Nephron believes drug patents should be controlled by a patent-approval system that reasonably rewards innovation but also incentivizes appropriate patent challenges, particularly for Orange Book-listed patents. A fair playing field would ensure erroneously granted patents are not used to prevent generic competition and maintain monopoly drug prices to the detriment of American consumers.

The Trump administration has published the American Patients First policy position which, if implemented, would encourage drug competition and reduce drug prices in the U.S. The American Patients First policy statement notes the negative impact of parking, the 180-day exclusivity awarded to eligible, first-to-file ANDAs, or abbreviated new drug applications.

Parking is the practice of delaying the introduction of a first-to-file ANDA, which goes directly against Hatch-Waxman Act, by entering into a delayed-entry settlement agreement between the ANDA filer and the original patent holder. This is commonly known as pay-to-delay. This is really an impediment to lowering the drug cost for Americans.

Nephron applauds this policy position for appropriate 180-day exclusivity, because of the immediate pricing reduction of second and follow-on suppliers of generic drug pricing.

Pricing data commonly demonstrates drug costs for a single med will drop approximately 80 percent when the fourth competitor enters the market. That is where we enter. Parking, along with Paragraph 4, patent challenges, and REMS program abuses add significant delays to generic competition, thereby maintaining higher

monopoly drug prices.

Nephron shares the goal of this committee and the administration of addressing the problem of purposeful parking that delays generic competition from tentatively approved subsequently submitted ANDAs. However, while Nephron shares the goal of H.R. 938, Blocking Low Cost Operation -- the BLOCKING Act of 2019, we are concerned as currently drafted the legislation would undermine the value of the 180-day exclusivity period.

This recent draft would prematurely terminate or reduce the first-to-file, 180-day exclusivity period by providing an overly broad, additional, exclusivity trigger that can result in forfeiture of the award. This outcome would not be in the best interest of American patients and taxpayers, and it would weaken this 180-day exclusivity incentive for generic manufacturers to drive challenges of brand patents.

The 180-day exclusivity period is important to allow the first filer to bring its product to market at the earliest possible time. We are also concerned that this well-intentioned legislation fails to address pay-to-delay settlements between a first-to-file generic company and its brand counterpart, which is the main source of delay for generic competition, particularly like us.

Nephron believes that pay-to-delay agreements allow weak, unchallenged patents to remain in place and serve as barriers to block subsequent, generic drug manufacturers from obtaining final approval. The current framework provides no incentive for subsequent applicants to challenge blocking patents that are left untested in pay-to-delay settlements.

Even if a subsequent applicant is successful in challenging all of the blocking patents, it cannot enter the market until a first applicant launches, allowing the 180-day

exclusivity period to expire. Delaying the start of this period results in higher prices for a drug.

Now, the FAIR Generics Act, H.R. 1506, would achieve the needed broader fix of the parking problem by allowing subsequent applicants that win their patent challenges to share the 180-day exclusivity award with the first generic to file an application challenging a brand patent. As such, Nephron urges Congress to take action to fix the broader parking problem, not just a narrow subset of the problem, by enacting legislation, along the lines of the FAIR Generics Act.

We would welcome the opportunity with the committee to strengthen and refine this legislation, which would enable a comprehensive solution to the parking problem. The Trump administration, the committee, and Nephron are all in agreeance of the need to lower drug costs for the American public.

Nephron supports pending bills relating to ANDAs and the 180-delay exclusivity, some of which are directly related to H.R. 938, and others that are necessary to remove stumbling blocks for ANDAs being filed. The Protecting Consumer Access to Generic Drugs of 2019 aims to prevent pay-to-delay settlements between first applicants and brand companies by adding a clause, exchange of anything of value, to current laws which prevents money from being exchanged for delayed marketing under a parked, 180-day exclusivity situation.

Ms. Eshoo. Your time is expired.

Ms. Kennedy. Thank you. I would entertain any questions from the panel.

[The prepared statement of Ms. Kennedy follows:]

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Ms. Eshoo. Thank you very much for your testimony and your written testimony.

Mr. Davis, good morning.

STATEMENT OF CHESTER "CHIP" DAVIS, JR

Mr. Davis. Good morning.

Ms. Eshoo. And welcome to you. You have 5 minutes to present your testimony to the committee.

Mr. Davis. Great. Chairman Eshoo, Ranking Member Burgess, Chairman Pallone, Ranking Member Walden, thank you on behalf of the Association for Accessible Medicines, our members, and the patients that we serve, for the invitation and opportunity to testify today.

Over the last decade, our members have delivered savings of nearly $1.8 trillion to patients in the U.S. healthcare system, and looking forward, FDA-approved biosimilars have the potential to provide even greater savings and access to live-saving treatments. However, current market realities and certain anticompetitive tactics that impede competition, threaten the long-term stability of both the generic and biosimilar markets here in the United States.

So as Congress considers steps to lower prescription-drug prices, we encourage this committee to advance policies that increase competition and patient access to generics and biosimilars. Equally important, however, is to avoid policies that could, despite best intentions, end up further delaying such competition and access, and address the very real sustainability challenges faced by generic and biosimilar

manufacturers here in the U.S. market.

To some of the specifics on the bills before you today, AAM greatly appreciates the leadership of Chairman Pallone, Congressman Welch, and Congressman McKinley on the CREATES and FAST Generics Acts. With the support of more than now 90 organizations, these strongly bipartisan, market-based solutions will stop anti-competitive abuses of FDA safety programs and reduce spending on prescription drugs by over $13 billion annually.

AAM strongly supports the CREATES and FAST Generics Act and encourages Congress to pass them into law immediately. AAM and our members value innovation and intellectual property, and the benefits that they provide to patients in the U.S. healthcare system. That said, it is equally important to recognize that perhaps the greatest barrier to competition occurs due to abuses of the U.S. patent system.

Increasingly, brand name companies are building so-called, quote, "patent estates," end quote, around blockbuster drugs. In fact, recent research shows that at least 78 percent of new patents are associated with existing drugs that are already on the market.

If Congress is going to meaningfully reduce drug prices, addressing abuse of the patent system must be front and center. To that end, we recommend three solutions: First, to provide a date certain for generic and biosimilar entry; second, to accelerate the biosimilar patent dance; and third, to harmonize Hatch-Waxman with the IPR process.

Despite the deterrent effect of brand name drug-patent thickets, a patent challenge and a potential settlement of that challenge is increasingly the only way a generic or biosimilar manufacturer can actually bring a competitive medicine to patients.

Thus, it is imperative to make sure, as these bills are deliberated, that two critical

elements are preserved: First, the right of two private parties to reach a settlement that is procompetitive, that brings generic drugs and biosimilars to market prior to the expiration of applicable patents; and second, the 180-day exclusivity period provided to the first generic filer.

Since the Supreme Court's decision in FTC v. Actavis, the FTC has reported that there are now very few patent settlements involving what is characterized as, quote, "pay-for-delay," end quote. In fact, the vast majority of patent settlements are now resolved without a transfer of value, since that decision, to the generic manufacturer or restrictions on generic competition.

It is our view that the patent-settlement legislation under consideration today is not yet quite aligned with the Supreme Court's Actavis decision. Moreover, the FTC is not required in the current bill to establish anticompetitive harm. As a result, we recommend that the proposal be narrowed to preserve agreements that are procompetitive, while making sure that those that are anticompetitive are held to account.

Patients and taxpayers also benefit when generic manufacturers take on significant risks and costs associated with being the first to file with the FDA and challenge a brand-name patent. The 180-day exclusivity incentive for first generics has helped fuel the growth of the American, generic drug market that today provides 90 percent of prescriptions for just 23 percent of drug spending, numbers that are unparalleled anywhere in the world.

Chairwoman, thank you for recognizing that earlier.

Importantly, Congress prohibited so-called parking as part of the Medicare Modernization Act. The FDA has the authority to address this issue, and despite our

requests, we have not been provided any examples yet, to date, to justify the legislative proposals and changes. For these reasons, at this point, recognizing that this is a fluid process, AAM is not supporting the legislation that would prohibit patent settlements or changes to the 180-day exclusivity for first generics, recognizing that this is a process.

In our view, while well-intentioned, these proposals have the risk of ending up delaying patient access to more affordable generics and biosimilars.

So let me close by thanking the committee for the opportunity to testify today and say that our members stand ready to work with you to ensure patients have access to generics and biosimilars. Thank you.

[The prepared statement of Mr. Davis follows:]

******** INSERT 1-2 ********

Ms. Eshoo. Thank you very much, Mr. Davis.

And now it is a pleasure to welcome and recognize Mr. Anthony Barrueta, the senior vice president of government relations at Kaiser Permanente, the first HMO in our country, correct?

Mr. Barrueta. Pretty close. Pretty close.

Ms. Eshoo. 1942, I think.

Mr. Barrueta. We have been around for a long time, so thank you.

Ms. Eshoo. You are recognized for your testimony for 5 minutes. And you are welcome.

STATEMENT OF ANTHONY A. BARRUETA

Mr. Barrueta. Thank you, Chairman Eshoo, Dr. Burgess, and distinguished committee members. I greatly appreciate the opportunity to testify today.

Ms. Eshoo. I think you need to bring your microphone closer.

Mr. Barrueta. How is this?

Ms. Eshoo. It is a little better.

Mr. Barrueta. Okay. I will lean in.

Ms. Eshoo. Move it again and lean forward.

Mr. Barrueta. I will lean in.

Ms. Eshoo. There you go.

Mr. Barrueta. So I am Tony Barrueta, senior VP for government relations for Kaiser Permanente. As the Nation's largest, private, integrated healthcare system, we

provide care and pharmacy benefits to over 12 million people across the country, dispensing approximately 90 million outpatient prescriptions and over 50 million outpatient and inpatient doses every year.

Our nonprofit model combines coverage and care delivery. We operate pharmacies that dispense drugs prescribed by our Permanente medical group physicians. We, therefore, have a unique perspective on the prescription-drug marketplace and prescription-drug pricing. Our mission for pharmacy, and all the services that we provide, is to deliver high quality, affordable care, and to improve the health of our members and the communities we serve.

We greatly appreciate this committee's attention to the problem of high drug prices. High drug prices impose a crippling burden on our members and our ability to carry out our mission. Drug companies -- random drug companies have virtually unfettered discretion to raise prices, which really imposes considerable and often devastating financial hardship on patients and families.

We are very concerned by overpatenting, exclusivity gaming, and pernicious lifecycle management trends. Too often the primary goal of these tactics is to leverage the law to stifle competition, rather than protect meaningful clinical advancements. It is past time for new policy framework that fosters competition and prices that patients and the healthcare system can actually afford, while still rewarding and incenting innovation.

Congress has a critical role to play in mitigating this behavior by evaluating the extent to which the current laws are subject to gaming that empowers the drug companies to extend monopoly pricing well beyond congressional intent.

We applaud the committee for working to make the patent landscape more transparent, curbing REMS abuses, and stopping tactics such as pay-for-delay settlements

and exclusivity parking. We are especially grateful that the committee is considering the CREATES Act. These anticompetitive practices significantly delay generic and biosimilar availability, hampering our ability to provide more affordable options for our members. They also create uncertainty that disrupts our ability to design optimal pharmacy benefits.

Our research pharmacists actively monitor drug pipelines to forecast when competition may enter the market. When competition doesn't occur at the expected time, it undermines our efforts to negotiate better prices from drug companies that would allow more affordable premiums and cost-sharing.

Our approach to pharmacy benefit shows what is possible when markets are competitive. We have industry-leading generic utilization, and every one-tenth of one percent increase in our generic utilization saves our system $28 million.

Many in the market have struggled to transition to biosimilars. At Kaiser Permanente, our physicians have embraced them. For example, within our system, Inflectra, the biosimilar, is used over 75 percent of the time instead of Remicade, the reference product. Inflectra utilization in the rest of the market is less than three percent.

Major contributors to our success include our evidence-driven formularies, developed by our physicians and pharmacists, our ability as an integrated system to generate and disseminate unbiassed information about drugs, and our restrictive approach to marketing by pharmaceutical sales representatives in our facilities.

Prescriber confidence is in excellent and unbiassed information, strong investment in clinical support and education, and our physician-pharmacist alignment, are all crucial to facilitating generic and biosimilar uptake. Breaking down barriers for generic entry is

of critical importance to our model of care. We simply cannot fully leverage our process to spar competition if generics and biosimilars are not available in the first place. That is why the work of this committee is so important.

We look at these as positive, first steps toward a more functional market for drugs. There is much more to be done. We think other things should be considered, including whether exclusivities on the books now should be narrowed to better balance access and rewarding innovation; whether the FTC should have more expansive authority to review drug companies' anticompetitive practices, including patent abuses; and whether agencies like FDA, NIH, PCORI, AHRQ, and others should play a role in educating through academic detailing and providing unbiased sources of information.

So thank you for considering our perspective on this important set of issues. We share your commitment to lowering drug prices and reducing barriers to biosimilar and generic market entry.

[The prepared statement of Mr. Barrueta follows:]

******** INSERT 1-3 ********

Ms. Eshoo. And look at that, you just stayed right within your 5 minutes. Excellent. Thank you very, very much.

I now would like to recognize Mr. Boutin, the chief executive officer of the National Health Council. Welcome, and you have 5 minutes for your oral testimony.

STATEMENT OF MARC M. BOUTIN

Mr. Boutin. Good morning, Chairwoman.

Ms. Eshoo. Put your microphone on, so everyone can hear every word.

Mr. Boutin. Good morning, Chairman, Chairwoman Eshoo Ranking Member Burgess, members of the Subcommittee on Health.

Bad actors have gamed the system, driving up costs for patients, and only Congress can fix it. My name is Marc Boutin. I am the CEO of the National Health Council. I became a patient advocate more than 20 years ago, when virtually every member of my family was diagnosed with one or more chronic conditions, ranging from cancer, heart disease, neurologic, autoimmune, an ultra rare condition, and HIV.

I sat in the doctor's office with my parents, when my father was told he had a terminal cancer. As a result of the treatments he underwent, he lost the dexterity in his fingers. The challenge was, he had an antique clock business. So he also lost the income for the family. Like so many people with chronic conditions, healthcare costs pile up. My sisters and I moved my mother to a smaller, more affordable home after his death. She died of a heart attack before all the boxes were unpacked.

The impact of medical debt on the financial, emotional, and clinical well-being of

more than 160 million people living with one or more chronic conditions has become a national crisis. The National Health Council is a nonprofit organization that was created by and for patient advocacy organizations.

While the patient groups control our governance, and our policy-making process, we welcome all stakeholders into membership. We have the biopharmaceutical companies, the device diagnostic, generics, payer, provider, researcher, and family caregiving communities all represented in membership.

Over the last few years, we have heard loud and clear from our members that while patients care deeply about getting better and new treatments, they are having incredible challenges affording the medications that they need. According to a recent poll, 49 percent of people in poor health, the people we represent, are having significant challenges getting their medications.

Young, expecting families used to tell us their greatest fear was having a child with a deadly disease and no effective treatment. What they tell us now is, their fear is having a child with a deadly disease for which there is a treatment but they cannot afford it.

The National Health Council reviewed nearly 200 policy proposals all aimed at reducing healthcare costs. We learned two things: One, the vast majority of those policies actually reduced costs by eliminating access. And for the remaining policies, there was virtually no data to show that they would actually drive down costs. With one major exception. And that is increased competition, especially among generics. On this point, the data is unequivocal and so are the experiences of millions of Americans.

Mackenzie is a 32-year-old, running her own business in North Carolina. She has a common, genetic condition called familial hypercholesterolemia. She was born with

cholesterol levels more than three times the level normal, putting her at extreme risk of an early heart attack. Adding Zetia, a brand product, to her statin regimen had the potential to greatly improve her cholesterol level. But the cost was an additional $60 a month on top of all her other medical expenses, a huge burden for a young professional just starting off in her own business. When the medicine went generic, her cost dropped to $5 a month.

We, in the patient community, keenly understand the need for intellectual property and exclusivities to drive innovation, but when bad actors abuse the current system to delay access to generics and biosimilars, people with chronic conditions and their family caregivers suffer. Congress needs to address this.

While some patent settlements can bring generics to market quicker, far too many delay entry and line the pockets of investors at the expense of patients. Similarly, without REMS, many people would not have access to medications to improve how they feel, function, and survive. When bad actors use REMS to block generics and biosimilars to markets, we have a serious problem.

We recognize this is a complex issue, but I want to tell you, this is a great first step. On behalf of Mackenzie, my family, more than 160 million people with chronic conditions and their family caregivers, thank you.

[The prepared statement of Mr. Boutin follows:]

******** INSERT 1-4 ********

Ms. Eshoo. Thank you, Mr. Boutin. Powerful testimony.

Now, I would like to recognize Mr. Karst. He is the director at Hyman, Phelps & McNamara. Welcome to you, and you have 5 minutes for your oral testimony.

STATEMENT OF KURT R. KARST

Mr. Karst. Thank you. Good morning, Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee on Health. My name is Kurt Karst. I am a director at the law firm of Hyman, Phelps & McNamara, where I specialize in food and drug law and, in particular, the Hatch-Waxman amendments -- and I say that as I look up at Chairman Waxman's portrait -- and the Biosimilars Act. I am a coauthor of the legal treatise Generic and Innovator Drugs: A Guide to FDA Approval Requirements, and a cofounder of the popular FDA Law Blog.

I am honored to participate in today's hearings and would like to make clear at the outset that I am testifying today in my personal capacity and that the views I express are solely my own and not the views of my law firm or any company or client of my firm.

The information and perspectives I provide today are based on nearly 20 years of experience, helping drug and biologic manufacturers, both on the brand and on the generic side, in helping them obtain approval of life-saving therapies.

So first, do no harm. It is a maxim as old as medicine itself, and it is one of the principal precepts of medicine and bioethics, and I believe it applies to the law just as much as it does to medicine. As an attorney who studies and cares deeply for the Hatch-Waxman amendments, I am always concerned about what good or what harm

proposals to amend these laws might cause, or if they are needed at all. In my experience, amending and tinkering with the Hatch-Waxman amendments is akin to performing brain surgery. One wrong move can have dire consequences. So it is through this first do-no-harm lens that I approach the package of bills at issue in today's hearing.

Now, we obviously don't have time to get into all the nitty-gritty for each of the bills. I place them into three buckets: First, those addressing drug and biologic product information transparency; those involving 180-day exclusivity and patent-settlement agreements; and third, those seeking to facilitate generic manufacturers' access to brand-name products.

In the first bucket, we have H.R. 1503, the Orange Book Transparency Act, and H.R. 1520, the Purple Book Continuity Act. H.R. 1503 seeks to clean up and, to some extent, modernize the Orange Book, a publication of approved prescription and over-the-counter products which I brought an example of here today.

The Orange Book is really the linchpin of the Hatch-Waxman amendments and the generic drug approval process. Generic drug manufacturers depend on it to list accurate patent and exclusivity information as they consider what generic drugs to develop.

H.R. 1503 authorizes FDA to remove from the Orange Book information on patents determined to be invalid, to allow the listing of unspecified, additional patent information and to prohibit the listing of information on drug-delivery devices. Broadening or narrowing the scope of information on patents that can be included in the Orange Book could dramatically impact the timing of generic market entry.

H.R. 1520 would require FDA to include in the Purple Book, which are two lists published by FDA of licensed biological products, certain patent information on

brand-name reference products, but this information would only be added after the initiation of the patent litigation provisions of the statute instead of immediately after licensure of a brand-name product.

While the proposed patent information provisions in the bill are, in my opinion, a good first step to facilitating biosimilar availability, Congress should consider whether an enhanced patent notice feature should be added to the law.

Moving on to the second bucket, we have the BLOCKING Act, the FAIR Generics Act, and then the Protecting Consumer Access to Generic Drugs Act. So 180-day market exclusivity for the first generic drug manufacturer that risks patent infringement litigation, incentivizes companies to clear the patent thicket. Today in a highly competitive, generic drug market, where only a handful of manufacturers may be able to successfully commercialize a drug, exclusivity is the brass ring. Legislative measures that dilute or obscure that prize could jeopardize the generic drug industry, and, in fact, the BLOCKING Act would do just that.

It seeks to prevent exclusivity-eligible applicants from parking their exclusivity when alleged deficiencies prevent FDA from granting final ANDA approval, when subsequent ANDA applicants otherwise eligible for approval are ready. Whatever merit that proposal may have, the BLOCKING Act would address it by imposing immensely and unnecessarily complex framework to trigger 180-day exclusivity, and the analysis under that framework becomes more complex with the addition of each variable.

As a food and drug lawyer, this proposal will certainly keep me in business for a generation, but few others will benefit from the costly and time-consuming litigation these changes will spur. The generic industry won't. This bill will make the 180-day exclusivity eligibility far more unpredictable. In my opinion, the BLOCKING Act is

unnecessary, and, in fact, FDA already has a statutory and regulatory authority to deal with this situation.

Both H.R. 1506 and 1499 address patent-settlement agreements peppered with a dash of exclusivity. From my standpoint, patent-settlement agreements are generally procompetitive and represent a fair balancing of the parties' relative risks from inherently uncertain litigation.

And, finally, the CREATES Act and the FAST Generics Act, both these bills would go a long way to address, I believe, legitimate concerns about reference product access.

[The prepared statement of Mr. Karst follows:]

******** INSERT 1-5 ********

Ms. Eshoo. Thank you very much.

Now I have the pleasure of recognizing Mr. -- Kushan.

Mr. Kushan. Kushan, yeah.

Ms. Eshoo. -- Kushan. He is a partner at Sidley Austin, and I am pleased to recognize you for your oral testimony for 5 minutes.

STATEMENT OF JEFFREY P. KUSHAN

Mr. Kushan. Thank you, Madam Chairwoman, and thank you to the members of the committee, to Ranking Member Burgess for giving me this opportunity to offer some remarks today. I am a private attorney. My comments today are my personal views, and they should not be attributed to any client of our firm.

I provided some general observations on innovation and the way that things work in the innovative side of the industry, and I would like to just address a few additional issues.

Before I do that, it is important for the subcommittee to appreciate the nature of innovation in this industry. Every life sciences company that I have had an opportunity to work with in my career has the same goal. They want to make the best new medicines to help patients. That is what is driving these companies to work every day.

They obviously start with the big bang, they come up with a new idea that leads to a new drug, a new therapy, but they don't stop innovating at that point, they keep innovating. They have to innovate as they develop the way to make this drug in large scale and in a way that is going to be safe and can be delivered to the patients.

They also don't stop innovating when they get FDA approval of their drugs. They keep innovating because they want to make their drugs better. They want to make better manufacturing processes. They want to develop new ways of making the drugs easier to use by patients. And all these things that they are developing are aimed at making better products that improve the lives of the patients.

And as you go through that process, as an innovator, you look for opportunities to deliver these things to the market. At the very beginning of the biotech industry, there were a number of drugs that came out, that had to be administered through injections, and you had to go into a hospital or outpatient center. Innovations after approval led to development of pen devices and other ways of getting those products into the patient safely where they could administer them in their home.

There are innumerable benefits that come from this continued process of innovation in the industry, and we don't want to do anything that is going to discourage these companies from stopping that innovative instinct they have, both before and after the initial approval of a drug.

Now, I have got a few observations on some of the bills that have been presented. First, I would like to talk about the patent listing ideas that have been proposed for biologics. This is H.R. 1520. One thing I think we need to clarify is that biotechnology companies, whether they are in the innovative or biosimilar side of the process, have no difficulty finding patents that are relative to what they are doing.

Patents are public. They are put into databases. We use sophisticated tools. I do this myself to find patents that are relevant to the technologies that are being used to make the products. These companies are also very large and sophisticated. They are going to make a significant investment in building factories or reconfiguring them to

make biosimilars. There is not a problem in finding patents that are relevant.

I think the other thing that it is important to appreciate about the design of the BPCIA is that it does not slow down the approval of a biosimilar based on whether there is patent litigation. The FDA approves those applications as they are submitted. There is no impact like in the Hatch-Waxman scheme, where there is a listed patent.

So at the end of the day, if a biosimilar has received approval for their product, they can launch. When they don't launch, they typically are looking at a patent they recognize as valid and will cause consequences if it is infringed. It is important to appreciate that variable in the equation, because what that is showing you, is that the incentive of the patent system is working. It is protecting the innovation that merited a patent, and it is driving conscious business decisions of these companies to not launch and risk infringement of that valid patent.

The third thing to keep in mind is that the innovators can't find the patents that are relevant to a particular biosimilar applicant because those are going to depend on information only the biosimilar applicant has. It is their manufacturing information.

I raise one practical concern that in the bill that was proposed, that there is a requirement for the innovator to immediately provide information to the FDA about which patents are implicated by the biosimilar's manufacturing process. As someone who is subject to protective orders, I am a little bit skittish about doing that before there is a public disclosure of the patent litigation, because that means you may be implicating the confidential information of the biosimilar.

The other thing I would like to flag, just very briefly, is the Orange Book Transparency Bill, and that is H.R. 1503. And this raises a question about which patents may no longer be put into the Orange Book. Particularly, they are excluding medical

device patents, and many of these technologies are used to make the drug effective. I think we want those patents to be part of the system of early notice and patent resolution, so they don't disrupt the later launch of the products after they are on the market.

I am happy to take any further questions the committee may have.

[The prepared statement of Mr. Kushan follows:]

******** INSERT 1-6 ********

Ms. Eshoo. Thank you very much for your testimony.

It is a pleasure to welcome you, Mr. Carrier. Mr. Carrier is a distinguished professor at Rutgers Law School. You have 5 minutes for your testimony.

RPTR TELL

EDTR HUMKE

[11:00 a.m.]

STATEMENT OF MICHAEL A. CARRIER

Mr. Carrier. Thank you. Drug prices are too high, and one central reason why they are too high is is that brand companies play all sorts of games to delay generic entry. Brands pay generics to delay entering the market. Brands deny samples the generics need to enter the market. Brands abuse the regulatory system, and as Ranking Member Burgess pointed out, we are going ruffle some feathers when we say that the brand companies cannot do this sort of conduct.

On the other hand, nothing that I say today will have anything to do with patents. Nothing that I say today will have anything to do with innovation. That is not at issue here.

My name is Michael Carrier. I am a distinguished professor at Rutgers Law School. I emphasize and focus on pharmaceutical antitrust law. I have written more than 115 articles, including 60 on pharmaceutical antitrust law. I write friend of the court briefs to courts on behalf of hundreds of professors, and I am frequently cited in the media and the courts.

The first thing that this committee can do is focus on samples. Under the Hatch-Waxman Act the generic was supposed to have a sample from a brand company, and that is how it can enter the market quicker. It doesn't have to replicate the costly clinical trials that brand companies have to do. The generic can do it a lot more easily.

The problem is that when the brand company denies a sample that a generic needs the generic can't even get to the starting line. So you look at the nonREM setting where there is no safety concern at all. Take Pharma Bro, Martin Shkreli, jacked up the price 5,000 percent. Everyone focuses on that. No one focuses on the fact that the restricted distribution system is the reason that he could do this.

So when he said you can only get it through Walgreens specialty pharmacy and his official said, oh, we don't give it to generics that is a problem. The REM setting is a safety setting, and so the FDA is allowed and is supposed to have restrictions that deal with safety. Brand companies, however, have abused this. And they have said that we are not going to give you the sample even if you have a letter from the FDA that says that it is safe. We have all sorts of concerns. We don't have a duty to deal.

The FDA has tried mightily to solve this problem. It is hard to think of an FDA commissioner doing more than Scott Gottlieb has to address this situation, but even so, it is still not enough to get samples in the hands of generics.

So the FDA can't solve the problem. Antitrust litigation is costly and nuanced and takes years, and so this Congress is the best place to do it. There are two great pieces of legislation I think the CREATES Act is even stronger because it would make clear that brand companies can't engage in these games that any excuse they have in relation to safety or product liability is addressed in the legislation. So I am a big fan of the legislation, including the CREATES Act

Something else that this committee could do is focus on settlements, so Chairman Eshoo talked about two to tango. That is exactly what is going on here. Under the Hatch-Waxman Act the 180-day period was designed to encourage early generic entry. So let's say you have the brand company dancing on the dance floor all by itself and it is a

dance floor of monopoly profits, what happens is that the goal was to have a generic that wants to break into the dance floor so consumers could get affordable medications.

Unfortunately, the 180-day provision has been completely twisted, so now you have a first filer who is rushing to be the first filer, going to tango with the brand company for years and all the meantime the consumers are paying monopoly prices and no other generic has an incentive to challenge the patent and enter the market.

And so the FAIR Generics Act would go a long way towards addressing this by dealing not just with the first filer, but saying if you are the first to win District Court litigation that is what we want to incentivize. So I am a big fan of that legislation.

In terms of other settlements legislation FTC v. Actavis solved a lot of the problems. It didn't solve all the problems. Courts are still getting it wrong. There are still pay-for-delay settlements, so if you make clear that these settlements are illegal that would be incredibly helpful to the FTC and courts and as a reminder to courts themselves.

In terms of the Orange Book, there is a lot that could be done. The FDA plays a ministerial role. It does not remove patents from the Orange Book when the patents are declared invalid by a court or the Patent Trial and Appeal Board. It would be useful to do that. You have device patents like the EpiPen. Why is that in the Orange Book for decades keeping generics off the market? That is something that can be addressed, as well.

And then finally the Purple Book could be brought into the 21st Century. It is now a PDF. Let's make it searchable. Let's make it more like the Orange Book. So in short, these are incredibly important pieces of legislation. They will not affect patents. They will not affect innovation, but they will get affordable medicines into the hands of consumers that need them. Thank you.

[The prepared statement of Mr. Carrier follows:]

******** INSERT 2-1 ********

Ms. Eshoo. Thank you very much. Well, that concludes the testimony from all of the witnesses, and I think each member had a very strong sense that their brain was trying to catch up with what you were saying to absorb it all because you have comments -- you have each made comments on not only what you agree on but how to strengthen the legislation and to fill in -- let's see how I can describe it -- where you think there is a blank somewhere in the legislation to strengthen it, but I think that collectively it has been excellent legislation.

Now, between -- I would like to pursue both the orange and the purple because, Mr. Kushan, you were smiling when Mr. Carrier was testifying. So I will start with Mr. Carrier. How -- synthesize for us where you think the improvements need to be made relative to the Orange Book and the Purple Book, and if you think the legislation regarding both comes up short?

Mr. Carrier. So I think that one --

Ms. Eshoo. As quickly as you can.

Mr. Carrier. So one problem with the Orange Book is that it does not make clear exactly when a patent is invalidated. When a patent is in the Orange Book that is very helpful --

Ms. Eshoo. Let me ask this because I don't know all that much about it. Why would something be carried in print when it is no longer in use?

Mr. Carrier. So the FDA regulates the Orange Book. It is a listing of patents and drugs that go along with them, but the FDA is not checking every day to see what happens in the court system, in the Patent Trial and Appeal Board. So it is possible that you have a patent that is listed in the Orange Book, which gives the brand company an

automatic 30-month stay where that is not the most up to date information. So if we get that --

Ms. Eshoo. Why not have something orange online?

Mr. Carrier. So, yes, the Orange Book --

Ms. Eshoo. I mean, as soon as it is printed it is out of date.

Mr. Carrier. So the Orange Book is online. It is just that some of the information is not as up to date as it could be, and so that is one improvement that could be done.

Ms. Eshoo. Okay. Mr. Kushan?

Mr. Kushan. So I think -- so I was smiling because I have downloaded the PDF for the Purple Book, and it is way less useful than the Orange Book, which is a very useful tool that --

Ms. Eshoo. Does the legislation address your concerns, though, that is what I want to know.

Mr. Kushan. So the issues that I see with the listing issues turn on the impact of these listing provisions. One of the things that Mr. Carrier had flagged was the idea of going in and updating patent status based on kind of current information on litigation around the patents or in something in the Patent and Trademark Office.

I think one of the concerns we have about going in and altering the status before there is a final determination about these patents is that you might have to change it later. There was a proposal I think in one of the bills that you would have to delist a patent if there was a decision of the Patent Trial and Appeal Board. Those are not final decisions, those are always appealed to the Federal Circuit. It is much better to have a system where you can get a final outcome on the patent before you start making these

changes.

It is also important to recognize that this is not an insular world. There is a very readily accessible information about the status of these outcomes in patent litigation they get into the news. So I think we have to just look at those very carefully and make sure we have stable system, thus people have more predictability, and I think, you know, more enhanced searchability, capability of the Purple Book certainly would be welcome.

One thing I did mention in the listing process for the patents for the biologics we really need to look at how we can do that as a practical matter because of that confidential information that we are looking at during the patent dance.

Ms. Eshoo. I appreciate that. Is there any witness that thinks that of the legislation that we are considering today and that you spoke to, do you all agree that it moves the needle to help consumers? Is there anyone that disagrees with that? Uh-oh, Mr. Kushan, you have a look on your face.

Mr. Kushan. No, I apologize. I don't want to dominate this hearing either.

Ms. Eshoo. You can tell that I take everything into consideration.

Mr. Kushan. I think you are making a lot of strong moves to help make the system more transparent. That is good --

Ms. Eshoo. And I appreciate your pointing out how important innovation is. We can do many, many things to lower drug prices to really -- so that the consumer, the patients, the stories that Mr. Boutin told as well as the testimony of all of you and still obviously protect innovation because the patients depend on breakthroughs in order to address what is ailing them. So I think that it is a set of book ends.

With that I would now like to recognize the ranking member for his 5 minutes for questioning, Dr. Burgess.

Mr. Burgess. I prefer the term Chief Republican.

Ms. Eshoo. Whatever you want.

Mr. Burgess. So I know when we had this hearing in December of 2017 I think I made the comment, it is still applicable today, that if we don't understand the difference between Sovaldi and Daraprim we may very get -- come to the wrong conclusions here, and several of you, Mr. Carrier, you brought up Daraprim, a medicine that has been around for a long time, really not protected by patent. Great medicine but it wasn't really something in breakthrough status, but because of the vagaries of the market now is -- if I go on my GoodRX app I can buy it for $60,000 for a month's supply so that is a problem.

Sovaldi, a medicine that was developed to treat hepatitis -- not treat hepatitis C, cure hepatitis C, and I made this point several times in this committee. I mean, that is a gift to humanity. Hepatitis C didn't even have a name when I was a resident at Parkland Hospital. We called it nonA/nonB hepatitis, and someone said, hey, that is hepatitis C, and the division of nomenclature said, yes, you are right, they blessed it hepatitis C, but there is a disease in 1977, 1978 didn't even have a name that now has a cure. I mean, that is a pretty good result.

So to balance the availability of medicines that will be affordable, and Mr. Boutin did a great job of illustrating why that is important. Same time innovation the world looks to the United States for innovation. I don't know of any other country that was going to cure hepatitis C, but the United States did, so thank you for that.

And actually and Mr. Davis or Mr. Barrueta you actually made the point in your testimony about the -- for Kaiser the medicines to cure hepatitis C and actually the cost has come down. I have got your brief history of drug pricing from 2015, and, of course,

there the concern was 2014 a lot of stuff went up, and I think the thesis was Sovaldi or Harvoni has cost, but now there has been without a generic actually but just different formulations and the price has come down, so competition did work. It may not have come down as much as Kaiser would like, but still it has come down, wouldn't you agree with that?

Mr. Barrueta. I do. I do think, Congressman Burgess, one thing to really recognize here is the system the way it is currently designed has a major impact on where manufacturers choose to launch their prices, and signals are set based on the way the system is operated.

And so with the case of Sovaldi in particular there was tremendous concern that the choice to price that product at the upwards of 80, $90,000 reflected what the old therapy was, which was not very useful for very many people, but that drug was going to be used in a huge number of people. So you need to look at the whole of this.

Mr. Burgess. Correct. And that is actually the point I was going to make. We are on the cusp of some rather dramatic cures, not just treatments but cures, and this committee is responsible for the Cures for the 21st Century. We worked on it for three Congresses. We have really pushed that along. 60 Minutes, a show I don't normally watch but had a special on sickle-cell and curing sickle-cell. I mean, who would have ever thought that that was possible?

But we do need to think about how are we going to amortize the cost of research and development and paying for that innovation, how are we going to amortize that into the system because we could agree that Sovaldi nearly broke the bank of a provider like Kaiser and our State Medicaid organizations really felt the brunt of that. They had no way to prepare for that. They didn't know it was around the corner.

One of the things that I have talked about in this committee, I think Mr. Guthrie has a bill that would at least allow CMS to talk to a manufacturer before the FDA approves if it looks like something coming down the pipe is going to be pretty dramatic but dramatically expensive it would be good that people could begin to at least make some decisions that might soften the blow. And I think we are going to have to look, if you look at some of these gene therapies that are single, single administrations that cure blindness, hemophilia, muscular dystrophy, and these are things that we are going to have to figure out. You are right, the old way of pricing and that extrapolating that as using some formula may not work at the same time, and this committee understands the value of the Cures legislation that we did. We cannot interfere with the scientific discovery process.

Mr. Carrier, just one thing because you had it in your testimony a medicine I wasn't even familiar with Xyrem, that is patent protected until 2024, but the REMs on that is going to be significant because it can be a dangerous product in the wrong hands.

Ms. Eshoo. The gentleman's time is expired.

Mr. Carrier. Repeat the last five seconds.

Mr. Burgess. I said that the REMs is going to be significant -- it is patent protected until 2024.

Ms. Eshoo. Why don't you let him answer because your time is expired.

Mr. Carrier. So, yes, there is a concern when there are patents on REMs that is not really what the patent system is about. I couldn't agree more that innovation is absolutely crucial, but sometimes at the margins we are not talking about innovation just like the Daraprim example you mentioned and this one, as well.

Ms. Eshoo. Thank you. I now would like to recognize the chairman of the full

committee, Mr. Pallone.

The Chairman. Thank you, Madame Chair. I wanted to start by asking Mr. Carrier a question and then move to Chip Davis, and, Chris, I want to acknowledge that Mr. Carrier is a professor at Rutgers Law School where I also went to school, so it is special to me that you are here today.

When the REMs program was put into place as part of the Food and Drug Administration Amendment Act of 2007 Congress contemplated and ultimately made it explicit that these safety protocols should not used as a means to delay generic competition. Unfortunately, congressional intent has been obfuscated by delay tactics by branded manufacturers that have thwarted generic attempts to develop their own versions of drug products or to impede the ability to enter into a shared safety protocol.

This committee has been considering for some time now how to best ensure that congressional intent was upheld, and Congressman Welch and myself have advocated for market-based solutions that would allow for streamlined processes for accessing samples, resolving challenges in establishing REM safety protocols.

So initially, Mr. Carrier, some concerns have been raised that the CREATES Act, which of course is a main vehicle for dealing with this problem, could unintentionally incentivize frivolous lawsuits in order to obtain monetary penalties, rather than seriously pursuing samples for purposes of drug development. While this is suggested maybe that maybe the CREATES Act could lead to additional patent settlements. What are your thoughts on these claims? I mean, obviously I support the CREATES Act. I am only being devil's advocate here kind of get your feeling on some of these suggestions against it. Do you believe that CREATES could lead to a different type of gaming?

Mr. Carrier. Absolutely not, and I do respect the brand companies for their

creativity in coming up with arguments like these. For starters, the CREATES Act only applies to eligible product developers. You can tell really quickly if it is a generic that is trying to get the sample or a trial lawyer with slick backed hair. I mean, you can figure that out quickly. Will it lead to settlements? Absolutely not. The problem with settlements today is that you have patents involved. Generally we don't have patents here. And also you have a 180-day exclusivity period that cues up that first generic that settles with the brand company. So when the brand settles with the first generic no other generic is able to enter the market.

Here that is not the case. The brand company would have to settle with every single generic that wants to enter the market. That is a lot harder than in the settlement context.

The Chairman. Thank you. And then Mr. Davis could you respond to the same question, then I want to ask you another question about CREATES.

Mr. Davis. Sure. Thank you, Chairman Pallone. I would completely associate AAM and our members with the comments of Professor Carrier. We do not see any concern about frivolous lawsuits. I think it is important to remember that the CREATES Act and the FAST Generics Act keep the FDA at the center of this issue, and ensuring the safety and certifying the safety and integrity of whether it is the branded manufacturer handling their lot or a generic manufacturer subsequently.

So we have always supported a bill that kept the FDA in the center and ensuring that no matter who is handling the samples that they get certified by the FDA accordingly. The other thing that I think it is important to point out is that it is a very limited cause of action that is only triggered if a branded company fails to negotiate in good faith at fair market value. So it is a very limited window, and one quite frankly our members hope

they never get to because it only reflects a failure of the ability to secure the samples through fair market value.

The Chairman. Chip, let me ask you another question. You know the CREATES Act contemplates a legal pathway by which the generic manufacturer could access samples, as well as possibly a monetary penalty if the brand manufacturer refuses to allow access. And I understand that other enforcement mechanisms have also been contemplated in this path. But will you discuss AAM's perspective on the CREATES Act and what your members believe will be the strongest deterrent to gaming of the REMs requirement.

Mr. Davis. Yes. Thank you, again, Mr. Chairman, for the question. Again, our mindset is that a cause of action is only an issue of last resort that we hope we never have to get to to be completely candid. The challenge is since REMs programs were created back as part of the Purdue for reauthorization in 2007 that bill specifically says REMs programs should not be used for anticompetitive purposes.

The problem is there is no enforcement provision. So unless there is a significant enforcement provision or risk of a significant penalty to the branded manufacturer the risk of having some sort of diluted remedy is that it just simply becomes the cost of doing business, and you are better off continuing the anticompetitive practices because the penalty on the back end won't be severe enough.

So we want to make sure that it is a very limited scope of action that is only triggered by a failure to negotiate in good faith, and at that point though there has to be something of significance to hopefully deter the actions that have now been going on for the better part of a decade.

The Chairman. Thank you. Thank you, Madam Chair.

Ms. Eshoo. Thank you, Mr. Chairman. It is a pleasure to recognize the former chairman of the full committee, the gentleman from Michigan, Mr. Upton.

Mr. Upton. Well, thank you, Madam Chair. This is an important hearing, and I appreciate everyone's testimony, that is for sure. And as you all may know every one of us on this committee worked very hard on the 21st Century Cures Act. We are all cosponsors. We all worked our networks of folks. We were all pleased when President Obama signed it into law in 2016. And one of the issues that I have some concern about, Mr. Kushan, as we think about that legislation with the unintended consequences of hampering innovation in medicine.

In your testimony you cautioned against legislation that would undermine the value of patents because the patent system was developed in part to encourage innovators to bring their discoveries into the public, rather than keeping it as a trade secret, and thus, be able to recoup all the value. Can you speak more to that dynamic and how it is facilitating continuing innovation and biologics and biosimilars, something relatively new?

Mr. Kushan. Sure. One of the things I tried to point out in my written testimony was that we are seeing a lot of innovation in the biologic space both from innovators and from biosimilars. When you have to actually figure out how to make a product and build a plan and reengineer it to make that product, you make innovations. That is just what is happening in that environment.

Mr. Upton. And that is different than the generic side of things.

Mr. Kushan. Correct. In the biologics space there is a much bigger investment needed to make these products, and what you are seeing with those investments is a lot of ancillary innovation. And I think one of the things that I didn't mention in my oral

remarks, but I think I have heard it from a number of other panelists is when you are getting into a setting where you are trying to settle litigation those entities in the biologics space actually are very sophisticated companies. They are both innovators and biosimilar manufacturers, and there may be settings for those interactions where they are going cross-license their technology to each other. We don't want to discourage that behavior if you are ultimately benefitting the patients with a procompetitive settlement.

I think what is very important in that process is to make sure you don't have punitive sanctions on the value of the IP voiding them or having them held unenforceable. There are some ideas floating around with patent listing concepts that I think would raise concerns on that front, but I think it is very important to keep that dynamic that is generating this type of ancillary innovation in the industry.

Mr. Upton. And I got to say I think you agree I am particularly concerned that existing settlements would suddenly become illegal because of the retroactive nature of some of the bills that we are considering today. Is that your impression, as well?

Mr. Kushan. Yes, there is one of the provisions in the bills that would kind of retroactively review some of the settlements that have already been entered into and, that is particularly troubling from a litigation perspective because you have companies who have relied on that settlement to then move forward with their commercial activities. If those things somehow change if those are no longer allowed, then you are going to have a fairly significant disruption in the commercial activity of these companies.

Mr. Upton. I will confess that I am not a lawyer. Most people would say good, but I think that we all recognize the problem of that. I yield the balance of my time back to Dr. Burgess.

Mr. Burgess. Thank you, Mr. Former Chairman, chairman for life, chairman in exile. Mr. Davis, if I could ask you as you are well aware, there was a version of the CREATES Act in the last Congress that was worked on with stakeholders. This version of CREATES is a little bit different, and some of the private action are perhaps more aggressive than this version today. Would you support a version of CREATES that perhaps was modified to make it once again bipartisan?

Mr. Davis. Thank you for the question. I think from my perspective the current version in both the House and the Senate does enjoy wide bipartisan support with over 90 stakeholders. I was saying the other day that I am not sure of another piece of legislation that enjoys from an external stakeholder perspective the support of both Public Citizen and FreedomWorks as an example, so it is a pretty diverse group of people that have come to the realization that after 10 years of abuse the time has come to end this problem. To that extent --

Mr. Burgess. That was the version from last Congress, correct?

Mr. Davis. That was actually the Senate version which has not been modified. So my short answer would be we have been and continue to be willing to work with anybody who is committed to solve the problem in a meaningful way. We think actually, Congressman, the real risk here is that if there are parties that say they want to work together with an intent to actually dilute the enforcement mechanisms then you get at the risk to my answer previously, which is there is not a sufficient back-end remedy to actually alter the behavior on the front end.

So provided at the end of the day there is that sufficient enforcement, we stand ready -- have been and continuing to stand ready to work with anybody.

Mr. Burgess. I thank you. I yield back to the gentleman from Michigan.

Mr. Upton. My time has expired.

Ms. Eshoo. Thank you. I now would like to recognize the gentleman from Oregon, Mr. Schrader, for 5 minutes of testimony.

Mr. Schrader. Thank you, Madam Chair.

Ms. Eshoo. Questioning.

Mr. Schrader. Thank you very much for calling the hearing today, very important hearing. I think we can all agree that bringing generic drugs to market faster brings down costs for all. We should all support efforts to challenge abuses in the system that would delay getting generic drugs into the hands of patients. Getting these drugs to the market and into the hands is where I think we need to focus. I am encouraged by the record number of generic approvals and was a proud author in the last Congress of legislation to help create the competitive generic pathways therapy that frankly just in the last 6 months has brought five more generic drugs on to the market where no competition had existed before.

I would like to emphasize today that getting drugs into the approved pipeline isn't the same as getting them on the market. As we discussed yesterday with Secretary Azar every year we see companies get tentatively approved as first filer, complete the bulk of the application process, and then stop before getting final approval. According to HHS this happens an average of five times a year. Drug companies wait so long to market their drug that they effectively block subsequent filers which could help drive down costs.

The Secretary indicated this lasts for an average of 12 months, far longer than the 180-day incentive that Congress created. Five drugs times an extra 12 months of exclusivity means much higher costs for patients in the healthcare system.

Why has this happened? Well, Secretary Azar says there are times when

applications have some deficiencies that need to be corrected in a timely manner, and there are other times when manufacturers struck a deal with brand manufacturers to refrain from moving their drug to the market.

My bill, which I introduced earlier this year bipartisanly with Mr. Carter will stop the practice of parking generic exclusivity by first filers. Under the BLOCKING Act when a first to file drug application is parked at the tentative approval stage and that is the only thing blocking the subsequent generic from coming to the market the first filers' 180 days of exclusivity begins to run. This concept has the support of the President and is part of his budget in the lowering drug costs section.

After our conversation with Secretary Azar yesterday the FDA got back to me with a data analysis that suggested this proposal might save $1.8 billion, and at this time I would like to ask unanimous consent to enter that into the record.

Ms. Eshoo. So ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Schrader. And contrary to what some in the industry may want you to believe this bill does not revoke, diminish, or shorten any period of exclusivity for any first filer. Very simply, it puts manufacturers on notice and requires them to keep the ball rolling after they have started the application process.

So, question for Mr. Carrier if I may, some have noted and it was -- the Secretary testified on this yesterday that there are some provisions in law that do require a generic manufacturer to forfeit their 180-day exclusivity. In your testimony you describe these forfeiture provisions as toothless. Could you expand on what you mean by the fact that they are toothless?

Mr. Carrier. The Medicare amendments of 2003 were designed to solve the problem of a generic not entering the market and forfeiting its exclusivity as a result. The problem is that the provisions were drafted in way that they only apply upon the later of two events, one of which is an Appellate Court decision, which could take place years down the road.

So there have been four settlements where the Appellate Court decision took place 6, 8, 11, and 13 years after the settlement was entered into. And so if forfeiture only kicks in a decade down the road in my mind it is toothless.

Then the other question is what incentive is there for a subsequent generic to actually bring one of these challenges if it is not going to get a piece of the 180, and so those are the two reasons why I think it is toothless.

Mr. Schrader. Well, Secretary Azar agreed with you yesterday, and for the record I would like to note that we did have FDA input on this product. We have talked at length with the different manufacturers in the industry, and this is a bipartisan bill

supported by the President of the United States.

Thank you, Madam Chair, and I appreciate your calling this hearing today. I yield back.

Ms. Eshoo. Thank you, Mr. Schrader, and thank you for your excellent, thoughtful work. It is a pleasure to recognize the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. Griffith. Thank you very much, Madam Chair. Mr. Kushan and Mr. Karst, in your view would H.R. 1499, the Protecting Consumer Access to Generic Drugs Act or H.R. 1506, the FAIR Generics Act, make it easier or harder for a generic medicine to come to market?

Mr. Karst. Thank you very much. I actually think it would make it more difficult, and particularly on the FAIR Generics Act, which intertwines these concepts of patent settlement agreements and 180-day exclusivity. I am in the trenches every day working with generic drug manufacturers, dealing with these immensely complex scenarios on exclusivity and forfeiture, and adding these two together which are complicated enough themselves separately I think would slow down things, could lead to further litigation. I don't think they are as procompetitive as the law currently is, in fact.

Mr. Griffith. Mr. Kushan.

Mr. Kushan. I generally share Mr. Karst's conclusion on this. On H.R. 1499 there seems to be kind of an idealized settlement defined, and it doesn't reflect some of the realities that I have seen when innovators are trying to find a way of settling a patent dispute with a generic. They tend to look at more variables that are going to be mutually beneficial, which is natural in any kind of settlement negotiation that are not going to disrupt the core point of delivering that product onto the market before the

patent expires. And so, I think we just need to have kind of a broader mindset when we look at these settlement agreements to look at the bottom line, is it going to get the product on the market as quickly as possible and yield procompetitive advantages to the market.

Mr. Griffith. So without significant amendment you all do not believe that the patients would benefit from these two bills if they were passed and signed into law. Is that correct? Without significant amendment.

Mr. Kushan. That is a hard question to answer, but my instinct is that it will make the negotiations much more complicated and less fruitful of what we are trying to do.

Mr. Karst. I fully agree. I think it will be a disincentive to -- there won't be an incentive to settle, therefore, there are will an incentive to carry on litigation, and that is simply going to delay generic drug competition all that much more.

Mr. Griffith. Thank you. Mr. Davis, in 2013 the Supreme Court ruled, as you know, in FTC versus Actavis that the so-called reverse payments from brand drug companies to generic companies with the intention of delaying the entry of a generic or biosimilar pharmaceutical could be deemed anticompetitive. Consequently, according to the Federal Trade Commission the number of patent settlements involving so-called pay-for-delay agreements between brand companies and generic manufacturers has declined significantly. Can you explain if patent settlements may be useful in some cases and what some of the unintended consequences of eliminating patent settlements may be?

Mr. Davis. Sure, Congressman. Thank you for the question. I think it is -- let me state up front that what has in the sort of public debate about patent settlements the

term "pay-for-delay" has become almost all encompassing. To be clear, AAM and our members we do not support pay-for-delay agreements full stop. What we do support is the ability of private parties to negotiate in good faith if, in fact, it leads to the acceleration of generics coming to the market. And there have been, and the FTC issued a report post the Actavis decision in 2013 that the vast majority of agreements that have been reached subsequent to that seminal decision have been ones that have not been found to be anticompetitive.

The other thing I would add Congressman is I think it is really important when you look within the context of patent settlements that it is we would submit to this committee problematic and quite frankly dangerous to disassociate issues around patent settlements without thinking about the larger context and the bigger financial impact of patent abuses. If you will, if patent settlements are the symptom, patent abuses are the disease because if we actually don't take on a significant effort to address some of the things about evergreening and patent stacking that increasingly generic and biosimilar manufacturers are only left downstream with the ability to decide to enter into negotiations to try and get some clarity and certainty on having a date certain in which they can come to the market.

So our recommendation to the committee would be to make sure that as you are continuing to review legislation around patent settlements I think the Humira example is prima facie, which is without the ability for those companies to settle in 2023 and 2024 for a drug that was approved in 2002 whose main ingredient patent expired in 2014, the first competition would not be until 2034. And so my concern is that the legislation before you would not address that issue, and, in fact, may incentivize innovator companies to continue to throw as many patents as they can against a product in the late

stage life cycle of the product.

Mr. Griffith. I thank you very much, and I yield back.

Ms. Eshoo. I now would like to recognize the gentlewoman from California, Ms. Matsui.

Ms. Matsui. Thank you very much, Madam Chair and thank you for having this hearing today. And I want to thank all of you for appearing here today.

I would like to focus for the moment on the potential for these policies to save real money for consumers. We are here to talk about high drug prices and some of the policy loopholes that allow drug manufacturers to maintain them for prolonged periods. We know that market competition lowers prices for consumers. That costs decreases exponentially when a third product comes on the market and continues to decrease with each additional generic product introduced into the market.

These dynamics have incentivized some companies to extend their market monopolies for certain products well beyond the period of reward initially granted to them by the drug approval process. And I would like to better understand how consumers are being impacted by this behavior and how the policy we are considering here today could make a difference.

First of all, Mr. Barrueta, could you please describe for us why payers like Kaiser Permanente are concerned about generic drug access and how gaming of the drug approval system prevents such access. In short, how does generic drug utilization impact your members? I am just thinking of the patient.

Mr. Barrueta. Thank you, Congresswoman Matsui. The ready availability of generics is really crucial to keeping the cost of prescription drug benefits stable over time. We do know that over time new drugs do come to the market, and if older drugs are not

leaving branded status and becoming generically available in an orderly manner you see spikes in the cost of prescription drug benefits, and we have seen that for several years. That results ultimately in the need for health plans to generally modify the shape of those benefits. This is one of the reasons why we have seen increased deductibles in benefits and things like that.

And this is why we are very eager, particularly as we move toward much more expensive biotech drugs in the future to make sure that we are dealing with this problem up front because the problem that we have seen over the last 5 or 6 years where coverage has shrunk some as the cost of drugs has gotten higher and higher that is a dangerous warning sign for what is to come if there isn't some kind of approach that looks to the future of these drugs, as Congressman Burgess said million dollar drugs for various therapies start coming to market. We need a more rational way to do this.

Ms. Matsui. Okay. Mr. Barrueta the solutions the committee is considering today, which would have the most direct immediate impact on high drug prices? Does Kaiser Permanente prioritize passage of any of these policies?

Mr. Barrueta. I think it would be great to move CREATES as soon as possible and get that on the market. I think that can help a lot.

Ms. Matsui. And that would be it, you wouldn't prioritize the rest of them at all?

Mr. Barrueta. I think it is really important that the committee is looking at all of this. I think the testimony we have heard today has demonstrated there are -- careful consideration needs to be taken on all of these. I think they are all very well intentioned to do the right thing and it is a complicated process as we have heard from some of the experts who actually practice in this field. CREATES for us is just very clear and should move forward.

Ms. Matsui. Okay. Well then as we move forward to consider additional action on drug pricing, are there other policies that we should consider in the future?

Mr. Barrueta. I do think that it would make sense to look more broadly around this. Some of this may not be within the jurisdiction of the committee, but one of the -- I didn't mean to imply anything, Congressman Burgess, but I do think there are some obvious targets. I think the way part B drugs are reimbursed in Medicare is driving higher and higher prices. B. Part B. I think that that is an area that needs to be looked at. Reimbursement policy could be changed, disincent -- to stop incenting the use of much more expensive drugs when less expensive drugs are available.

The Medicaid rebate program has in it a formula that deters discounting by drug manufacturers. I think that could be modified in a way to leave the States and the Medicaid programs at least whole and encourage competition in the marketplace. And then the last one and we have talked a little bit about this is I do think we have an excellent agency that is focused on competition and markets and protecting competition, and I think providing broader authority and broader resources to the Federal Trade Commission to take a more active role in examining how this market is actually operating would be beneficial.

Ms. Matsui. Okay. Well, thank you very much. We appreciate your ideas, and I yield back.

Ms. Eshoo. I thank the gentlewoman. Now I am pleased to recognize the gentleman from Kentucky, Mr. Guthrie.

Mr. Guthrie. Thank you, Madam Chair. Thanks for holding this meeting and the important meetings that we are having on prescription drug prices, and I have said for the last year or two that we need to deal with prescription drug prices and preferably

through the marketplace and bringing competition to the marketplace, so this is an important hearing today, and I appreciate you doing that.

And, Mr. Karst, I want to kind of follow-up on my friend from Virginia's questioning of Mr. Davis, the pay-for-delay particularly. And I really looked at getting involved in moving this bill, and what I want to do is make sure that it is right and it does what we want it to do. And I think Mr. Davis talked about -- and I don't want any unintended consequences. I think you might have been the one who said sometimes it is like brain surgery, if you mess up you can really mess the problem up.

And I understand there were five out of 170 cases that have ruled to be noncompetitive that went before the Federal Trade Commission, and so how can these settlements in the pay-for-delay, how can these settlements actually be procompetitive?

Mr. Karst. Sure. Thank you very much, Congressman. So often times you have, of course, patents that extend years beyond any other type of regulatory exclusivities that may be granted by FDA, and, of course, you have generic manufacturers challenging these patents, paragraph 4 litigation, and if they have to continue to litigate these patents all the way to the end, as Mr. Carrier pointed out, sometimes these cases can go on up to the Federal Circuit for 10, 12 years after the initial litigation.

By being able to settle the litigation by some form of patent settlement agreement that allows for an earlier market entry date that is prior to the actual patent expiration not only means that companies, generic manufacturers can save millions of dollars when it comes to patent litigation, attorneys fees and what not, but they are also able to develop -- put those moneys back into the company to develop other generic drugs to have more generic competition on the market, and they have date certain when they are going to be coming to market.

They could decide to go through the litigation process, and maybe they end up losing in the end. Well, what happens then, of course, is they are not even going to get approved until that patent expires years later than they might have otherwise been able to get on the market because of a settlement agreement. So in that respect I view these agreements as very -- as procompetitive.

Mr. Guthrie. Well, are there cases where that brand has paid a generic and the generic doesn't pursue moving forward, and if so, what would be the solutions for that? That is what we want to prevent, and my understanding as I dig deeper into this it seems to be more the way you describe is the situation then just the generic accepting a payment not to come into the marketplace.

Mr. Karst. Well, it is not necessarily a payment. Whatever value you may exchange hands, I mean, again, it is for the benefit of getting that product on the market. I am a generic manufacturer, that is what I need to do. I need to get my product on the market and sooner rather than later.

And when you do the calculus of patent litigation the calculus may add up to if we are able to settle this patent litigation for an entry date certain that knocks off X number of years on the term of the patent for us to be able to get in, that is again procompetitive.

Mr. Guthrie. Thank you. Mr. Kushan, one of the concerns in the CREATES Act is it provides incentives for generic manufacturers to initiate litigation with the real purpose of extracting a settlement, rather than acquiring samples necessary to get a generic approval, I guess the argument for pay-for-delay they would rather have the settlement than access to the marketplace. Should we consider provisions that would deter these type of frivolous lawsuits?

Mr. Kushan. I will start by noting I am a patent litigator, so I don't have all

knowing insights into some of these things. I do have instincts that when you create a right of action that gives an opportunity for a monetary outcome of the litigation you are just going to incentivize some activity that may not ultimately deliver what you are hoping for. I think this is a complicated topic. I have not had a lot of experience with the whole process of providing samples, but it seems like, you know, there should be a way to make sure that samples are made available for the purposes that they are needed to get the testing done to make these products available.

Mr. Guthrie. Okay. I just have a few seconds, and Mr. Davis the prelude to an O&I hearing. Working with Congresswoman DeGette her staff has worked tirelessly to try to find real solutions for millions of Americans who depend on insulin. Can you explain why more generic insulins are not on the market, and how a March 2020 deadline for insulin approval will hurt generic insulins from coming to the marketplace?

Mr. Davis. I will do it as briefly as I can, Congressman, and thank you for your leadership on this issue. I think insulin is a classic case of a convergence of a number of troublesome and concerning issue, not the least of which is the sort of the perverse rebate incentive system that we have now where list prices increase to absorb a larger demand for a rebate. There is late stage patenting with some of the insulins that are currently on the market.

And then to your specific question about the FDA's guidance about moving forward into March 2020 with what is being referred to as the regulatory dead zone, that was actually a requirement coming through the BPCIA that was passed in 2010, but the reality is if you have a pending biosimilar application pending with the agency you are actually going to have to go back to the drawing boards and actually start over again if we encroach upon that time frame.

Mr. Guthrie. My time has expired, so tune in March 11 for our next -- April for our next hearing.

Mr. Davis. Thank you for your leadership on it because it is a very real issue.

Ms. Eshoo. I allowed the gentleman to finish his answer because I think that it is important that we hear the answers, but we will be following up with you, Mr. Davis. Thank you very much.

I now would like to recognize the gentleman from California, Mr. Cardenas, for his 5 minutes of questioning.

Mr. Cardenas. Thank you, Madam Chair. I would like to thank the ranking member, as well, for agendizing this important hearing. I hope that the Americans are watching because 1 out of every $5 in Americans' wallets somehow some way goes back into their healthcare needs, and this is an important aspect of that. So and also I would like to thank the witnesses for coming forward and giving us your expertise and your perspectives, and when it comes to prescription drug pricing it is a complicated topic, but it is one that impacts the lives of Americans all over the country.

There are many moving pieces here, but I want to focus for a moment on biosimilar entry to the market. Despite the fact that the FDA has approved 17 biosimilars in the U.S., only 7 are on the market and available to providers and patients. This is a sharp contrast to the experience in Europe where more than 50 biosimilars are available. While it is true the Europe regulatory experience with biosimilars is more mature than here in the U.S. I am worried that if we do not start to address the barriers to biosimilar entry sooner than later patients will not be able to realize the benefits.

We know that spending on specialty drugs, which include biologics, has grown rapidly and is now nearly half of all of our spending. Biosimilars hold the potential to

help cut down these costs with marked -- with marketed biosimilars being priced an average of 40 percent less than the biologic.

So my first question is to you, Mr. Barrueta. I was impressed to learn that Kaiser Permanente has taken such a leading stance on biosimilar utilization, but what is the biosimilar utilization rate for Kaiser Permanente, and what led Kaiser to take such an aggressive stance on generic and biosimilar utilization?

Mr. Barrueta. Thanks Congressman Cardenas. We are using biosimilars as they are available pretty quite intensively, so I mentioned in my testimony that on one drug we are over 75 percent use of the biosimilar as opposed to the referenced product. We have intensive use of Zarzio over Neupogen as another example, and, in fact, that is one where the data that we are able to see within our clinical records is demonstrating that drug is performing excellently. So we are having the European experience on biosimilars within Kaiser Permanente in many respects.

I think the critical thing is to make sure that good information is available to practitioners across the country who are faced with the opportunity to consider biosimilars for their patients and to make sure there is a regular source of objective unbiased and very solid information, and I think it would be important to use the governmental resources that are charged with bringing information forward to make that available.

Mr. Cardenas. Okay. In your opinion, what are the key barriers that are blocking or delaying biosimilar entry into the marketplace today in America?

Mr. Barrueta. I think it is clear what we have heard much of the testimony today that the patent thicket problem, I think, is inevitably a problem. I do think that as Mr. Davis said it is hard to separate the issues of some of the conduct that is going on in

the existing system versus just the ability to throw vast numbers of patents forward, and there is a need to look at this broadly as the committee is today and try to create more transparency and more clarity to allow these things to come to market faster.

Mr. Cardenas. There are some manufacturers that have benefitted from several loopholes in our current regulations, including agreeing to multiple patent settlements to further delay competition. In some cases these products lack competition in the U.S. but have several competitors on the market in Europe and much lower list prices there as a result.

Again, Mr. Barrueta, will the legislation we are considering today help to close some of these loopholes and get competition to the market more quickly in America?

Mr. Barrueta. I think it is a start. I think it is a move in the right direction. I think we have heard it is a multifaceted problem, but certainly pay-for-delay problems continue to exist that there should be further examination on these even moving forward. Whether that is the total reason why some of these are delayed as opposed to the broader patent thicket problem it is hard to pull apart, but I think absolutely what is being considered is a step in the right direction.

Mr. Cardenas. I believe Congress has a role to play in this in correcting this problem, and hopefully we will be able to advance some legislation in the right partisan manner so that we can get this through for the American people.

My time having expired, I yield back. Thank you, Madam Chair.

Ms. Eshoo. I thank the gentleman, and just for the record on the issue of biosimilars, the legislation that created the pathway for biosimilars to actually move to generic was the legislation of the late Senator Kennedy and myself. So anything that blocks that from occurring we are going to do a deep dive on.

I now would like to recognize the ranking member of the full committee, Mr. Walden, of Oregon.

Mr. Walden. Good morning, Madam Chair, and thanks for recognizing me for questions. Mr. Boutin, H.R. 938, the BLOCKING Act has bipartisan support on this subcommittee, and I understand that the goal of the legislation is to prompt generic manufacturers to launch their products as early as possible. Can you walk us through the issues in the market currently in the way this bill attempts to resolve those issues?

Mr. Boutin. I can tell you on that issue the National Health Council has not taken a formal position, but I will tell you that we are very supportive of the intent of this legislation. I know looking more closely at how we can help ensure that generics are getting to market as quickly as possible.

Mr. Walden. All right. Mr. -- and I probably will get this wrong, Barrueta.

Mr. Barrueta. Barrueta.

Mr. Walden. Barrueta all right. What was the 2018 operating revenue of Kaiser Permanente?

Mr. Barrueta. The operating --

Ms. Eshoo. Turn your microphone on.

Mr. Walden. I am told 79.7, so --

Mr. Barrueta. Just under 80.

Mr. Walden. Almost 80. What kind of impact would losing $79.7 billion have on your organization?

Mr. Barrueta. That would be very bad.

Mr. Walden. It wouldn't help your employees, would it? Would you expect your company to have to lay off some workers, and how might it impact your

organization's ability to continue operations?

Mr. Barrueta. The loss of revenue obviously is something that any business has to accommodate itself to.

Mr. Walden. And we are all obviously interested in finding a powerful deterrent for bad actors, but I want to be sure we all understand what is at stake we are talking about revenue not profit or actual damages. As you well know there is a big difference there.

Mr. Davis, Dr. Burgess touched on some of the concerns he has about the unintended consequences of the pay-for-delay bill, and I think it is an important issue to consider fully. Can you provide some additional insight on how the agreements actually work, and would you say that they lead to earlier competition than we would otherwise see on the market?

Mr. Davis. Yes, thank you, Congressman Walden, for the question. So the short answer is, yes, there are situations, and I think the FTC has spoken to this in the report I referenced earlier, that in the wake of the Supreme Court's guidance in the seminal decision back in 2013 about their scrutiny that they would apply to a transferral of anything of value that the number of anticompetitive agreements as determined by the FTC has dropped significantly. That is a good thing. It is a good thing for the market. We support more market-based competition. In fact, competition if you will, is the DNA of the generic and biosimilar sector.

What we want to do is make sure that as our companies are doing everything in their power to get safe, effective, and affordable generics or biosimilars to the market as quickly as possible is that in those instances where settling, whether it be because of late stage patent stacking or patent abuse and filings the generic companies don't generate

the revenue the brands do, so even in litigation there is a potential that they will get worn out of resources to the point about loss of revenue where they cannot continue. There is not a generic company that is going to be able to debate in court 100 pending patents for way of example.

So to not have the ability to settle on a date certain admittedly quite frankly because of certain patent abuses one that is longer out than they would have liked to otherwise is still important to make sure that they can preserve so they have some clarity and certainty about being able to go forward on a certain date. We used to have that complete -- to be candid as an industry, and that is getting away from us year over year as the absolute certainty of when our manufacturers are going to be able to come to market with a competitive product.

Mr. Walden. All right. Anybody else want to add anything to that? Yes.

Mr. Kushan. I have just heard a few times the concerns about these patent thicket issues, and I want to make sure that we recognize that it is a slightly more nuanced circumstance. A lot of times the patents that come out later are very narrow, and when you are an innovator or when you are a biosimilar manufacturer you can make a choice whether to use the technology that is covered by the patent or not use it. And so when you look at all these patents, there is ways around the patents that are not involving invalidation of the patents.

It is important when we engage in this discussion to make sure that we don't kind of oversimplify the patent issue into an assumption that all patents do the same thing. Some are very narrow, some dominate the product, but you have to look at the actual obstacles if there are any that are in front of the biosimilar manufacturer and how they might best navigate around those obstacles.

Mr. Walden. All right. I see Mr. Carrier wants to say something. I have 14 seconds, it is all yours.

Mr. Carrier. Very quickly, certainty for the brand and the generic companies is a lot of what we have talked about today, but on the other hand the Supreme Court in Actavis said it is the risk of competition that is the anticompetitive harm. Nine out of ten of these patents are not on the active ingredient, let's litigate them.

Mr. Walden. Thank you. Thank you, Madam Chair.

Ms. Eshoo. Thank you. Let's see, who is next? Mr. Welch of Vermont, one of the key members of our committee whose name is on more than one of the bills that we are considering today, you are recognized for 5 minutes.

Mr. Welch. Thank you very much, Madam Chair. It is kind of exciting to be here because we are actually on the threshold of doing something, and that is something that eludes us in Congress, so it is nice to show up for work today. And we are actually building on work that was done when Dr. Burgess was the chair of this subcommittee and Ms Eshoo was following on. So I am pretty excited.

The second thing is I really appreciated the testimony. It is like you all like know something about what you are talking about, and that is refreshing, as well. And I have got a request for everybody because you have been talking concretely about legislation, and one of the big challenges around here is to start getting into the details.

So if you have specific suggestions about how any of these bills can be improved I think that would be of great interest to our committee because we want to get this right. And you have concrete, practical knowledge and experience that can help us do that. So my request to you is to send in your bullet points about areas on each of these bills where you have improvements. So thank you. But I want to just make a few comments and

ask a few questions.

Mr. Davis, you said something that makes total sense to me, and that is that we want a deal on the front end where we eliminate patent abuse, so that we don't have to argue on the back end where no matter what the remedy is it is going to be tough. Can you just elaborate a little bit on that?

RPTR MOLNAR

EDTR HUMKE

[12:00 p.m.]

Mr. Davis. Sure, happy to, Congressman, and thank you for your sustained leadership on the issue of REMS abuse. It is greatly appreciated.

The larger dynamic in terms of -- and again, I want to be clear here -- that the generic and biosimilar industries recognize the importance of strong patent protection of intellectual property. We like to say that we rely every bit --

Mr. Welch. You have got to be brief here because I only have 5 minutes.

Mr. Davis. So -- but what we have more of a concern with, is, after sort of the initial filings on the patent and the product comes to market, as it is nearing the end of its product lifecycle, you see a lot of subsequent filings, particularly on expensive specialty drugs that further delay competition.

Mr. Welch. Okay. And, Mr. Carrier, an amazing number of articles you have written, congratulations and thank you for your contribution, but one of the pushbacks that we have had from branded pharma is that if we do anything about pricing, it is going to affect innovation. And I heard you say -- and I just want to make sure I am right -- that the various proposals that are under consideration today would not, in your view, adversely affect innovation?

Mr. Carrier. That is correct. And so that is always the argument that the brand companies offer -- if you do anything at all, that is going to hurt innovation. On the other hand, what is complicated about this area is that we have innovation on the one hand and generic competition on the other.

You look at Hatch-Waxman. Half of it is for innovation. Half of it is for generic

competition. The brand companies have gotten everything they have wanted for innovation -- the 30-month stay, the patent term extension, the nonpatent market exclusivity. But when it comes to the generic side, like the 180, they have now taken that for themselves. There has to be something there for generic competition.

Mr. Welch. All right. Thank you for making that point. Mr. Barrueta, I want to ask you, do you have a view on the pros and cons of CREATES versus FAST? I am a cosponsor of both pieces of legislation, but I want you to tell us what you think is -- should we combine them, or do you have a view on which one would be more effective?

Mr. Barrueta. I guess my comment is probably more of a process one. Whichever one you can get done more quickly, I would go with that.

Mr. Welch. Either way.

Now, Mr. Karst, you were talking about litigation. I have a confession. In addition to now being an active politician, I am a recovering trial lawyer.

Mr. Karst. Okay.

Mr. Welch. And public approval about 3 percent. I don't like litigation, all right? It just -- it is the last resort, and there is other agendas that are usually involved in it. And do you see a way where we can try to do what Mr. Carrier is talking about, protect intellectual property and innovation, but on the other hand, spur biologics and generics? You know, you seem to be raising some questions about the necessity litigation, and I would like to get away from that, really, by doing what Mr. Davis is suggesting.

Mr. Karst. Yeah, it is -- as, of course, a lawyer, litigation is part of my job, but I was really raising that in the context of the BLOCKING Act, which, again, I am in the

trenches all day when it comes to 180-day exclusivity generic drug approval, and anything that makes an amazingly complex law have all that much more complex tapestry is simply not good, in my opinion.

Mr. Welch. Well, send us your suggestions.

Mr. Karst. This is in the context of the -- yeah, certainly -- the BLOCKING Act, which I --

Mr. Welch. Right.

Mr. Karst. -- just don't think is necessary, and it is just going to lead unnecessarily to more litigation.

Mr. Welch. Yeah, I mean, see -- I know my time is up, but this is where there is some common ground here. We all want to protect innovation, but we want to get the prices down and make it affordable. So thank you. I yield back.

Ms. Eshoo. I thank the gentleman. It is a pleasure to recognize my favorite Greek in the Congress, the gentleman from Florida, Mr. Bilirakis.

Mr. Bilirakis. Thank you very much. I appreciate that, Madam Chair. Thank you for holding this hearing, by the way. This is a priority for all of us, because our constituents talk about this all the time, again, the high prices -- the high, prescription drug prices. So we must lower the prescription drug prices, and I hear this from our veterans population, our senior population, but the general population.

So I remain committed to working with my colleagues on both sides of the aisle to achieve that desired result in a way that does not undermine progress and that has already been made, so -- the progress that has been made. And I agree with Representative Welch, I appreciate your testimony, and keep sending us your suggestions, because it means so very much. We have got to get this right.

Mr. Davis, can you share with us what is currently working and how we might double down on these efforts? That is the bottom line.

Mr. Davis. Sure. Congressman, thank you for the question.

I think when you look at the bills that are before you, I think both transparency bills, on the Orange Book and Purple Book, are, as has been referenced before by experts far greater than I, a really positive step in the right direction, and AAM is supporting both the CREATES and FAST Generics Act that are also under consideration here.

I think one other area that is really important that hasn't been touched on yet today because it is not reflected in a bill currently before the committee, but relates to -- and I think Mr. Barrueta's talked about how biosimilar uptake has been so significant at Kaiser -- is about benefit design and formulary placement and the importance of ensuring that when generics and biosimilars get onto the market that they have a preferred position on the formulary.

We actually have an increasing case year over year, where follow-on competition from an out-of-pocket cost perspective may be more expensive because of agreements between originators and plans than the follow-on competition. If that happens, I would submit to you that Hatch-Waxman and BPCIA don't work. So ultimately now, and a credit to CMS, they are looking at this very issue as we speak for the 2020 Part D plans.

And so we encourage any Member of Congress who wants to make sure that generics are on a generic tier, biosimilars are on a biosimilars tier, and that the out-of-pocket costs, which, as we all know is what consumers and patients are really focused on, is making sure that those are lower for the subsequent, low-cost alternative as opposed to being higher.

Mr. Bilirakis. Thank you. Very recently this committee passed legislation to

address the products with limited competition by creating the competitive generics therapy Program at FBA, also known as the Schrader-Bilirakis bill, and it extended the 180-day exclusivity to products without competition, and by all accounts, the program has been successful, with FDA receiving over 100 applications from generics manufacturers looking to bring competition to these products.

To me, this is a perfect example of the value that a 180-day exclusivity holds for generic manufacturers. But my concern with some of the bills we are discussing today, that, you know, we have a solution in search of a problem and should we move forward. The consequences of undermining the 180-day exclusivity and the adverse effect it may have on generics.

Mr. Karst -- and you have touched on this -- actually the entire panel has, but let me ask the question again. In your opening statement, you stated the BLOCKING Act is not necessary. Why is that, and could you elaborate more? You referenced the medical maxim in your testimony, do not harm, and we don't want to harm. Could this bill end up weakening the 180-day exclusivity that has proven to be such a powerful incentive for bringing generics to market as quickly as possible?

Mr. Karst. Thank you very much for your questions, Congressman Bilirakis. And as an initial matter, thank you very much for the CGT, the competitive generic therapy legislation. It has been -- it has been a smashing success. I can tell you, working with a lot of companies in the generic drug industry, this is -- this is very important to them, and I am constantly working with companies to get the designations and the approvals, and companies are very much responding to your legislation and Congressman Schrader's legislation.

On the BLOCKING Act, quite simply, I don't think the bill is necessary, because,

one, FDA already has the statutory and regulatory authority it needs to address the problem. Now, this has been, I guess, characterized by Secretary Azar as squatting on exclusivity, and it is not, I don't think, an accurate description of the situation.

In fact, these companies may, for one reason or another, whether it is due to FDA or their own fault, unable to get final approval, but FDA does have authority under the statute to deal with that situation already. Putting new provisions into the statute that are amazingly complex, again, not only will lead to litigation, but they are so complex in nature that I am afraid that it is going to significantly hurt the 180-day exclusivity incentive.

Mr. Bilirakis. Thank you.

Madam Chair, I will yield back to my favorite Syrian-Armenian chairman. Thank you.

Ms. Eshoo. We really got something going here.

It is a pleasure to recognize the gentleman from New Mexico, Mr. Lujan.

Mr. Lujan. Thank you very much, Madam Chair.

Issues with REMS programs have been coming up for years. These requirements are meant to help ensure the safe use of certain drugs. Unfortunately, we have heard testimony over the years that REMS have been gamed to delay generic drug development activities. The FDA Commissioner has said that REMS abuse needs to stop, and the agency has taken a number of steps to try to facilitate generic access to samples.

I am concerned, though, that some have tried to argue that such access by generic drug developers could put patient safety at risk. Both the CREATES Act and FAST Generics Act lay out a process by which generic manufacturers could access samples of a branded drug product, provided that certain conditions have been met.

Ms. Kennedy, can you please describe the kind of testing you might do on a product before it comes to market? What do you have to show the agency to obtain approval?

Ms. Kennedy. Yes. Delighted to answer. As the only manufacturer who gets up every day to lower healthcare and costs to American patients on this panel, I'm --

Ms. Eshoo. Move your microphone. Maybe it is not on. We really want to hear from you.

Ms. Kennedy. I am pretty loud anyway.

Ms. Eshoo. There you are.

Ms. Kennedy. Okay. And I like your first name. At any rate, I would like to say that we are absolutely equipped with all the innovation and knowledge that we need to deformulate any brand product on the market with the exception of some of the biologics.

And as such, we are hoping that it is made easier by Congress and others to get those REM samples and make sure that we can begin our innovative process, and from that, we then are expected to prove to the FDA, with regular standards in place, that we are qualitatively and quantitatively equal and efficacious to the brand product.

As such, we are doing that over and over again, and particularly in the Part B Medicare space, and that is truly lowering the cost of drugs to American patients, because our drugs that we are making as generics today are the 100 top movers list. They are taken by emphysema patients and others four times a day, and we hope to expand that as other drugs are -- are closing -- closing to near the end of their patent life.

And we hope that the Congress and all of the laws that will be enacted as a part of what we are talking about today, encourage us and help us to get our products to market

and truly lower the cost of healthcare. That is where we are.

Mr. Lujan. Ms. Kennedy, can you touch on the safety as well --

Ms. Kennedy. Yes.

Mr. Lujan. -- that you have to be attentive to, to ensure the product is, in fact, safe?

Ms. Kennedy. Yes, we have to prove every test that the brand innovator has to prove, and we have also other tests required of us if we, for example, move to a different container closure, something that would be innovative and perhaps a less expensive way to package those products. We are required to test from soup to nuts, all C of As must be passed, all matters of assay identity, osmolarity and all the other tests, including sterility, must be passed. So the quality is not at issue. We will not receive approval unless we are perfectly 100 percent efficacious or better than the brand.

Mr. Lujan. So, Mr. Davis, based on your review of the CREATES Act, do you believe that this legislation changes the safety standard or patient protections that are currently in place for equivalent branded products, and do you believe the bill opens a possibility of additional risk to patients?

Mr. Davis. So I believe it maintains the level of safety certification requirements that the FDA has, and actually puts more, sort of, teeth into it, Congressman. I would associate our comments with everything that I think was perfectly articulated by Ms. Kennedy as well. I do not think it exposes anyone along the continuum to any increased risk of safety whatsoever, because we actually trust the FDA to get it right.

Mr. Lujan. Mr. Davis and Ms. Kennedy, do you believe that either the CREATES Act or the FAST Generics Act would hamper the FDA's ability to ensure all drugs, regardless of whether they are brand or generic, are safe and effective and adequately

protect against patient safety risks? Mr. Davis?

Mr. Davis. None whatsoever.

Mr. Lujan. Ms. Kennedy?

Ms. Kennedy. Agreed. Their governance is what is expected of us. That is the law.

Mr. Lujan. And I guess as I close, Madam Chair, I take comfort in knowing that both pieces of legislation preserve a process by which the FDA can register any concerns with that plan before the samples are transferred, which is also something that is important for us to be noting as we move forward with consideration of legislation.

With that I yield back the balance of my time.

Ms. Eshoo. I thank the gentleman.

I now would like to recognize the gentleman from Indiana, Dr. Bucshon.

Mr. Bucshon. Thank you, Madam Chairwoman.

Mr. Davis, I want to clarify, earlier you said -- you listed a long list of people that supported the CREATES Act, and I want to clarify the version of that that you are talking about. The version was introduced to this Congress -- or is this a previous version, and I think you mentioned it might have been the previous Senate version. Can you clarify that?

Mr. Davis. Yes, Congressman. Thank you for the question. So, yeah, the list of supporters of which AAM is one, that has been tracked as actually a list that has been growing year over year, as this problem has become more significant, dating back to 2007 when the REMS programs were created. So that list applied to the version that was being considered last fall, in the Senate. The CREATES Act that actually passed out of the Judiciary Committee, is, I believe, the one where all of those stakeholders actually

wrote a letter in support.

Mr. Bucshon. Okay, in that vein, I want to be able to support a version of the CREATES Act, but the current version seems to me, it could potentially and perversely incentivize litigation. As currently drafted, it appears that the generic company could simply not accept the valid offer from a brand manufacturer and go to court because -- understanding the damages available to them could be much more lucrative. If an offer to sell samples on commercially reasonable, market-based terms has been made, should a generic be able to reject that offer and go to court?

Mr. Davis. I think the issue will be determining what fair market value is. As they always say, beauty is in the eye of the beholder in the negotiations. So I think that is actually one of --

Mr. Bucshon. But that is defined in the law, right?

Mr. Davis. I am sorry?

Mr. Bucshon. What fair market value is, is --

Mr. Davis. That would actually be based upon what is available in the marketplace, what the originator would be offering to sell to the generic manufacturer.

Mr. Bucshon. Right, so commercially reasonable market based. I mean, I am not a lawyer, but --

Mr. Davis. Correct.

Mr. Bucshon. -- that is probably a definable, legal term, I would imagine, correct?

Mr. Davis. Correct.

Mr. Bucshon. So would you maybe then because since you were talking about the one that were supporting was the previous version last fall, and would you then support potentially adding language to the current version that might clarify that that

type of scenario wouldn't unfold?

Mr. Davis. I would have to see the language, sir, and we are happy to take a look at the proposed language. I think from our perspective, the real issue is making sure this problem gets solved now.

Mr. Bucshon. Okay, great. Anyone else want to comment on that? Do you have any other comments?

Ms. Kennedy. I think we have to encourage competition at every turn. We look to you guys for guidance and keeping people in their lanes and really putting a stop to the gaming and the things that we are faced with.

Mr. Bucshon. Well I don't think anyone disagrees --

Ms. Kennedy. We are ready to serve.

Mr. Bucshon. Yeah, I don't think anyone disagrees with that.

Mr. Carrier. And one other thing on litigation --

Mr. Bucshon. Yeah.

Mr. Carrier. -- sure, it sounds pretty crazy, but nothing else has worked. And you have the FDA Commissioner saying, we are trying everything, it is not working, cut out the shenanigans. If you have deterrents and you have attorneys fees, then finally the brand companies might wake up and say it is not worth the cost of doing business in this case.

Mr. Bucshon. So then maybe that, you know, the language, "commercially reasonable and market-based" is not strong enough and that could be an area that could be strengthened to make sure that companies aren't purposefully turning down settlements that could be reasonable and commercially reasonable, in order to litigate? Mr. Karst, do you have a comment on that?

Mr. Karst. We are typically talking -- I mean, again, for the amount of product we are talking about, maybe several hundred pills or tablets or capsules. So we are not probably talking about, in the end, a significant cost in the overall development program here for that generic manufacturer.

Mr. Bucshon. But it is a very complicated subject, and I am not a lawyer. That is why I am asking you all.

Mr. Davis. Congressman, I would only add in the discussions that we have had with our members who were engaged in this and have been frustrated for the better part of a decade, I have never heard anybody talk about the interests in actually being able to go to court and sue on the grounds of not being able to recover as opposed to their interest in getting the samples, to bring product to park that so patients would benefit.

Mr. Bucshon. Fair enough. Yeah, I was a cardiovascular surgeon before, so obviously I am averse to frivolous litigation. And, you know, in all of our specialties, as providers, we all -- if you practice long enough, you have to go through that process. And so, you know, anything that might potentially exacerbate that type of a problem, and whatever our solution is, to this issue, which we all agree needs to be addressed, is something that I wouldn't -- I wouldn't support. So with that, I yield back.

Ms. Eshoo. Thank you, Doctor.

I now would like to recognize the gentlewoman from New Hampshire, Ms. Kuster, 5 minutes of questioning.

Ms. Kuster. Thank you, Madam Chair, I appreciate it.

One of the most egregious abuses that we are discussing today is the abuse of measures intended to provide additional safety protections to consumers, as we have discussed, commonly known as REMS, risk evaluation and mitigation strategies, and plans

that the FDA requires companies to develop as a response to a particularly serious safety risk posed by the drug.

At the front end of development, some companies are citing these REMS requirements as a reason not to provide product samples to generic drug developers for bioequivalence testing that supports their drug applications. And on the back end of development, some branded drug manufacturers are negotiating in bad faith with generic developers to enter one -- into one single system REMS.

So let me start, Mr. Davis, with you, if I could. Please describe for us the various safety measures in place to ensure that generic drugs come to market with the same level of safety as their branded counterparts. I know that is a broad question. Have in mind, I have 5 minutes.

Mr. Davis. Congresswoman, thank you for the question. I will try to be as brief as possible. I think the requirements are the same, right, that the generic manufacturers have to meet in terms of convincing the FDA from a pharmaco-vigilance perspective that we will adhere to the same standards and criteria as set forth for the originators.

As part of that, when it comes to actually doing the reverse engineering, if you will, the FDA is actually required to look at the generic manufacturer, look at a company like Ms. Kennedy's, and actually certify that they have the confidence in their ability the same as the originator.

Ms. Kuster. Great. Thank you.

Mr. Carrier, let me turn to you, you have been very helpful this morning. Do you have any concerns about the FDA issuing waivers of the single shared system REMS requirement?

Mr. Carrier. So I have no concerns. The issue here is that the brand company will slow off the process of a shared REMS. When the brand and the generic each have a REMS, the brand will say, sure, I will get back to you, and then 3 years later it gets back to the generic. So eventually the FDA has to wade in. Thirteen times it has been asked to get in the middle of these. All 13 times, it says, generic, you can go your own way, because the brand has no interest in working with you. And so at the end of the day, the FDA is able to waive the shared REMS requirements.

Still a hundred percent safe, absolutely no concerns there, but it would be a little better to have us not go through that whole song and dance and have the generic be able to enter the market a lot quicker with a completely safe REMS.

Ms. Kuster. So the 19 times it was always -- the brand dragging their feet?

Mr. Carrier. Yes. That is my sense, that the FDA has -- was asked to get involved and the generic has a REMS, it has FDA approval, and still it is not able to be worked out between the two.

Ms. Kuster. Okay. That is very helpful. Thank you.

And then Ms. Kennedy, do you agree that legislation, such as the CREATES Act, is needed to address these kind of gaming tactics?

Ms. Kennedy. One-hundred percent. We have watched over the last decade as many missed opportunities for generics to get to market and lower the price of healthcare have come and gone. Whatever we can do to help American taxpayers and patients, is incumbent upon us to do that. This is America.

Ms. Kuster. Do you have a sense of the cost of these types of delay tactics and gaming techniques on healthcare overall, cost to consumers?

Ms. Kennedy. The costs are amazing. Imagine that we sell a product 50 million

doses a month, to people like Kaiser Permanente, for 6.8 cents a dose. Now, we have to be lean and mean. We don't have the money to do expensive litigation. I am always a fourth or fifth to file. And I am lowering the cost of healthcare and drug products, and I want to do it, and I want to do it with safety and efficacy.

Ms. Kuster. And what is the impact on multiple filers? When you say you are fourth or fifth into the market, is there still an impact --

Ms. Kennedy. Yes.

Ms. Kuster. -- at that point on price?

Ms. Kennedy. Yes. The first filer typically lowers the cost 25 percent. That is great. But when I get to market, it is 80 to 85 to 90 percent. That is real savings.

Ms. Kuster. And what is the impact on the quality of that --

Ms. Kennedy. There is no impact to quality because we are -- it is incumbent upon us to prove to the FDA that we are equal or better. And we have to file each and every lot with all complete C of A testing and sterility testing.

Ms. Kuster. Well, I will just close by saying, it seems clear to me that there are some manufacturers using these REMS requirements as a way to keep competition off the market, and as we have all just heard, that is not the original intention of REMS. And I think we have bipartisan agreement to wade into this and make it a top priority. So thank you. I yield back.

Ms. Eshoo. I thank the gentlewoman.

It is a pleasure to recognize the gentleman from North Carolina, Mr. Hudson.

Mr. Hudson. Thank you, Chairwoman Eshoo, for holding this important hearing. One of the things I hear constantly from my constituents is their out-of-pocket costs are too high. I think working in a bipartisan way to make generic access to the market as

simple as possible is important, not only for our government spend on drug prices but also for our consumers' out-of-pocket cost. Simply put, generics save money.

I do worry, though, we are using generics as a silver bullet for issues facing us with high drug prices. I believe robust protection for innovation needs to remain in place, to continue to nurture the high level of innovation we have seen recently with technology such as CAR-T and CRISPER.

I noticed almost half of my Democratic colleagues on this committee support a policy that allows the government to strip innovators of their patents through compulsory licensing and allow other manufacturers to produce a generic. Generics need to come to market as soon as provided protections for innovations run out, but not before. Otherwise, we threaten therapies like these new CAR-T drugs which can have an over 80 percent success rate for some cancers. That is a four out of five chance your parent comes home from the hospital after a cancer diagnosis.

To that same point, though, I believe we should reward innovative science, not innovative legal work. I am happy to see the committee consider concepts that will help end legal gamesmanship and support bringing generics to the market, but the process behind this hearing does concern me.

And we don't have the Food and Drug Administration, the agency responsible for implementing these bills, here to testify and give us a chance to ask them questions. As Congress, we should seek the input of the agency that will be regulating this space.

And so, Chairwoman Eshoo, as I have said to you before, I really want to work with you on this issue, want to work with my colleagues across the aisle in a bipartisan way, to advance the concepts we are talking about here today. Could you commit to getting the FDA's written, technical assistance on these bills before we mark up?

Ms. Eshoo. We will.

Mr. Hudson. Great. I appreciate that. I think that would be very valuable input for us.

And then I appreciate all the witnesses being here today. I have read your testimony. It has been extremely helpful for me in my understanding of this space.

Mr. Karst, I have had concerns with the Purple Book legislation being offered here today. Where -- oh, there you are, sir. The transparency is something we all support and we all want, and certainly we have seen the Orange Book requirements since Hatch-Waxman provide benefits to the small-molecule market. Could you provide more detail on how you think the Purple Book legislation could be improved so it could be equally as useful in the statute?

Mr. Karst. Sure. Thank you for the question, Congressman. So -- and part of this, I have to say, couched in terms of, it may require a broader change to the BPCIA, but as least as an initial start -- and Mr. Kushan and I may disagree to some extent on this -- having a list of patents in the Orange -- excuse me -- in the Purple Book, somewhat akin to the Orange Book, I think, would be helpful for manufacturers.

Now, I recognize Mr. Kushan's concerns that under the current -- the proposed bill that the patent information would go in after the first biosimilar challenge and could raise issues about confidentiality, but we can get rid of all that simply by requiring the brand to list all of its patents in the Purple Book, upon licensure of its product. Then potential biosimilar applicants will know the entire patent estate that is out there, that may be shot at them in litigation.

Mr. Hudson. Great. Well, I appreciate that. That is very helpful.

With that, Mr. Bucshon, do you want the last minute of my time?

Mr. Bucshon. No, I am good.

Mr. Hudson. Okay. Seeing that, Madam Chairman, I will yield back. Thank you.

Ms. Eshoo. I thank the gentleman.

I think those members that are left are getting -- they have an appetite for lunch. Let's see. I would like to recognize the gentlewoman from California, Ms. Barragan, 5 minutes for questioning.

Ms. Barragan. Thank you, Madam Chairwoman, and thank you to our panel for being here today. It has been great to have conversation on a bipartisan basis that we all want to lower prescription drug prices for Americans. When I have townhalls in my district, it is one of the top issues I hear about, and how people have to choose between prescription drugs and rent or groceries. And in a district like mine, -- it is very working class -- it is so nice to hear, on the other side, say, hey, we have a common goal to bringing these down. Obviously, we have this hearing today and we see that there is -- there is a lot of details, there are some differences, but I am hoping that we can get through them to find a solution.

And, you know, I think back in 1984, when Congress passed the Drug Price Competition and Patent Term Restoration Act which we all know as Hatch-Waxman, the bill kind of laid the ground work for the modern, generic drug, approval system. Now, Congress has worked hard to try to strike this balance between innovation and getting generics to the market as soon as possible. We had the Secretary here yesterday also talking about what we are talking about here today, and it was good to hear from him that he agreed that this delay in getting generics is an issue.

And one aspect of the framework is an incentive for the first generic drug

manufacturer to submit their application and come to market, 180 days of market exclusivity. In other words, 180 days during which the FDA could not approve additional generic versions of the same product.

Now, I have been reading, and we have been certainly learning in recent years, that some of the generic drug manufacturers are abusing this reward. They are signing agreements to keep their products off the market longer, or for other business reasons, they do not launch their products as early as can be.

Now, I am the author of one of the pieces of legislation here today, the FAIR Generics Act. I happen to believe that this would help the problem by realigning incentives for generics to come to market sooner.

Mr. Carrier, in your research, have you seen this to be a problem, and could you maybe explain and tell us more about it? You know, why are generic drug manufacturers behaving in this way?

Mr. Carrier. Absolutely. Thank you for the question, and thank you for your support of this incredibly important legislation. The problem is that the brand company is settling with the first filing generic, agreeing not to enter the market for years, and as a result, no one else can enter. As I mentioned before, the Medicare Amendments Act of 2003 was designed to deal with the issue; it has not.

And so the 180-day provision here really needs to be opened up. It is not just the first company to file a Paragraph 4 certification, but it is also a company that is not sued by the brand company. It is the first generic that wins a district court ruling in court, that the patent is invalid or not infringed. So whenever anything about the 180 comes up, the question is, oh, do you need the incentives for the 180? And I would just say, you do not need the full, exclusive 180 just for the first filer. Because right now we

have shared exclusivity. You have many generics on the first day. Still tons of generic applications filed. There is an FTC report on authorized generics a decade ago, that found that there is no effect on filing a first-filer application when there is an authorized generic in a small market.

So at the end of the day, we need this. And it is not just me who is saying it. So you go back to the Supreme Court in Actavis, the justices said -- Justice Scalia said, Hatch-Waxman made a mistake. You look at what Representative Waxman and Senator Hatch have said. They said it is appalling, the legislation is turned on its head. The 180 was designed for a certain purpose. It is not being used for that purpose. This is the simplest place to deal with it, not an antitrust law, but with your legislation.

Ms. Barragan. And earlier on there was some conversation between some of the panelists. Mr. Kushan and Mr. Karst, they had raised concern about the bill. They questioned whether it was an appropriate realignment of market incentives. Is there anything you want to add to kind of respond to those concerns that they raised, and, you know, could this legislation be an effective deterrent?

Mr. Carrier. This legislation would be the most effective deterrent for settlements. And the problem is, a lot of the discussion that we heard this morning was about settlements being good, about entry before the scope of the patent expires. This was all rejected by the Supreme Court in Actavis. Actavis made clear that, sure, settlement is good for the brand and the generic company, but it is outweighed by five public-policy considerations.

The Supreme Court made clear that you don't get to say entries before the end of the patent, so therefore it is procompetitive. That is the scope of the patent test that was rejected because antitrust has to play a crucial role.

And just one final point here, we have heard a lot about the FTC and the number of pay-for-delay settlements going down, but there still are a ton of settlements and there is still a ton of delay. So if you go back through the past 5 years, there have been 771 settlements, 653 of them involved delayed entry. Might not be payment, still delayed entry. Your legislation would solve the problem.

Ms. Barragan. Thank you, I yield back.

Ms. Eshoo. I thank the gentlewoman.

I now would like to recognize Mr. Carter of Georgia for 5 minutes of questions.

Mr. Carter. Thank you very much, Madam Chair, and thank all of you for being here. Currently, I am the only pharmacist serving in Congress and have over 30 years of experience in practicing pharmacy. This is a real problem, getting generics to the market. I have seen prices on brand-name drugs drop dramatically whenever generics entered the market. And that is why we need to get it there as soon as we can.

I have so much respect for the pharmaceutical manufacturers who devote and invest in research and development. I have seen nothing short of miracles in my years of practice, that have come out as a result of research and development. However, when a drug is too expensive, and not accessible or affordable, it does no one any good whatsoever. So that is why this is so very important.

I will tell you that I find some of this discussion -- in fact, I find much of this discussion more lawyerly than I do pharmacy. So out of all due respect, I am just a little bit taken aback by the legal aspects and how this ever got to this point. But at the same time, that is where we are, so that is what I am going to deal with.

Mr. Davis, I am going to start with you, because quite honestly, you confused me earlier. Dr. Burgess asked you about the CREATES Act, which I think we all agree needs

to be done and needs to be done as soon as possible. However, last session, we had an agreement where everyone was on the same page, and now, all of a sudden, this has changed somewhat, where not everyone is on the same page. And you confused me in your answer to him. Which one do you support, or do you support both of them?

Mr. Davis. I believe that the CREATES Act, as has been introduced, we support the CREATES Act --

Mr. Carter. As has been introduced here, that we are looking at here --

Mr. Davis. I will have to go back and will report back to you, Congressman, about any significant differences. I don't believe there are significant differences between what was introduced in the last Congress and this provision --

Mr. Carter. Well, that is where I get confused at because we are told there are some things that are different. And out of all due respect, if you will just get back with me and let me know, I would appreciate that.

But would you agree -- and Ms. Kennedy, you might be able to answer this, too -- do you ever do any of the 180-day exclusive, or do you just primarily do after everybody is eligible?

Ms. Kennedy. We do not have the -- we do not have the resources to fight the big litigation, and so, no, we haven't taken a part of the 180-day exclusivity, except for in one case where we are the manufacturer of record for someone who did fight the patent challenges, a company named Apotex. We manufacture for them, a product called Budesonide, a corticosteroid. That is the only time.

Mr. Carter. Okay. Well, as was mentioned, Representative Schrader and I have bipartisan legislation, the BLOCKING Act, that we feel like is good legislation. It is going to make a difference. And that is the key here -- how do we make a difference.

You know, of all the committees in Congress, I would submit to you that the Energy and Commerce Committee works in a more bipartisan fashion than any other committee, and I have always been very proud of that. And I continue to be proud of that, and I hope that in this session, we will continue that. That is why this legislation, the BLOCKING Act, that Representative Schrader and I are cosponsoring, is so very important to me, and I want to see us continue with that.

But back to the CREATES, if a -- if a generic company asks of a brand manufacturer, I need samples, and they provide it, and there are no other kind of agreements or, you know, no other kind of stipulations, should they have the right to still sue? Because if a brand-name manufacturer provides them with everything they have been asked for, shouldn't that be enough? Anyone want to tackle that?

Mr. Carrier. So --

Mr. Carter. Anyone want to tackle that?

Mr. Carrier. Yeah, the problem is that they are not getting the samples. So --

Mr. Carter. No, no, no, no, that is not what I asked, Mr. Carrier. I said that if they got the samples and if we required it as part of the CREATES Act, said you have to give the samples, and if you give the samples, then you have no other excuse. You have 180 days, at that point. That is what I asked.

Mr. Carrier. So if the brand company is giving the sample, that is fine. The problem is --

Mr. Carter. Okay.

Mr. Carrier. -- now they are not.

Mr. Carter. Okay. But if we say that they have complied and they have given the samples, then isn't that a no-brainer? Mr. Davis?

Mr. Davis. Just so I understand correctly, Congressman, you are saying that the originator would give the samples --

Mr. Carter. Right.

Mr. Davis. -- to the generic manufacturer?

Mr. Carter. And there is no other kind of stipulations. If they --

Mr. Davis. Would give them? That is actually what we are trying to address here, is --

Mr. Carter. Right, exactly.

Mr. Davis. -- they are not. And often times it comes down to -- and I would also suggest that it is not an issue of where generics are asking for them. They are willing to purchase them at fair market price.

Mr. Carter. Okay, I have got 5 seconds left. I just want to mention again that the BLOCKING Act is a perfect example of us working in a bipartisan fashion, and I hope that is what this committee will do.

Also, tomorrow I am going to be introducing more legislation that is more bipartisan, that Mr. Welch and I are -- and Mr. Gianforte, we are all cosponsors on this. It is called the Payment Commission Data Act. This will allow MedPAC and MACPAC to get the pricing information from Medicare and from CMS, in order to make recommendations to Congress that we need. So I hope you will be looking out for that as well.

Madam Chair, thank you very much for your indulgence, and I yield back.

Ms. Eshoo. You don't have anything to yield back. It is a term we use around here. I thank the gentleman.

I now would like to recognize a new member of the Energy and Commerce

Committee, and we are thrilled that she is high value added to our subcommittee, the gentlewoman from Delaware, Ms. Blunt Rochester.

Ms. Blunt Rochester. Thank you so much, Madam Chairwoman, and thank you specifically for this important hearing on drug pricing. I also want to thank the panel for your testimony.

I would like to focus our attention on generic drugs and their potential, through market competition, to lower drug prices for American consumers. We have heard today that one of the best ways to reduce drug prices is to ensure generics can come to market as soon as possible, after patent and exclusivity periods expire.

Generic market entry saved $265 billion in 2017, including $82.7 billion for Medicare alone, or $1,952 per enrollee. In fact, according to one estimate, the average drug price decreased by 50 percent in the first year of generic entry, with an 80 percent reduction within 5 years.

I am especially concerned about the impact on patients, when generic drug developers are unable to develop their products due to difficulties with access to samples, as was just stated.

I recently had a constituent write to me about her experience trying to purchase an asthma inhaler she had been using for 20 years. She found that starting in January 2019, the copay for her inhaler had more than doubled. She explored paying out of pocket, but the costs would have been more than twice her new copay. She looked for a generic, but found there was none.

These samples are vital to the development of their applications and without them, they will not be able to come to market. Both the CREATES Act and the FAST Generics Act attempt to deal with this problem.

Mr. Barrueta, do the bills before the committee today constitute meaningful progress in the drug-pricing debate, and from a payer perspective, how do generics and biosimilars help with cost containment?

Mr. Barrueta. Thank you for the question. I would say, yes, these bills are very important. You know, certainly CREATES, as we said before, needs to get going and get that across the line, and that will be enormously helpful. From a coverage standpoint, generics are crucial. Getting generics on the market in a timely way enables us to continue to provide as comprehensive benefits as we can, so that as we have an orderly process of brand-name drugs becoming eventually generically available, it helps us afford the newer drugs that are coming along as well. So it is absolutely essential to provide stability and access for consumers.

Ms. Blunt Rochester. I asked the question about cost containment, I actually served as State personnel director in the State of Delaware, and trying to contain cost is a pivotal area.

Of the solutions that the committee is considering today, which would you say have the most direct, immediate impact on high drug prices?

Mr. Barrueta. Again, I think CREATES, getting that done, getting the REMS issue cleared up, I think that will help enormously.

Ms. Blunt Rochester. And I guess I want to just shift, I know there has been conversation about patents and our patent system. And we know of the high value of patents and also some of the challenges. Can you share with us policies that you think we should be considering in regard to our patent system?

Mr. Barrueta. That is a -- that is a good question, and it is a challenging question. You know, the patent laws are crucial. I do -- I personally feel that we assume that the

law that is in place is something that has been set in stone and shouldn't be revised. We have seen, particularly in the pharmaceutical space, fundamental changes in the economics of the pharmaceutical industry. We have seen incremental extensions in terms -- in the 1990s, we saw patents extended from 17 to 20 years. We have seen similar activities around market exclusivities, and it has crept and crept and crept.

What we really want to do is make sure that we are providing innovation -- that we are providing incentives to maximize innovation. Maximize innovation, and at the same time, promote access. And there has been a case made for many years that if you over- -- if you overprotect certain things, if you provide too much of an incentive for something in the short-term, it actually detracts from the incentive to innovate more. So we want to make sure we are achieving the right balance to optimize innovation in the pharmaceutical industry. It is a great industry, we need to make sure that it is very healthy in delivering what is possible for American consumers.

Ms. Blunt Rochester. And my last question is for Mr. Boutin -- did I pronounce that correctly?

Mr. Boutin. Sure.

Ms. Blunt Rochester. You know firsthand how important it is that patients are able to afford their medications, and in your testimony you mentioned that studies have shown that multiple generic drugs on the market dramatically lower drug prices. Can you speak briefly, or actually follow up, with the entry of multiple generics on the market, how it could benefit patients and how Congress could help increase generic utilization?

Mr. Boutin. So quickly, as a patient advocate, I am sick and tired of other stakeholders using patient safety to justify their actions when it harms patients. We support CREATES. We do not see a safety concern. And when you have multiple

generics on the market, you see a dramatic reduction in out-of-pocket costs to the patient, their family. It has huge implications for their livelihood.

Ms. Blunt Rochester. I am out of time. Thank you so much, Madam Chairwoman.

Ms. Eshoo. Thank you.

And now we recognize Mr. Gianforte from Montana for 5 minutes of questioning.

Mr. Gianforte. Thank you, Madam Chair, and thank you to the panel for being here. This is a very important topic. We are seeing skyrocketing prescription drug prices that are difficult for Montanans and certainly all Americans.

Just last month, I was talking with a constituent in Great Falls, Montana, who saw her lupus medication increase significantly. It got in the way of her continuing to run her small business and, ultimately, created financial instability for her family. So this is a very important topic we are discussing.

I fully believe that everyone in this chamber is committed to working to get lower drug prices, and I am committed to finding commonsense, bipartisan solutions. To that end, I have been working with my friends on the subcommittee here -- Mr. Carter, Mr. Welch -- and tomorrow we will be introducing a bill specifically around drug-price transparency, which I think is a step in the right direction.

I look forward to continuing to find innovative and creative ways to solve this problem and working across the aisle to promote them.

I want to start with the CREATES Act, and, Mr. Karst, I have a question if I could. I have two questions, if you could just give me a yes, no, these are easy questions, all right?

Mr. Karst. Yeah.

Mr. Gianforte. So in 2012, the FTC voted to allow the commission to pursue

recovery of ill-gotten gains, more frequently than it had in the past. When pursuing such recovery, the FTC attempts to recapture the profit -- key word "profit" -- made by the company due to its anticompetitive behavior. Is that correct?

Mr. Karst. I believe so, but I don't know for sure, quite honestly.

Mr. Gianforte. Yeah, my information says that that is correct, that they were able to go after the profit of a company.

Do you know of any Federal statute that allows for recapture of a company's revenue, rather than profit, derived from anticompetitive behavior?

Mr. Karst. Honestly, I am not a competition attorney, food and drug attorney. That being said, I can't think of any off the top of my head.

Mr. Gianforte. Okay. And I just want to point out, that essentially this CREATES Act that we are considering would basically put all of the revenue of all drug companies in play for potential lawsuits and capture. And just in my own experience in business, when you have a big pot, it tends to encourage litigation. I have grave concerns about this. You had stated in your testimony, we want to do no harm, and yet creating a target to go after all of the revenues of all drug companies seems to be a step in the wrong direction.

Mr. Kushan, as I read moving to pay-for-delay, as I read the pay-for-delay bill we are considering, I see it would apply retroactively to existing agreements. I have fundamental concerns here with deciding that a behavior that has been lawful for some number of years, and had been the basis of business decisions, would now be open to litigation and lawsuits, particularly because it has been lawful behavior in the past.

This provision seems like it is opening up a can of worms. I am just interested -- I am not a lawyer, but I would be interested in your perspective on this. Can you give us a

sense of any concerns you may have with the change that we are -- is being proposed under this bill?

Mr. Kushan. Thank you. So the idea of opening up or voiding one of the settlement agreements after the parties have kind of moved on, you know, is essentially what you are doing, is, you have a patent fight, you come to a settlement, and then the generic launches, the parties have moved on.

When the companies enter into that settlement agreement, the innovator's going to make some calculus about what is appropriate for the market launch. They are going to withhold use of their patents that they might otherwise be able to use, and then you obviously see the product going generic.

We also -- I think everybody recognizes on the panel that within a year of the generic going onto the market, you know, the innovator's out. The market share of the innovator goes down to 7 percent or 9 percent. So it is kind of an irrevocable consequence to the innovator. So you can see some very significant disruptions, the business planning of both parties if those settlements fall apart.

Mr. Gianforte. In the limited time I have, I want to stay on patents for a second. In our technology business, we were subjected to a couple of dozen, frivolous, patent-related lawsuits that sucked resources away from research in our business. We have heard a lot about a patent abuse. Could you just briefly talk about patent abuses that you have seen, and what we should do about it?

Mr. Kushan. Well, obviously, we want to make sure that we don't have patent litigation where the patents are not valid or are not infringed. I mean, you have to -- that is the essence of the patent fight. You have to make sure that you are fighting about valid patents, and if you can find a way to avoid burdening courts, burdening the

parties with the litigation, you always want to find a solution that drives parties to that outcome.

And I think it is important that we look at these patent scenarios. You really, unfortunately, have to drill into what the parties are doing, and not make kind of a blanket assumption that a patent assertion is bad or good. You have to just look at the merits.

Mr. Gianforte. Okay. My time is expired, and I yield back, Madam Chair.

Ms. Eshoo. I thank the gentleman. It is a pleasure to recognize the gentleman from Illinois, Mr. Rush.

Mr. Rush. I want to thank you, Madam Chairwoman, and I am pleased the subcommittee, included my legislation, H.R. 1499, the Protecting Consumer Access to Generic Drugs Act in this important discussion on how best to lower the price of prescription drugs.

No American should be forced to make the choice between paying their bills and buying their pills. For too long, brand-name drug companies have reaped the benefits of limited competition, which forced consumers to pay more for their medications. My bill prohibits the practice of, quote, "pay-for-delay," end of quote, in which brand-name drug companies compensate generic drug manufacturers to delay the entry of cheaper drugs into the market.

I was pleased that a version of this legislation was passed out of this committee during consideration of the Affordable Care Act, but, unfortunately, it was not included in the final bill. So I am proud to continue my fight to stop drug companies from rigging the system in order to take advantage of hardworking Americans, and I am pleased that advancing market competition is a priority for this subcommittee.

Madam Chair, I ask for unanimous consent to submit two letters in support of my bill into the record.

Ms. Eshoo. So ordered.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Rush. Thank you.

My question is for Professor Carrier. In your testimony, you said that brand-name pharmaceuticals who pay generics to delay entry into the market cost consumers $3.5 billion a year. Can you briefly expand on how you reached this $3.5 billion figure, and how we know the high prices are due to the lack of generic competition.

Mr. Carrier. Sure. So the Federal Trade Commission is the expert on this issue, and they submitted a report a few years ago, where they figured out how much consumers are paying too much each year, and they calculated that it was $3.5 billion a year.

Mr. Rush. And you concur with that?

Mr. Carrier. I do.

Mr. Rush. All right. Mr. Boutin, in your testimony, you said that the National Health Council evaluated almost 200 policy proposals that aim to reduce the cost of healthcare and found that the most expensive policies increased generic drug competition. Can you speak to whether my bill, H.R. 1499, which addresses the presence of pay-for-delay, whether my bill would be expected to increase competition and lower the cost of prescription drugs?

Mr. Boutin. Certainly. Competition is the key to driving down costs. There is no question about it. When you look at the patent settlements, there is clearly a spectrum. Clearly some that work well, but -- that will actually bring benefit to patients, but there are clearly some that do not, and we need to actually root them out. So we are supportive. Thank you.

Mr. Rush. Thank you.

Mr. Barrueta, how do you see this pay-for-delay problem impacting drug prices for your members, and do you think that legislation is necessary to formally deter or outlaw these agreements?

Mr. Barrueta. I would say, you know, particularly in some of the more expensive products that we are still seeing branded, that are widely available in Europe and elsewhere, whatever is going on, and it does look -- I imagine pay-for-delay is some piece of that -- I think we should be moving as quickly as we can to make sure that those transactions are appropriately adjudicated and moving it forward so that we are not waiting for an extensive, lengthy, legal process to get that done. So I think this is a step in the right direction.

Mr. Rush. Thank you, Madam Chair. I yield back.

Ms. Eshoo. I thank the gentleman.

I now would like to recognize the gentleman from Illinois, my friend, Mr. Shimkus.

Mr. Shimkus. Thank you, Madam Chairman, it is great to be here. Sorry, I was doing a very simple issue of toxic chemicals upstairs, so I am glad to come down here for a more simpler debate.

So I am going to ask a question to the whole panel. Obviously, there is a big panel here, if you can kind of keep it as short as possible because there is like two or three more I want to try to get to. I understand that there is broad support for the CREATES and FAST Act because of the concern that brand manufacturers game the REM system.

However, we can have a tremendously productive generic market. So I think we can also acknowledge that in the majority of situations, brand manufacturers must be

willingly providing samples to generic developers. Does anyone on this panel agree that in most cases, samples necessary for equivalence testing are provided without FDA intervention or litigation?

Anybody? Ms. Kennedy, just go across. If you don't want to -- you can't -- it is not in your purview, that is fine.

Ms. Kennedy. Could you repeat the -- could you repeat the part about FDA intervention? I think you asked, are they being provided, and, no, to my knowledge, the FDA has no part in that. But make sure I heard you --

Mr. Shimkus. Are they being provided -- does the FDA have to intervene for it to be provided, or does it have to be litigation?

Ms. Kennedy. I don't think that has fully been determined. I think that is why we are here in this panel because we have got all manner of issues taking place, you know, really disincentivizing us.

Mr. Shimkus. Okay. Mr. Davis, I think you understand.

Mr. Davis. Congressman, thank you for the question. I don't know of and will look at the number of times where there has been a transfer or sale. I know that there has been at least 170 complaints over 55 products where it hasn't happened.

Mr. Shimkus. Okay. Great.

Mr. Barrueta?

Mr. Barrueta. That is as good as I can do. So you can keep going.

Mr. Shimkus. Okay.

Mr. Boutin. Same here. I will add that we do hear from companies when they are looking to do comparative tests on their products. They also have difficulty getting samples.

Mr. Shimkus. Okay.

Mr. Karst. I imagine there are cases where product is provided, but of course you see the numbers FDA has put out and others have been talking about. So it is an issue.

Mr. Kushan. I don't have any personal experience in this space. I think one thing that might be helpful is to actually reach out to the different sectors to see what the experiences are, to see how frequent it is.

Mr. Shimkus. Okay.

Mr. Kushan. You know, I hear the examples that are given, and it strikes me that, you know, there are many more situations where there aren't even --

Mr. Shimkus. Thank you.

Mr. Carrier?

Mr. Carrier. I don't know how many times the samples have been provided, but on the website it says 173 times it has not been provided, and the person who would know best, the Commissioner of the FDA, is trying to do everything about it, showing that it is a real problem.

Mr. Shimkus. Okay. So then I am going to transfer, following up on Mr. Welch's question -- and this is to Mr. Davis -- about CREATES versus FAST Generics, does AAM have an opinion on whether revenue or treble damages is a preferable approach, and can you explain why?

RPTR TELL

EDTR HUMKE

[1:00 p.m.]

Mr. Davis. Thank you, Congressman. We do not have a position on that. We just want to make sure that the end product, the legislative vehicle that is moved forward ultimately has a sufficient enforcement mechanism on the back end such that this problem is eliminated.

Mr. Shimkus. Okay. Going back to you, Mr. Davis, your member companies have been saying their profit margins are getting smaller and smaller given the high cost of litigating patents and to the -- to the bitter end. Shouldn't we have -- be concerned that limits on settlements will lead to fewer generics challenging brand drug patents and inhibit generic competition and resulting cost savings?

Mr. Davis. Thank you, Congressman. It is a concern that the inability, and I think as Ms. Kennedy also testified previously that in the current environment we are in, given the amount of patents that can be filed late stage against an innovator product, that taking away the ability to settle is likely to have the unintended consequence of keeping certain specialty medications on the market longer without competition.

Mr. Shimkus. Okay. And let me try to get this last one in. Mr. Barrueta, your organization is not just a payer, your organization is also made of healthcare providers. Know that not all drugs are created equal, and some have particular dangers and even deadly effects when not handled properly. When it comes to these exceptional dangerous products do you think that anyone seeking possession of them should be required to demonstrate to the FDA their ability to properly safeguard the use of these products?

Mr. Barrueta. Absolutely. And, in fact, we do have a specialty pharmacy operation that has the capacity to comply with REMS' requirements, and sometimes we are not permitted to actually do that because of commercial choices that the manufacturer is making, which actually impairs the ability to get these drugs in an orderly way to our patients. So but the answer to your question is yes.

Mr. Shimkus. So this might have been as difficult as toxic chemicals, so I wish I would have been here, but thanks for letting me join at the last minute.

Ms. Eshoo. I thank the gentleman. I now have the pleasure of recognizing the gentlewoman from Illinois, Ms. Kelly.

Ms. Kelly. Three Illinois in a row. Thank you, Madam Chair, and I ask for unanimous consent to submit a letter from Advocate Aurora Health for the hearing record.

Ms. Eshoo. I am sorry, I didn't hear you.

Ms. Kelly. I ask for unanimous consent to enter in --

Ms. Eshoo. So ordered.

[The information follows:]

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Ms. Kelly. Okay. I want to spend some time talking about my bill, the Orange Book Transparency Act. We talked about the Orange Book already, but can you, Mr. Carrier, talk about how the how does the FDA receive the information to put into the Orange Book?

Mr. Carrier. Sure. So the Orange Book is very useful. As a collection of drugs and patents it puts generic companies on notice. It gives brand companies a lot of benefits in terms of an automatic stay and other benefits to keeping generics at bay. The benefits of this legislation, and thank you for introducing it, is that it makes clear that when a patent is found to be invalid that it is no longer blocking generics from the market.

And so you have an Appellate Court decision, which is basically the final word on the issue. You have a PTAB decision, which is upheld seven out of eight times. It is only 13 percent of the time that it is not upheld by the Federal Circuit. This is important information to have. The brand companies should not be keeping the generic off the market when the patent is no longer any good.

And I am also grateful for the attention to device patents. You look at the EpiPen, you look at insulin pens, and you say, well, why is the price so high? Well, because patents keep getting listed in the Orange Book, and every time the patent is in the Orange Book you keep the generic away, an automatic 30-month stay. There is a lot of power that the brand companies have, so this is very important legislation.

Ms. Kelly. And then what is the FDA's role in maintaining and updating it?

Mr. Carrier. So the FDA collects this information, but it has said that it only has, quote, a ministerial role. It is not going out and litigating every patent. It is not even

going out and looking in the court system to see what has happened. And so sometimes this arises in the courts, and the FDA says we are just ministerial, we mark it in the book, we do nothing more than that, and that is why this legislation is important.

Ms. Kelly. And how can this resource be used as a barrier to generic entry, and how is it abused by companies?

Mr. Carrier. The problem is that a brand company by listing a patent in the Orange Book forces the generic to do a whole bunch of things. For starters, it is kept off the market for 30 months. Another hurdle is by having to list one of four certifications that you are going to wait for the patent to expire, that you have to challenge the patent saying it is invalid or noninfringed. The brand company can sue the generic even before the generic enters the market. A paragraph 4 certification counts as an act of patent infringement, and so, this is a concern that the brand company can list these patents, and a REMS patent is another example, as well. It is it is not a patent on innovation, it is a patent on how your label is set up where using a computer in a hospital system, this has nothing to do with innovation, this can really harm generics.

Ms. Kelly. And are there any additional policy changes that Congress should be considering to ensure that this list is not being misused by drug manufacturers? And after you answer if anybody else wants to answer is fine.

Mr. Carrier. So I think focusing on these requirements of a determination by a court, an Appellate Court or a PTAB is very useful, the device patents, and I would add REMS patents to the list, as well. REMS patents have nothing to do with innovation. They should not be listed in the Orange Book.

Mr. Kushan. Just on a couple of points, so the PTAB statistics are a little misleading because the trend line is going way down on institution and the increase in

instances of reversals. The real problem with anchoring a decision to remove one of the patents from the Orange Book because of a PTAB outcome is that it may get changed, it may get reversed. And that is happening with more frequency, so, you know, from a certainty perspective not just for the innovator but for the generic we don't want to have -- one of the essential points of the Hatch-Waxman scheme is that you are going to resolve the patent fight before the generic launches because you don't want to disrupt the marketing of the generic once it is on the market. That is the essence, that is the beauty of the Hatch-Waxman listing scheme. So if you have scenarios where you are going to take a patent out of the Orange Book, launch the generic, then the innovator wins after appeal, you have to pull the generic potentially from the market. That is very disruptive for everybody. And that is why we want to have final outcomes that aren't going to change.

Mr. Karst. And just one point of clarification on Mr. Carrier's testimony, even though the Transparency Act does say that an invalid patent, one that is ruled invalid would have to come out of the Orange Book, the FDA actually will not take it out of the Orange Book if there is a generic applicant who has 180-day exclusivity pending on that. So the agency has to maintain that in order to maintain that first applicant's exclusivity, so just to be clear on that point.

Ms. Kelly. Okay. Thank you very much. It is clear to me that we must act to clarify the role of the Orange Book and prevent abuse of this important resource. I look forward to working with stakeholders to strengthen the role of the Orange Book and close loopholes that allow it to be misused.

I yield back.

Ms. Eshoo. I thank the gentlewoman and thank her for her work for her work

product. Let's see, I think is he next? I would like to recognize Dr. Raul Ruiz from the beautiful, magnificent State of California.

Mr. Ruiz. Right on, chairwoman. California is definitely the best State in the Nation.

Mr. Boutin, I want to thank you for joining us today to share your experience representing a coalition that brings together over 160 million patients with chronic diseases and disabilities. I think all members of this committee have heard loud and clear from our constituents that the rising costs of prescription drugs is forcing them to make tough decisions about their healthcare and the care of their family members.

Both in the farm worker community where I grew up in the Coachella Valley, and when I was practicing in the emergency department I saw many families who had to choose between filling their prescriptions and putting food on the table.

In fact, I will tell you a story. I was doing some policy work out in the rural community church and after I left I noticed one of the participants digging in the trash and I went over and I said, What are you doing? This was before I ran for Congress. And she is like, I am collecting cans. I said, Why. She said I have to pay for my diabetes, my insulin medication, and she said, but don't worry, doctor, I only take half my dose so that I can make it last, and you know what dangers that imposes. So, you know, she rationed -- many people ration their medications or delay filling prescriptions all together.

As a doctor I know firsthand the long-term impacts these decisions may have on a patient's health and the healthcare system at large, as well as the immediate risk posed to these patients. Addressing this problem will require us to work together both across the aisle and the country, and it will also require a range of policy solutions. There is no

one-size-fits-all.

I am pleased that the committee under your leadership, Congresswoman Eshoo, is examining a number of policies that will help to encourage generic competition. Generic competition is one of the best evidence-based methods to control the cost of drugs. In 2017 the use of generics in Medicaid alone saved $40.6 billion or $568 per patient. Likewise, the use of generics in Medicare saved taxpayers $82.7 billion annually, and it is estimated that expanded generic use would save Medicare even more up to $14 billion, $14 billion per year. While not a silver bullet, generic competition is vital in saving money for taxpayers and out-of-pocket costs for patience.

Mr. Boutin, you noted in your testimony the story of Mackenzie and her struggle with the high out-of-pocket costs and how generic entry has helped to adhere to her medications and stay healthy. The national -- my question is how would increased generic competition help your members? And I know that the National Health Council represents a wide array of patients with multiple health conditions, so how would generic competition help your members?

Mr. Boutin. So there are 160 million people in the United States living with one or more chronic conditions. Many of them use medications to treat those conditions. Many of them rely on generics. When they have the generics they are able to dramatically drive down their costs. We have done a great job of expanding access to insurance. We have an incredible number of people who are underinsured who are running into out-of-pocket expenses that are to your point causing them to make decisions about rent, about food, about foregoing that for their family's college or education. The decisions that they are making are becoming huge and the long-term costs are huge.

Mr. Ruiz. How much costs are they bringing home in savings?

Mr. Boutin. When they are able to take generics they can reduce their costs often down to $5 per prescription and sometimes even less.

Mr. Ruiz. From down to from what initial price?

Mr. Boutin. It can be anywhere from $60 and sometimes as high as several hundred, and there are some extreme cases where it can be even higher than that.

Mr. Ruiz. And I believe we both would agree that increasing generic and biosimilar competition is only part of the solution to lowering costs, and there are also needs to be more awareness of the availability of these treatment options. So what actions do you think this administration or Congress should be taking to ensure that patients and healthcare providers are aware of available generic and biosimilar medications?

Mr. Boutin. Systemwide transparency, so the people have a meaningful opportunity to understand what the options are. We need to provide that transparency in the relationship with their providers and with a pharmacist. So it needs to happen in real time. Technology can enable that.

Mr. Ruiz. Excellent. One thing I was struck by in your testimony was the fact that 43 percent of generic drugs or about 700 have been approved by FDA since January 2017 but still are not available on the market. So what policy solutions does your organization support that would help to reverse this trend?

Mr. Boutin. An important issue that needs to be addressed is looking at how we fundamentally pay for generics. We have a process that drives them down to a commodity to drive the price down low, which is good, but if it reaches a point where it creates a disincentive for additional generics to come into the market.

If we were to look at how we could elevate the price only slightly, we are not talking about major tweaks to drive additional entrants into the market and ensure vibrant competition, we would save dramatic amounts of money because people would actually be able to take their medications and not drive long-term costs to the health system.

Mr. Ruiz. Thank you.

Ms. Eshoo. I thank Dr. Ruiz, and it is a pleasure to recognize the gentleman from Maryland, Mr. Sarbanes, my favorite democratic Greek.

Mr. Sarbanes. Thank you very much. I appreciate that. I want to thank the panel for your testimony. Mr. Carrier, I wanted to talk to you a little bit more about the pay-for-delay deals. We have had quite a bit of discussion about it so far today. In full disclosure I strongly support, as you probably are surprised to hear, Congressman Rush's proposal.

As we have heard a number of times according to the FTC these agreements were estimated to cost consumers, between 2010 and 2020, about three and a half billion dollars in increased drug costs, and you have spoken to that today. And the Supreme Court did in the Actavis case note that these types of agreements are anticompetitive, but they still happen. They still continue to occur. We know that there is a lot of time and energy that has to be expended by the FTC in conducting a review, and in a sense they are doing these reviews from scratch without being able to operate with a presumption that is leaning against them based on their anticompetitive nature. So it is really a kind of case-by-case thing, which takes a lot of -- a lot of the commission's time and focus.

Can you -- can you just describe a little bit why the Actavis decision may or may not have been sufficient in terms of discouraging these pay-for-delay settlements, why

we are at a point where they continue to go on with the anticompetitive impact that it has?

Mr. Carrier. They continue to go on because brand companies and settling generic companies are dancing together to go back to the analogy that started this hearing. It is in the interest of the brand and the settling generic to agree not to enter the market with a generic maybe getting more money than it would have gotten by entering the market.

The Supreme Court made clear that these agreements could have anticompetitive effects. The Supreme Court rejected a lot of the arguments we have heard this morning about settlements being good and entry before the end of the patent, that was all rejected by Actavis, and it has no reason coming up right now.

Nonetheless, there is a lot of play in the joints, and there is reason for brand companies to try to do everything possible to sow ambiguity. And sometimes you see courts getting it wrong. Sometimes courts focus on the patent. Sometimes courts say risk aversion is a good thing, entry before the end of the patent is a good thing, and so courts are still struggling with these issues and making clear that the agreements are illegal would be very helpful.

And if I could just say one thing on retroactivity because that has come up a lot, as well, and so the bill is absolutely clear that there is no penalty until after the date of the agreement, and the only retroactive part goes back to June 17, 2013, the date of Actavis.

So it is only retroactive if you are going to ignore the Supreme Court. The Supreme Court said it was illegal to enter into pay-for-delay settlements, and so, there is complete notice that the parties then would be violating the law.

Mr. Sarbanes. Thank you. And the value of creating a kind of bright line

standard here makes a lot of sense to me. Obviously it would put the agency in a much stronger position because it would come to these cases and these pay-for-delay deals with a presumption that they are anticompetitive, they are illegal and would be able to take the kind of steps of enforcement and oversight that that would -- that that would provide.

And I know that -- I know that there has been some pretty stark examples here. Humira entered into eight different patent settlement agreements. I was very happy to work on a Biosimilars Competition Act that we were able to get passed into law last year as you may know. Before that they weren't even required to report these kinds of settlements to the FTC.

But I think what Congressman Rush has proposed makes perfect sense in the wake of the Actavis case. It makes perfect sense when you look at the burden that it places on the FTC to have to do this review on a case-by-case basis, and what the new authority that they would come with if we were to put Congressman Rush's bill in place.

So I very strongly support it, and I appreciate the testimony that you have offered today, which certainly provides further justification for the proposal.

And with that I would yield back my time to the gentlewoman.

Ms. Eshoo. I thank the gentleman and especially for his patience because this has been a long hearing. And speaking of patience the tenacious, the patient gentlewoman from Illinois, Ms. Schakowsky, for 5 minutes of questioning.

Ms. Schakowsky. I want to thank you again, Madam Chair. I am waiving on to this subcommittee, and you have been very generous in that, and I appreciate it so much.

In the 114th Congress I first introduced the FAIR Drug Pricing Act, which would require pharmaceutical manufacturers to notify HHS and submit a transparency and

justification report 30 days before they increase the price of certain drugs by more than 10 percent or by more than 25 percent over 3 years.

Though the bill will not prohibit manufacturers from increasing prices it will for the first time give taxpayer notice of price increases and bring basic transparency to the makers of prescription drugs. And so I reintroduced this legislation in the last Congress, and I plan to do so in the coming weeks.

Mr. Barrueta, do you believe that this very basic form of transparency could ultimately lower prescription drug prices for Americans?

Mr. Barrueta. I think absolutely. We have been eagerly pursuing legislation of this nature at the State level in a number of States in which we operate, and having I think a national law would significantly encourage manufacturers to at least know that the people will know how their pricing and why they are claiming to price it. And --

Ms. Schakowsky. I feel like we have been beat over the head so many times by, oh, we have to charge this much because of research and development, and we know nothing about how much the drug actually costs to make. I hope we can pass that.

Under current law brand pharmaceutical manufacturers are able to extend the length of the patent protection on their brand drug products by introducing a reformulated version of the same medication, which then receives extended exclusivity. This practice commonly referred to as evergreening often involves really no change to the drug's clinical effectiveness, and the extended patent protection can often be achieved, for example, by simply reformulating an immediate-release product into an extended-release pill.

This practice of taking the same medication and changing its delivery is estimated to cost Medicare -- the Medicare program approximately a billion dollars per year in

additional drug costs.

Mr. Carrier, I wanted to ask you, given that evergreening incentivizes brand drug manufacturers to intentionally delay, we talked a bit about pay-for-delay, but this is another way to get at it, would -- so let me get your comment on that. What are the policy changes that you believe should be considered?

Mr. Carrier. I think that Congress can do two things. One is to give the FTC power to investigate the phenomenon. So usually what happens in the courts is it falls into one of two situations. One is called the hard switch, the other is called the soft switch. With the hard switch the brand company is pulling the old drug off the market, and the courts say oh, that is bad because you are going from two down to one. With a soft switch they leave the old drug the market, and courts say oh, that is good because you have two drugs to choose from.

The problem is that these are unique markets, they are characterized by a price disconnect where the decisionmaker is different than the buyer, and so the FTC should look into this conduct to show that soft switches can be anticompetitive, as well.

And the only other thing I would say is to think about offering a test that I have offered called the no economic sense test. Rather than the rule of reason, let's give the brand company every benefit of the doubt. If there is any reason at all for your switch then we will allow it. We just can't allow it where the only reason is to keep the generic off the market.

Namenda, the brand company pulls a $1.5 billion drug off the market. Suboxone, the brand company disparages its own product. Why does it do this? The only reason is to hurt the generic. That is not allowed. That should be an antitrust violation. Congress can do something about that.

Ms. Schakowsky. Well, actually, my subcommittee deals with the FTC and those kinds of questions, and so I am hoping we can deal with evergreening in that way. All right. I want to say that I do support all the bills that have been suggested today, and I really look forward to working with you, Madam Chair. Thank you. Bye. I mean, I yield back, not bye.

Ms. Eshoo. I thank you, and good-bye. I will see you on the floor. I thank the gentlewoman.

Let me offer my sincerest thanks to each one of you. I notice that you were looking at your watch -- oh, who is back? Oh, I am sorry. The gentleman from Florida, Mr. Soto, last but not least.

Mr. Soto. I will be brief, Madam Chair. I know --

Ms. Eshoo. That is music to our ears.

Mr. Soto. We are getting to voting soon. You know, we live in an amazing time where diseases and conditions that would have easily killed our grandparents or great grandparents or parents are now things that people readily survive from because of the great research done in the United States, and in countries, only a few in Europe and Japan and other places that are really changing the world. And I believe we have to bend the arc of prescription prices without breaking the innovation arc in the process, so it really is quite the balance.

I want to start out by just talking a little bit about some constituents who have been concerned about diabetes medication. Jeff Dunlop from my district said imagine being extorted into paying a 15 to $20 fee every day of your life in order to stay alive, welcome to Type 1 diabetes. Obviously there is a frustration on behalf of patients who are now taking advantage of these lifesaving drugs.

So I just want to hear from each of you from this specific scenario of diabetes medication, whether you think making generics more accessible and competitive would be helpful in this scenario and why, and we will start from the left.

Ms. Kennedy. I am not in the diabetic space, but I am in a space very near and dear to that one, and that is COPD. Often times both -- patients have both problems. I would suggest that everything we have discussed here today to involve more competition and let Americans do what Americans do, which is appreciate capitalism gets us to where we need to be, and I support all of the things that have been introduced today that really upholds that spirit of competition.

Mr. Soto. And Mr. Davis?

Mr. Davis. Congressman, thank you for the question. I think the story you shared about your constituent just reinforces how vital it is, and I said earlier that issues related to insulin are sort of the perfect storm of what is not working. Whether it is the rebate scheme, whether it is late staging patenting or this regulatory challenge that we have heading into March of 2020, they are all issues that need to be resolved so we can get biosimilars to market.

Mr. Soto. Mr. Barrueta?

Mr. Barrueta. Absolutely, completely agree. It is one of the biggest problems that we have and that is a big reason why we are here is to start working on exactly insulin.

Mr. Soto. Mr. Boutin?

Mr. Boutin. Agreed and systemwide transparency so we understand how products flow and how they are priced so that we can effectively get the most effective product that works and the most effective in terms of cost to patients.

Mr. Soto. Thanks. Mr. Karst?

Mr. Karst. If you agree that greater competition yields lower prices absolutely, which is why it is important to preserve 180-day exclusivity, which is why I would really oppose the BLOCKING Act.

Mr. Soto. Mr. Kushan?

Mr. Kushan. So certainly everybody supports a generic drug's role in driving prices down. I think what we all hope for is the technology that we are living with today gives you the solution that you don't need to take that drug every day. We are seeing cures for diseases that were uncurable before delivered by biotech and these amazing innovations.

So we want to make sure that we drive both solutions. We want the solutions that solve the bigger problem, which is having to take drugs every day, and that -- now we are living in an era, which is amazing that we can get cures to things that nobody could have imagined before.

Mr. Soto. Thanks. And Mr. Carrier?

Mr. Carrier. So first focus on PBMs and formularies and what products appear on the formulary, and second, deal with the patent issue.

So IMAC has put out a report that shows that the Lantus insulin injector pen has 74 patents, 95 percent of which were introduced after the device entered the market. And so the Orange Book Transparency Act would go a long way towards dealing with this in focusing on devices being listed in the Orange Book.

Mr. Soto. Thank you. I appreciate it. I know Mr. Dunlap back in my district appreciates your responses, as well, and I yield back.

Ms. Eshoo. I thank the gentleman.

Let me once again thank all the witnesses. Legislative hearings are very important, and while this was long, each one of you are really value added to this because, number one, all of your experience and your knowledge no one can say to any one of you you don't know what you are talking about, but it takes it a step further in terms of where you were hesitant, what you support, the recommendations that you were making to us on the seven bills in order to improve them.

So I can't thank you enough. This is a worthy experience on behalf of the American people, and I would also like to add that I hope from where you sit that Members from both sides of the aisle are a source of inspiration to you for the work that they are doing together in order to produce legislative products that are going to, again, be worthy of the American people. I think that we are a can-do committee, and that we can certainly bring the costs down, close the loopholes, protect the innovation.

The United States of America is the leader in the world. You can't -- no one can point to any other country that produces the -- you know, lifesaving and cures turning death sentences into chronic conditions, so I think that we can lower prices, protect what I just described and obviously keep competition in the system because that always brings down prices. So I hope that we have been a little bit of a source of inspiration to you.

I have a homework assignment for you though, and I think every member was asking for this. You made some very important recommendations of how we could improve the bills. I ask that each one of you send us your bullet points. It can be on one bill. It can be on all seven. It can be four, whatever it is, but I really want to -- and all the members do want to review that. We don't want it to be lost, and I think that it would be, again, very good ideas.

Does the gentleman from Indiana want to say anything? No? All right.

At this point I am asking for unanimous consent to submit the following documents for the record. Bear with me, it is a long list. I will read as fast as I can. Letter of support from AARP for the CREATES Act and the Protection Consumer Access to Generic Drugs Act of 2019, a letter of support from AFSCME.

Mr. Griffith. Madam Chair, I move that we waive the reading of the documents and accept them without objection.

Ms. Eshoo. I thank the gentleman.

[The information follows:]

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Ms. Eshoo. With that I think that we will adjourn now. It is lunchtime. Thank you everyone.

[Whereupon, at 1:35 p.m., the subcommittee was adjourned.]