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House Energy and Commerce Committee, Subcommittee on Health

"Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

March 13, 2019

10:00 AM, 2123 Rayburn

Purpose

To hold a legislative hearing on the following bills: the Orange Book Transparency Act of 2019 (H.R. 1503), the Purple Book Continuity Act of 2019 (H.R. 1520), the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965), the Fair Access for Safe and Timely (FAST) Generics Act of 2019 (H.R. 985), the Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act of 2019 (H.R. 938), the Protecting Consumer Access to Generic Drugs Act of 2019 (H.R. 1499) and the Fair and Immediate Release (FAIR) of Generic Drugs Act (H.R. 1506).

Members Present

Chairman Eshoo, Ranking Member Burgess, Chairman Pallone, Ranking Member Walden, Representatives Welch, Upton, Schrader, Matsui, Guthrie, Griffith, Cardenas, Welch, Lujan, Hudson, Barragan, Carter, Blunt Rochester, Rush, Shimkus, Gianforte, Kelly, Ruiz, Schakowsky

Witnesses

Ms. Lou Kennedy, CEO and Owner, Nephron Pharmaceuticals
Mr. Anthony Barrueta, SVP of Government Relations, Kaiser Permanente
Mr. Michael Carrier, Distinguished Professor, Rutgers Law School
Mr. Kurt Karst, Director, Hyman, Phelps & McNamara, PC
Mr. Jeff Kushan, Partner, Sidley Austin LLP
Mr. Marc M. Boutin, CEO, National Health Council
Mr. Chester "Chip" Davis, Jr., President and CEO, Association for Accessible Medicines

Opening Statements

Chairman Eshoo said that the American people have been subjected to the abuse of the patent system by pharmaceutical companies. When brand and generic manufacturers block competition, Americans pay the price. The US has the lowest generic drug prices in the world, so competition works. The bills considered today will move drugs to the market more quickly and lower costs. The first group of bills (CREATES Act, Fast Generics Act) addresses the stalling tactics brand manufacturers use to restrict access to samples for generic bills. The second group of bills (BLOCKING Act, FAIR Act, Protecting Consumer Access to Generic Drugs Act) address marketing abuse barriers and pay-for-delay agreements. Secretary Azar referred to the act of delaying generics from coming to market as "squatting," yesterday. Secretary Azar said that this parking behavior leads to an average delay of 12 months for generics to come to market. The Protecting Consumer Access Act prohibits pay-for-delay outright. The last group of bills makes important updates to the Orange and Purple Books of the FDA by amending what information must be published in a user-friendly way. This hearing is to close loopholes and eliminate bad practices in the market.

Rep. Welch said that there is a bipartisan opportunity to tackle the rip-off pricing in the system. Yesterday Secretary Azar said that the Administration supports efforts to end the enormous burden on the consumer and taxpayer.

Ranking Member Burgess said that he will submit additional questions to the record and a written statement. Additional policies must be considered. As evidenced at an earlier hearing, there are conflicting opinions held by each member along the drug pricing chain. It is not acceptable to legislate with a black box. The text of the bills was not share with the Republicans until last Monday, which is a longstanding rule. Bipartisanship is asking for input and not just the vote. Collaboration is still possible going forward, but it is discourteous to give a Member less than 24 hours to sign onto a bill. No stakeholders had been consulted in the drafting of these bills, including the Association for Accessible Medicines. In fact, the generic manufacturers have not commented on or opposed any of these bills. These bills have received no technical assistance from the FDA or FTC or the stakeholders. It is unthinkable that the FDA was not invited to testify. These are seven pieces of complex legislation that are all intricately involved and not only was the FDA not invited, it was not consulted for technical assistance. The agency had more questions than answers when staff members spoke with them yesterday. The Republicans did not get the notice for the hearing in time to call the FDA as witnesses.

Chairman Eshoo said that the sky is not caving in. Half of the bills have been introduced in previous Congresses and multiple are bipartisan, with shared language and open opportunities for collaboration. Agencies do not come to legislative hearings to comment on legislation. This subcommittee is the first to be taking up seven bills on drug pricing.

Chairman Pallone said that the E&C committee is the only one to have complete regular order. There are hearings and markups on the subcommittee then the committee that are done on a bipartisan basis. Congress must facilitate greater competition in the pharmaceutical market. Congress is all about capitalism. In 2017 the entry of generic drugs saved patients $265 billion, over $1,900 per enrollee in Medicare. The proposals will close loopholes that drug companies are exploiting. They address three key barriers for generics: patent listing, drug development and market barriers. The Orange Book and Purple Book Acts would help increase accuracy and transparency of the databases that guide development for biosimilar manufactures. The CREATES Act and Fast Generics would address the barrier of drug development and market entry through eliminating the REMS barriers. The BLOCKING Act, Protecting Consumer Access Act and the FAIR Act would again remove unnecessary barriers to competition through disincentivizing pay-for-delay settlements.

Ranking Member Walden said that the majority added a witness to the panel that the minority did not find out about until after 5 pm on Friday. Thanks to the new pathway granted to the FDA granted by the committee have allowed for about 1,275 approvals, including the approval of a generic Epipen. This is a win for consumers. The real results are a bipartisan cooperative approach. While Republicans share the goals of this hearing, they wish it were more inclusive. Only three of the seven bills have Republican cosponsors since they were only give notice eight days ago, and they were only given 24 hours to find witnesses. The committee can do better than that. It is also an issue that the FDA is not serving as a witness. Dr. Gottlieb would be a terrific witness for this committee.

<u>Testimony</u>

Ms. Kennedy said that Nephron is a leader manufacturer of sterile generic medications and compounder of drugs on the FDA shortage list. Nephron believes that drug patents should be controlled by an approval system that rewards innovation but rewards appropriate patent challenges, especially the Orange Book listed patents. A fair playing field would ensure erroneously granted patents are not used to maintain monopolies. The Trump Blueprint would encourage drug competition and notes the use of parking, which goes directly against the Hatch-Waxman Act. Pay-for-delay is a real impediment. Pricing data commonly shows that drug costs will drop approximately 80 percent when the fourth competitor enters the market. REMS program abuses add significant delays to competition. Nephron supports the goal of addressing purposeful parking. Nephron is concerned that the drafted BLOCKING Act will undermine the value of the 180-day exclusivity period since it would provide an overly broad exclusivity period, which would weaken the 180-day incentive for generic companies. Nephron is also concerned that it fails to address pay-for-delay settlements between a first-to-file company and its brand counterpart. The current framework provides no incentive for applicants to challenge blocking settlements. The FAIR Act would achieve a solution for the broader parking problem. Nephron urges Congress to fix the broader parking problem.

Mr. Davis said that over the last decade, the members of the Association for Accessible Medicines (AAM) have delivered over $1.3 trillion in savings to patients. FDA approved biosimilars have the potential to provide similar savings, but anticompetitive tactics threaten the longterm stability of generic and biosimilar markets. This committee must advance patient access to generics and biosimilars and avoid policies that further delay competition and access. AAM greatly appreciates the CREATES and FAST Acts. These market based solutions will stop anticompetitive abuses of FDA safety programs and reduce spending on prescription drugs by $13 billion annually. AAM value innovation and intellectual property, but it is equally important to recognize that the greatest barrier to innovation occurs when companies build “patent estates” around blockbuster drugs. At least 78 percent of new patents are associated with existing drugs. AAM recommends three solutions. First, to provide a date certain for biosimilar and generic entry. Second, to accelerate the biosimilar and patent dance. Third, to harmonize Hatch-Waxman with the IPR process. Despite patent thickets, a settlement is becoming the only way for generics to be brought to patients. It is imperative to ensure that two critical elements are preserved. First, the right of two private parties to reach a settlement that is procompetitive. Second, the 180 day exclusivity period provided to the first generic filer. The FTC has said that there are very few pay-for-delay settlements now. The patent settlement legislation under consideration is not aligned with the recent Supreme Court Actavis case. At this point, AAM is not supporting the legislation that is prohibit patent settlements or changes to the 180-day exclusivity period. These proposals have the risk of delaying patient access.

Mr. Barrueta said that Kaiser Permanente has a mission to deliver high quality and affordable care. High drug prices imposes a crippling burden on KP’s members. KP is concerned by overpatenting, exclusivity gaming and pernicious lifecycle management trends. The primary goal is to leverage the law to stifle competition, not protect meaningful clinical advancements. New policy framework must foster affordable prices. Congress must evaluate how the current laws are subject to gaming. KP applauds the committee for curbing REMS abuse and stopping exclusivity parking and pay-for-delay. KP is grateful the Committee is considering the CREATES Act. When competition doesn’t occur at the expected time, it undermines KP’s efforts to negotiate

better drug prices. Many in the market have struggled to transition to biosimilars, but KP's physicians have embraced them. KP uses evidence-driven formularies and generates unbiased information about drugs. Physician-pharmacist alignment is of critical importance. Generics and biosimilars must be openly available. Exclusivity could also be narrowed to reward innovation.

Mr. Boutin said that bad actors have driven up costs for patients and only Congress can fix it. The impact of medical debt on the wellbeing of people with chronic conditions has become a national crisis. The National Health Council (NHC) is a bipartisan organization that welcomes all stakeholders into its membership. NHC has heard loud and clear that while patients care about getting better, they are having incredible challenges affording medications. NHC reviewed nearly 200 policy proposals and learned that the vast majority lower costs by eliminating access, and the remaining policies had virtually no data to show that they would actually drive down costs. The only exception is increased competition among generics. For McKenzie, when a generic of one of the medications in her statin regimen became available, it went from $60 to $5 a month. When bad actors use REMS to block entry of generics, it becomes a serious problem.

Mr. Karst said that "do no harm" is one of the principal precepts of bioethics and the law. Tinkering with the Hatch-Waxman Act is akin to brain surgery. The bills can placed into three buckets: addressing drug and biologic product information transparency; those addressing the 180 day exclusivity and patent settlement; those facilitating generic manufacturers' access to product. In the first bucket are the Orange and Purple Book Acts. The Orange Book is the lynchpin of the generic drug approval process. HR 1503 authorizes the FDA to make changes to the listings that could dramatically impact generic market entry. HR 1520 would require the FDA to include in the Purple Book certain patent information, but it would be added only after the initiation fo the patent litigation. While the bill is a good first step, Congress should consider whether a more enhanced patent enforcement feature should be added. In the second bucket, is the BLOCKING Act, Fair Generics and Protecting Consumer Access Act. The 180-day payment incentivizes company to clear the thicket. Exclusivity is the brass ring. Legislative measures that dilute the incentive could jeopardize the generic industry, which is just what the BLOCKING Act does. The BLOCKING Act is unnecessary and redundant. HR 1506 and HR 1499 address patent settlement agreements, which are procompetitive and fair. The CREATES Act and Fast Generics Act would address legitimate concerns about reference product access.

Mr. Kushan said that the subcommittee should appreciate innovation in the life sciences industry. Companies don't stop innovating even after FDA approval. For example, pen injections were invented so patients no longer had to go to hospitals for drug injections. For HR 1520, it must be clarified that biotech companies have no difficulty finding patents relevant to what they're doing and it must be appreciated that the BPCIA does not slow down the approval of biosimilars based on patent litigation. It is important to appreciate that variable, which is showing that the patent system is working. Third, the innovator must find the patents relevant to a particular patent because it depends on information only the biosimilar manufacturer has. There is a concern that the innovator must provide information immediately to the FDA, which may implicate confidential information of the biosimilar. HR 1503 raises the question about which patents may no longer be put in the Orange Book, such as medical device patents. They should be part of the system so they don't disrupt the later launch into the market.

Mr. Carrier said that brands play all sorts of games to keep drug prices high. The committee should focus on samples. Under the Hatch-Waxman Act, the generic was supposed to have a sample from a brand company to enter the market quicker. The problem is that when the brand company denies a sample, the generic can't even get to the sample line. Take Martin Shkreli: no one focuses on how the restricted distribution system allowed him to jack up the price. REMS is a safety measure, which brand companies abuse. Scott Gottlieb has done much to address the situation, but it's not enough. The FDA can't solve the problem. CREATES Act would make it clear that brand companies can't engage in these games. The Committee should also focus on settlements. Under the Hatch-Waxman Act, the 180 day period was designed to encourage early generic entry, but it was completely twisted so first filers can tango with the brand company for years. The Fair Generics Act would go a long way towards addressing this and would help the FTC immensely. The Orange Book has a lot to be done, especially with the Epipen being there for decades. The Purple Book could be brought into the 21st century by making it a searchable PDF like the Orange Book.

Questions and Answers

Chairman Eshoo asked Mr. Carrier to synthesize where the improvements need to be made relative to the Orange Book and the Purple Book and where the legislation comes up short. **Mr. Carrier** said that one problem with the Orange Book is that it doesn't clearly note when the patent is invalidated. **Chairman Eshoo** asked why something should be carried in print when it's no longer in use. **Mr. Carrier** said that the FDA is not checking every day what happens in the court systems, so it's possible that a patent is listed in the Orange Book when it's the most up to date book. The Orange Book is online but not all of the information is as up to date as it could be. **Mr. Kushan** said that one of the concerns about altering the status before there is a final determination in the cases is that many of the cases will be appealed. A stable system outweighs quick changes to the listings. **Chairman Eshoo** asked if the proposed legislation moves the needle to help consumers. **All the witnesses** agreed. **Chairman Eshoo** said that the patients depend on breakthroughs for medication to help them.

Ranking Member Burgess said that the world looks to the US for innovation. He named the example of the progress made in curing Hepatitis C. He referred to Mr. Barrueta's 2014 presentation on the history of drug pricing. Competition did work to bring down the price of Sovaldi. **Mr. Barrueta** replied that signals are set based on the way the system is operating. So for Sovaldi, there was tremendous concern that the choice to price that product upwards of $90 would reflect how ineffective the old drug was. **Ranking Member Burgess** said that Congress must think of how to amortize paying for innovation. He mentioned Rep. Guthrie's bill to allow CMS to look at drugs that look like they may be potentially expensive, and reiterated the importance of not interfering with the scientific discovery process. **Mr. Carrier** said that innovation is important but in cases like Daraprim, it is not the issue.

Chairman Pallone said that congressional intent in creating REMS was obfuscated by drug manufacturers. He and Rep. Welch have advocated for market-based solutions that would allow for streamlined processes for acquiring samples and resolving challenges in establishing REMS safety protocols. Some concern has been raised that the CREATES Act would unintentionally incentivize frivolous lawsuits instead of seriously pursuing samples for drug development. It could lead to additional patent settlements. (Note that Pallone stated he was playing devil's

advocate and supports the CREATES Act). **Chairman Pallone** asked if that is a legitimate concern. **Mr. Carrier** disagreed. It is easy to tell if it's a generic company trying to get the sample or a lawyer. **Mr. Davis** also disagreed that CREATES would create frivolous lawsuits. The CREATES and Fast Generics Act keep the FDA at the center. **Chairman Pallone** asked for AAM's perspective on CREATES and what the strongest deterrent is for the gaming of REMS. **Mr. Davis** said that a cause of action is only an issue of last resort. Since REMS programs were created in an authorization in 2017, that bill says REMS should not be used for anticompetitive purposes, but there is no enforcement provision or significant penalty. There must be a very limited scope of action that is only triggered by a failure to negotiate in good faith.

Rep. Upton said that one of the issues of concern is the unintended consequences of hampering innovation in medicine. He asked how the patent system is facilitating innovation between biologics and biosimilars. **Mr. Kushan** said that innovators and biosimilars are being very innovative when forced to reengineer a product. In the biologics space there is a lot of insular innovation since much more investment is needed. Those entities are both innovators and biosimilar manufacturers and can cross license technology. That behavior cannot be discouraged with punitive sanctions on the value of an IP. **Rep. Upton** said he is concerned that existing settlements would become illegal due to the retroactive provisions of the bills. **Mr. Kushan** agreed. There are companies that have relied on those settlements to move forward.

Ranking Member Burgess said that there was a version of the CREATES Act in the last Congress, but this version has more aggressive restriction of private action. He asked if Mr. Davis would support a more bipartisan version. **Mr. Davis** said that the unmodified Senate version of the CREATES Act has a diverse group of supporters, including stakeholders. The real risk here is if there are parties that say they want to work together but only to dilute the enforcement mechanism.

Rep. Schrader said that focus must be on getting drugs from the market to patients. Getting the drug into the approval pipeline isn't the same as getting it onto the market. As discussed with Secretary Azar, manufacturers sometimes block subsequent filers by waiting too long to get on the market, resulting in much higher costs to patients. There are times when applications have deficiencies or manufacturers strike a deal to have brand names refrain from moving to the market. BLOCKING Act would stop the practice of parking and it might save $1.8 billion according to an analysis by the FDA. **Rep. Schrader** asked for the FDA report to be entered into the market. He asked Mr. Carrier what he meant when he described the forfeiture provisions as "toothless." **Mr. Carrier** said that the Medicare Amendments of 2003 were designed to solve the problem of generics forfeiting exclusivity but the provisions were drafted in a way to apply to only one of two events, including an appellate court decision that could take place years down the road. There have been four appellate decisions where forfeiture took place almost a decade down the road. What incentive is there for a subsequent generic to enter the market if they won't get a portion of the 180-day incentive? **Rep. Schrader** reiterated that BLOCKING is a bipartisan bill supported by the President.

Rep. Griffith asked if HR 1499 or HR 1506 make it easier or harder for generics to come to market. **Mr. Karst** said that it would make it more difficult, especially the FAIR Act. Adding these two together would slow down things, leading to further litigation. They are not as

procompetive as current law. **Mr. Kushan** agreed. HR 1499 has an idealized settlement defined that does not reflect reality when innovators try to settle a patent dispute. **Rep. Griffith** asked if patients would benefit from those two bills being passed and signed. **Mr. Karst** and **Mr. Kushan** said no. **Rep. Griffith** said that in Actavis, pay-for-delay could be deemed anticompetitive. He asked if patent settlements may be useful in some cases and what the unintended consequences of eliminating them may be. **Mr. Davis** said that AAM does not support pay-for-delay settlements, but they do support private parties negotiating in good faith. It is dangerous to disassociate patent settlements from the larger context of patent abuses. The Humira example is prima facie, where the manufacturer successfully applied for patents in the late stage life cycle of the drug.

Rep. Matsui asked how the legislation being considered will affect consumers in the face of companies abusing patent privileges to monopolize the market. She asked Mr. Barrueta how gaming the patent system affects KP's patients. **Mr. Barrueta** said that the availability of generics is crucial to keeping the cost of prescription drug benefits stable over time. Health plans will have to modify the shape of their benefits if name brands do not become readily available as generics. Coverage has shrunk as drug prices have gotten higher and higher. **Rep. Matsui** asked which of the bills would have the highest impact on drug prices. **Mr. Barruetea** said CREATES must be prioritized. **Rep. Matsui** asked if there are policies to be considered in the future. **Mr. Barrueta** said that it would make more sense to look more broadly at Medicare Part B's reimbursement policy and the Medicaid Rebate Program's deterrence of discounting drug prices. Providing broader authority and resources to the FTC would be beneficial.

Rep. Guthrie said that there were five out 170 cases that were ruled to be noncompetitive that went before the FTC. He asked how pay-for-delay settlements can be procompetitive. **Mr. Karst** said that by being able to settle the litigation, generics can save millions in attorney's fees and can reinvest that money and they have a date certain for coming to market. **Rep. Guthrie** asked what the solutions are for pay-for-delays where the generic doesn't come into the marketplace. **Mr. Karst** said that patents are procompetitive. **Rep. Guthrie** asked if provisions should be considered to deter frivolous lawsuits. **Mr. Kushan** said that when a right of action provides a possibility of monetary award, it incentivizes some action that may be counterproductive. It seems like there is a way to ensure that samples are available for what they are needed. **Rep. Guthrie** asked why there aren't more generic insulins on the market and how the March 2020 deadline hurts insulin providers. **Mr. Davis** said that insulin is a classic case of convergence of troubling issues, like the perverse rebate system and the list price increases. There is late state patenting for some of the insulins on the market. The regulatory deadzone was actually a requirement passed by the BCPIA. If there is a pending biosimilar application pending with the Agency, applicants have to go back to the drawing board if the timeframe is encroached upon.

Rep. Cardenas said that despite the FDA has approved 17 biosimilars, only seven are available to patients and providers. In Europe, more than 50 biosimilars are available. The barriers to biosimilar entry must be addressed. Spending on biologics has grown rapidly, and biosimilars have the potential to cut down those costs. **Rep. Cardenas** asked what the biosimilar use rate is for KP and why KP was lead to take such an aggressive stance on biosimilar utilization. **Mr. Barrueta** said that KP uses biosimilars as they are available, such as Zarzio over Neupogen. The data demonstrates that Zarzio is performing excellently. It is critical to ensure that good

information is available to practitioners and that there is a regular source of objective and unbiased information. **Rep. Cardenas** asked what the key barriers are for biosimilar market entry. **Mr. Barrueta** said that the patent thicket is a problem. There is a need for more transparency. **Rep. Cardenas** said that companies use loopholes like agreeing to multiple patent settlements. In some cases they lack competition in the US but have much lower prices in Europe due to having competitors. He asked Mr. Barrueta if any of the legislation today will close loopholes. **Mr. Barrueta** said yes. There should be further examination of pay-for-delay.

Chairman Eshoo said that Congress will do a deep dive on anything that blocks the biosimilar to generic pathway.

Ranking Member Walden said that the BLOCKING Act has bipartisan support. He asked **Mr. Boutin** to walk through how the bill attempts to resolve market issues. **Mr. Boutin** said that the NHC has not taken a formal position but are very supportive of the intent. **Ranking Member Walden** asked what the 2018 operating revenue of KP. **Mr. Barrueta** said almost $79.7 billion. **Ranking Member Walden** asked if loss of revenue would lead to laying off workers or impact the organization's ability to operate. **Mr. Barrueta** said the loss of revenue is an important consideration. **Ranking Member Walden** said there is a big difference between revenue and profit. He asked Mr. Davis how the pay for delay agreements work and if they lead to earlier competition nthan seen on the market. **Mr. Davis** said that in the wake of the seminal Supreme Court *Actavis* decision, the number of anticompetitive agreements as determined by the FTC has dropped significantly. Competition is the DNA of the biosimilar market. Generics get worn down by the cost of litigation. To not have the ability to settle on a date certain on coming to market leads to a lack of clarity. **Mr. Kushan** said that it is important to recognize that a lot of patents that come out later are very narrow. Biosimilar manufacturers have to make a choice about whether to use patent-covered technology. There are ways around the patents. Patents are not the same. **Mr. Carrier** said that *Actavis* said that the risk of competition is the anticompetitive harm.

Rep. Welch asked the witnesses to send in a list of improvements they have for the bills. Patent abuse must be eliminated on the front end. **Mr. Davis** said the generic and biosimilar industries have a concern that as products near the end of its lifecycle, there are more filings of expensive specialty drugs that further delay competition. **Rep. Welch** said that one of the pushbacks from branded pharma is that anything done to pricing will affect innovation. **Mr. Carrier** said that none of the legislation today will hurt competition. The brand companies have gotten everything they want for innovation, as evidenced by Hatch-Waxman. They even took 180 for themselves. **Rep. Welch** asked if CREATES or FAST is more effective. **Mr. Barrueta** said that whichever can get done more quickly is better. **Rep. Welch** said that he does not like litigation. He asked if there is a way to protect IP and innovation but spur biologics and generics. **Mr. Karst** said that the BLOCKING Act is unnecessary.

Rep. Bilirakis said that he agrees with Rep. Welch. He asked Mr. Davis to share what is currently working. **Mr. Davis** said that both transparency bills on the Orange and Purple Book are good, as well as CREATES and FAST Generics. Benefit design and formulary placement are important but not on any books. When generics and biosimilars get to the market, there are increasing cases where follow-on competition make out-of-pocket costs more expensive.

Ultimately, CMS is looking at this issue for 2020 Part D plans, so Congress should ensure out-of-pocket costs are lower for subsequent low-cost alternatives. **Rep. Bilirakis** said that he is concerned with some of the bills discussed today because of the consequences of undermining the 180-day exclusivity and the adverse effects on generics. **Mr. Karst** said that the Competitive Generic Therapy legislation has been a smashing success with companies. The BLOCKING Act is unnecessary because the FDA already has the regulatory and statutory authority it needs. Secretary Azar's characterization of squatting on exclusivity is not accurate.

Rep. Lujan said that issues with the REMS program have been coming up for years. The FDA has taken steps to facilitate generic access to samples, but some have tried to argue that this could put patient safety at risk. Both CREATES and FAST Act lay out a process for companies to get samples. **Rep. Lujan** asked Ms. Kennedy what testing Nephron has to do on a product and what must be shown to obtain approval. **Ms. Kennedy** said that Nephron is equipped with sufficient knowledge to deformulate any brand product with the exception of some biologics. Nephron is hoping that Congress makes it easier to get REMS samples. From then, Nephron must qualitatively and quantitatively prove efficacy to the FDA. Nephron must complete tests set by the brand innovator. **Rep. Lujan** asked Mr. Davis if CREATES opens additional risk to patients. **Mr. Davis** said it maintains the safety certification requirements set by the FDA and puts more teeth into it. It does not expose anyone to increased risks. **Rep. Lujan** asked if CREATES or FAST would hamper the FDA's ability to test the safety of drugs. **Mr. Davis and Ms. Kennedy** said no.

Rep. Bucshon said that the current CREATES Act version could perversely incentivize litigation. Generics could simply not accept a valid offer and go to court. **Mr. Davis** responded that the issue is determining fair market value in the negotiation. **Rep. Bucshon** asked if Mr. Davis would support adding language to current version that would prevent that situation from unfolding. **Mr. Davis** said they would have to see the language and are happy to review it. **Ms. Kennedy** said that it is important to stop the gaming and encourage competition. **Mr. Carrier** said that litigation is the only thing that works. If there are deterrents then the brand companies might wake up. **Mr. Davis** said that companies are primarily concerned with getting the samples, not going to court. **Rep. Bucshon** reiterated his concern with frivolous litigation.

Rep. Kuster said that REMS is being abused on the front-end. On the backend, some branded drug manufacturers are negotiating in bad faith to enter single-system REMS. She asked wjat safety measures are in place to ensure generics come into the market with the same level of safety as their branded counterparts. **Mr. Davis** said that the FDA requirements are the same. For reverse engineering, the FDA is required to certify the generic company. **Rep. Kuster** asked if Mr. Carrier has concerns about the FDA issuing waivers of the single-shared system REMS requirement. **Mr. Carrier** said no. **Rep. Kuster** asked if legislation like CREATES is required to address gaming tactics. **Ms. Kennedy** said yes. **Rep. Kuster** asked what the cost incurred to consumers by these gaming tactics is. **Ms. Kennedy** said that costs are immense. Nephron lowers the cost of a drug by 80 to 90 percent as the fourth- to fifth-filer, with no decrease in quality or safety.

Rep. Hudson said that generics save money, but they cannot be a silver bullet. Robust protections for innovation need to remain in place. Generics cannot come to the market before

protections run out. Congress should seek the input of the agency that will be regulating the space. He asked for the FDA's written technical assistance before marking up the bills. **Rep. Hudson** asked how the Purple Book legislation could be improved to be equally useful as the Orange Book legislation. **Mr. Karst** said it may require broader change to BCPIA. Having a list of patents in the Purple Book would be helpful for manufacturers.

Rep. Barragan said that when Congress passed Hatch-Waxman, the bill laid the groundwork for the modern generic approval system. The delay for getting generics is an issue. FAIR Generics Act would realign incentives for generics coming to market sooner. **Mr. Carrier** said that the problem is the brand company is settling with the first-filing generic to not enter the market and then no one else can enter. The full exclusive 180 is not needed for the first filer since there is shared exclusivity for the first day. In *Actavis***,** Justice Scalia said that Hatch-Waxman made a mistake. **Rep. Barragan** asked if FAIR is an effective deterrent for settlements. **Mr. Carrier** said yes.

Rep. Carter said that he is taken aback by the legal aspects. He asked Mr. Davis about his support of the CREATES Act. **Mr. Davis** said that AAM supports the CREATES Act as introduced. **Rep. Carter** asked Ms. Kennedy if Nephron gets the 180-day exclusivity. **Ms. Kennedy** said no, except for Apotex's budesonide. **Rep. Carter** asked if generics should be able to sue brand originators even if they got samples. **Mr. Carrier** said no. **Mr. Davis** said no. **Rep. Carter** said that the BLOCKING Act and Payment Commission Data Act are a good example of bipartisan legislation.

Rep. Blunt Rochester said that generic market entry saved $205 billion in 2017. The average drug price decreased by 15 percent in the first year of generic entry. There was a constituent whose inhaler copay more than doubled and could not find a generic. CREATES and FAST Generics Act attempt to deal with this problem. **Rep. Blunt Rochester** asked how generics and biosimilars help with cost containment from a payor perspective, and if CREATES will help. **Mr. Barrueta** said yes. Generics are crucial from a coverage standpoint. **Rep. Blunt Rochester** asked which solutions will have the most direct impact on drug prices. **Mr. Barrueta** said CREATES and cleaning up the REMS system. **Rep. Blunt Rochester** asked which policies should be considered for the patent system. **Mr. Barrueta** said that patent laws are crucial. There have been incremental extensions in patents, but incentives must be balanced to maximize innovation and promote access. **Rep. Blunt Rochester** asked how multiple generics on the market could benefit patients. **Mr. Boutin** said he is sick and tired of stakeholders using patient safety to justify actions when it really hurts patients. There is no safety concern with CREATES.

Rep. Gianforte said that the committee is committed to bipartisan solutions. Tomorrow a bill will be introduced around drug pricing transparency. In 2012, the FTC voted to allow the Commission to pursue ill-gotten gains. When pursuing such recovery, the FTC attempts to recapture the profit made through anticompetitive behavior. Is that correct? **Mr. Karst** said yes. **Rep. Gianforte** asked if Mr. Karst knows of any federal statute that allows for recapturing a company's revenue, rather than profit. **Mr. Karst** said he could not think of any. **Rep. Gianforte** said that the CREATES Act will put all of the revenue of the drug companies in play for recapturing through lawsuits. He stated his concerns of this. Creating a target to go after all the revenue of the drug companies is a step in the wrong direction. **Rep. Gianforte** said he has

fundamental concerns over the retroactive application of the pay-for-delay bill to once-lawful business behavior. The provision will open up a can of worms. **Mr. Kushan** said when companies enter a settlement agreement, they will withhold the use of patents, and within a year of the generic going onto the market, the innovator is out. There will be significant disruptions to the planning of both parties. **Rep. Gianforte** said that he was subjected frivolous patent lawsuits in his previous companies and he asked Mr. Kushan which cases of patent abuse he has seen. **Mr. Kushan** said that litigation must be about valid patents and their merits.

Rep. Rush said that he is pleased that the Protecting Consumer Access to Generic Drugs Act is being considered before the committee. He asked to submit two letters in support of his bill to the record. He asked Mr. Carrier about pay-for-delay costing consumers $3.5 billion a year and how the lack of generic competition affects consumers. **Mr. Carrier** said that the FTC calculated this. **Rep. Rush** asked if HR 1499 will lower the cost of prescription drugs. **Mr. Boutin** replied that competition is the key to driving down costs. Drugs that do not bring benefits to patients must be rooted out. **Rep. Rush** asked how pay-for-delay payments impact patients and if legislation is necessary to outlaw those agreements. **Mr. Barrueta** said that pay-for-delay transactions must be appropriately adjudicated.

Rep. Shimkus said that there is broad support for CREATES and FAST, but it can be acknowledged that brand manufacturers must willingly provide samples to generic developers. He asked the witnesses if in most cases, samples for equivalence testing are provided without FDA intervention or litigation. **All the witnesses** said no. **Rep. Shimkus** asked if AAM has an opinion on whether revenue or troubled damages is a preferred approach. **Mr. Davis** said AAM does not have a position on that. **Rep. Shimkus** asked if it is a concern that limits on settlements will lead to fewer generics challenging brand patents, leading to lower cost savings. **Mr. Davis** said yes. Taking away the ability to settle will keep certain specialty medications on the market without competition. **Rep. Shimkus** asked if anyone seeking possession of potentially dangerous drugs should be required to demonstrate to the FDA their ability to properly safeguard the products. **Mr. Barrueta** said yes. KP has a specialty pharmacy to comply with REMS requirements.

Rep. Kelly submitted to the record a letter from Aurora Health. She asked how the FDA receives the information to be included in the Orange Book. **Mr. Carrier** said it gives a lot of benefits for keeping generics at bay. The benefits of the Orange Book legislation are that it makes it clear that when a patent is found invalid, it no longer blocks generics from the market. For example, patents for insulin and Epipens keep getting listed in the Orange Book, keeping list prices high. The FDA collects information but only has a ministerial role. **Rep. Kelly** asked if there additional policy that Congress should consider for preventing abuse of the Orange Book. **Mr. Carrier** said that REMS patents have nothing to do with innovation and should not be listed. **Mr. Kushan** responded that the PTAB statistics are misleading. If a brand medication is wrongly pulled from the Orange Book, it is disruptive for all parties involved.

Rep. Ruiz said many families had to choose between food and medicine. Addressing this problem requires working across the aisle and a range of policy solutions. The use of generics in Medicare save taxpayers $82 billion annually, and expanded generic use would save an additional $14 billion per year. He asked Mr. Boutin how increased generic competition would

help the National Health Council's members. **Mr. Boutin** said that generics allow uninsured people to reduce their prescription costs down to $5 per month some times. **Rep. Ruiz** said that there needs to be more awareness of the availability of treatment options and asked what Congress can do. **Mr. Boutin** said system wide transparency in relationships with providers and pharmacists. **Rep. Ruiz** said 700 generics have been approved by the FDA since January 2017 but are not on the market. **Mr. Boutin** said that it must be assessed how generics are paid for and vibrant competition must be ensured.

Rep. Sarbanes said pay-for-delay settlements cost $3.5 billion between 2010 and 2020. The Supreme Court did note in the Actavis case that they are anticompetitive but they still occur. Those FTC reviews are done from scratch and they cannot operate with the presumption, which takes a lot of time and focus. He asked why *Actavis* may or may not have been sufficient. **Mr. Carrier** said that brand and generic companies both benefit from those agreements. Brand companies will do everything possible to sow ambiguity and sometimes courts get it wrong and are still struggling with the issues. **Rep. Sarbanes** said that pay-for-delay settlements must have the presumption of being illegal. Humira entered into eight different patent settlements. Rep. Rush's proposed bill makes perfect sense in the wake of *Actavis.*

Rep. Schakowsky said that the FAIR Act was first introduced in 2014. Though the bill will not prohibit manufacturers from increasing prices, it will give transparency to the makers of prescription drugs. She asked Mr. Barrueta if increased transparency could potentially lower prescription drug prices for Americans. **Mr. Barrueta** said yes. **Rep. Schakowsky** said that evergreening costs Medicare program approximately $1 billion per year. She asked Mr. Carrier if evergreening incentivizes the intentional delay and what policy changes could be considered. **Mr. Carrier** said Congress can give the FTC the power to investigate the phenomenon of anticompetitive soft switches and subjecting the brand to the "No Economic Reason" common sense test. **Rep. Schakowsky** supports all the bills proposed today.

Rep. Soto said that some of his constituents feel extorted by the price of diabetes drugs. He asked the witnesses whether making the generics more accessible will help in diabetes medication. **Ms. Kennedy** said she is not in the diabetes space, but she supports everything that upholds the spirit of competition. **Mr. Davis** said that issues related to insulin are the perfect storm of what's not working. Biosimilars must be brought to market. **Mr. Barrueta** agrees. **Mr. Boutin** agrees. **Mr. Karst** agrees. 180 day exclusivity must be preserved and the BLOCKING Act should not pass. **Mr. Kushan** said that solutions should work to solve the bigger problem of having to take drugs every day to stay alive. **Mr. Carrier** said that PBMs and formularies should be the first priority to focus on, then deal with the patent issue. The Lantus insulin injector pen has 74 patents, 94 percent which were introduced after the device entered the market. The Orange Book Act would go a long way towards dealing with this.

Chairman Eshoo asked for all the witnesses to submit their recommendations to the committee. She submitted to the record multiple letters of support.