

# ANTITRUST CONCERNS AND THE FDA APPROVAL PROCESS

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## HEARING BEFORE THE SUBCOMMITTEE ON REGULATORY REFORM, COMMERCIAL AND ANTITRUST LAW OF THE COMMITTEE ON THE JUDICIARY HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS FIRST SESSION

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<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-20170727-SD002.pdf>

Article submitted by the Honorable David Cicilline, Rhode Island, Ranking Member, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Committee on the Judiciary. These materials are available at the Committee and can be accessed on the Committee Repository at:

<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-20170727-SD003.pdf>

Oral Statement —Continued  
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*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-20170727-SD005.pdf>*

## ANTITRUST CONCERNS AND THE FDA APPROVAL PROCESS

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THURSDAY, JULY 27, 2017

HOUSE OF REPRESENTATIVES  
SUBCOMMITTEE ON REGULATORY REFORM  
COMMERCIAL AND ANTITRUST LAW  
COMMITTEE ON THE JUDICIARY  
*Washington, DC.*

The Subcommittee met, pursuant to call, at 1:00 p.m., in room 2141, Rayburn House Office Building, Hon. Tom Marino (Chairman of the Subcommittee) presiding.

Present: Representatives Marino, Goodlatte, Gaetz, Cicilline, Conyers, Johnson, Swalwell, and Schneider.

Staff Present: Ryan Dattilo, Counsel; Andrea Woodard, Clerk; and Slade Bond, Minority Counsel.

Mr. MARINO. Good morning. The Subcommittee on Regulatory Reform, Commercial and Antitrust Law will come to order.

We are going to vote in anywhere from 20 to 30 minutes. I may be speaking a little faster than I normally do because I would like to get our opening statements in and our distinguished witnesses' opening statements in.

So let's begin.

Without objection, the Chair is authorized to declare a recess of the committee at any time.

We welcome everyone to today's hearing on antitrust concerns and the FDA approval process. And I now recognize myself for an opening statement.

The Committee has a robust history of examining competition in the healthcare marketplace to ensure patients receive the highest quality treatment at the lowest cost. In the past few years, the Subcommittee has held four hearings in this area, covering the topics of market consolidation, the impact of the Patient Protection and Affordable Care Act on competition, opioid addiction, and trends in pharmacy benefit management. We continue that tradition today, focusing on the pharmaceutical industry and antitrust concerns surrounding the FDA drug approval process.

Competition in the pharmaceutical market involves a delicate balance. On one hand, we want to encourage pharmaceutical manufacturers to invest in needed, but often expensive research and development in order to bring innovative and life-saving drugs to the market. On the other hand, we want to encourage sufficient com-

petition to ensure that there is an appropriate check on consumer prices.

Innovation is one of the hallmarks of our pharmaceutical industry and should be celebrated. However, there have been allegations that some companies may be abusing their roles as innovators to engage in the manipulation of regulations to preclude generic manufacturers from bringing competing products to the market. Such conduct is anticompetitive and should be put to a stop.

Since its enactment, the Hatch-Waxman Act has provided opportunities for manufacturers to make lower-cost generic versions of previously approved drugs available to the people of the United States in a timely manner, thereby lowering overall prescription drug costs for patients and taxpayers by billions of dollars each year.

An essential piece of this framework is the ability of generic drug manufacturers to obtain sufficient samples of branded drugs to conduct the testing necessary to support an application for FDA approval of the drugs' generic version. Concerns have been raised that generic manufacturers have been prevented from obtaining such samples, in some instances based on the position that the drugs in question are subject to a risk evaluation and mitigation strategy with elements to assure safe use under Section 505-1, the Federal Food, Drug, and Cosmetic Act. This is more commonly referred to as the REMS program.

While the enforcement of existing antitrust laws could address the refusal by some branded manufacturers to provide samples to a generic drug manufacturer, a more tailored legal pathway would help to ensure timely resolution of disputes over sample testing, provide clear guidelines, and facilitate healthy competition in the marketplace, benefiting all consumers.

For these reasons, Ranking Member Cicilline and I introduced the Creating and Restoring Equal Access to Equivalent Samples, more commonly known as the CREATES Act. This legislation will deter pharmaceutical companies from manipulating sample availability to block cheaper generic alternatives from entering the marketplace.

The CREATES Act will lead to lower costs for patients by ensuring that they have access to safe and effective FDA-approved generic medicines. It will also ensure consumer safety by maintaining safeguard features of the REMS program while closing regulatory loopholes that are used to keep prices artificially high.

The Congressional Budget Office has estimated that the bill would result in a \$3.3 billion—that's with a B—billion dollar net decrease in the Federal deficit. Savings to consumers and private insurers likely would be far greater.

I look forward to hearing our witnesses' views on the CREATES Act as well as on other areas of the FDA approval process which may be subject to anticompetitive measures.

And just to get a piece of work out of the way, if there are no objections, I would like to enter into the record that I have several letters in support of the CREATES Act and our efforts with this hearing.

So without objection, I would like to enter this, and I'll read off who sent us letters and statements: FreedomWorks, America's

Health Insurance Plans, West-Ward Pharmaceuticals, International Center for Law and Economics, Coalition to Reduce Spending, the Academy of Managed Care Pharmacy, Association for Accessible Medicines, the American Society of Health-System Pharmacists, Pharmaceutical Care Management Association, Consumers Union, Premier Healthcare Alliance, Campaign for Sustainable Rx Pricing, Blue Cross Blue Shield, CVS Health, and Express Scripts.

*This Material is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-20170727-SD002.pdf>*

The Chair now recognizes the Ranking Member of the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Mr. Cicilline of Rhode Island, for his opening statement.

Mr. CICILLINE. Thank you, Mr. Chairman, for your leadership and for holding today's hearing.

Every year hardworking Americans pay too much for prescription drugs. The cost of prescription drugs has increased by over 200 percent over the past decade. These soaring prices are life threatening. Kaiser Health reports that a quarter of Americans cannot afford their prescription medicines, while many are skipping or reducing their dosages.

This heartbreaking epidemic is particularly harmful for the hundreds of thousands of cancer patients who are forced to skip or delay their treatments because of the immense financial burden of prescription cancer drugs, which can cost more than \$159,000 a year. Leading oncologists report that these skyrocketing costs are causing deaths and harming patients on a daily basis.

And beyond the human toll of this epidemic, spiking drug prices have a direct impact on Federal spending because most cancer patients are older than 65 and are enrolled in Medicare. And there is no upper limit on out-of-pocket costs for these patients, so they can pay as much as \$57,000 in lifetime expenses, or about 11 percent of their income, even if they're insured.

We must find lasting policy solutions to save lives by lowering the cost of prescription drugs. Earlier this week Democrats announced A Better Deal for Americans to stop outrageous prescription drug price increases.

The American people deserve a government that is in their corner fighting for them to take on drug profiteering and price hikes. And that's why I'm extremely proud of my work with Chairman Marino and our introduction of H.R. 2122, the CREATES Act, a targeted solution to reduce drugs prices by increasing generic competition.

The Federal Trade Commission reports that generic drugs can reduce the price of branded drugs by more than 85 percent, while the presence of just one generic competitor can decrease prescription drug prices by 20 to 30 percent.

But over the past decade some branded drug companies have abused safety protocols at the Food and Drug Administration in order to keep affordable drugs out of the market at the expense of hardworking Americans.

Congress never intended these safety programs, called risk evaluation and mitigation strategies, to allow a branded drug company to block or delay generic competitors from receiving FDA approval and enter the market.

And yet, some drug companies have exploited these safety programs to delay generic competition, if only by days and months, to prolong high drug prices.

That's because months of delay could be worth hundreds of millions of dollars in additional monopoly revenues as the generic sits on the sideline, as Professor Robin Feldman has noted.

While this abusive behavior often violates the antitrust laws, as the Federal Trade Commission will testify today, these cases are often two-timing to provide effective relief. The CREATES Act addresses these delay tactics by creating a tailored path for generic drug manufacturers to obtain the samples that are necessary to bring low cost drugs to market.

The Congressional Budget Office estimates, as the Chairman has said, that the bill would result in a \$3.3 billion net decrease in the Federal deficit, while the estimate of the total cost of this delay for consumers is \$5.4 billion.

This bill is supported by numerous physicians, hospitals, health insurers, and patient groups, along with public interest organizations, such as Consumer Union and Public Citizen. CVS Health, which is located in my district strongly supports this bill because, "it is vitally important in end practices that delay competition and ultimately lead to higher drug prices."

I again thank the Chairman for calling today's hearing, along with our esteemed witnesses for their appearances here today. And I look forward to working with my colleagues to ensure an end to profiteering and price gouging by prescription drug companies.

And with that, I yield back.

Mr. MARINO. Thank you, David.

The Chair now recognizes the Ranking Member of the full Judiciary Committee, Congressman Conyers of Michigan, for his opening statement.

Mr. CONYERS. Thank you, Chairman Marino.

What we're doing today is examining the process for the Food and Drug Administration's method of approval for branded and generic drugs and its effect on competition and drug prices. And it sure is timely.

Just this past month, my colleagues in the House, Leader Pelosi and Senator Schumer, Mr. Cicilline, and others, have released an excellent white paper called "A Better Deal: Lowering Prescription Drug Costs." And it calls for rewriting rules to stop prescription drug price increases, lowering drug prices for Medicare, and requiring drug manufacturers to publicly release data justifying any significant price increases.

I support the idea of making prescription drugs affordable and accessible for all Americans, for everybody. Additionally, the ability of lower-priced generic drugs to compete against branded drugs is a pretty important consideration that I hope we will get into this afternoon.

With this overarching goal in mind, I'd like our distinguished witnesses present to consider the following: What extent to which

the Food and Drug Administration's use of risk evaluation and mitigation strategies make it harder for lower-price generic drugs to enter the market in competition with, of course, the branded drugs.

These regulatory requirements are an important safeguard to ensure that drugs with potentially dangerous characteristics and side effects are safely and carefully distributed. The process, however, may also serve to stifle competition and keep drug prices high, artificially high at that.

For instance, these requirements may make it difficult for generic drug manufacturers to obtain samples in order to conduct the bioequivalence testing necessary to gain regulatory approval of a lower-priced generic equivalent to a branded drug. Indeed, some have alleged that branded drug companies deliberately cite these restrictions as a way of refusing to provide such samples to potential generic competitors.

In addition, we should of course remain vigilant about pay-for-delay schemes, whereby branded drug manufacturers pay generic manufacturers to delay the entry of a version of branded drugs as the patent on the branded drug expires.

These arrangements are cause for some concern—and in some areas a lot of concern—because the Supreme Court has already held in *Federal Trade Commission v. Actavis* they may violate the antitrust laws. They may contravene longstanding Federal policy encouraging the rapid entry of generic drugs into the marketplace in order to dramatically reduce drug prices.

So to what extent should we be concerned about potential abuse of the citizen petition process at the Food and Drug Administration? That agency allows any concerned citizen to solicit changes to agency regulations and other administrative actions. While in principle this is admirably democratic procedure, branded drug manufacturers may manipulate it to stifle entry of generic drug competition, for example, by challenging generic drug approvals using this process.

Because the agency must review every citizen petition it receives, generic drug manufacturers allege that branded manufacturers use the petition process to stop or delay agency approval of competing generic drugs with multiple and unwarranted petitions. And despite amendments made in 2007 to address such potential abuse, the agency reports that it remains concerned that many nonmeritorious citizen petitions are being filed primarily to delay the entry of generic drugs into the marketplace.

Wouldn't it be nice if we could solve this this afternoon, at this hearing?

I thank Chairman Marino and my Ranking Member Cicilline for their work on this important matter. And a word of welcome to our witnesses being here today. Thank you so much, Mr. Chairman.

Mr. MARINO. Thank you, John.

The Chair now recognizes the Chairman of the full Judiciary Committee, Congressman Goodlatte of Virginia, for his opening statement.

Chairman GOODLATTE. Thank you very much, Mr. Chairman. And welcome to our witnesses.

The United States has been and continues to be a champion of free and open markets. An open marketplace cultivates competition among sellers and is the very foundation of maintaining lower prices, higher quality, both in products and services, and superior innovation.

The antitrust laws established in this country serve a valuable role in promoting competition, and the Judiciary Committee routinely exercises its oversight authority to ensure that these laws are applied in a manner that is transparent, fair, predictable, and reasonably stable over time.

One area of essential antitrust oversight is the healthcare industry. Healthcare and its related markets have long been subject to extensive antitrust scrutiny and have been a focal point of the Committee for the past several years.

This hearing marks the fifth in our series focused on competition in the healthcare marketplace and continues the Committee's history of vigilant oversight into this important industry that touches nearly every American.

Today the Committee turns its attention to antitrust concerns surrounding the Food and Drug Administration drug approval process and its impacts on competition between branded and generic drug manufacturers. As with approval processes for any industry subject to government regulations, the drug approval process can provide a fertile environment to secure and abuse market power.

Although Congress has passed laws aimed at facilitating competition from lower-priced generic drug manufacturers, while maintaining incentives for branded drug manufacturers to invest in developing new and innovative drugs, the Hatch-Waxman Act and the surrounding regulatory environment create unique issues that are only present in the pharmaceutical marketplace.

For example, a generic drug manufacturer must rely on its competitor's product in order to test bioequivalence so that FDA approval may be sought.

One of the most common antitrust concerns in pharmaceutical conduct cases occurs when companies engage in activity aimed at delaying the entry of generic drugs, thus leading to higher prices for consumers.

Of particular concern today is the potential abuse of certain Food and Drug Administration approval processes intended to ensure safety. Although the FDA has no authority to regulate the cost of a drug, certain FDA policies and practices have substantial ramifications throughout the drug pricing market.

Today, the United States has the largest pharmaceutical market in the world, accounting for roughly 40 percent of the global market. U.S. firms conduct the majority of the world's pharmaceutical research and development and currently hold the intellectual property rights pertaining to most new medicines.

While it is imperative that the U.S. continue to remain the world leader and innovator in the pharmaceutical market, it is important that these antitrust concerns be given significant deliberation. The benefits from such leadership and innovation are undermined if our consumers unfairly bear the brunt of anticompetitive conduct through above-market prices.

I look forward to hearing the witnesses' views on these issues and whether our existing antitrust laws are equipped to address these antitrust concerns in the FDA approval process.

I'd like to again thank Chairman Marino for holding today's hearing. And today's testimony will help the Committee gain a better understanding of the seriousness of these issues and how they might be addressed.

Thank you, Mr. Chairman.

Mr. MARINO. Thank you, Bob.

Without objection, other members' opening statements will be made part of the record. We'll begin by swearing in our witnesses before introducing them.

Would you please stand and raise your right arm?

Do you swear or affirm that the testimony you are about to give before this Committee is the truth, the whole truth, and nothing but the truth, so help you God?

Please be seated.

Let the record reflect that the witnesses have responded in the affirmative.

Dr. Scott Gottlieb was sworn in as the 23rd Commissioner of Food and Drug on May 11, 2017. Mr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs, and before that, as a senior adviser to the FDA Commissioner. Mr. Gottlieb has also served as a senior policy adviser at the Centers for Medicare and Medicaid Services.

Mr. Gottlieb was previously a resident fellow at the American Enterprise Institute and a clinical assistant professor at the New York University School of Medicine in Manhattan where he also practiced medicine as a physician.

Having authored over 300 articles appearing in leading medical journals and other well-respected periodicals, Mr. Gottlieb's career has included working as a staff writer for the *British Medical Journal*, serving as a senior editor to the *Pulse*, *Journal of the American Medical Association*, and serving on multiple editorial boards, including Food and Drug Law Institute's Policy Forum, Value-Based Cancer Care, and Cancer Commons. He is also a member of the Leukemia and Lymphoma Society, the Public Policy Committee of the Society of Hospitalist Medicine, and a member of the board for Keystone Center.

Mr. Gottlieb received his BA in economics from the Wesleyan University and his MD from Mount Sinai School of Medicine in New York University, where he completed his residency in internal medicine.

Welcome, Doctor.

Mr. Meier is the Assistant Director in charge of the Federal Trade Commission's Healthcare Division in Washington, D.C. He leads an office of 35 lawyers—that's got to be a tough job—and other professionals who investigate and litigate alleged violations of antitrust law by pharmaceutical companies, physicians, and other healthcare providers.

Since November 2015, Mr. Meier has also been serving as the Acting Deputy Director, and more recently as the Acting Director of the FTC's Bureau of Competition, where he oversees more than

280 lawyers and other professionals investigating and litigating merger and nonmerger cases.

Mr. Meier joined the FTC in 1990 and became head of the Healthcare Division in 2006. In addition to his work at the FTC, Mr. Meier has worked in private practice, where he focused on antitrust litigation and represented clients before the FTC and the Department of Justice. He has served as a Special Assistant United States Attorney—we have a little fraternity going here now—prosecuting criminal cases in the Eastern District of Virginia.

He was also a resident adviser to the Indonesian Competition Commission in Jakarta in 2001. Before joining the FTC, Mr. Meier served as an officer in the United States Army.

Thank you for your service.

He is a graduate of the George Mason School of Law, has a master's degree in public administration from Old Dominion University and a bachelor's degree from the University of Virginia.

Welcome, sir.

Each of the witnesses' written statements will be entered into the record in its entirety. I will ask that each of you summarize your testimony in 5 minutes or less.

And to help you with that, you have some lights in front of you. The light will switch from green to yellow when you have a minute left, and then when it switches to red, the time's out. I've been in your position and I don't pay attention to the lights. So what I'm going to do is very politely and diplomatically pick up the gavel and hopefully that will give you an incentive to wrap up.

Dr. Gottlieb, the floor is yours.

**TESTIMONY OF MR. SCOTT GOTTLIEB, M.D., COMMISSIONER, FOOD & DRUG ADMINISTRATION; AND MR. MARKUS H. MEIER, ACTING DIRECTOR, BUREAU OF COMPETITION, ASSISTANT DIRECTOR, HEALTH CARE DIVISION, FEDERAL TRADE COMMISSION**

**TESTIMONY OF SCOTT GOTTLIEB**

Dr. GOTTLIEB. Thanks a lot, Mr. Chairman and Ranking Member. Thank you for the opportunity to testify before the Committee. My name is Scott Gottlieb. I'm a physician and Commissioner of the Food and Drug Administration.

At FDA we've undertaken a broad initiative to promote prescription drug competition with the aim of lowering drug costs to consumers. FDA doesn't oversee any aspect of drug pricing as part of our regulatory mandate, but our policies can have a significant impact on the cost of medicines, and ensuring American patients have access to affordable medicines is a top priority for FDA and for the administration.

In particular, our policies related to generic drugs can promote competition, which lowers drug costs. Similarly, our regulatory policies related to the clinical development of new drugs ultimately impact the cost of these endeavors. Our requirements and their impact on the risks and costs of new drug development can affect the way that entrepreneurs price their finished products in order to justify their investments.

In each case, we're closely examining the impacts of our policies. We want to strike the right balance between access and innovation while we hold steadfast to our core consumer protection mandate to make sure the drugs we approve are safe and effective.

Today, I'd like to briefly review with your policies we're considering and steps we're taking to promote generic drug competition.

First, we're improving the efficiency of the generic review and approval process to help new generic drugs reach consumers more quickly, but without sacrificing the assurance of safety and effectiveness.

Historically, the average generic drug application undergoes four cycles of review by FDA. Through new policies we're implementing, we believe we can sharply reduce this number and reduce total development times.

Our average total time to approval for legacy applications has averaged 42 months. We're significantly bringing down that time. Beginning this October, if we get a high quality submission, we'll be able to review and approve it in 8 to 10 months, depending on the type of application, and I'll report on our progress the following fall.

A second major part of our efforts is to improve our policies and scientific approach to the approval of generic competitors to complex or difficult-to-duplicate brand name drugs.

Collectively, this represents a sizable category of medicines that in many cases could be subject to generic competition, but are not. We're looking at how to change that, such as developing clear principles for approving generic versions of these products and issuing those principles well in advance of the time of the first patent expiry.

The third part of our plan relates most directly to the topics we're here to discuss today. I want to make sure that companies aren't gaming our own rules to extend their monopolies on brand drugs and maintain their monopoly pricing by forestalling competition that Congress intended for when it crafted the Hatch-Waxman amendment.

One example of this relates to risk management programs we've put in place in order to assure the safe use of drugs but where brand manufacturers have then denied generic drug manufacturers access, even at fair market value and despite assurances from FDA, to the doses they need in order to run the bioequivalent studies required for applications.

This is clearly not what Congress intended. While at least some of these restrictions on access may fall outside our direct purview, we're exploring potential measures we could take, including actions we might take in concert with our colleagues at CMS and the FTC, to prevent this sort of activity.

We're also looking at steps we can take to reduce the potential for brand companies to block generic entry by extending the negotiations they're obligated to have over the application of a single shared REMS program.

These are cases where they have a REMS program in place to help manage the safe use of a product and the generic entrant is seeking to share the REMS program with the brand sponsor.

Here is the bottom line, in my view. We have a market-based system for pricing medicines that functions in part as a way to make sure entrepreneurs have appropriate rewards for their risk taking. This system has unlocked unprecedented drug innovation that's saving lives and quite literally curing disease.

But we need to balance access with innovation. We need to make sure that when the patent and exclusivity periods have lapsed, the point at which Congress intended for vigorous competition to be possible, consumers are able to benefit from the savings that come from generic drug entry and the choice it enables.

That's our goal, to do all that we can to make sure markets are efficient and close loopholes that are letting a handful of market participants game the rules in ways that hurt consumers.

Thank you, Mr. Chairman.

*Hon. Gottlieb's written statement is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-GottliebS-20170727.pdf>*

Mr. MARINO. Thank you, Doctor.

Attorney Meier.

#### **TESTIMONY OF MARKUS MEIER**

Mr. MEIER. Chairman Marino, Ranking Member Cicilline, and members of the Subcommittee, thank you for the opportunity to address the hearing today. It's a very important subject. And I'm pleased to testify about one of the FTC's top priorities: stopping anticompetitive conduct in the pharmaceutical industry. Such conduct harms American consumers through higher drug prices.

I'm also pleased to be here sitting next to FDA Commissioner Dr. Gottlieb. The FTC and the FDA have had a long history of working closely together on these issues and many others as well, and the FTC looks forward to continuing to build on our relationship with the FDA in the months and years to come.

Unlike the FDA, however, the FTC is not a sector regulator. Instead, we are primarily a law enforcement agency, and the laws we're charged with enforcing are intended to promote competition for the benefit of consumers, and they apply across wide ranges of industries in the United States, not just the pharmaceutical industry.

The way we do our job is we do it by challenging three broad categories of business practices known to harm competition. First, we challenge agreements among competitors that unreasonably restrain trade. Second, we challenge acts of monopolization. And third, we challenge mergers that may substantially lessen competition. The FTC has a long history of applying these laws in the pharmaceutical industry.

With respect to the three topics of today's hearing, the FTC has brought cases and filed amicus briefs addressing antitrust problems with abuse of the FDA processes in each of the three areas.

First are the abuses that occur when brands use FDA-mandated REMS or when they use voluntary distribution systems, either to prevent a generic company from gaining access to the samples it needs to go through the FDA-approval process, or secondly, by refusing to negotiate a single shared REMS distribution system.

To date, the FTC's actions in this area have been to file amicus briefs in private litigation, because private parties can also bring antitrust cases, not just the FTC, and to explain to courts how the REMS abuse can in fact violate the antitrust laws.

Second are the abuses arising from so-called pay-for-delay agreements. Pay-for-delay agreements occur in the context in which a brand and a generic company are in patent litigation, the generic is trying to gain entry into the marketplace. It says to the brand company, your patent is not valid or I do not infringe your patent. They're fighting out a patent case. And at some point they settle the litigation, in which the brand, one, offers money to the generic, and two, the generic agrees to stay out for some period of time. And we've had a lot of cases in this area and currently have cases, a case called Actavis, AbbVie, Allergan, Watson and Impax.

Third are abuses that can occur with the citizen petition process. Brands may use the FDA's citizen petition process to delay generic approval by raising scientific or legal issues that the FDA must respond to before approving a generic. Studies have shown that while these petitions often lack merit, they delay entry of lower-cost generics. FTC actions to date include a recent lawsuit that we filed in the case of ViroPharma in the District of Delaware.

Despite our many efforts, however, there are limits on antitrust law enforcement. First, and possibly most importantly, it's not a violation of Federal law simply to charge high prices. Secondly, litigation, which is what I do and what we do at the FTC, can be slow, it's expensive, and it's uncertain. I personally have been working to stop pay-for-delay agreements for more than 17 years, as have a handful of my colleagues who have been there from the very beginning, and we're still years away from court resolutions of some of those cases.

These limitations are the reason why the Commission supports the goals of the CREATES Act, and if enacted, the FTC believes that the CREATES Act would reduce the incentive for brands to use REMS to impede competition from lower-cost generics.

In closing, I look forward to addressing your questions, and again, thank you for inviting me here today.

*Mr. Meier's written statement is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-MeierM-20170727.pdf>*

Mr. MARINO. Thank you, Attorney Meier.

We will now begin the Congress members' 5 minutes of questioning. And I will recognize myself for 5 minutes of questioning.

Dr. Gottlieb, I want to commend you, first of all, for shining the light on the issues that we're addressing here today. It's critically important. These competition problems have been around for a long time, so I want to better understand FDA's current authorities in this area.

One of the principal objects of the CREATES Act is to allow a generic company to seek an injunction from the court to require the sale of a brand's product. To be clear, a court can only order a sale once the generic has received FDA authorization to handle the product.

When Congress established REMS authority in 2007, Congress included a provision that said a REMS should not be used to delay competition. It is my understanding that the FDA has authority to level civil monetary penalties when they determine a brand company is delaying competition using the REMS program. Is that correct?

Dr. GOTTLIEB. There is a provision in the law, Congressman.

Mr. MARINO. I also understand the FDA has never used that authority. Are you aware of that?

Dr. GOTTLIEB. I know it's a complex authority to exercise, Congressman.

Mr. MARINO. If they did use that authority, it would require the development of a lengthy record, be time-consuming, and use resources. Would you agree with me?

Dr. GOTTLIEB. I know it's highly complex to develop the administrative record to exercise the authority, so it would take time—it would take a lot of time.

Mr. MARINO. In a determination by the FDA that the brand's actions were taken to block or delay the generic application, would you agree with me concerning that?

Dr. GOTTLIEB. I'm sorry, I missed the question.

Mr. MARINO. The brand's actions, if taken, would delay the generic application.

Dr. GOTTLIEB. There are a lot of brand actions that delay generic entry, yes.

Mr. MARINO. And once all these steps have happened, you have to work with DOJ to level penalties, correct?

Dr. GOTTLIEB. If we were to exercise that authority, yes. And penalties, I believe, are relatively modest.

Mr. MARINO. This seems, as a prosecutor, as a former U.S. Attorney, these are pretty intense and time-consuming processes, and the FDA only has the authority for drugs that are behind a REMS, not for voluntary manufacturer's schemes. That's correct also?

Dr. GOTTLIEB. It's a good point that a lot of the restrictions on the ability of the generic companies to get access to the doses are commercially driven as well through contracting.

Mr. MARINO. It would seem to me that we could resolve these issues and these disputes quicker if competitors had limited resources in the courts to require the sale of some samples when the FDA has found it can safely handle those samples. That's not a question, but could you please share with us some of your insight on how we streamline this?

Dr. GOTTLIEB. Well, Congressman, you've raised a lot of concerns that are our concerns. The fact that generic companies literally can't get access to the doses they need, the units they need, to run the bioequivalent studies to go through the regulatory approval process, that is clearly not what Congress prescribed under Hatch-Waxman.

Some of these fall within the scope of gaming regulations that exist within FDA's purview, and the REMS is an example. Some of them fall within the scope of things branded companies do in the context of commercial contracts to deny the ability of generic companies to get the drugs from either specialty pharmacy companies or other intermediaries like wholesalers.

But it requires between 1,500 and 5,000 physical doses in order to run the bioequivalent studies, and quite literally, there are situations, and we see them, where the generics can't get access to those doses in a timely fashion.

Mr. MARINO. Attorney Meier, while the FTC has expressed concerns about anticompetitive abuse of the REMS process, and I think you filed two amicus briefs in disputes between manufacturers, it doesn't appear to have brought any enforcement suits. Can you explain why enforcement suits haven't been brought and what would we do to better improve the system?

Mr. MEIER. This is an area where we've spent a lot of time looking into it. We've chased down a lot of leads and taken, heard a lot of different complaints. In fact, the FDA sent us a list of approximately 150 inquiries it's received, and we've reviewed those very carefully to look for a good test case to bring.

But in addition to the activities of the FTC, there are private litigations. Private companies can bring antitrust cases, too, and they have. And as I said before, we filed amicus briefs in a number of those cases to try to assist the court in understanding how the antitrust laws can apply to those behaviors.

Mr. MARINO. Thank you.

My time has expired, and I do now recognize the Ranking Member of the Committee, Congressman Cicilline, for his questions.

Mr. CICILLINE. Thank you, Mr. Chairman.

And thank you again to our witnesses.

Mr. Meier, you explained in your written testimony that delaying generic competition through REMS abuse results in about \$5.4 billion dollars in annual costs to consumers.

Could you please explain how delaying competition through REMS abuses increases costs to consumers? You know, sort of explain a little bit, when does the FTC require the REMS safety protocol for a drug and how does it result in that kind of an impact on consumers?

Mr. MEIER. So, first of all, with respect to the testimony and the \$5.4 billion figure in the testimony, I do want to point out that that was a study done by the generic pharmaceutical industry, as we indicated in the report. So we haven't independently verified that number. But it does suggest that this is a problem.

With respect to your question about what exactly the FDA has to do when it does a review process, that's really a question I think that might be better addressed to the FDA.

But having said that, in a number of instances where we have done investigations I've come to learn some about the standards that the FDA uses. And obviously what they want to do and what they have to do is make sure that the drug supply is safe and effective, and I think they do a very good job of doing that. And there are certain drugs that, when certain patient populations are exposed to it, can be dangerous for those patients and can be dangerous for other people.

The classic example that often comes up is the Thalidomide example, which obviously results in horrible, horrible potential birth defects if a pregnant woman is exposed to that, and that is in fact subject to a REMS program.

So it's those types of drugs that I understand are subject to REMS programs with what are known as ETASU or elements to assure safe use. But, again, I think it might be a question that the FDA can better address than I can.

Mr. CICILLINE. Dr. Gottlieb.

Dr. GOTTLIEB. Congressman, these are drugs that have certain what we call elements to assure safe use, certain provisions that are put in place at the time of approval to help ensure their safe prescribing by providers. So typically they'll have certain side effects or risks associated with them that we feel in order to strike the right risk-benefit balance we have to have certain measures in place, like provider education, or requirements that providers take certain measures, to subject patients to certain tests, to look for the manifestation of certain side effects.

Just as a general matter, and you asked the question about how would it save consumers money, by and large, the majority of the drugs for which we have risk management plans in place tend to be specialty drugs, and they tend to be higher priced drugs.

And to the extent that manipulation of the REMS to forestall the ability of the generic companies to get access to the samples they need to do the bioequivalent studies would then delay the generic from filing the application and getting onto the market, that's going to disadvantage consumers, because it's just a delay in getting competition where patents might have lapsed that would be lower cost. So, you know, just month by month, every month, to your point, could add up to a lot of money.

Mr. CICILLINE. Thank you.

Mr. Meier, you made reference in your testimony, obviously, to one of the ways that brand drug companies realize profits is to prevent—refuse to provide samples that are necessary for the development of the generic, which the CREATES Act attempts to address. I think you've already said that you consider that anticompetitive behavior.

I guess the question I have is, should we consider simply a prohibition against that, an outright prohibition against these pay-for-delay or refusal to provide? I know they're two different issues, but—

Mr. MEIER. So you're right, they're two different issues. But with respect to the samples, I do want to be careful that it's not just merely the refusal to provide a sample that causes an antitrust problem. When we do an antitrust case, the type of case that you would have to bring in this instance would be a charge of monopolization. That's basically a single company acting unilaterally, saying, I'm not going to turn over the samples.

One of the elements you'd have to show is exclusionary conduct, but an additional element in that case you'd have to show is that the company actually has a monopoly and is maintaining or holding on to that monopoly as a result.

So the challenge is not just to say refusing to provide a sample is an antitrust problem, but it's the combination of the refusal to provide it by a monopolist under certain circumstances can violate the law.

Mr. CICILLINE. And what about with respect to pay-for-delay? What would be— wouldn't it be sensible public policy simply to pro-

hibit those outright, that you couldn't contract with another entity to prevent the introduction into the marketplace. I mean, that seems pretty, obviously, on its face anticompetitive.

Mr. MEIER. Well, that have been a number of different bills that have been floated over the years that would come close to doing what you're describing, both on the House side and the Senate side, and there have been various times when the FTC has been asked to look at that and comment on that, and we have. And should somebody put together such a bill again in the future, we'd be happy to provide whatever technical assistance we could on that.

Mr. CICILLINE. Thank you.

Thank you, Mr. Chairman. I yield back.

Mr. MARINO. The Chair recognizes the Chairman of the full Judiciary Committee, Congressman Goodlatte.

Chairman GOODLATTE. Thank you, Mr. Chairman.

Thank you, gentlemen, for your testimony. Let me start with Dr. GOTTLIEB.

I have received several inquiries over the years from constituents regarding escalating prices for specific drugs, some of them 100 years old, that have been on the market in every instance for long periods of time, decades. I understand that some of this may be the result of the FDA's Unapproved Drug Initiative.

Can you explain what the goal of that program is and whether you think it's been effective?

Dr. GOTTLIEB. Congressman, there's a large category of drugs that were effectively grandfathered in when the modern statute to require the demonstration of safety and effectiveness was put in place in the 1960s. We refer to them as the DESI drugs. And they never went through a traditional approval process. They never had to demonstrate safety and efficacy through the traditional clinical trial requirements.

We have a program in place to both take these drugs off the market when we feel that there are certain concerns relative to their safety and effectiveness or the way they're being manufactured. We've taken over a thousand unapproved drugs off the market.

And also to try to move certain drugs into the approved space, especially for critical medicines where it might have a narrow therapeutic window and you want to make sure it's being manufactured in an appropriate fashion. We've moved these drugs into the market through the approval process.

Now, it is the case that when that happens, in some instances, and in a lot of instances, when a drug that's previously unapproved becomes an approved drug and we clear the market of the other formulations that might be on the market, they will have some exclusivity. They might have 3 years of exclusivity under Hatch-Waxman for doing clinical studies. They might have 5 years of exclusivity in rare cases where there is a new molecular entity. So they will have a period of exclusivity.

I will say that the juxtaposition here is that you now have a formal reference listed drug for which you can then bring generics onto the market when that exclusivity period lapses.

And the final point I would make is—

Chairman GOODLATTE. Why did they get a period of exclusivity for a drug that's not new?

Dr. GOTTLIEB. If they do clinical studies to demonstrate safety and effectiveness as part of the FDA approval process, they get a short period of exclusivity.

Chairman GOODLATTE. How long is a short about?

Dr. GOTTLIEB. That's 3 years, is what's prescribed under Hatch-Waxman.

I will say, I've been around FDA for about 15 years now and I've gone through different cycles where at various points in time we've been criticized for not moving aggressively enough on the unapproved drugs. So it's a real public health challenge.

Chairman GOODLATTE. Well, let me ask you about that. Because when you take them off the market, is it based on safety? Is it based on efficacy? What is your standard? And what kind of research do you do, or does somebody else do that research for you, and might it be one of the competitors that does the research for you? What do you rely upon to take the drug off the market in the first place?

Dr. GOTTLIEB. We're careful in how we take the drug off the market in these instances to make sure that the new entrant can actually supply the market.

Chairman GOODLATTE. You say you've done a thousand or more?

Dr. GOTTLIEB. Those aren't situations where we've necessarily cleared the market of all the drugs in a category. Those are situations where there might have been one drug on the market that had certain problems associated with it. There's only 23 cases where we've had one approved drug come onto the market and made an attempt to clear the market of the competitors. And I think those are the situations that you're referencing. I believe it's 23.

You know, it is the case that in order to—and this is a balance, and Congress can speak to this because we went through the last time I was at the agency and worked very closely with Congress on this.

But you want to provide—if you want these unapproved drugs to come through a regulatory process and develop the data to demonstrate safety and effectiveness and go through the manufacturing requirements, you have to provide an incentive. And the incentive is that if they go through that process and spend the money to do it, they're going to get a short period of exclusivity, and the FDA is going to make an attempt to clear the market of potential competitors.

Chairman GOODLATTE. They're going to clear the market of people who haven't done that, even though they don't want to spend the money and they may have exactly the same result if they were to do it for their drug, because they may be identical drugs.

Dr. GOTTLIEB. I understand the concern you're raising, and I would say—

Chairman GOODLATTE. I've seen drugs that have cost 50 times, after they get this exclusivity, what it costs on the—you're talking about some things that cost \$2, \$3 for a prescription, and suddenly they become several hundred dollars or even a thousand dollars for a little tube of some kind of a skin ointment or a gout drug.

Dr. GOTTLIEB. Right. I would simply say, if we want to go down the path of unwinding FDA's current policy, we need to accept that

the unapproved drugs will stay unapproved in perpetuity. And if Congress is comfortable with that, we can contemplate that. But I will tell you, I have been at the FDA when we've been vigorously criticized for not bringing the unapproved drugs through the approval process.

Chairman GOODLATTE. Surely, there must be other sources of information about the lack of safety. If the issue is, well, the drug doesn't really work, you know, obviously, if it's been around for 100 years and people still want to buy it, I'm not sure we should be too concerned about it.

Safety, that's a different concern. But if the mechanism is to let somebody buy into exclusivity as opposed to doing some independent research through universities or something to find out that the drug truly is harmful, or based upon medical testimony or medical history with the use of the drug, that's a different situation to me.

Dr. GOTTLIEB. We focus in situations where there are safety questions, and that's where we tend to focus our resources. The one that I remember was, I believe, pancreatic enzymes, which are used by patients with cystic fibrosis, there was a lot of variability in how those drugs were being formulated that had clinical implications, and the CF community wanted FDA to exert more oversight over the safety and efficacy of those products.

There are situations where these unapproved drugs on the market do present certain questions of safety and effectiveness, and that's where FDA has tended to focus its attention.

Chairman GOODLATTE. Let me ask one more question, if I may. I know I'm over the time.

But if the company that comes in and does these tests for you and gets the exclusivity, if there's no difference between their drug and the drugs that you're taking off the market based upon the formulation of it, why, what would be in the best interest to do that? Just to get the work done to prove the safety and the efficacy of the one?

Because to me, if that's the case, there ought to be some limitation, some control. And is this authority based upon the law or is the authority based upon FDA regulations.

Dr. GOTTLIEB. The application of this authority is based on what we have been told to do by Congress in the past. Congress has raised questions around the—

Chairman GOODLATTE. With the statutory language.

Dr. GOTTLIEB. Well, the way Hatch-Waxman is written, this is how the statute should be exercised. Congress has told us they have concerns around the DESI drugs, the unapproved drugs. And I realize when we then take action to move these drugs into the approved column and prices go up in certain anecdotal cases, that raises concerns as well. So I'm sympathetic to it.

Chairman GOODLATTE. Look, I would expect they would go up something so that the company can recover the cost of doing that.

Dr. GOTTLIEB. Exactly.

Chairman GOODLATTE. But a hundred times?

Dr. GOTTLIEB. Well, that's a separate question, whether it's being priced to value.

Chairman GOODLATTE. Yeah, but it all comes together, right? I mean, if you're the consumer who has been relying upon a drug that your doctor has told you that you should take, and then it suddenly costs a hundred times as much money—

Dr. GOTTLIEB. I fully understand your concerns, Congressman. Fully understand them.

Chairman GOODLATTE. Thank you, Mr. Chairman.

Mr. MARINO. The Chair now recognizes the Ranking Member of the full Committee, the full Judiciary Committee, Mr. CONYERS.

Mr. CONYERS. Thank you, Mr. Chairman.

This is a tremendously important subject. Let me ask Director Meier of the bureau about Professor Lietzan's testimony, which characterizes requiring access to drug samples as "a duty to deal," which "may undermine incentives for investment and innovation." What do you think of that characterization of providing drug samples as a duty to deal, sir?

Mr. MEIER. So the antitrust issue is not whether a brand has a duty to deal. Actually, the antitrust issue is the conditions under which a brand's refusal to deal—it's refusal to deal—results in the creation or maintenance of monopoly power.

And this is a longstanding concept in the law. It goes all the way back to a 1919 case involving Colgate in which the Supreme Court said, yeah, parties do not have an obligation to deal with each other, but there may be certain circumstances in which that refusal to deal creates the purpose—has the purpose or the action of creating or maintaining a monopoly, and that's illegal.

And that case law has continued to develop all the way through the present with a case that is often cited actually by the defense bar in these issues, the Trinko case, where Justice Scalia said under certain circumstances a refusal to cooperate with rivals can constitute anticompetitive conduct and violate Section 2.

As this Committee knows, when you have—take an action where you provide no samples to the generic, it means there's going to be no generic filings with the FDA, there's going to be no generics, and there's going to be no competition, and that could go on literally forever. Even when all the patents have expired, a company could continue to refuse to provide samples and there could still be a monopoly that simply wasn't what Congress intended.

Mr. CONYERS. How prevalent a problem is this?

Mr. MEIER. Well, there are different views, and the difficulty is, I don't have any means to get perfect insight into it. On the one hand, you have the generic pharmaceutical industry and the study that was done by Matrix economics company, by a person, an economist named Alex Brill, that says it costs consumers \$5.4 billion a year. On the other hand, you have Professor Lietzan suggesting that perhaps it really only involves 20, 22 drugs, something like that.

My suspicion or my intuition is that it's probably somewhere in between those numbers. But I think some of these drugs are very significant and these prices compete very, very significant. And even if it's only a few drugs, it could be a very, very significant problem.

Moreover, if companies understand that they can get away with this, the expectation is not just what the problem is today, but

what might the problem be tomorrow and further into the future as companies recognize that they can adopt this same strategy and apply it to drug products that currently aren't even subject to these restricted distribution systems.

Mr. CONYERS. What can we up here approach—how do we approach this in a sensible way?

Mr. MEIER. So as we put forward in our testimony, we believe that the CREATES Act—that the FTC supports the goals of the CREATES Act and that the CREATES Act goes a very far way to readjust the incentives to address this problem.

Mr. CONYERS. You do? What does that mean?

Mr. MEIER. Well, one of the problems right now is if a brand company refuses to provide the samples, it basically can just sit back and run out the clock and let it just continue.

What the CREATES Act does, as I understand it, is it readjusts those incentives so that it provides greater incentives for the branded company to actually engage in a negotiation and engage in bargaining with the generic to ultimately provide them with samples. And if the bargain doesn't work, it gives the generic companies additional rights to pursue—that they could possibly pursue through litigation.

Mr. CONYERS. So when you combine CREATES with the antitrust laws, you may get an effective strategy. Do you think that's right?

Mr. MEIER. I think that's a fair statement.

Mr. CONYERS. Now, I think you've noted that there are several ways that branded firms can use programs strategically to delay generic entry. And at least some of these methods will be difficult to reach effectively under antitrust laws. Is that a fair assessment?

Mr. MEIER. That's a fair statement also. Antitrust law doesn't necessarily break down every possible barrier to entry and barrier to competition. We are limited, as I said during the prepared remarks, to bringing cases that fit within one of these three broad categories of antitrust violation.

Mr. CONYERS. So what ought we do?

Mr. MEIER. I think, as I've said before, I think the CREATES Act goes a long way to trying to resolve some of these issues.

Mr. CONYERS. Now, last question, about vertical agreements. Could this be a violation of the Sherman Act?

Mr. MEIER. Yes. It can be under certain circumstances.

Mr. CONYERS. So how do we approach that?

Mr. MEIER. As the Congress or as an antitrust enforcer?

Mr. CONYERS. Well, we're not antitrust enforcers, although we oversee that because it's the law. But, you know, in our congressional capacity here with our Chairman and the rest of my colleagues, how do we deal with this Sherman Act challenge?

Mr. MEIER. So if you are talking about the specific challenge of how do you deal with vertical agreements under the antitrust laws, it is my view, and speaking for myself, that we have adequate means under the antitrust laws as currently written to address ourselves to vertical agreements. That might be anticompetitive.

Mr. CONYERS. Okay. This is a good start.

Thank you, sir, very much.

Mr. MEIER. Thank you.

Mr. CONYERS. Thank you, Mr. Chairman.

Mr. MARINO. If you want to continue when we come back, you are very welcome to do that. They have called votes. We have about 20 minutes or 25 minutes we are going to be delayed. But we stand in recess, and we will return as quickly as possible.

[Recess.]

Mr. MARINO. The hearing will begin. Sorry for the delay. The Chair now recognizes the gentleman from Georgia, Mr. Hank Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman, and thank the witnesses for their appearance today.

I have heard reports that a significant portion of the patients either skip, delay, or reduce doses of prescription medication because of high drug prices. What is the FDA doing to address soaring drug prices? And do you believe that the FDA has adequate statutory authority to meaningfully address drug price increases, Dr. Gottlieb.

Dr. GOTTLIEB. Thanks for the question. I share your concerns when patients forego necessary doses because they can't afford their drugs. That is a concern of ours. It falls squarely on our public health mandate to worry about issues of access to needed medications.

With respect to your question about do we have adequate authority, I would answer by saying I think we have untapped authority. I think there are things we could do within the scope of our current authorities to try to provide for more competition in the marketplace consistent with what Congress intended when it passed Hatch-Waxman. So, for example, we are looking at places we can make our generic drug approval process more efficient without sacrificing on the safety and effectiveness that people depend on. With respect to that, the standard that we maintain the markets so that people can't come into the market, buy—for example, buy off low-volume generics that might be used infrequently, raise the price substantially knowing that it might take us an average of 42 months, which was the old standard, to get a subsequent generic drug approved in that category.

So they are taking advantage of what I have called a regulatory arbitrage knowing that they could raise prices. And even if competition comes into the market, it is going to take us a long time to approve that. So we have committed to reviewing generic applications in eight to ten months for high-quality applications going forward.

I think there is a number of places like this where we could address issues of access which would give people more low-cost options. Clearly, another one is the topic of today's hearing, which is places where the generic companies can't get access to the samples they need where the branded companies might be gaining certain rules to deny them the access that the bio—the sample they need to do their bioequivalent studies.

Mr. JOHNSON. Well, with the authority that can be expanded that would enable drug pricing to be more competitive, do you believe that the FDA needs additional resources to address that challenge, or are the resources that you are getting now and what is projected for you to get according to the Trump budget plan—

Dr. GOTTLIEB. Well, we could always do more with more, Congressman. And the generic drug approval group that offers generic drugs in particular has a very heavy burden and a very heavy workload. And we are not at the point we are at steady state with respect to generic applications where we will—we will always have a certain cohort in-house that are being worked. But we are continuing to build that number. So we are not—we are not getting out generic applications at the same pace we are getting them in. We will get there shortly, I believe. But it is a very—it is a challenging dynamic, because the market is continuing to expand, we are getting more applications. And so that group works very hard.

I wouldn't say that we—there is not an opportunity to look at new authorities that could address some—

Mr. JOHNSON. No. No. I am speaking of resources.

Dr. GOTTLIEB. Resources.

No. I was—when I was addressing resources, we also researched about authorities. But we can always do more with more, Congressman. There is no question that there—

Mr. JOHNSON. Do you need more to do your job more effectively?

Dr. GOTTLIEB. I feel confident that we are going to meet our goals with the resources we have if the user fees are passed in a timely fashion by the deadline.

Mr. JOHNSON. I understand. You don't really want to delve into that issue—

Dr. GOTTLIEB. Fair enough.

Mr. JOHNSON [continuing]. Forthrightly. But let me turn to Mr. Meier.

And—some have suggested that there is no need for legislation to address reverse settlements, also known as pay-for-delay agreements, in light of the Supreme Court's holding in *FTC versus Actavis*, that these agreements, "have significant adverse effects on competition."

Do you agree?

Mr. MEIER. What I would say is we have made a great deal of progress, and it is not just the FTC. There are private cases. There are cases brought by States' attorneys general. And I have lost the exact count, but there may be more than 20 cases going on right now across the country. And I do think, based on evidence we have seen, that pharmaceutical companies have pulled back on how frequently they are doing these and to what degree and how long the delay is.

You know, the Commission itself hasn't taken a position on any specific legislation. But, again, I think if there -- if somebody's got a legislative proposal and thinks that they can address the problem more rapidly and better than what we are able to do through law enforcement, I am sure that we would be happy to help in any way that we can to provide any technical assistance that we could.

Mr. JOHNSON. Thank you.

I yield back.

Mr. MARINO. The Chair recognizes the Congressman from Florida, Mr. Gaetz.

Mr. GAETZ. I thank for the Chairman, and I am grateful for the hearing.

Currently, the Federal Government maintains a patent on Cannabis. And for those that may find that surprising, it is Patent No. 6,630,507. And I also believe that the Federal Government, through its various appendages, has engaged in anticompetitive practices as it relates to Cannabis. And so I am grateful for the Chairman calling a hearing, having the FDA here.

Dr. Gottlieb, marijuana is a schedule 1 drug, right?

Dr. GOTTLIEB. Yes, that is right, Congressman.

Mr. GAETZ. And for those watching, a schedule 1 drug means that the Federal Government has taken the position that marijuana has no medical use. Is that right?

Dr. GOTTLIEB. It has not demonstrated to be safe and effective for clinical use. That is right, Congressman.

Mr. GAETZ. And so as we look schedule 1 in some context with the schedules of other drugs, hydrocodone is a schedule 2, right?

Dr. GOTTLIEB. I believe so, Congressman.

Mr. GAETZ. And raw opium is a schedule 2, right?

Dr. GOTTLIEB. I believe it has certain clinical applications. That is right.

Mr. GAETZ. And powdered opium is a schedule 2, right?

Dr. GOTTLIEB. You probably have a list.

I believe that is correct, yes.

Mr. GAETZ. And fentanyl is a schedule 2, right?

Dr. GOTTLIEB. That is correct.

Mr. GAETZ. And methamphetamine is a schedule 2, right?

Dr. GOTTLIEB. That is correct.

Mr. GAETZ. And even cocaine is a schedule 2, right?

Dr. GOTTLIEB. It has certain clinical uses. Yes, Congressman.

Mr. GAETZ. And so when assessing whether or not it has—a drug has these acceptable medical uses, there is a five-part test that assesses the merits. Is one of the elements of that test that there must be adequate safety studies demonstrating appropriate medical use?

Dr. GOTTLIEB. I believe so. I am not intimately familiar with the five-part test. I know what you are referring to. I believe it is.

Mr. GAETZ. And so in order to meet that test and demonstrate potential medical use, one would presumably need to do research, right?

Dr. GOTTLIEB. You would need to do clinical studies.

Mr. GAETZ. And how does one do a clinic study on a schedule 1 drug, currently?

Dr. GOTTLIEB. It is currently the ability to study marijuana. And there is a number of INDs. There is probably a few dozen INDs in-house right now studying either the ingredient itself or an extract from it. And there is an—there is some approved therapies based on the extract from medicinal—from marijuana.

Mr. GAETZ. If the University of Florida in my State wanted to engage in studies regarding the medical use of Cannabis, would that be more or less difficult than if they wanted to study the medical use of cocaine?

Dr. GOTTLIEB. I don't know, Congressman. I would have to get back to you on that and ask the experts at the—my drug center.

Mr. GAETZ. Well, I would very much like to hear that. If anyone in the Federal Government and anyone who works at the FDA is

taking the position that it is not more difficult to study medical application of a schedule 2 drug, like cocaine, than a schedule 1 drug, like marijuana, I would be very eager to see what the basis for that was.

Right now, I have been told by universities in my State that, were they to engage in research on the medical application of marijuana, they could potentially impair over \$100 million dollars in other Federal grants that they receive. Is that something that you are familiar with?

Dr. GOTTLIEB. Congressman, it probably wouldn't fall within our purview if there are issues with getting access to it. It falls outside the scope of our jurisdiction. A lot of that falls within the jurisdiction of DEA.

Mr. GAETZ. Well, as a physician yourself, as an FDA commissioner, do you have an opinion on whether or not marijuana ought to be listed as a schedule 1 drug?

Dr. GOTTLIEB. I haven't reviewed the literature, Congressman. There is no—there is no clinically demonstrated use for marijuana right now. There is no approved use for smoked marijuana. It has not gone through clinical studies to prove safety and effectiveness for any indication.

Mr. GAETZ. Does it seem like a logical tautology that we say we cannot declassify marijuana as a schedule 1 drug because we don't have the clinical studies and its status as a schedule 1 drug impairs further clinical studies?

Dr. GOTTLIEB. Well, look. Congress has the authority to take this up. And I think it has been taken up in some forms in the past and contemplated by Congress.

The clinical studies, as I understand it, and I made the point that there is a number of INDs in-house, some of that is, I believe, for the raw ingredient, which I think is the subject of your question. Some of it is for the extracts of marijuana. So there are clinical studies going on in people who are studying the safety and effectiveness in rigorous trials that could potentially lead to an approved indication if they are successful.

Mr. GAETZ. Yeah. And I know that right now—I believe it is the University of Mississippi that is the only place where they can grow the product in order to do the studies. Are you familiar with that dynamic?

Dr. GOTTLIEB. The issues around access and growing—growing and then access to product to do clinical studies for regulatory purposes falls outside of our direct jurisdiction, Congressman.

Mr. GAETZ. Well, I want to take my remaining few moments to thank Chairman Goodlatte for the public commitment that he made at a recent Judiciary Committee meeting that we are going to study this question of research. I also want to thank the Ranking Member of this Subcommittee for his desire to work on research applications for medical Cannabis. It seems entirely unacceptable to me that we block research that could potentially show us the medical use that would then justify delisting Cannabis.

And I yield back.

Mr. MARINO. The Chair now recognizes the Congressman from California, Congressman Swalwell.

Mr. SWALWELL. Thank you, Chair. And, Chair, the beauty of our democracy is that I sat here for hours yesterday, and I think I disagreed with 100 percent of the things that Mr. Gaetz said yesterday. But today I sit here, and I agree 100 percent with what he just said. So I am glad that he and I, and Mr. Cicilline, and others can work together on what I agree is an important issue.

But I do thank the Chair and the Ranking Member for calling us here to talk about how we can lower drug prices and increase the therapeutic drugs—the therapies and drugs that can get to the market to help people.

I did have some questions. Dr. Gottlieb and Mr. Meier, thank you both for appearing. With respect to REMS, Risk Evaluation and Mitigation Strategies, what is the percentage of REMs on the market with respect to total number of drugs on the market?

Dr. GOTTLIEB. I don't know what—I couldn't tell you what the total is right now. In 2016, there were 115 new drugs or new biologics approved, and nine were approved with REMS. So that gives you sense of the proportion by year. And it has been fairly steady with respect to the number of drugs that are getting approved with REMS. So it is not something that is spiking up.

Mr. SWALWELL. Do you believe that all REMs are created equally? And what I mean is, for example, certain controlled substances like opioids, and fentanyl, and sodium oxybate, which is, you know, commonly referred to as the date rape drug, they are regulated under REMs, but they seem to be quite unique in that they are, to me, at least, in the category of those that you especially want to control and protect. Would you agree with that?

Dr. GOTTLIEB. Yeah, there are some common situations where you see REMS apply drugs that have abuse potential. It can be diverted. Drugs, for example, that have risk of teratogenicity associated with them where you might want to implement certain testing before the application of drugs. So there are some standard categories. If you look to all the drugs that have REMs, you will see some patterns appearance for sure.

Mr. SWALWELL. And, Commissioner, you wrote, on July 6, 2017, in a JAMA network.com article entitled “Marshaling FDA Benefit-Risk Expertise to Address the Current Opioid Abuse Epidemic” that the FDA limits prescribing of sodium oxybate to certified prescribers. In addition, the drug may be dispensed only to enrolled patients by a certified pharmacy and only by a certified pharmacy that shifts drugs directly to patients. Sodium oxybate is not available in retail pharmacies. Then you actually laid out, I think, a good case as to why opioids should also, you know, be controlled and regulated, you know, in that same manner in talking about the opioid crisis.

Do you foresee, as we look at making sure that drugs can get to the market and that, you know, we are not allowing anticompetitive practices to take place, that there is a special category, though, for those types of drugs that have, as I just mentioned, those certain characteristics that you really want to make sure controls are in place?

Dr. GOTTLIEB. That is absolutely true, Congressman. It has been the case that, for certain drugs, historically, certain controls have

been put in place when there are special circumstances where there are very unique risks associated with them.

The thrust of that article was related to an imperative by the FDA to consider the risks associated with the potential illicit use of the drugs and how it looks at risk-benefit balance both pre and post-market as well as the risks associated with the labeled use of the drugs. And we were laying out the basis for why we believe we need to look at the illicit risk as well.

But it is the case, to your underlying point, that there are certain risks associated with drugs where, historically, we have applied REMS, and historic—and we will likely apply them going forward. And a lot of them are well-defined.

Mr. SWALWELL. Right. It sounds like a challenge for us, Mr. Meier. I would be interested in your thoughts, as lawmakers, to make sure that we don't have anticompetitive practices but that we are still doing everything we can to protect the public from, you know, God forbid, a date rape drug being, you know, widely accessible without any restraints or controls.

Mr. MEIER. Well, I think that is precisely right is finding that balance.

Mr. SWALWELL. Thank you, Mr. Chairman.

I yield back.

Mr. MARINO. Thank you. Seeing no other Congress Members on the dais for questioning, this concludes our first panel. I want to thank Dr. Gottlieb. I want to thank Attorney Meier for being here. You were very helpful, and you are excused.

Now we call the second panel to come up and—to the table.

Now that you-all are comfortably seated, I would ask you to stand and raise your right hand to be sworn in.

Do you swear or affirm that the testimony you are about to give before this Committee is the whole truth, nothing but truth, so help you God?

Please be seated.

Let the record reflect that the witnesses have responded in the affirmative.

I am going to read each of your bios, and then we will begin with you then making your 5 minute statements. But I will go through all four bios first.

David Olson is an associate professor at Boston College Law School teaching patents, intellectual property, and antitrust law. Prior to joining Boston College, he worked at Stanford Law School's Center for Internet and Society where he researched in patent law and litigated copyright fair use impact cases.

Before entering academia, Professor Olson practiced as a patent litigator at the law of the Kirkland & Ellis, LLP, and clerked for Judge Jerry Smith of the U.S. Court of Appeals for the Fifth Circuit. He earned his bachelor's degree from the University of Kansas and his JD from Harvard Law School.

Welcome, Professor.

Professor Erika Lietzan is an associate professor of law at the University of Missouri School of Law. Professor Lietzan researches, writes, and teaches primarily in the areas of drug and device regulations, intellectual property, and administrative law. She recently completed a historical and empirical examination of the new drug

research and development paradigm in the United States and the relationship between the length of that process and incentives to innovate.

Prior to teaching, she was in private practice, including eight years as a partner at Covington & Burlington in Washington, D.C. Professor Lietzan was involved in every major amendment to the Federal Food Drug and Cosmetic Act between 1997 and 2014 working as outside counsel and sometimes lobbyist for various individual companies as well as the trade association PhRMA.

She serves in the leadership of the Food and Drug Law Institute and served for many years in the leadership of the Science and Technology section of the American Bar Association. The professor received a bachelor's degree in history from the University of North Carolina where she graduated with honors, her master's degree in history from UCLA, and a law degree with high honors from Duke Law School. Professor, welcome.

Alden Abbott is the Rumpel Senior Legal Fellow and Deputy Director of the Meese Center for legal and judicial studies at the Heritage Foundation. Prior to joining the Heritage Foundation, he served as director of Patent and Antitrust Strategy for BlackBerry and in a variety of senior Government positions, including director of antitrust policy for the Federal Trade Commission, acting general counsel of the Commerce Department, chief counsel for the National Telecommunications and Information Administration, and senior counsel in the Justice Department.

Mr. Abbott is an adjunct professor at the Antonin Scalia Law School at George Mason University and was a visiting fellow at All Souls College, Oxford University, and a Wasserstein Fellow at Harvard Law School. He is also a member of the Leadership of the American Bar Association's Antitrust Section and a Non-Governmental Advisor to the International Competition Network.

Attorney Abbott received his bachelor's degree from the University of Virginia, his master's degree in economics from Georgetown University, and his JD from Harvard Law School. Welcome.

Aaron Kesselheim is an associate professor of medicine at Harvard Medical School and a faculty member in the Division of pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. His research focuses on the effects of intellectual property law and regular policies on pharmaceutical development, the drug approval process, and the cost, availability, and use of prescription drugs both domestically and in resource-poor settings, Jen Center for primary care at Brigham and Women's Hospital.

He is a member of the New York State Bar and is a patent attorney. And within the Division, Dr. Kesselheim leads the program on regulation, therapeutics and law, an interdisciplinary research core focuses on intersections among prescription drugs and medical devices, patent health outcomes, and regulatory practices and the law. And modernizing clinical trials and served as a consultant for the NIH, FDA, Institute of Medicine, USPTO, and numerous state government offices.

He has been a visiting scholar at the Yale School of Medicine and School of Management and the visiting associate professor of law at Yale Law School.

Dr. Kesselheim earned his bachelor's degree from Harvard College, his JD from the University of Pennsylvania Law School, his MD from the University of Pennsylvania School of Medicine, and his MBH from Harvard School of Public Health. Doctor, welcome.

Each of the witness's written statements will be entered into the record in its entirety. I ask that each of you summarize your statements in 5 minutes or less. And to help you, you have lights in front of you. When that light switches from the green to yellow, you have a minute left, and from yellow to red means your time's expired. But as I told the last group, when I sit there, I never look at the lights. So I will diplomatically pick up the gavel, and maybe that will give you an indication to wrap it up.

Now we are going to hear from our distinguished panel. And, Professor, the floor is yours.

**TESTIMONY OF PROFESSOR DAVID S. OLSON, ESQUIRE, ASSOCIATE PROFESSOR OF LAW, BOSTON COLLEGE LAW SCHOOL; PROFESSOR ERIKA LIETZAN, ESQUIRE, ASSOCIATE PROFESSOR OF LAW, UNIVERSITY OF MISSOURI SCHOOL OF LAW; ALDEN ABBOTT, ESQUIRE, DEPUTY DIRECTOR AND SENIOR FELLOW, THE HERITAGE FOUNDATION; AND PROFESSOR AARON KESSELHEIM, M.D., M.P.H., ASSOCIATE PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL**

**TESTIMONY OF PROFESSOR DAVID S. OLSON**

Mr. OLSON. Thank you, Chairman Marino, Ranking Member Cicilline, and members of the Subcommittee. I appreciate the opportunity to testify today. A more detailed version of my remarks is available in the written testimony, as you said.

Let me state from the outset my firm belief that patents are necessary to give adequate incentive to develop new drugs. After patent expiration, however, market competition from generics is the best way to provide patients with lifesaving drugs that they need at the best prices. I believe that the CREATES Act, which is one of the things being considered at this hearing, can be an important step in addressing abuse of FDA regulations.

Forcing brand companies to share samples with generics is necessary, will not undermine incentives to invest in inventing new drugs, and does not violate patent or antitrust policy. Moreover, the narrowly tailored approach of the CREATES Act is superior to antitrust litigation.

I would be pleased to discuss these issues more with the Subcommittee. But I want to focus my oral remarks on the problem abuse of REMs patents and the FDA approval process. In addition to performing bioequivalent studies to support an ANDA, FDAAA—the FDAAA Act requires that generic and brand manufacturers use a single shared REMS system for risk mitigation unless the brand manufacturer's system is either, one, too burdensome or, two, is protected by a patent or a trade secret that the brand company will not license.

The problem that has arisen is that some brand companies have patented their REMs systems, or their REMs, with Elements to Assure Safe Use, ETASU, and then have refused to license generics. This means the generics cannot use that system. But more prob-

lematically, in some cases, the brand companies have then gone on to file citizen petitions arguing that a generic may not use another or comparable version of a REMS with ETASU program that the generic comes up with on its own because no other system would be as safe or effective as the patented ETASU. What this effectively does is keep generics off the market for the entirety of the period of the REMS with ETASU patent if successful.

This has been done—asserted more than once. For example, Celgene took this approach in arguing that generic versions of Thalomid could not be sold. Besides this, brand companies also list REMS patents in the Orange Book notwithstanding the fact that a REMS patent is for a method of—is not for a method of use but, rather, a method of distribution. This could result in extension of the monopoly over a drug for almost 20 more years depending on the data filing of the REMS patent.

It is worth noting that the parameters for a REMS with ETASU system are set forth in the FDAAA of 2007, and specific requirements for ETASU are given in the act. For instance, the FDAA sets out the requirements for ETASU including very simple and straightforward things like only—like educating doctors and hospitals, only allowing doctors and hospitals that have been educated and certified to prescribe the drug, having restricted distribution of the drug, patient testing and information, counseling patients, monitoring patients to make sure the drug is administered safely, and maintaining the database to coordinate all this information. This is set out in the statute.

If you look at REMS with ETASU patents, which I have spent some time doing, what you note is that they track very closely to the statute. For example, claim 1 from Merck's REMS patent for Entereg contains the following steps: Identifying relevant hospitals; providing such hospitals with literature about the drug, wherein the drug is Entereg or a generic; identifying a subpopulation of hospitals which have measures in place to limit use of the drug wherein said measures comprise order sets, protocols, or guidelines; then registering the subpopulation using a computer-readable storage medium, authorizing them to dispense the drug, and monitoring the patients. Very closely track the statute and yet this is being patented.

The problem with this is that not only might this be obvious, but if generics may not use the patented system, they may not be able to safely distribute the drugs and may be kept off the market. There is no solution to this problem under the status quo.

The CREATES Act does provide a narrowly tailored and appropriate solution. By requiring branded and generic drugs to—companies to enter into a shared single REMS system within 120 days of a request, this forces them to share unless a comparable system can be approved by the Secretary. The beauty of this is that what it will do—this approach will do is it will stop REMS companies from abusing REMS patents if they argue that there is no ability to distribute the drug except through the REMS process. Then what the statute does force them to do is to share their process.

And I would just wrap up by saying that that forced sharing is neither a violation of patent policy nor of antitrust law. And I

would be happy to speak more to that in the question and answer. Thank you.

*Mr. Olson's written statement is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-OlsonD-20170727.pdf>*

Mr. MARINO. Thank you, Professor. Professor Lietzan.

#### **TESTIMONY OF PROFESSOR ERIKA LIETZAN, ESQUIRE**

Ms. LIETZAN. Chairman Marino, Ranking Member Cicilline, and members of the Subcommittee, thank you for this opportunity to speak with you today.

I was asked to talk about three aspects of the FDA framework that are the focus of complaints that brand companies are acting improperly and may be violating antitrust law.

The first is FDA's citizen petition process which furthers the open Government principles of transparency, public access, and accountability. Anyone may petition FDA to take any administrative action, and the petition and any comments on it are public documents. Petitions play an important role in our political system. The public has a strong interest in ensuring that executive branch agencies work within the constraints of the laws that Congress writes, and a robust petitioning practice adds a layer of surveillance to complement the oversight function of the legislative branch and the review function of the judicial branch.

You have been told that brand companies file frivolous petitions that delay generic drug approval. These claims rest on anecdotes and a rhetoric, not evidence. Congress passed a law in 2007 stating that FDA may not delay approval of a generic drug due to a petition, unless necessary, to protect the public health. Since then, FDA reports only five generic drugs have been delayed without public health justification out of more than 4,000 copies approved.

A high denial rate is not proof that petitions are frivolous. Drug approval decisions can require difficult judgment calls about appropriate regulatory policy in the face of scientific uncertainty and about the flexibility of the law to accommodate new facts. Differences in opinion and perspective are natural. A valid petition may simply lack persuasiveness at the end of the day.

Congress has also been told that innovative companies use REMS restrictions to block generic drug approval. To the best of my knowledge, though, innovators refuse to provide samples primarily because they have concerns that requesting companies lack adequate safeguards to address the risks presented by these drugs. And these concerns are reasonable.

Access restrictions are usually imposed to mitigate severe side effects, like birth defects or irreversible organ damage. And even minor lapses in safety protocols by any party at any point can have horrific consequences.

If Congress wants to encourage innovators to provide samples, it should protect them from liability arising out of the actions of the third party once a restricted drug has left the innovator's special access system. We should not force innovators to provide their products to generic companies. If a drug is under patent, this would require the company to practice its patent for the benefit of

a competitor. It is a bedrock principle of U.S. law that a patent owner has no duty to practice its patent at all.

We lack evidence of a systemic problem that would justify such a fundamental change to the intellectual property system. Only 22 brand drugs have access restrictions and no generic application. And more than half of those are so new that FDA statute doesn't allow approval of a generic or by a similar anyway. It is not clear how many, if any, lack generic competition because an innovator didn't share its drug.

Finally, there are concerns when the price jumps on a drug that has been inexpensive for years. Sometimes this results from FDA's unapproved drugs initiatives. And it is important to understand why this happens. Several thousand drug products are marketed without the required FDA approval.

Many have been used for half a century or longer, and some are even covered by insurance. Some are not safe. Others are not effective, which is a problem because it keeps patients from drugs that do work.

FDA focuses its enforcement efforts on the companies that sell these drugs which present a public health concern. FDA can't force the other companies to file applications. They would have to threaten enforcement action. And enforcement action threats are effective only if backed up. This would require resources that FDA doesn't have. It would also take medicines away from patients.

So after approving an application, FDA removes the competing products from the market. This ensures that patients receive the specific product that was studied, and it preserves the integrity of the approval system. It also encourages applications.

Usually generics can be approved three years later. But in the meantime, the company that submitted the application can recover its costs. This company hasn't done anything wrong. In fact, it is the one company that chose to comply with the law to bring an illegally marked product into the FDA system, but the system has taken away a cheap medicine from patients. Clearly we need a better solution that maintains the integrity of the drug-approval scheme but doesn't deprive patients of drugs they rely on.

In sum, regulated industries, consumers, and other stakeholders share responsibility with FDA for the public health mission enshrined in the statute. When the rhetoric and anecdote are laid aside, the evidence suggests that regulated entities generally operate in good faith within this framework. And when companies protect their property rights, participate in open Government, or protect themselves from unfair liability exposure, it would be a mistake to take action against them. Instead we should look for ways to support FDA in its public health mission and to encourage private choices that we prefer as a public policy matter. Thank you.

*Ms. Lietzan's written statement is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-LietzanE-20170727.pdf>*

Mr. MARINO. Thank you, Professor. Attorney Abbott.

**TESTIMONY OF ALDEN ABBOTT, ESQUIRE**

Mr. ABBOTT. Chairman Marino, Ranking Member Cicilline, and distinguished members of the Subcommittee, I applaud you for convening this hearing on a very important public policy matter.

The views I express today are my own and should not necessarily be construed as representing any official position of the Heritage Foundation.

Today I will briefly note the interplay between regulation of the competitive process before commenting specifically on the potential abuse of FDA citizen petitions. And I will summarize my views on a CREATES Act of 2017.

Extensive economic research demonstrates that regulated entities may manipulate regulatory process to undermine competition. Such regulatory manipulation is harmful to the American economy. It often defers entry into a market and thus precludes competition on the merits thereby raising prices above competitive levels, reducing product quality spawning economic inefficiency and deterring innovation which is a key driver of economic growth.

As a general matter, in order to maximize economic welfare, Federal regulators should seek to devise rules that are as procompetitive and adds little subject to an anticompetitive manipulation by private parties as possible consistent with statutorily set goals.

And I am not commenting specifically on FDA rules, but I think the FDA certainly should and probably will go about doing that. There are principles of guidance provided by organizations such as the OECD/International Competition Network in which I am involved. And there is also general guidance available from competition economists, for example, at the Federal Trade Commission and Justice Department, who actually, in the past, in the 1970s, provided a very important role in promoting regulatory reform and transportation, in aviation.

Now, one particular sort of regulatory manipulation that undermines competition is a taking of actions by an incumbent firm to forestall entry into the market by a potential competitor. References have been made to potential abuse of FDA citizen petitions to delay entry from producers of generic versions of branded drugs. Our current regulations require the FDA review and respond to every citizen petition receives creating the potential of delay.

Now, claims have been made that citizen petitions have been filed to undermine competitive generic entry into certain pharmaceutical matters. Those concerns have been noted by the FDA, for example, in a 2015 report. And most recently, in February 2017, the Federal Trade Commission filed a complaint in Federal District Court alleging that Shire ViroPharma, a branded pharmaceutical company, engaged in a series of meritless filings, including 24 FDA citizen petitions to delay generic entry into a particular market.

Now, clearly, baseless FDA filings made by brand name Pharma firms lacking any plausible efficiency justification used solely to forestall competition undermine the competitive process. FDA and Congress certainly should consider what, if any, additional legislative or regulatory steps may be appropriate to curb such abusive filings including, but not necessarily limited to, reform of citizen petition process.

Now, the Federal Trade Commission's suit against Shire ViroPharma appears to advance sound policy. I would note, however, a slight bit of caution. Although antitrust actions occurred clearly pretextual petitioning, at a potential to reduce harmful regulatory delays, such cases need to be selected with great care by public officials. I believe the Federal Trade Commission certainly appears to have done that in this case. But certainly, you want to be careful. And the Supreme Court in its case law is sort of cavalier to bringing suits of that kind.

Now, the CREATES Act of 2007 is a modified, and I believe, an improved version of its 2016 CREATES Act on which I testified favorably before Senate Judiciary. Now, the 2017 act gives the FDA more discretion than 2016 act to approve alternative safety protocols for high-risk drugs rather than require parties to develop shared safety protocols, and it does away with a concern of alleged free riding on safety protocols developed by the branded company.

Now, that 2017 act also creates a statutory gap. I explain in my testimony, as I did my testimony last year, there are real limitations in the application of the antitrust laws to cases of regulatory violations and refusals to supply. Not that it is necessarily impossible, but these cases are very hard to bring. And because of that, I think the CREATES Act is appropriate and narrowly tailored to fill a niche that antitrust may not really be able to address appropriately.

Thank you once again. I look forward to your questions.

Mr. MARINO. Thank you, Attorney Abbott. Dr. Kesselheim.

*Mr. Abbott's written statement is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-AbbottA-20170727.pdf>*

Dr. KESSELHEIM. Chairman Marino, Ranking Member Cicilline, and other members of the Subcommittee, thank you for this opportunity to join you today.

The reason today's hearing is so important is that low-cost generics and biosimilars improve patient adherence and clinical outcomes. And generics have led to trillion dollars in healthcare system savings over the last decade. However, too often branding manufactures work to delay the availability of generics using different business strategies. I am going to mention, briefly, five.

First, most drugs have patents covering their active ingredients, but manufacturers will seek secondary patents on peripheral features such as the drug's metabolite or method of administration. Generic manufacturers then have to design around these patents or challenge their validity in court. One classic example with the anti-ulcer medication, Prilosec, which was protected for additional years by a patent on the pill's coating.

In one study I led, we found that Medicaid alone could have saved \$600 million on this single drug had a low-cost generic been available before this delay. In another study of two HIV drugs, we found nearly 200 such secondary patent claims threatening to delay generic availability for 12 years.

Another strategy aided by these secondary patents is product hopping in which manufacturers switch to different products, sometimes trivially different, pulling their old generic—their old product

off the market to stay one step ahead of generic manufacturers. For one antibiotic drug, the manufacturer switched first from a capsule to a tablet, then to a slightly different dose, then to a tablet with a single score, and finally to be tablet with two scores.

Problematic patents may be challenged in court. But a third delaying strategy is for branding manufacturers to make substantial payments to generics to end these cases in so-called pay-for-delay settlements.

The FTC estimated in 2010 that such settlements would cost Americans \$3.5 billion annually extra over the subsequent decade. An analysis revealed that, when these cases were litigated to completion, two-thirds of the cases related to secondary patents. And in those cases, generics were victorious. Pay-for-delay settlements are naturally much more likely to cover challenges over secondary patents.

A fourth strategy involves preventing generic manufacturers from getting samples or other key information that they need for FDA approval. And we have talked about that a lot today already. To help the HIV drug Daraprim sustain its 5000 percent price increase, the manufacturer restricted the distribution through a single specialty pharmacy in part so the generics couldn't get it.

The FDA has received about 150 inquiries from generic manufacturers regarding inability to secure samples. For drugs protected by special REMS-prescribing restrictions, generic manufacturers need to be able to use the same system for their interchangeable drugs. But branding manufacturers have delayed generic entry by refusing to share information about their REMS or getting secondary patents covering their REMS processes.

Finally, as Mr. Abbott explained, manufacturers use citizen petition requests to the FDA to delay generic drug entry. One review of 5 years of petitions found that 87 percent of these petitions were filed by manufacturers of brand-name drugs, and 92 percent were ultimately denied.

Relying on FDC antitrust enforcement is not sufficient to stop these tactics. Patients need Congress to step in. A first step would be to pass the CREATES Act which provides a process for requiring manufacturers to provide key drug samples and to prevent some REMS abuses. But this Committee should also consider other potential reforms. I am going to mention four, and I have other suggestions in my written comments.

First, to prevent improper secondary patents from delaying generic entry, Congress should require formal patent review when these patents are listed with the FDA. Many secondary patents would not pass such scrutiny and could be weeded out before lengthy litigation is required.

Second, the Committee should consider additional mechanism to address problematic pay-for-delay settlements that continue to this day even after the FTC versus Actavis case. Including preventing settlements with transfers of value for delayed entry over the cost of the litigation or increasing the penalties for settlements found to be anticompetitive, such as full disclosure of profits or treble damages.

Third, all terms of REMS should be public information, and REMS patents should not be able to be listed with the FDA. Ulti-

mately, I believe we should move to a system in which it is the FDA with sufficient resources that controls and manages the REMS as a public good, because it will increase efficiency for patients if brand names and their interchangeable generics are all part of the same REMS.

To address the misuse of citizen petitions, the Committee could also expand the opportunities for the FDA to summarily reject petitions without requiring an in-depth review.

Manufacturers of brand-name drugs use many strategies to delay generic entry, of which I have only highlighted some of them today. That is bad for patients, bad for the economy, and it reduces innovation. One study found that it was the ending of market exclusivity periods in contrast to their indefinite extension that was most associated with the introduction of new branding products.

The CREATES Act is a laudable first step in helping address some of these strategies, but other policy reforms are also needed. I appreciate the Committee's commitment to solving these issues and would be happy to continue to be involved in the deliberative process.

*Mr. Kesselheim's written statement is available at the Committee and on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-Wstate-KesselheimA-20170727.pdf>*

Mr. MARINO. Thank you, Doctor. We will now begin with questioning. There will be other members that may come in and out.

I am going to start off with a question for each, you if you care to answer it. I will start with Professor Olson and work our way down to Dr. Kesselheim, and then I have another question that I would like each of you to respond to, if you care to. Then I would start with Dr. Kesselheim. Okay.

Concerns have been raised that the approval of a generic alternative REMS distribution system will inevitably lead to patent infringement systems. Given the likely overlap with the branded manufacturers original distribution system, do you anticipate this being a problem? And I have been a critic of bringing—wanting to so much bring the Patent and Copyright Office into the 21st Century.

So Professor Olson.

Mr. OLSON. Yes, Mr. Chairman. I do think that the way that patents are written, the fact that they have to track the statute very closely, means that it will be very easy to bring infringement suits. Even if the patent is found invalid or the suit is not successful, this listing them in the Orange Book and the litigation can significantly delay generic entrance.

Furthermore, there is no additional incentive that is given by granting REMS patents that is needed, because there is already an incentive to create the REMS in ETASU systems because you don't get to market your drug unless you create it. They are a tiny fraction of a cost of drug development. And so by forcing sharing, or at stopping companies from arguing that if generics don't share they may not market the drug, we are not going to be losing anything. We are not going to lose any benefit.

Mr. MARINO. Professor.

Ms. LIETZAN. Well, first of all, I disagree with Professor Olson that there isn't much difference between the statutory language and the REMS patents the statute describes in very general terms the type of access restrictions that are permitted. And anyone who has ever worked on designing a risk management plan or negotiating a REMS with FDA can tell you that there are many ways to mitigate a risk. And the REMS themselves are very detailed, and there are a lot of decision points along the way.

I think the question that matters is whether it is possible to mitigate a particular risk more than one way. And that is a clinical question and a regulatory question. It has to be answered case-by-case. But having worked on REMS issues for companies, my instinct is, yes, there is—there is absolutely more than one way to design a system.

Mr. MARINO. Thank you.

Attorney Abbott, do you care to comment?

Mr. ABBOTT. Well, it is certainly possible, Mr. Chairman, as I mentioned, the possibility of designing around a patent. That may be tricky. There is certainly a possibility of infringement lawsuits. It could also, perhaps, be dealt with legislative. And if Congress wanted to, could make it clear that any actions taken to develop sort of a REMS system by potential entrant, is not going to constitute patent infringement, I am just not saying good it is a good idea or not, but there may be ways to have very, very narrow modifications to try and forestall the problem of opportunistic patent litigation here. You have to be very careful, you know, and maintain appropriate incentives to innovate.

But I think, as Professor Olson mentioned, they probably already are given the need to meet FDA regulatory requirements to develop these systems. But I am not an expert in this area, but that is just my initial reaction.

Mr. MARINO. Doctor.

Dr. KESSELHEIM. I think that here we should be thinking about what is best for the patient. And to me the best thing for our patients is to have a single REMS system, because, again, these are otherwise interchangeable drugs. It doesn't make any sense if you are a clinician or a patient to be enrolling people in different REMS for otherwise interchangeable drugs based on a manufacturer that you may not know.

And so I think that ultimately we should be trying to develop a system where shared REMS are able to be done and are able to be established in an efficient way. And I think that we can do that by, for example, creating royalty free licenses for patented REMS so that generic manufacturers can use them or other mechanisms to try to encourage the development of shared REMS for patients' benefits.

Mr. MARINO. I am going to play a little devil's advocate with myself here, and I would like to hear what you folks have to say about it. And we will start with you, Dr. Kesselheim.

I am very familiar with, because I have a very dear friend who is now retired from his 90s, who was a researcher, Ph.D., and come working in with drug companies, which I won't mention. And I saw, and he has explained to me over the years, the time, the labor, the expense that goes into developing a drug.

How do we—or should be even think about that concept of the profit or not meeting the profit to make sure that companies still are in the research aspect of creating life-saving drugs.

Do you understand my question?

Dr. KESSELHEIM. Sure. So, I mean, I—obviously I think it is very important for there to be a period of time when companies can make back the investment that they had in their product and make a profit on that. But at some point that period has to end. And currently, manufacturers on average get about 12 to 16 years of market exclusivity.

How much longer—how much more market exclusively is necessary? I mean, you know, manufacturers—pharmaceutical manufacturers currently make about 22 percent profit margins as compared to 7 percent profit margins for the rest of the Fortune 500, you know.

And so—I mean, I think that it is—it is important both for there to be a fair return on investment but then at some point for that to end and for a competitive market to be in so that patients can get the benefit of lower-cost generic products.

And I don't think what we are talking about here has any, necessarily, bearing on the questions of innovation. We are talking about getting timely access to generic products after an extended period of market exclusivity that already exists.

Mr. MARINO. Thank you.

Attorney Abbott.

Mr. ABBOTT. I think, yes, one may agree or disagree about the appropriate length of exclusivity. I think once the exclusivity period is over, whatever decision you make, you want to get the competitive products to the market as quickly as possible.

I will just note very briefly. It is beyond the scope of this hearing, but it is very important. One issue that American pharma firms face that is very serious is a single purchaser. Many foreign countries are sort of monopsony purchasers of American pharmaceuticals. And they say if you want to enter our market, you know, we are going to dictate these price terms.

So, unfortunately, the American consumer has sort of been losing because of that. In the cross subsidization, American consumers and the American economy has paid more for drugs than foreign countries. But often that is an artifact of the foreign systems. And I don't know if you can talk about international agreements or something to deal with it. But it is part of the bigger again that is beyond the scope of this hearing.

Mr. MARINO. Thank you.

Professor Lietzan.

Ms. LIETZAN. Yes. Thank you. This is actually an area in which I have done a fair amount of research recently.

You are right about the cost. In addition, there is a high degree of risk. There are a lot of products that are—compounds that look promising at the beginning and fail through the long process. It is expensive and risky. And a company that does this research has to recover not only the cost of researching the drug that actually got approved but the cost of starting to research, starting the process with the drugs that failed.

So I have serious concerns about the adequacy of our incentives right now. And I am particularly concerned about the products that take a really long time—products, for example, that might prevent Alzheimer's, things that—things for which we may need to do trials that exceed 10 or 15a years.

Dr. Kesselheim is right about the average market exclusivity data. But I think recent economic data suggests suggestion the break-even point for new molecular entities is somewhere in that 12- to 16-year range. And innovators and other industries benefit from 17 to 20 years of patent life. And if you compare that with 12 to 14 for the drugs that we desperately need, that leaves me concerned.

Thank you.

Mr. MARINO. Thank you.

Professor Olson.

Mr. OLSON. I echo the comments of Dr. Kesselheim. And just to add one thing to that. Professor Lietzan's right, of course, that the risk is very high. But the profit margin overall tells you that you are getting high risk and a pretty high reward. That takes into account all the failures.

The other thing I would just add is that in my proud city of Boston, we have many biological biotech companies. Some of them are taking 20 or 30 years to get a pathway to a drug. And yet we have this amazing ecosystem that supports that.

The system has worked without needing extension. When we grant extensions of exclusivity or if we can end the granting of some of these extensions of exclusivity, the drug companies will also stop focusing on trying to extend and move back to focus on R&D. And that is where we want them to focus once their drug has been patented.

Mr. MARINO. Thank you.

The Chair now recognizes Congressman Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman.

Professor Lietzan, in your written testimony you state that requiring branded drug companies to provide drug samples to generic drug competitors is a duty to deal that will undermine innovation.

How would requiring samples to all patent drugs or drugs nearing the ending of their patent exclusivity harm innovation?

Ms. LIETZAN. So I do believe that requiring the sale of a product ultimately requires—if it is a patented product, it requires the company to manufacture enough of the product to satisfy all of the generic applicants, all the biosimilar applicants that wanted that. And if a product is under patent, that requires the company to practice its patent for the benefit of one of its competitors. That is contrary to bedrock principles of U.S. patent law right now and in and of itself will devalue the patent, which, to me, is concerning because decades of research show that robust patent protection is essential for pharmaceutical innovation.

Mr. JOHNSON. All right.

And, Mr. Abbott, do you agree with Professor Lietzan's characterization that providing drug samples is a duty to deal? Do you agree with that?

Mr. ABBOTT. Well, Congressman, I think one has to look at this duty as a general matter, non-regulated contacts. There isn't nor-

mally a duty to deal here. The problem is that, in order to enter the market, you need to get hold of these samples.

So, yes, you are, in some sense, constraining potentially intellectual property right. But it may be near the end of the patent life, and it is sort of necessary to be able to entry—to enter. And if it is necessary to be able to enter, that is, you know, one of the trade-offs.

I think that—so I—that would be my response.

Mr. JOHNSON. Dr. Kesselheim, as a practicing doctor, are you concerned that requiring access to branded drug samples would undermine—

Dr. KESSELHEIM. No, I'm not. I mean, I feel like the statute is well constructed to try to prevent any risk of patient safety.

But, again, these samples are not being collected to then be distributed to patients. They are being collected to be put into laboratory and other clinical testing that is necessary to demonstrate to the FDA that the drug is bioequivalent and therefore the generic drug and be approved.

I don't really see the risk that, for example, a drug that is used in elderly patients with a type of cancer called multiple myeloma, but also, unfortunately, has a birth defect risk, because it's being transmitted to a generic for the purpose of conducting clinical testing so that the generic can get on the market, would somehow end up in the hands of patients for whom it would cause risk.

I don't see that as a reasonable safety risk. And I do think that to the extent that there are weird ways that we could think of that that might exist, the statute does a good job of trying to prevent that from happening by forcing the company to develop a plan and register that with the FDA.

Mr. JOHNSON. Professor Lietzan, I feel compelled to offer you the opportunity to respond.

Ms. LIETZAN. Yes. So these drugs are—they present very serious risks to patients, and some of them are toxic. And many times the generic companies that request samples have no experience with drugs of this sort. Some of sophisticated, but some do not.

And I think that the concern has always been that if anybody in the process of conducting, especially when you get to the clinical trials, if there's any sort of lapse by anybody, the contract—the clinical research organization, not the generic company, the group that they contracted with to do the bioequivalent study, if there's any sort of lapse, the consequences can be horrific.

And my own view is that the concerns that the companies have are valid, and I know that many of the companies that have been the focus of attention, because they have demanded assurances about safety protocols, have in fact sold their products to generic companies that have adequate safety protocols. And to me that is very strong evidence of good faith.

Mr. JOHNSON. Mr. Abbott, would you care to respond?

Mr. ABBOTT. Well, I don't know if you're asking about the questions of safety and risk. I mean, perhaps Dr. Kesselheim might be best.

I do know that most generic companies, they have to meet very rigorous—generic companies, some of the largest pharmaceutical companies in the United States, they have to meet, in general, very

rigorous safety controls. They are subject to potential liability of various sorts.

But perhaps Dr. Kesselheim might want to have some additional comments.

Mr. JOHNSON. Doctor.

Dr. KESSELHEIM. Sure. I mean, I think I said—I mean, I said what I said before. But I think you also have to take into account the risk of not allowing this kind of normal business practice to happen, which is that very expensive drugs do not get timely generic competition, which keeps the price high, reduces access to important drugs for patients who are unable to afford access.

And I think you also have to take into account that whole risk of not having a system in which businesses can exchange the product that they need in order to do the various basic FDA testing as well.

Mr. JOHNSON. Thank you. And I yield back.

Mr. MARINO. The Chair now recognizes the Ranking Member, Congressman Cicilline.

Mr. CICILLINE. Thank you, Mr. Chairman.

I'd like to begin, if I may, with you, Professor Lietzan. I wonder if you're familiar with the Harvard Law—Harvard Journal on Legislation written by Robin Feldman that spoke specifically about this pay-for-delay problem. And in her writing, she gives an example, *In Re: Flonase Antitrust Litigation*.

At its peak, Flonase, a steroid nasal spray for allergy treatment, received \$1.3 billion a year in sales. Through a complicated series of citizen petitions, GlaxoSmithKline was able to stave off generic entry for 23 months. Thus, the delay achieved through citizen petitions was worth approximately \$2.5 billion, assuming it maintained the peak \$1.3 billion in sales per year.

They ended up settling that case for \$185 million. So even with that large settlement, the delay may have been worth \$2.3 billion.

That's just a single example. So I just wonder how you square that with the suggestion in your testimony that this doesn't continue to be a problem and that citizen petitions aren't used by brand companies for the specific purpose of delaying entry into the market and causing them to realize significant financial gains.

Ms. LIETZAN. Sure. I appreciate the question.

I'm not familiar with that particular article that Professor Feldman wrote, and I haven't looked at this particular example. And I don't know the date on it, if it might be prior to the change in the law that Congress enacted in 2007.

Mr. CICILLINE. I think it was written last year.

Ms. LIETZAN. No, no, I'm sorry, the actual Flonase example.

Because I do know that FDA itself has told Congress that there have only been five generic drug approvals delayed that didn't have a public health justification since that law was enacted. So it's possible, I'm not familiar with that particular example, it's possible that predates the current situation.

Mr. CICILLINE. Thank you very much.

Dr. Kesselheim, am I pronouncing that correctly.

Dr. KESSELHEIM. Yes.

Mr. CICILLINE. Thank you again for your testimony.

I'm wondering whether you could speak a little bit about whether or not the Supreme Court's decision in *FTC v. Actavis* has affected the use for pay-for-delay settlements. Do you assess that this continues to be a problem? Even if it's not a lot of instances, these instances can impose significant costs on the consumer and significantly enrich the brand companies.

Dr. KESSELHEIM. Sure. I mean, I do think that the *FTC v. Actavis* case has caused some shifts in—you know, the *FTC v. Actavis* case was really about the FTC being able to review pay-for-delay settlements that included extremely large monetary transfers like handing over of suitcases full of cash.

But since then, pay-for-delay settlements have continued. Many of them also still involve monetary settlements. But many of them also now involve more complex co-marketing arrangements or other kinds of business deals, some of which may not necessarily be at the sort of fair value that they might have otherwise been, and these kinds of agreements persist.

And I think the problem is that allowing FTC to review them is great, but it takes a really long time and a lot of resources to get through this. The *Actavis* case itself, which was the subject of the Supreme Court case, was started back in 2006, and we still haven't had really a full trial of it.

So I do think that congressional action is needed to try to prevent settlements that are—that go beyond mere exchanges of litigation costs.

Mr. CICILLINE. And do you think we ought to consider as well enactment of a prohibition, a statutory prohibition of pay-for-delay, like completely prohibit that activity as a matter of law?

Dr. KESSELHEIM. Well, I do think that the FTC in the past has said that it would prefer kind of a *per se* rule where these kinds of agreements are presumed not to be legitimate unless there is a sort of compelling justification that is provided for them.

Mr. CICILLINE. Other than the enrichment of the brand drug company.

Dr. KESSELHEIM. Right, a compelling public health justification, not a compelling personal or market profit justification. And I do think that that might be a good model to consider.

Mr. CICILLINE. Professor Olson, would you—I'd like your thoughts on that as well.

Mr. OLSON. Yes, I agree. I think that there is a case to be made for *per se* treatment. The Supreme Court did not do that in *Actavis*. But I think the Court eventually is getting to the right answer, but it will take many, many years. And it's hard to come up with much significant harm that would come from simply prohibiting transfers of value to the generic company for basically delaying.

Mr. CICILLINE. And I'm wondering whether any of the members of the panel, it's my last question, have any suggestions of improvements that we might make to the *CREATES* Act or consider.

I expect that, Professor Olson, you were nice enough to describe the *CREATES* Act as an elegant narrowly tailored fix. Nobody has ever called our legislation elegant, so we like that. But I'm just curious to know whether or not you think there are ways that we could improve the legislation that you've reviewed.

Mr. OLSON. Yes, sir.

So I, you know, I do think that it's narrowly tailored, and I'll stick by the word "elegant." I think there could be some leeway on the period of, you know, is it 30 days or 45 days. I wouldn't go, you know, is 120 or 150 days, but I wouldn't go much farther.

And I would point out that coming up with an ETASU in the first place, the company is only given 120 days. So I think the timeframes you've chosen are very good.

And I think there are other ways to address the issues you're getting at that would go beyond the CREATES Act, but for what the CREATES Act is specifically getting at, I think it does a very good job.

Mr. CICILLINE. Thank you.

Doctor.

Dr. KESSELHEIM. I guess I would just go back to my point that I think that—if you want to focus on just the issues that the CREATES Act covers, which is the REMS and the products, I mean, I think that you could add provisions that would again require REMS information to be public so there is no proprietary information about REMS, so that everybody knows what's in REMS and generic manufacturers can create their own REMS without having to haggle with the manufacturer for proprietary information. And I think you could include provisions that do not allow REMS patents to be listed with the FDA so that they don't block entry of generic drugs as secondary patents.

Mr. CICILLINE. Great.

Mr. ABBOTT. I'll just briefly say, it's interesting, this notion of REMS as sort of a regulated public utility model. And it's certainly possible, there are to the extent—and again, I don't know enough about the science—but to the extent you have to have one sort of optimal set of safety protocols, there are some issues.

I think in that situation, though, if you wanted access to this, you would not necessarily—the brand name drug company might say, wait a second, okay, I can see that argument, but we shouldn't have to bear all the costs and the risks of developing it. There should be some way of having the FDA or getting some compensation, making sure that everyone has sort of access to this efficient public facility. You have to also take that potential cost to the brand companies as well.

Dr. KESSELHEIM. I just want to echo that. And I agree. And I think that managing the REMS through the FDA instead of making it be—making them be managed through the companies would be helpful, again, with the proper resources, because, as I said before, it is optimal for patients who are otherwise—who don't know who their generic manufacturer is.

Because generic drugs are interchangeable with each other, to have to go to different REMS based on whoever the generic manufacturer is, is inefficient and would be frustrating for me as a clinician to try to figure out, well, who should I be calling, which registry should I be calling.

It should all be centralized. And maybe the optimal way to do that would be to have the REMS authority be within the FDA and the FDA to be properly resource to run the single central REMS and then none of these issues would exist.

Mr. CICILLINE. Great. I know my time. I thank the Chairman for indulging me. Thank you very much. I yield back.

Mr. MARINO. Would each of you, if you care to respond to my question, give an explanation for the general public, because we're throwing around a lot of language here in testing and retesting, what an originator of a drug has to go through to get that drug to the market? And what difference is there, if any, for the generic company to get that drug to the market?

So, please.

Dr. KESSELHEIM. I'll start. So, you know, a brand name manufacturer usually has to go through a period of preclinical testing that leads ultimately to an investigational new drug application, and then a period of clinical trials that takes on average about 6 to 7 years, and then files a new drug application with the FDA that then is reviewed in, on average, about 8 months.

Brand name manufacturers—that's brand name manufacturers—generic manufacturers have to prove that their drug is bioequivalent, which is to say, you know, based on preclinical and very limited clinical trials, show that the bioavailability of the drug and the blood levels of the drug for their version is the same as the brand name version, which is why, of course, the samples of brand name version are so critical, and then go through sort of, again, a more limited FDA review process only because there's less data that the generic manufacturer is submitting to the FDA. And then the generic manufacturer's drug may be evaluated with the FDA as being interchangeable and be able to go on the market.

Mr. MARINO. Could you give an estimate of some time? Because you did bring out estimates for the original company of 7 to 8 years of just one segment of testing.

Dr. KESSELHEIM. Right. I think that that pre—the bioequivalence testing can take far less than that. It probably takes, you know, in the sort of months to small number of years, rather than, on average, about 6 to 7 years.

And the generic review period by the FDA, as of 5 years ago, was actually much longer than the brand name review period because of far less resources that are dedicated to the Office of Generic Drugs. That's changed in the last few years and now the generic drug review process is faster, although still, I think, averages more like 12 to 18 months, rather than on average about 8 months for brand name drugs.

Mr. MARINO. Anyone else?

Ms. LIETZAN. No. I think, actually, Dr. Kesselheim's description of the approval—the two different approval pathways is entirely right. The only thing I would add is that I believe the Federal Trade Commission wrote a few years ago that the process for developing and getting a generic drug approved was 3 to 5 years. I don't know if that remains true, but that's what they said in, I think, 2009.

Mr. MARINO. Professor Olson.

Mr. OLSON. Yes. I just wanted to—I agree with that process. I want to add on, though, it's a little bit different for large molecule biologics.

So for large molecule biologics, the testing for a generic takes longer and it's much more complex because it's a more complex

molecule and because the cell lines can change over time. So it's key that these generics are provided samples not just once, but several times over a period of could be a year or so.

And that actually make the CREATES Act or some approach like it very important, because a brand name could basically disrupt and ruin the testing of someone trying to do a biosimilar simply by not providing samples in the middle of a testing procedure.

Ms. LIETZAN. Congressman, could I just make one comment on that?

Mr. MARINO. Sure.

Ms. LIETZAN. FDA has actually said that a biosimilar company can use a foreign-sourced version of the reference product for much, probably not all, but much of that application. I just wanted to make sure you were aware of that.

Mr. MARINO. Obviously, there's no other—Congressman Cicilline has something.

Mr. CICILLINE. Yeah. Mr. Chairman, I would just ask unanimous consent to make a part of the record this article, "Drug Wars: A New Generation of Generic Pharmaceutical Delay," by Robin Feldman and Evan Frondorf, as a part of the record.

Mr. MARINO. Without objection.

*This material is available at the Committee or on the Committee Repository at:*

*<https://docs.house.gov/meetings/JU/JU05/20170727/106333/HHRG-115-JU05-20170727-SD003.pdf>*

Mr. MARINO. This concludes today's hearing. I want to thank you very much. We could sit here for another 24 hours and I got a million questions in my head. But, as always, if you have anything to offer us. Mr. Cicilline has what we usually say, either one of us, is, what do you think of our legislation? That's important to us. You're the experts. We're the legislators and we need your assistance as well.

So, again, thank each and every one of you for being here. I'm sure we'll see each other in the future at some time.

So without objection, all members will have 5 legislative days to submit additional written questions for the witnesses or additional materials for the record.

This hearing is adjourned. And we're going to go vote again shortly.

[Whereupon, at 3:48 p.m., the Subcommittee was adjourned.]



The Honorable Bob Goodlatte  
Chairman  
Committee on the Judiciary  
House of Representatives  
Washington, D.C. 20515-6216

**APR 20 2018**

Dear Chairman Goodlatte:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the July 27, 2017, hearing before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law, House Committee on the Judiciary, entitled "Antitrust Concerns and the FDA Approval Process." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "John Martin", is written over the word "Sincerely,".

John Martin  
Principal Associate Commissioner  
for Legislative Affairs

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We have restated your questions below in bold, followed by our responses.

**The Honorable Tom Marino**

- 1. Under the DESI process, FDA has discretion to remove generics from the marketplace, ease generics off the marketplace, or allow them to remain if it is in the best interest of the patient community. What factors or criteria are used to make these determinations?**

DESI drugs are not the same as “generic drugs” subject to section 505(j) of the FD&C Act and these DESI drugs have not been approved by FDA. FDA assumes that the question’s reference to “generics” was intended to mean drug products related to the DESI process, which is explained below.

By way of background and context, the Drug Efficacy Study Implementation (DESI) is the FDA’s administrative implementation of the 1962 Kefauver-Harris amendments to the Federal Food, Drug, & Cosmetic (FD&C) Act. The 1962 amendments required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962 through the new drug approval process. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to initially evaluate the effectiveness of these products. FDA reviewed and re-evaluated the findings of the NAS/NRC panels and published its findings on the effectiveness of these products, sometimes referred to as “DESI drugs,” in the Federal Register. The Agency provided a notice of opportunity for hearing (NOOH) for any indication for which a product subject to a DESI proceeding was found to be less than fully effective. Currently, there are very few DESI proceedings for which a final determination regarding effectiveness has not yet been made.

Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS) to the approved drug to be covered by that approval, and allowed those IRS drugs to be marketed without independent approval. Drug products that are IRS to the products listed in a DESI notice are also considered to be subject to the DESI proceeding. As noted above, these IRS drugs are not the same as “generic drugs” subject to section 505(j) of the FD&C Act. In addition, they have not been approved by FDA.

FDA’s current policy on drug products subject to an ongoing DESI proceeding, including IRS drug products, is outlined in FDA’s Compliance Policy Guide (CPG) (Marketed Unapproved Drugs CPG, at p. 10) published in 2011. Specifically, the CPG in part states that “[i]t is the Agency’s longstanding policy that products subject to an ongoing DESI proceeding may remain on the market during the pendency of the proceeding.”

Once a DESI proceeding is completed, if the products subject to it are found not effective for a particular indication, FDA generally will evaluate on a case-by-case basis whether the Agency does not intend to object to a period of continued marketing for IRS products. The factors we may consider in such a situation are enumerated in the Marketed Unapproved Drugs CPG (at pp. 6-7), and include the following:

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- the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of legally marketed products to meet the needs of patients taking the drug);
- the difficulty associated with conducting any required studies, preparing and submitting applications, and obtaining approval of an application;
- the burden on affected parties of immediately removing the products from the market;
- the Agency’s available enforcement resources; and
- any special circumstances relevant to the particular case under consideration.

For additional information on DESI proceedings and related enforcement aspects, see 21 CFR 310.6 and the Marketed Unapproved Drugs CPG. See <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>.

**2. What is FDA doing to ensure that there are no drug shortages when, under the DESI process, the agency asks generic manufacturers to leave the marketplace? I am greatly concerned that we will be in a situation where my constituents don’t have access to potentially life-saving drugs.**

As discussed in the response to Question 1 and in the Marketed Unapproved Drugs CPG, one factor FDA may consider when deciding whether it does not intend to object to continued marketing for a period of time is “the effects on the public health of proceeding immediately to remove the illegal products from the market (including whether the product is medically necessary and, if so, the ability of legally marketed products to meet the needs of patients taking the drug)” (Marketed Unapproved Drugs CPG, p. 6).

FDA’s Center for Drug Evaluation and Research’s Office of Compliance consults with FDA’s Drug Shortages Staff before instituting any regulatory action to remove a drug from the market, to proactively prevent or mitigate any shortage which may occur from its removal. This process is used regardless of the regulatory status of the drug being removed from the market. For more information that describes FDA’s efforts to prevent the shortage of potentially life-saving drugs, please visit FDA’s Drug Shortages website: <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

**3. While companies are going through the ANDA approval process, what steps can FDA do to ensure that there is a smooth transition in the marketplace thereby ensuring that patients are not harmed nor lose access to lower cost alternatives? I want to ensure that my constituents maintain access to lower cost alternatives and not held hostage to the pricing decisions of one manufacturer.**

FDA strongly agrees it is important to expand access to affordable medicines. First, FDA’s Office of Generic Drugs prioritizes and expedites the review of certain generic drug applications, including potential first generics that can open the market to competition for the first time. FDA recognizes these applications as public health priorities and expedite their review with the goal of

expanding access to affordable medicines. This policy is set forth in the Center for Drug Evaluation and Research’s Manual of Policy and Procedures (MAPP) 5240.3, Revision 3, “Prioritization of the Review of Original ANDAs, Amendments and Supplements.”<sup>1</sup>

Second, FDA has taken steps to target the specific problem you reference – namely, sole source drug products vulnerable to potential price gouging by unscrupulous bad actors. It recently published an updated list<sup>2</sup> of off-patent, off-exclusivity brand drugs for which FDA has not approved a generic, and encouraged generic companies to submit applications for these drugs. FDA will expedite the review of any such applications. This, too, is described in the MAPP referenced above. By law, FDA generally cannot approve a generic drug until patent and exclusivity protections on the innovator product have been exhausted.

Third, to foster competition broadly, FDA has developed a Drug Competition Action Plan. Under the plan, FDA is implementing new initiatives to streamline the generic drug application review process, enhance the development and review of difficult-to-develop complex generic drug products, and crack down on brand company “gaming” that frustrates and delays the approval and/or marketing of generic drugs that would compete with the branded drug. FDA held a public meeting on July 18, 2017, to solicit stakeholder input on these initiatives. It received feedback from stakeholders in the public docket for these initiatives, which closed November 17, 2017. For your reference, the public docket comments can be accessed at [www.regulations.gov](http://www.regulations.gov) using docket number FDA-2017-N-3615.

About half of all generic drugs FDA has approved are no longer marketed, marketed intermittently, or were not initially marketed until long after approval. Sometimes this is for valid commercial reasons or because the standard of care has evolved. In other cases, generic drug manufacturers view FDA approval as an option to market, and realize the value of the option by deferring marketing pursuant to patent settlement or like agreements with the brand company. Anticompetitive conduct is within the purview of the Federal Trade Commission (FTC). A senior FTC official was a co-panelist at FDA’s recent public meeting, and FDA is exploring opportunities to further collaborate with FTC.

- 4. On June 23, 2017, the Subcommittee on the Constitution and Civil Justice held a hearing titled “Examining Ethical Responsibilities Regarding Attorney Advertising.” That hearing examined the ethical issues around some attorney advertising about FDA regulated and approved products. Does the FDA have the authority to regulate legal advertising about FDA approved and regulated products including biopharmaceuticals,**

<sup>1</sup> Center for Drug Evaluation and Research’s Manual of Policy and Procedures (MAPP) 5240.3, Revision 3, “Prioritization of the Review of Original ANDAs, Amendments and Supplements”. See <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf>.

<sup>2</sup> FDA’s List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic. See <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM564441.pdf>.

**medical devices, and regulated consumer healthcare products is sufficient to ensure patient safety?**

The FD&C Act and its implementing regulations provide authority for FDA to regulate advertising for prescription drugs. By way of background, under section 502(n) of the FD&C Act (21 U.S.C. 352(n)) and 21 CFR Part 202, a prescription drug marketed in the United States is misbranded unless advertisements issued by the “manufacturer, packer, or distributor thereof” meet specific requirements, including that they contain accurate information about the drug, addressing both risks and benefits, and that the advertising is truthful, balanced and not misleading. It is a prohibited act under section 301(a) of the FD&C Act (21 USC 331(a)) to introduce (or cause to be introduced) or deliver (or cause to be delivered) into interstate commerce a misbranded drug.

The FD&C Act also gives the Agency authority over the advertising of restricted medical devices (21 U.S.C. 352(q) and (r)). Devices may become restricted by regulation issued under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), by performance standard issued pursuant to section 514(a)(2)(B)(v) (21 U.S.C. 360d(a)(2)(B)(v)), or by order approving an application for premarket approval (i.e., a PMA) pursuant to section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)). Section 502(r) of the FD&C Act requires a “brief statement of intended uses” and relevant risk information in restricted-device advertising issued by the device manufacturer, packer, or distributor. Section 502(q) of the FD&C Act provides that restricted-device advertising that “is false or misleading in any particular” misbrands the device.

The legal advertisements you refer to are disseminated by lawyers seeking clients for their legal services; they are not advertisements for the medical product itself issued by a manufacturer or other party responsible for marketing the drug or restricted device within the scope of section 502 of the FD&C Act.

**5. Some legal advertising about FDA approved and regulated products use the FDA’s logo as part of that advertising. Is the use of the FDA’s logo sanctioned by the FDA? If not, should Congress prohibit the use of the term “Food and Drug Administration,” “FDA,” the FDA’s insignia or provide the FDA the authority to regulate the use of those or related terms and insignia?**

FDA has not authorized, or sanctioned, the use of the FDA logo in attorney advertising. FDA notes that there are existing legal authorities that may be applicable to use of the FDA logo in attorney advertising, such as the Lanham Act (15 U.S.C. 1125 et seq.), section 5 of the Federal Trade Commission Act (15 U.S.C. 45), and relevant case law, which address the fair use of terms and logos (a/k/a “trade names” and “marks”), the infringement of trade names and marks, and unfair or deceptive acts or practices affecting commerce.

**6. With respect to citizen petitions, several scholars have called for increased transparency to make data on citizen petition filings and dispositions more publicly available. Do you have any concerns about increasing the disclosure of such information?**

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All citizen petitions received by FDA are assigned a docket number and made available on [www.regulations.gov](http://www.regulations.gov). The website currently has several features that allow the public to identify citizen petitions filed with the Agency, determine the status of citizen petitions, and be notified when a change to the status occurs. The public can identify citizen petitions that have been submitted to FDA by using the advanced search feature available on [www.regulations.gov](http://www.regulations.gov) ([www.regulations.gov/AdvancedSearch](http://www.regulations.gov/AdvancedSearch)) by using both the “By Agency” (i.e., FDA) and Document Type (i.e., Citizen Petition) filters. The public can identify the status of citizen petitions by opening the relevant docket folder, which will allow them to see whether comments have been submitted and whether FDA has issued a response (interim or final). Additionally, [www.regulations.gov](http://www.regulations.gov) includes a feature that allows any individual to receive email updates if there are changes to a citizen petition docket. Any individual who does not have access to the internet can view citizen petition dockets by visiting FDA’s Dockets Management Staff at 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA believes the availability of citizen petitions through the [www.regulations.gov](http://www.regulations.gov) website and through FDA’s Dockets Management Staff provides an appropriate level of transparency.

**The Honorable Darrell E. Issa**

- 1. The FDA website currently lists forty-two products with FDA authorized risk evaluation and mitigation strategies (REMS) with elements to assure safe use (ETASU). Of those forty-two reference products, how many have been subject to at least one abbreviated new drug application filed or biologics license application? How many of the forty-two reference products have been subject to multiple ANDA filings?**

As of December 15, 2017, there are 43 approved drugs that have risk evaluation and mitigation strategies (REMS) with elements to assure safe use (ETASU), covering a total of 68 new drug applications (NDAs). Of these 68 NDAs, 23 have at least one approved abbreviated new drug application (ANDA). Fifteen of the 68 have multiple pending ANDAs, eight have just one pending ANDA, and 22 have no pending ANDAs. In addition, 10 of these 43 REMS are for products approved under biologic license applications (BLAs) licensed under section 351(a) of the Public Health Service Act (i.e., “stand-alone” BLAs). There are no biological products that have been licensed under section 351(k) as biosimilar to any of the biological products on this list. In addition, FDA is not aware of any company that has publicly announced the submission of a 351(k) BLA for a proposed biosimilar to any biological product on the list.

- 2. How many products are in shared systems? How many times has FDA exercised its existing authority to grant a waiver from shared REMS?**

There are seven approved single, shared systems (i.e., REMS shared between NDA and the ANDAs referencing them). Collectively these seven shared REMS cover 130 applications (38 NDAs and 92 ANDAs). To date, FDA has granted three waivers of the single, shared system REMS requirement and permitted ANDA holders to use a separate system for the ETASU. These programs are: the Buprenorphine-containing Transmucosal Products for Opioid Dependence (BTOD) REMS, the Shared System for Alosetron, and Shared System REMS Program for Sodium Oxybate Oral Solution.

**3. How many of those forty-two REMS ETASU reference products are considered by the FDA to be older, off-patent, off-exclusivity drugs without an approved generic or biosimilar? If any REMS ETASU are considered to be older, off-patent, off-exclusivity drugs without an approved generic please name them.**

The only reference product with an ETASU REMS considered by FDA to be an older, off-patent, off-exclusivity drug without an approved generic is Bosentan (NDA 021290). The Agency's defined criteria for an off-patent, off-exclusivity drug can be found at <https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/UCM564441.pdf>.

**The Honorable Doug Collins**

**1. I would like to hear what the Agency is doing to enforce the [FDA's unapproved drug] policy, [Compliance Policy Guide Sec. 440.100 "Marketed New Drugs Without Approved NDAs and ANDAs" (CPG)], which was published in 2006 and revised in 2011] as well as what action the Agency plans to take to complete removal of phenobarbital products that have come to the market in contravention of FDA policy after September 19, 2011.**

Phenobarbital is an example of a medically necessary drug that has never been approved by FDA. Because patients rely on phenobarbital, it has been a low priority for FDA enforcement action. FDA's position is that the best course of action is to encourage manufacturers to seek FDA approval of their phenobarbital products.

FDA's current policies regarding marketed unapproved drugs are articulated in the Compliance Policy Guide Sec. 440.100 "Marketed New Drugs Without Approved NDAs and ANDAs" (CPG), which was published in 2006 and revised in 2011. Both versions of the CPG made clear that "any product that is being marketed illegally is subject to FDA enforcement action at any time" and encouraged firms to submit applications for their unapproved new drugs.

Despite the publication of the CPG in 2006, new unapproved drugs continued to be added to the market each year. FDA issued an update to the CPG on September 19, 2011, clarifying how the Agency expects to prioritize its compliance actions.

The purpose of the revisions to the CPG was to further discourage manufacturers from introducing new unapproved drugs on the market, not to provide special marketing rights to unapproved drugs already being marketed. Nevertheless, manufacturers of pre-2011 unapproved drugs often advocate for FDA enforcement action against their post-2011 competitors based upon the revisions in the 2011 CPG, while ignoring that all illegally marketed unapproved drugs, whether pre-2011 or post-2011, are subject to FDA enforcement action at any time, as clearly stated in both the 2006 and 2011 versions of the CPG.

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There are both pre-2011 and post-2011 unapproved versions of phenobarbital on the market. Before taking action against any unapproved phenobarbital product, FDA would carefully evaluate whether the action might cause a shortage. The initial marketing date of specific unapproved versions of phenobarbital is not necessarily the best public health criterion to use when deciding whether to remove medically necessary unapproved products such as phenobarbital from the market. FDA does not have information supporting a conclusion that the pre-2011 unapproved phenobarbital drug products are any better in terms of safety, efficacy, or quality than the post-2011 unapproved versions. However, FDA will evaluate any information that becomes available about the marketed products and will continue to encourage firms to submit applications for approval.

