First Listening Session on Lowering Drug Prices Through Competition:

Anticompetitive Conduct by Pharmaceutical Companies Impeding Generic or Biosimilar Competition

U.S. Department of Justice, June 30, 2025

Assistant Attorney General Abigail Slater:

Okay. So I'm Gail Slater. Thank you, everyone, for being here to kick off these listening sessions, it's one of three we're tasked with--the Executive Order. I had a few thank yous. So Markus Brazill, who is over there. The other Markus, not to be confused with Markus Meier, formerly of the FTC. Meredyth Andrus. Hey, Meredyth. Good to see you. And Kara Monahan to my right, and Jill Maguire to my left. Thanks to everyone. These were the principal organizers for this listening session and others going forward. I have a few prepared remarks. Thank you again, Markus, for those. To kick off, just to frame the issue a bit and tee us off today. So welcome to the first of three listening sessions hosted jointly by the Department of Justice Antitrust Division and the Federal Trade Commission on drug pricing. We are here today because President Trump has given us a mandate under several executive orders now to investigate anticompetitive practices in the pharmaceutical industry and to take decisive action to combat those practices. As assistant attorney general for the Antitrust Division, I hear constantly from Americans about the high cost of prescription drugs. These costs are particularly acute for patients who must take medications to treat

lengthy or chronic conditions--and we have a few of those folks with us today--like cancer or autoimmune disorders. Working class Americans should not have to skimp on life's necessities to afford life sustaining medicine for their families. And high drug costs impose a steep tax on businesses, both small and large, that offer health insurance to their employees. Competition can play an important role in lowering drug prices. Without doubt, it's important to incentivize innovation that brings new, life-saving treatments to market. Many candidate drugs fail, and shepherding a drug through the new drug approval process often costs a great deal of money. But there's a crucial difference between supporting innovation and gamesmanship. We do not condone rent seeking that blocks or raises the price of generic or biosimilar treatments, and we must be vigilant that regulatory barriers do not unnecessarily favor incumbents or make markets susceptible to this rent seeking. Today, several scholars and advocates will speak about these issues, and we have received many questions from the public already. But I know that these topics touch many other people and businesses in America, and we want to hear from you because we work for you at the end of the day. If you have concerns about specific anti-competitive practices, please reach out to the DOJ and FTC directly or through the Healthy Competition Complaint Center. And the web address for that is healthycompetition.gov. The Trump-Vance Administration is committed to putting Americans first by promoting more competitive drug prices. So let's get to work. Thanks, everyone.

Moderator Kara Monahan:

Thank you for that introduction. My name is Kara Monahan. I am the Deputy Assistant Director of the FTC's Healthcare Division, and I will be one of the moderators for today's session, along with Jill Maguire from the DOJ's Antitrust Division. Today's session considers anti-competitive conduct by pharmaceutical companies that delays or impedes generic or biosimilar competition. We will have two one-hour panel discussions. Upon the conclusion of the first panel, we will move into the second panel after a very short break. We invited members of the public to submit questions for our panelists, and we have incorporated some of those questions into today's program. We have a lot to cover in the next two hours, so I'm going to do my best to keep us on track. And I would ask that all panelists be mindful of time constraints when responding to questions. Our first panel today will focus on anti-competitive conduct by pharmaceutical manufacturers that delays competition from lower-priced generics or biosimilar alternatives. Among other things, this panel will touch on current

trends related to pay for delay agreements, exclusive supply agreements, and the impacts of restricted distribution on competition.

Moderator Jill Maguire:
Good afternoon. Hi, everybody. My name is Jill Maguire, and I'm the Acting Chief of the Healthcare and Consumer Products Section at the Department of Justice's Antitrust Division. We're going to go ahead and introduce the members of our panel this afternoon. On our first panel to my right, we have Ms. Sneha Dave. She is the Founder and Executive Director at Generation Patient, an organization representing over 25 million young adults with chronic conditions in the United States and abroad. Generation Patient leads research and policy reform in a number of key areas, including the patent system. Ms. Dave has testified on Capitol Hill, spoken at the World Economic Forum, and serves on editorial and advisory boards related to medical research.

Moderator Kara Monahan:
Markus Meier was the Assistant Director of the Healthcare Division at the Federal Trade Commission until his retirement at the end of 2023. Mr. Meier was responsible for investigating and litigating violations of antitrust law in the pharmaceutical and healthcare sectors. During his tenure, Mr. Meier and his team had two cases that went to the U.S. Supreme Court and numerous other cases that collectively resulted in judgments or settlements of more than $1.8 billion for consumers.

Moderator Jill Maguire:
Hans Sauer is Deputy General Counsel and Vice President for Intellectual Property at the Biotechnology Innovation Organization, which is a major trade association representing biotechnology companies, industry leaders, and state biotech associations in the United States and abroad. At BIO, Mr. Sauer advises the organization's staff and members on patent and other intellectual property-related matters. Mr. Sauer also has significant in-house experience in the pharmaceutical and biotechnology industries, where he worked on, among other things, several drug development programs, patent prosecution, and patent portfolio oversight.

Moderator Kara Monahan:
Stephen Schondelmeyer is a professor of pharmaceutical economics in the College of Pharmacy at the University of Minnesota, where he holds the Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics. Dr. Schondelmeyer is the Director of the PRIME

Institute, which focuses on pharmaceutical research related to management and economics. He has broad expertise in prescription drug reimbursement, drug benefit plan management, and pharmaceutical pricing patterns.

Moderator Jill Maguire:
Shashank Upadhye is a partner at Upadhye Tang LLP and is also a former chief in-house counsel at three leading pharmaceutical companies. He has focused his career on pharmaceutical law, with an emphasis on IP and FDA issues, and he is a prolific speaker and writer on various topics such as drug development and approval, the Hatch-Waxman Act, and patent law. Mr. Upadhye is the author of the leading treatise on FDA laws for drug development, generic pharmaceutical patent, and FDA law.

Moderator Jill Maguire:
All right, all right. Panelists, we're so glad that you're here, and we're ready to have a great discussion with you. So I'm going to kick us off with a question first to Mr. Upadhye. Generic drugs and biosimilars play an important role in fostering price competition in pharmaceutical markets. As a result, they can be targets of anticompetitive conduct by brand drugs whose monopolies they threaten. The FTC and private plaintiffs have challenged various restrictions that brands use to delay generic competition, such as exclusive agreements or restricted distribution systems. Can you address these strategies and identify where you see the most risk to competition?

Speaker Shashank Upadhye:
Great. Thank you very much. And I appreciate the FTC and the DOJ having us over to talk about these important issues. As a private law firm lawyer, I have to give a standard disclaimer that these represent my personal views and not any views of any client, past, present, or in the future. So with that in mind, my experience is both on the brand side and the generic side, and my goal in addressing these types of solutions is for fairness, predictability, and certainty, because that's exactly what our clients need. We can't be operating in the nebulous or the ambiguous zone. So with respect to the question that's been presented, there are several contracts that can be scrutinized or maybe, you know, warrant further scrutiny. The first one relates to contracts on exclusive supply of the key intermediates that then get formed into the API. There are sometimes very few companies that make these critical ingredients, and therefore getting exclusive contracts on the key intermediates means that ultimately, bulk suppliers may not be able to produce the API at the end and then make

it available. Another area is obviously in the contracts in which there's an exclusive supply for the approved DMF holders. Consequence of that is that it takes time for an unapproved DMF holder to go through the FDA regulatory approval process in order to get approval and then can become a supermarket of API to finished dosage form companies in the ANDA world. There's patent settlements, you know, that are there between the first filer and the first ANDA applicant, in which the contract will protect the 180-day exclusivity, whether or not the 180-day exclusivity has been legally forfeited. So, in other words, if there's a settlement by subsequent filers in the ANDA world, they are necessarily going to be day-181 launch as opposed to a day-one launch when they could normally be approved at day one from an FDA perspective. But by contract, they cannot actually launch until day 181. But the area I'd really like to focus on in the last, you know, few minutes is the contracts on devices when the device is part of the drug-device combination. Because the FDA wants strict compliance between the physical characteristics between the RLD and the generic drug, more often than not, there are physical characteristics that are just only suited by the branded drug device. So what that means is that the generic company will either face the situation or the dilemma that if they are going to be "TE-rated," they're going to have to basically have the same or similar characteristics or physical characteristics. And if they change the device, in a way, it causes two problems. Number one, the FDA actually has to do the scientific work to evaluate those differences, which it doesn't want to do, and therefore is prone to actually just issue a rejection or at least not permit you to go ahead with the different device. Or secondly, even if you're lucky enough to get this device through the FDA, then they are going to review these characteristics from a scientific perspective. This is a huge consequence, especially when you think about inhalers. Inhalers--the FDA requires similarity or identicality in plume geometry, particle size distribution, spray pattern. And so basically it means that when you take a nasal spray, you don't want it to shoot in your nose like a gun and then have it drip out. Right? You want it to be a plume and kind of coat the inside of your nose, and then maybe you're also inhaling it. In emergency devices, it's not enough for a generic device to also show that it's safe and efficacious, meaning that it works in the same way as the RLD. However, the FDA also requires comparative human factor studies that allow the patient or the patient's grandmother, teachers, nurses, or other people to be able to use that with first-use success. And the FDA requires almost 99% first-use success studies. So again, it's in one of those situations where if the exclusive contract exists on the RLD device itself, it makes it very problematic for generic companies to use different devices. Thank you.

Moderator Kara Monohan:

Our next--our next question is for Ms. Dave. You are a patient who has spoken out about anti-competitive practices that hamper generic and biosimilar availability for American patients. Could you speak to why generic and biosimilar availability is so important?

Speaker Sneha Dave:

Yeah. Hi everyone. My name is Sneha Dave and I'm the executive director at Generation Patient. And we have been working on antitrust and particularly on patent issues for the last couple of years. And we believe strongly in making the connection between antitrust and patient lives, particularly young adult patients, because there's two unique aspects of young adulthood and living with a chronic illness during this time period that should be highlighted. One: unchecked monopolies' power stifles innovation and distorts R&D priorities. Young adults, many in our community who are in their early 20s, rely on breakthrough innovations and real novel innovations rather than incremental advances and--and medications. Our community is going to live with these conditions for the rest of our lives, so these innovations really matter as we consider the rest of our lives. There's also oftentimes an unfortunate loss of insurance in our community, creating gaps in coverage and making biosimilars, and particularly generics, even crucial during this time period. We commend the FTC and DOJ for their leadership in uncovering and addressing these anticompetitive tactics, and hopeful--hope for meaningful policy change and administrative action to address pharma's anti-competitive behavior so all Americans, especially the next generation of Americans, can readily access and afford their medications. We began initially investigating pharma's monopolization practices because many of us, including myself, were on therapeutics like Humira. What we uncovered were that patents, and not necessarily the cost of ingredients or manufacturing, were the reasons why our drug prices so--were so high, and why so many of our community members were unable to afford their therapeutics. While Humira gets a lot of attention, it is unfortunately not an isolated case. We see lately, with Ozempic having filed about three--over 300 patents and cases of patent thicketing, product hopping and pay for delay becoming incredible barriers for our community to be able to thrive into adulthood and to be able to have meaningful futures. FTC's work has shown that brand name companies are using tactics to undermine price competition, and they are using these patent thickets to force generic and biosimilar drug companies into agreements that restrict access, and that should be considered anticompetitive. When we look at pay-for-delay agreements, we also look at some of the upstream factors that enable this to occur.

The excessive granting of low-quality patents and secondary and continuation patents, which are weaker and oftentimes not even on the compound, which is what's the most meaningful for patients. As we think about challenges with patient access to generics and biosimilars and the systems that enable this lack of timely access, we think about the issues that fall for generic drug companies and biosimilar drug companies from entering the market. Today, brand name pharma companies are nonstop patent machines, defining the smallest product changes as innovative and worthy of patents, and making changes just so that they can apply for more patents. And these are patents that are, again, not meaningful for patient lives. Brand name companies repeatedly sue to prevent generics from coming to the market, effectively keeping our drug prices high and our--the costs of our therapeutics unaffordable. We also know that the automatic 30-months stay was meant to resolve disputes over core compound patents while generic drugs sought--sought approval. Hatch-Waxman was not intended for secondary and continuation patents, AKA weaker patents. As far as our struggles with access to biosimilars, we look at issues of private labeling and rebates, which I know will be covered in later panels. But I would like to bring attention to the fact that PBMs use their power to favor their own biosimilars, delaying adoption of other biosimilars. There's also cases of brand name companies launching authorized generic and biosimilar and private labeling deals with some PBMs, which allow competitors to enter the market, but it's not the competition due to the manipulation of the market by the brand name company. This ultimately undermines the intent of the BPCIA. We believe, as a patient advocacy group, that the DOJ and the FTC have an opportunity to continue to elevate patent quality as a public interest issue and agency rulemakings and reports. Addressing antitrust behaviors and upstream issues would greatly advance the President's goal to lower drug prices and increase competition and would complement FTC and DOJ's efforts to rein in pay-for-delay deals and other patent abuse tactics. FDA, HHS, FTC, and DOJ can together enact meaningful solutions to lower drug costs for Americans while promoting fair competition. And lastly, before I conclude, I just want to comment on two common points that we hear from the pharmaceutical industry. One is focus on R&D and innovation. Contrary to industry claims, strengthening patent protections reduces rather than increases pharmaceutical innovation and meaningful innovation for patients. I have to wrap up, but I also want to acknowledge the risk of investing in new therapeutics and innovations. But that does not necessitate the creation of unfair monopolies. The current patent system creates perverse incentives that direct research toward incremental modifications of existing drugs, rather than genuine breakthroughs. Lastly, PBMs, hospitals, insurers, and just about everyone is blamed by the pharmaceutical industry.

They all have a role to play. However, the pharmaceutical industry must take advantage for their antitrust violations and poor patent quality submissions to keep monopolies. Legislation also has to move at the speed at which they are engaging in such practices. And finally, we see patients as the drivers of this work. We can come share the stories of ourselves and the devastating stories of our peers, but it will only make a difference if we are at the table and patient experiences are taken into consideration when thinking about patent quality and the impact of monopolies on our daily lives. Our community of the current and next generation of patients looks forward to ensuring that antitrust issues continued to be prioritized within this Administration. Thank you.

Moderator Jill McGuire:

Our next question is from Mr. Sauer. The President's Executive Order on lowering drug prices for American patients emphasizes the importance of harnessing competition to increase access to affordable medicines. What are some of the IP-related strategies used by drug manufacturers that impact the entry of lower cost competition, especially those that might delay or prevent market entry of generics or biosimilars?

Speaker Hans Sauer:

First, thank you for having me. So to frame the question in my own mind, as I see the panelists, when talking about the cost of drugs or the cost of drugs to consumers, sometimes the question is how much are we paying? Well, I understand this panel to be about how long are we paying? Like when does lower cost competition enter the market, and what are the determinants of when that market entry occurs? Much of that, you know, is a bit clouded by there are very large amounts of information out there in the public sphere that have been published, that have been published sometimes in peer reviewed journals, other times in white papers. Sometimes they're being amplified in the public media. But there is a body of information that--that we can also rely on where we say, this is pretty well established and has been studied a number of times. So before I can talk a little bit about strategies, I want to offer a few data points that we can state with confidence, because they've been studied for a long time and they've been looked at repeatedly with different methodologies. So I would start perhaps by the number of patents, what it's often being said that hmm it feels like pharmaceutical companies are getting like large numbers of patents on their products. Why do pharmaceutical companies have more than one patent on a product, which seems to be the normal paradigm? What at least in public narrative. It's--it's not a very normal paradigm. I can show you golf balls that have 50 patents on them. Right? So the embedding of multiple innovations in a single

product is not unique to the biotech industry. And if there's concern that, for example, a modern biotech drug may be covered by--pick a number of patents, more than one what? The answer on one level would be, well, modern biotech drugs are not much more simple than golf balls. In fact, I think they're often more complicated. So it's not particularly surprising that, you know, modern advanced drug products would be covered by more than one patent. Well, how many? What? We have an idea of how many, at least on some level. For small molecule drugs, the typical number is 4 to 6 that have been found in the orange book. So when you go through the orange book, that is the average number today, a very typical number. For biosimilar litigation, the number is different. There are more. The typical number is about 10 to 15 patents that get litigated, what, when there is litigation. We also know that these patents, when you look at them, are of roughly similar, sometimes better quality than in other technology areas. But these patents don't stand out like as being uniquely different from the way other innovative industries claim their inventions and patents. And--and this has been studied, the number of patents that I just gave you, 5 to 6 for small molecules, or about a dozen for biosimilars, has been studied repeatedly over the years and--and was most recently confirmed by the Patent and Trademark Office in last year's study on pharmaceutical, patent and exclusivity parameters. All right, time to entry. I guess that's where the rubber meets the road. But how long does it take, typically, before lower cost competition does enter the market? What, very much has been said about that. But it's very, again, amenable to empirical study. We've known for a very long time that new chemical entity drugs before they face generic competition in the marketplace, enjoy approximately 13 years in the marketplace before generic entry does occur. What? It's about ten years for none--for--for other than new chemical entity drugs. But 13 and ten years. That time frame has been seen again and again and again by different groups looking at different parameters. And more importantly, it's been stable for about 30 years. Ever since people started looking, that's been the time frame until generic entry occurs, when it occurs. I have one minute left. Strategies. You asked about strategies, so I will leave you with this. There has been over time, this is true, a trend to file more patents in the orange book on the small molecule side. What it used to be 2 to 3 in the early '90s and 1980s. The current number is roughly 4 to 6, sometimes more, but--but not much more. So 4 to 6. That trend is there. Anecdotally, we also know that there are fewer new chemical entity drugs that enter the market that don't have patents that protect the molecule itself. It used to be 20, 25 years ago that about one third of new chemical entity drugs that enter the market and that get FDA approval don't even have patents on the molecule. But that I think is changing. Drugs tend to go to market less if they don't have patents that protect the

molecule itself. But that is one trend that we've seen over time. So the increased patent filing, I think, is part of a trend that we're seeing. On the generic side, it's also been established that generics have, over time, brought more patent challenges, paragraph four challenges, earlier in time than they did in the early 1990s. So practices have changed on the generic side as well. The effect has been, certainly it looks that way to us, that both parties to these litigations, the innovators and the generics, are employing strategies that have the effect of maintaining rather than changing historic levels of market exclusivity. Right. So one side, through their tactics, prevents this market exclusivity from becoming longer. The other side prevents it from becoming shorter. The effect is that for 30 years, we've had, you know, a normal market life on the small molecule side of about 13 years for new chemical entities, and that hasn't really been changing. So this will be my last remark. As we go forward, right, it's going to be very important to account for the reality that the system is in a kind of steady state, both sides on the V are and have been changing their strategies, but the effect has been, right, to produce largely the same outcomes, at least time wise, that we had 30 years ago. And that will be an important consideration going forward. Also, to keep in mind, in the face of narratives that the system is unstable, what has been changing that there are recent abuses that really tilt the system in ways in which it hasn't been. That's not an observation we can make. We can reserve another conversation for biosimilars, you know, where we have fewer data, less information, where we have reason to think that incentives are different and where we can also have a more differentiated discussion. But it's the steady state notion that I want to leave you with, with respect to timing. Thank you.

Moderator Kara Monohan:

Our next question is for Dr. Schondelmeyer. Even when pharmaceutical treatments for a condition are available, that doesn't mean that every patient with that condition will have access to those treatments. The complexity of the pharmaceutical supply chain offers many opportunities for ultimate market access to be impacted. Could you speak to some of the competition concerns that affect generic and biosimilar availability that stem from the pharmaceutical supply chain?

Speaker Stephen Schondelmeyer:

Thanks for the question. And as my colleagues said, I'm presenting my own views and not that of the university where I work. And it's based on about 50 years of studying the pharmaceutical market and virtually every drug in the market during that time and the market behaviors. First, let me remind us that virtually everyone uses, has used, or will use a prescription drug in their lifetime.

They're valuable to us. They provide help to us in many ways. They can provide a life-saving therapy. They can extend care. They can even improve the quality of life. But inability to access a drug when it's needed is critical and can result in life-ending consequences for an individual, or even threaten the health of a community, the nation, or even our military, for example. Also, let me remind us that generic drugs that we're primarily focusing on today and biosimilars I would lump in with that generically, so to speak, generic drugs are a cornerstone of our American pharmaceutical market, and nine out of ten prescriptions filled in a pharmacy are for generic drugs. They've helped hold down the cost of paying for drugs for the American population. If--if we didn't have generics and weren't using them as extensively and with the low-cost products that are in the market today, Congress would be struggling even harder to figure out how to pay for Medicare and Medicaid. It would be a real challenge. We may not be able to provide all of the care that we do. And then I want to point out, it would be shortsighted to think that after decades long development of the anticompetitive behaviors we see in the market today, and I'm talking for 3 or 4 decades of development, there's no single simple change that's going to solve all this, but I think change is worth pursuing. Policies are available, but we need integrated and coordinated policies that cut across different issues that you'll hear about from our panel in the next panel and the next two listening sessions. So we need coordinated approaches. Competition is a dynamic process. When you squeeze one place in the market, you see bulges somewhere else in the market, and policies need to be developed not only with a focus on what to squeeze, but where's the bulge going to be and how do we keep it in bounds also. So we need to look at the dynamic of that marketplace. In particular, the market behavior over the last 40 years that has occurred after the Hatch-Waxman Act is very important for us to understand and to realize that this market was changed dramatically by Hatch-Waxman. But over those 40 years, we've had many unintended consequences actively pursued by various players in the market, and many have been institutionalized in the market and made the market more anticompetitive rather than less anticompetitive. And so we need to go back and reexamine what is the net effect of that Hatch-Waxman Act over time? I think it was good, the right thing for the right reasons. And I remind you that the title of that act is the--the Drug Price Competition and Patent Term Restoration Act. Two major objectives. And I think there's been a lot more done to support the patent term restoration side than there has drug price competition. There has been some on the drug price competition side, but we've seen that eroding away over time as various changes come to play. Finally, I want to focus on specialty drugs and this limited drug distribution systems in our market. Specialty drugs. First of all, there is no statutory definition of

specialty drugs in general in the marketplace, and the marketplace has defined specialty drugs and even among different players in the market, there's no standardized definition of specialty drugs. Each player defines specialty to be what serves their needs and their interests in operating a business and generating revenue. It may or may not be in the best interest of the patients they serve, or the economy as a whole, or driving competition, but it's more of a market-driven, self-serving definition. I think we need some standardization in the specialty market and definitions and some guardrails. Specialty drugs, ten years ago, represented about 1% of the prescriptions and 30% of the dollars we spend on drugs. Today, they represent 2 or 3% of the prescriptions, and about two thirds of the dollars we spend on prescription drugs just for those 2 or 3% of the market. They are the fastest growing, the highest expenditure component in the pharmaceutical market space today. Likewise, specialty pharmacies are not defined or licensed any differently than any other retail pharmacy, although they would have you believe that they're substantially different and they're authorized to do things that a pharmacy can't do. That's not necessarily true. In summary, really, the definition of specialty products results in steering of patients into limited distribution channels in the marketplace. We have drugs that you can only get at 1 to 5 pharmacies for the whole nation. So whether I'm in Indianapolis or Minneapolis or Los Angeles or New York or Washington, I have to contact and get the drug from one pharmacy that may be in Florida. And limited distribution drugs limit access. They take time delays, and it puts the control of the economics of that drug product in the hands of the manufacturer and the few players they contract with to distribute their drug and allows them to engage in price maintenance schemes and contractual terms that restrict sale of the drug to generic companies, for example, to develop a standard against a reference listed drug or other issues. Most other developed countries have a process for evaluating the value of drugs in their market, and for determining the relative value of that drug, and holding drug firms accountable for reasonable prices, yet still rewarding them for true innovations in the market. I think we can do that in America as well. Value is not about price only, but value must always include an accounting for price, and we aren't very good at that in the U.S. market space. Finally, limited distribution drugs for each drug would mean that if I had 7 or 8 drugs I was taking, I might have to contact 7 or 8 different manufacturers to get each of those drugs. As a patient, can you imagine your grandmother doing that? Can you imagine you doing that, having the time to do that? And keep in mind, when a patent or exclusivity period ends for a specialty drug or biologic you might be on, will the specialty channel or the drug manufacturer who you buy that drug from encourage you to use a generic or a biosimilar? Not likely. Thank you.

Moderator Jill Maguire:

Our next question on the panel is for Mr. Meier. Mr. Meier, you have had a front row seat to pay for delay agreements from the beginning and have been involved in all the landmark cases. It has now been just over 20 years since Congress enacted the Medicare Prescription Drug Improvement and Modernization Act, which requires pharmaceutical companies to report certain patent settlements to the FTC and DOJ. What are the current trends in pharmaceutical patent settlements, and what additional steps should Congress, the FTC, and others take to curb pay for delay agreements?

Speaker Markus Meier:

So first of all, thanks for inviting me and a quick caveat myself. I'm only speaking for myself. I'm retired, but I spent 33 years at the FTC, and you just asked me to give 25 years in five minutes or less, I am going to--I am going to restrict my comments to public information only, and I apologize in advance to the audience. And like the other speakers here today, there's just no way to avoid some of the jargon and some of the acronyms. And so there will be some of that. I just don't--I don't have the time to explain everything. But of course, the listening tour is to the experts. So the experts know these things. I've asked--been asked to talk about reverse payments, also sometimes referred to as pay for delay. Let me do the setup real quickly. The situation that occurs is you have a brand company suing on patent issues against a generic company, and it's saying the generic company wants to launch a competitive product to the brand and the brand, saying you--you violate my patents. And the generic says in return, first of all, your patents aren't even valid. And secondly, I've invented around your patents. And so therefore, one way or another, I should be allowed to come in. And this all occurs under what's been referred to a number of times already as the Hatch-Waxman Act, an act passed in 1984. And as Professor Schondelmeyer so aptly described it, it had two objectives. One objective was to continue to promote innovation in America, and the other objective was to get lower cost generic products to market sooner so that consumers could benefit from the lower costs. The concern that the FTC had, as we saw these things, and this started back in 1999, back in my early days when I wasn't quite as white-haired as now. And as we started to look at these things, we started to see a disturbing trend in these settlements in which the brand company was paying the generic company--that's at least what we were alleging--to stay out of the market. And the reason it was called a reverse payment was because, generally speaking, in most patent litigation, the putative infringer, which would be the generic company in this case is paying for a license to the patent holder, to the putative valid patent and is trying to pay to get in, is not being

paid by the patent holder, who allegedly has a valid patent, to stay out. And that's why it's sometimes called a reverse payment. And the two terms that we found that had to be present in any agreement that would cause us concern is one, there's some form of consideration or payment running to the generic company and two, the generic company in return agrees to stay out for some period of time. The problem with that, from an antitrust standpoint, is it reflects a sharing of monopoly profits between the brand and the generic, because before the entry, the brand is making all the sales and getting all the profits, and now it's giving some portion of those profits through the payment to the generic. And the person that's being screwed in that deal is the consumer who would otherwise expect to get a generic product that is priced significantly lower. So instead of letting the consumers have the lower price, they're finding a way to share that excess gain between the two. So in response to the question about sort of what the evolution of these payments, that's been probably the most interesting thing that we've observed over time is how these payments flowed. In the very, very early agreements, 2000 to 2002, you saw essentially what was a bag of cash. I mean, it was a wire transfer, it wasn't physical money, but it was a wire transfer from the brand to the generic. But at some point, companies kind of got the picture that this doesn't look too good. And we stopped that practice pretty--pretty well, had a number of consents early in 2000, 2001 and 2002 where companies just agreed we're not going to do this anymore, but they got more sophisticated. There's a lot at stake here. There's a lot of financial interest here, there's a lot of really clever people and clever lawyering going on and--and smart people. So they started doing a lot of, in addition to doing a patent license, they started doing a lot of side business deals. Now, again, in these side business deals, the cash flow or the money flow, I should say, always went from the brand to the generic. They found these side deals. So in the second generation you had these side deals. What we now have is a third generation that's very aptly described by the FTC in a recent January 2025 blog and some MMA reports--that's under the Medicare Modernization Act, the fact that the agencies FTC and DOJ get all these agreements and can review them, and they have found that there's a whole bunch of little additional kinds of ways that this, that this money is flowing or that these payments are flowing. And these third-generation cases haven't been investigated to date. Now, I'm not a politician, and I didn't come here to make political statements. I was a career civil servant, but frankly, it just was not a priority of the FTC chairman in my last--before I retired, during the Biden Administration. And so I would recommend, my recommendation would be that the FTC consider opening one or more investigations into some of these additional practices that we're now seeing that you've identified so aptly in the blog. Thank you.

Moderator Kara Monahan:

Our next question is for Ms. Dave. As a patient advocate for young adults with chronic conditions, what changes would you like to see to improve access to affordable medicines?

Speaker Sneha Dave

Yes. So now I'm going to focus a little less on the FTC DOJ side, even though I know this listening session is for the FTC and DOJ, I think as a patient and a patient advocacy group, we are really excited about current legislative solutions that exist to reframe and reform the patent system, namely on legislation related to patent thickets, USPTO FDA collaboration to ensure better data sharing between both agencies and so that brand companies are not telling FDA something and--and PTO something else. I also think we're really excited to push the Patent and Trademark Office to reframe their role as a public interest agency, rather than favoring private industry. As we think about PTO's current standard of novelty and non-obviousness, continuing to push them to really grant patents that are novel and not obvious and that have a real impact on patient lives. We also would love to see reforms at the PTO, such as increasing patent examiner time on scientific patents, so making sure that they have adequate time to review information. There's a recent Government Accountability Office report that showed that patent examiners were begging for extra time. And so thinking about the holistic nature of what it takes to review and grant a patent to prevent monopolies. And lastly, to increase public engagement within the patent system. We as a patient advocacy group, the public is craving to have a greater role in these decisions that agencies make on behalf of us and our communities. And so as we think about increasing the opportunity to challenge bad patents against the Patent and Trial Appeal Board, for example, instead of rescinding that opportunity, making sure that PTAB decisions include patient voices as they're thinking about invalidating or not invalidating bad patents. So these are reforms that we'd like to see both on the legislative side, but within agencies, as we think about what will move the needle forward to prevent monopolies and promote fair competition for American patients

Assistant Attorney General Abigail Slater:

I neglected at the top of the session to welcome--and Ms. Dave kindly reminded me. We have a couple of PTO colleagues here today in the audience, as well as a colleague from the Commerce Department front office. And so welcome. Thank you for being here today, and we look forward to your collaboration.

Moderator Jill Maguire:

Our--our next question is back to Dr. Schondelmeyer So, Dr. Schondelmeyer our discussion has touched on anticompetitive conduct that is largely driven by brand companies, but there have been several lawsuits against generic drug manufacturers for alleged price fixing of generic drugs. How can collusive agreements to artificially inflate prices and reduce competition be deterred?

Speaker Stephen Schondelmeyer:

Thanks for that question. Actually, the best case or broadest case of price fixing of that type occurred a little over a decade ago. Actually, the behaviors maybe in 2010, '11, '12. And then the suits came in 2013-14, I believe. These involve generic companies who--their leaders would often meet informally at various meetings, at, you know, professional meetings or trade associations. And in the hallways they would have discussions. And these are allegations that were documented in the lawsuits that were filed and so one can refer to those to see the kinds of discussions they had. But what it resulted in was--also we had had mergers and acquisitions and consolidation in the generic market so there were a lot fewer players. And so the key players began discussions and said, we're not going to fix the price per se directly, but what we're going to do is we'll decide who gets the next new generic that comes on the market, and we'll--we'll allocate the new generic market. You get this one and we'll get this one and we'll give them this one. And they allocated, decided who gets the market for new generic. And then that left those players in that market as the only or the dominant player and able to set much higher prices than a economically competitive market would do. So price fixing can occur by blocking others out of the market or allocating markets that one will take. I think in much the same way we see those behaviors happening in the specialty market today. So what can be done? One, we need to very carefully review mergers and acquisitions. Not long ago, maybe five, six years ago, we had the largest generic company based in the U.S. merged with the largest, one of the largest brand name companies in the world who had a big generic division, merged. And there was a lot of overlap in their products. It really took competition and players out of the market, but that was let through as a merger that wasn't challenged. I think we need to look more carefully at mergers and acquisitions. We need to look at allocation of how companies end up with different products. It may be they deal with the API or the key starting materials, but they may just do it by saying, I don't care how you get there, you get this product and I get that one. So we need to watch for. I saw that behavior in the pricing data I monitor even before the lawsuits occurred. So I think one could also monitor pricing behavior in the market and see signals that say,

hey, there's something going on here that needs to be investigated. So I think we need to watch pricing patterns in the market and act upon those as well.

Moderator Kara Monahan:

Our next question is for Mr. Upadhye. In addition to patents, pharmaceutical products can obtain regulatory exclusivities that can further extend the horizon for generic or biosimilar entry. Could you address concerns about the use of regulatory exclusivities by brand companies to delay entry of lower priced competitors?

Speaker Shashank Upadhye:

Sure. Thanks for the question. So on regulatory exclusivities independent of patent exclusivities--and oftentimes they're actually intertwined. So for regulatory exclusivity the company--the brand company may, you know, do some type of new patient population studies. They may do orphan drug studies. And they're entitled to, generally speaking, three years of FDA market exclusivity. So this is not data exclusivity but market exclusivity. And so for a generic company's perspective, they would look at this exclusivity and say, does this keep us off the market or the ANDA sponsor off the market completely because they can't get around the regulatory exclusivity? Or is it something in which they could so-called carve out the three-year regulatory exclusivity and still go to the market with less than all of the indications or less than all of the exclusivities that are there? But regulatory exclusivities are often also intertwined with the patents that follow along. So if there's a new indication that comes along, generally speaking, there might be a second or third method of use patent related to using that--that drug molecule X for the new treatment of disease condition Y. And then again that factors into the ANDA sponsor's patent challenge strategy, their regulatory exclusivity strategies. How are they going to be doing their marketing? And then of course, whether these exclusivities come after an ANDA sponsor has already launched, then it largely becomes an irrelevant consequence for the ANDA sponsor because they're already on the market. And so then if the FDA requires them to put some type of regulatory exclusivity in there, they don't need to necessarily, because they have a fully approved ANDA drug and with an ANDA label. But I do want to also mention that at the end of the day, patent exclusivities, you know, can be intertwined. And, you know, if--can I make one comment on some of the things that I've also heard? Okay. So I wanted to mention that there's a lot of talk about patenting too much and there's too many patents. Generic companies get patents too, you know, and generic companies get patents on polymorphs, formulations, you know, other methods of manufacture. And while generic versus generic patent

infringement is not the norm, it does happen. So we can't obviously demonize any one side of the industry for obtaining patents. Secondly, I also wanted to say is who's in this room is going to be the person that's going to say, there's too many patents. What's the number? Is there a number? When we hear 140, 130, should it be 110? Who's to adjudicate how many patents that are there? And there was a comment made about, you know, patents on incremental. 99% of all patents that are issued by the United States Patent Office are not on the core technology, it's on the incremental basis of it. So there's nothing that the pharmaceutical industry is doing differently in terms of patenting another formulation or a second or third formulation that is beyond the bare-naked compound. So I agree, once the bare-naked compound is patented, then you have series of formulation patents, method of use patents, polymorph enantiomers, racemates, I mean you name it. But whether they're called incremental or not should not at all be a castigation of their value or their worth. They drive innovation. And like any other person in the generic industry, once the brand company has launched the product, it becomes a target for the generic company. There is no generic industry if there's no innovation by the pharma industry. There's no innovation that's going to be rewarded if there's no patents available to them. So it's a natural flow that once the branded product, you know, earns its life cycle. And as Hans was saying, maybe 12 years, 13 years down the road, the generic companies, you know, enter and that becomes the natural life cycle. And this is something I learned when I was at Novartis, where we had the Sandoz generic division, and we were, in a sense, told that the brand companies' profits flow to Sandoz, Sandoz then uses the money it makes on the generic industry to go to the top of the Novartis pipeline, which then funds the next branded drug. So I just wanted to kind of dispel, you know, some myths. Thank you.

Moderator Jill Maguire:

Our next question is for Mr. Sauer. The number of patents that drug companies apply for and obtain has--has significantly increased in recent years, which in turn has expanded the scope of litigation against generic or biosimilar manufacturers. How does this dynamic impact market access and incentives for future development of generic and biosimilar products?

Speaker Hans Sauer:

Hmm. Well, you know, first, you know, short of—I'm not sure I would, like, endorse the notion of, oh, the number of patents has increased in recent years because I don't think we have much of a baseline to go on except for, you know, what we can observe over time in the Orange Book, and I mentioned earlier, there has been a trend, it's true. But the number--the typical number, the average

number of patents per drug new chemical entity that's listed in the Orange Book has gone from about 2 to 3 in the early '90s to 4 to 6 or a little more today, right. So that is an increase over time. It's a doubling, but it's still not a very large number of patents, but there are no generic litigations that involve 50, 60 or however numbers of patents that you might be hearing in the public sphere. For biosimilars litigation, we don't have a baseline over time. But it has been observed though, that well, yeah, it is true, it looks like, you know, biologic innovators do keep filing patents after their drug is already on the market. And there's a suspicion that this reflects somehow strategic behavior where the patent lawyers sit down with the CEOs and the medical people are somewhere in the background, but the company behaves strategically in the way they generate patents solely to maintain whatever it is, right, some kind of--you might describe it as a monopoly. I'm not quite sure that's a proper description. There's nothing unusual about innovative companies once their products reach the marketplace, to continue to spend money on the product, broaden its usefulness in the marketplace, make it more useful for broader patient populations, change it in ways that promote adherence, or even just to manufacture the product in ways that are more cheap, more consistent today than they were 15 years ago when the drug was launched. What people often say when they mean, oh, large numbers of patents are apparently being filed on this drug, that there's something going on that reflects something other than innovation. I don't think I want to be the judge of that. It is very pithy, right, and simple and facile almost to say, well, there are lots of patents cover medically meaningless innovations. I would leave that decision to caretakers, doctors, physicians, patients and others who actually use this drug because the objection that these innovations are meaningless usually comes from people other than the medical community or the people who actually use these products. Very quickly, when--when we look at both the numbers and the expiration dates of patents that cover a drug, right, and we look at, you know, what's the effect of either the number of patents or these expiration dates on the date of entry. When you see what's going on, you will find that the numbers don't correlate. So the numbers of patents or the expiration dates of patents are a very poor predictor of generic entry. There are drugs in the Orange Book today, innovator drugs that have had generic competition for ten years, that still have patents listed that go out for another 5 or 10 years in the future. But competition is already happening. One way that's happening, I'll just give you a few because they've been mentioned, right. Skinny labeling is a very important aspect of generic entry. People speak about patents as if they had this incredible blocking power. When a fully one third of, or by some accounts, 40% of generics actually go to market with less than all the indications that the innovator drug is labeled for. What that is one way

of sidestepping either regulatory exclusivity, the three-year new clinical trial exclusivity, or patents on the uses of these drugs that are listed in the Orange Book. They very often don't form a realistic obstacle to market entry. Right? Another thing that has been mentioned the 30-month stay, right, of great interest to the FTC. The 30-month stay for all the attention it gets actually has also been shown to have like relatively little impact on the actual market entry of generic drugs. What when you look at when generic drugs launch, it is almost never at the expiration of a 30 month stay or at the--at the end of litigation, if there even is litigation, right. Generic entry occurs years after the expiration of the 30 months stay and I would almost suggest, as a field of study, to figure out what happens if we didn't have a 30-months stay at all. Would anything change with respect to the timing of generic market entry? I'm not sure it would, partly for the reason that the FDA review time from submission of an ANDA to its actual approval is in excess of 30 months anyway, right? So to have a more realistic appraisal of, what I would say, these narratives is going to be very important going forward. And I actually look forward as you develop your study, that I hope you will receive a lot of information that—that's been empirically studied and given so that that will inform your study in ways that I think are more reliable than a lot of narratives that we've seen in the marketplace that we don't think are always particularly trustworthy. Thank you.

Moderator Kara Monahan:

Our final question for panel one goes to Mr. Meier. Mr. Meier, you've had many years of experience with antitrust enforcement in the pharmaceutical industry. What lessons can you share with us?

Speaker Markus Meier:

Well, I've got three minutes for three lessons, so thank you for that question. And I'm not restricting myself to just reverse payments. Virtually everything this panel identified as problems were things that we have touched on or done directly, taken actions at the FTC, or written amicus briefs about or done research on. And it's all aptly summarized in a publication. I have the last version with my name on it from 2023. It's been updated. My good colleague Kara has--updates it every 2 or 3 times a year, but so anybody's interested. Like I said, I've already used up a minute, so I've got two minutes left. Look, here's my biggest--here's my big lessons. One--number one, antitrust enforcement is at--is at best a distant second best to real legislative reform and regulatory reform and working together with the FDA, with the Patent and Trademark Office, with the centers for Medicare and Medicaid, with the FTC and DOJ working with them is just hugely important and was--was a big part of what we used to do. We used to do a lot of technical assistance on the Hill to

provide on legislative, and we got some pretty important legislation done over the years. But there's still additional things that need to be done. The problem with antitrust enforcement, as you heard from my 25 years in five minutes, is, look, it's slow, and it's uncertain, and it's limited, and you can't just do--you can't just go in and fix every problem, because a lot of problems aren't really antitrust problems at their core. Number two, despite all the gaming we've heard, and I would have said this even when I was at the FTC, the Hatch-Waxman Act was largely successful, has largely been successful in accomplishing its two goals. We have a very innovative pharmaceutical industry in the United States, and I think--I hope it continues. It certainly was very innovative during the time I worked on these issues. And U.S. consumers do benefit, as Doctor Schondelmeyer said, from generics. 90% of prescriptions, as he pointed out, 20% of the spend, 10% of prescriptions are brand, 80% of the spend. Okay, we spend less on generics than most of our other developed countries around the world. Because they don't get the generics as cheaply as we do. We pay a lot more for the brands, but we pay a lot less for the generics. So we have to be careful, we have to be careful. This has to be surgical. We can't just disrupt the whole system. And again, I would have said that even if somebody had asked me during my government working days. I don't know what the state of play is today, Gail, my good friend Gail. I don't know what the state of play is on legislation, Kara, how much openness there is in the Administration for legislative fixes. I think there is limited scope, more limited scope than it used to be for regulatory fixes because of some of the things the Supreme Court has done to dial back the administrative state. So, absolutely, there's still a role for antitrust, despite the fact that it's slow and uncertain and limited. Thank you.

Moderator Kara Monahan:

Thank you to all our panelists for your insights. We are going to take a momentary break, and then we're going to come back and move into panel two. Thank you. Okay. Thank you. Three minutes.

Moderator Jill Maguire:

All right everybody back. Oh no worries no worries. All right, well, welcome back for our second panel which will focus on anticompetitive conduct by incumbent manufacturers that reduces as opposed to delays competition from lower priced generics or biosimilar alternatives, including rebating strategies and product hopping. Again, I would ask that all panelists be mindful of time constraints when responding to questions. Our listening session today will conclude promptly at four. But let's go ahead and introduce you all.

And I'll start with Alex Brill. Mr. Brill is a senior fellow at the American Enterprise Institute. His public policy and public finance research includes work on healthcare matters, including drug competition and drug innovation. He has testified numerous times before Congress and written on a host of issues. Before joining AEI, Mr. Brill served as the policy director and chief economist of the House Ways and Means Committee, and prior to that served on the staff of the White House Council of Economic Advisers.

Moderator Kara Monahan:
Michael Carrier is a Board of Governors Professor at Rutgers Law School, where he specializes in antitrust and IP law. He is coauthor of the leading IP antitrust treatise, and he is a prolific writer and speaker on pharmaceutical antitrust issues. Professor Carrier has testified numerous times before Congress, the FDA, and the FTC.

Moderator Jill Maguire:
All right. James Gelfand is President and CEO of the ERISA Industry Committee, having previously served as its senior and then Executive Vice President. Mr. Gelfand oversees all aspects of the association's activities, which focus on programs that shape federal and state health and retirement benefit priorities, and that impact member companies' ability to operate under federal ERISA protection from a patchwork of conflicting state and local laws.

Moderator Kara Monahan:
Julie Reed is the Executive Director of the Biosimilars Forum, a trade association for the US biosimilars industry, where she represents companies with U.S. biosimilar development portfolios. Mr. Reed has also worked as a clinician, hospital administrator and health care executive in the global pharmaceutical and medical device industries.

Moderator Jill Maguire:
And our last panelist is Jocelyn Ulrich. She is Vice President of policy and research at the Pharmaceutical Research and Manufacturers of America. At PhRMA, she is responsible for developing legislative and policy analysis and research studies on a range of issues impacting biopharmaceutical companies, including intellectual property issues, FDA policy issues, the R&D process, and the value of innovation. In addition to her experience at PhRMA, she has over 15 years of experience in the pharmaceutical industry.

Moderator Kara Monahan:

Our first question is for Mr. Brill. The FDA approved the first biosimilar in March of 2015, and in the decade since, 75 biosimilars have been approved. What are the key economic and regulatory challenges that have impacted adoption of these biosimilar products in the United States?

Speaker Alex Brill:

Thank you. And thank you for the question and the opportunity to be here with--with colleagues to talk about this important issue. I'd like to begin by acknowledging first the importance of balancing two policy objectives in this marketplace, both the importance of encouraging competition as well as the importance of encouraging innovation. As has been said in the first session, tremendous clinical benefits are derived from today's innovative medicines, and additional R&D in new medicines will yield new valuable cures and treatments. These innovative incentives need to be carefully designed to be predictable, efficient and adequate. But I would also stress designed to minimize the risk that they can be misused to thwart competition. Now, recognizing the importance of incentives for innovation should not be misconstrued. Large, complex, high-stakes drug markets do attract aggressive anticompetitive behaviors. Moreover, legal and regulatory practices can impede or be exploited to impede desirable improvements in the competitiveness of these important markets. With that broad framework, let me offer a few specific observations. First, the burdens of these anticompetitive tactics that we've been discussing exceed what is generally observable in the market today. Biosimilar manufacturers, their decisions to pursue market entry, factor in the risk that anticompetitive tactics will be used in the future to thwart their market entry or their ability to capture market share. This risk that--that these manufacturers face, this potential risk, can have a chilling effect on their early-stage decisions to develop and seek approval for their competitive products. Now, these effects will not be readily observable in the market because they reflect the competitive battles not waged, rather than the effects of the battles we see play out in the courts and in the media. The collective effects of a host of anti-competitive tactics, some of which we've already discussed but including things like patent thickets and product hopping, raise the risk that manufacturers--to manufacturers that the time and cost required to bring a biosimilar market will be extended in an unpredictable manner. These strategies create uncertainty and are unequivocally inefficient. They add cost to the system with little to no benefit. Second, I'd like to note that the barriers to competition are not limited to the actions of private actors in the marketplace, something that was acknowledged earlier as well. The government's own regulatory structures impose barriers

that can have important consequences on market competition. And two examples I think are worth highlighting. First, as you noted, while the FDA has approved over 70 biosimilars, these products represent competition primarily among the blockbuster reference products. In fact, data from IQVIA indicates that approximately 90% of biologics that are expected to lose patent protection in the coming decade are not currently expected to face competition. High fixed costs associated with the development and approval of biosimilars are likely one critical factor limiting this pipeline, and to foster competition across a wider array of biologic drugs, smaller biologic drugs, in particular, regulators and policymakers should consider streamlining the approval process. And second, and finally, I'll note that the incentive for biosimilar competition, for competitors to undertake these large risks and investments to enter the market to drive down prices, is predicated on their expectation for some initial economic return. However, new government price setting mechanisms in Medicare can negate, delay, or diminish the incentives for this market-based competition. This disincentive for market-based competition should be acknowledged and should be rectified by policymakers. And with that, I'll close and say again, thank you for the opportunity to--to be here.

Moderator Jill Maguire:
Thank you. Our next question is for Ms. Reed. Patient access to biologics and biosimilars is largely dependent on drug formularies designed by pharmacy benefit managers. The drug manufacturers pay rebates in exchange for placement on those formularies. Could you speak about these rebating practices and how they impact biosimilar market uptake?

Speaker Juliana Reed:
How many hours do I have?

Moderator Jill Maguire:
You've got 5 to 6 minutes.

Speaker Juliana Reed:
Okay. Darn. Alright. Well thank you, first of all for the opportunity to be here and to be participating on this important panel. I represent the biosimilars industry through the Biosimilars Forum here in the United States. Our members are the companies around--not just in the U.S. but around the globe with the greatest number of biosimilars either in development, on the market and approved in the U.S., but also in over 80 countries. I've been around the biosimilar industry now

globally for 25 years. The anticompetitive practices have--of PBMs have had significant, significant negative impact on the biosimilars industry. Three PBMs control, as everyone knows, 80% of the access to the market in the U.S., and they have not given access to lower cost biosimilars. The best story of this is our Humira experience. Our members have had over ten Humira biosimilars, both approved by the FDA and launched in this U.S. market. The PBMs have not given them access to the U.S. market. That's ten. That's over $1 billion in development, probably a half--a billion and a half to 3 billion. As Alex said, it takes 7 to 9 years to develop a biosimilar, and it takes anywhere between $100 million and $250 million. These are not short-term decisions. Today, those ten biosimilar--Humira biosimilars combined have less than 10% of the market share in the U.S. Those ten biosimilars are at a minimum 80% discounted from the reference Humira, 80%--80% off an $84,000 a year drug. And there is no market share because the PBMs prefer the highly rebated, full priced, fully loaded brand drug. So patients like Shauna do not get access to an 85% decreased cost and at a young age, and I apologize for that, for in our industry would like to help you. You've got your whole life ahead of you, and you should not worry that you can't have access to a lower cost drug. So with that, PBMs have, as Alex have just said, PBMs are also creating the biosimilar void. You need to take that very seriously. Companies are already making pipeline decisions. Out of 118 bio--reference products that will lose patent in the next ten years, only 12 are being developed, 12 out of 118. Currently, the country's saving $56 billion. You could save over $181 billion in five years if we don't have that void, and if we continue to be able to be an industry in the U.S. The biosimilars industry was created under ACA and BPCIA and it's the first new competitive drug industry for things that come off patent or we can get them on the market. One of the key things there's a void already. Within ten years, we're celebrating our 10th year. The PBMs are blocking us. They're not giving us access. So what has to happen? There has to be--there has to be PBM reform. There has to be delinking. There has to be preferred status on formularies for lower cost products. The PBM industry made the generic industry. We all got to--all of a sudden got $0 copay generics. No one's getting that with a biosimilar. And these are $100,000 drugs. So there's a void. We're not going to make them ten years from now. I mean, I hope I'm not sitting here, I hope I get to retire, but I hope there's an industry and I think everyone needs to take this seriously. I've been talking at FTC and on the Hill and--since 2006, and talking around the world about biosimilars. We got to stop talking about the problem. We got to solve the problem. I appreciate being here. My members are devoted to bringing a low cost, competitive, FDA approved product, but we can't continue to do it without anyone's support. So thank you.

Moderator Kara Monahan:

Our next question is for Ms. Ulrich. The development of biologic products has transformed various therapeutic areas and expanded treatment options, but the high cost of these products may put them out of reach for some American patients. What are some sustainable solutions to balance the support of innovation while increasing access to affordable drugs?

Speaker Jocelyn Ulrich:

Thank you. Thank you very much for having me. I will start by saying it is no accident that today the United States leads the world in the development of treatments and cures for patients. This is the direct result of our carefully designed ecosystem, built over many years through smart public policies that encourage risk taking and collaboration. Critical to the biopharmaceutical industry success in the United States is strong and reliable intellectual property protections that give companies the certainty they need to make the long-term investments required to bring new medicines to patients, as well as to improve them for additional patient benefit. However, this leadership is not guaranteed. China now barely trails the United States in the share of new clinical trial starts globally, and has already surpassed us in hosting cancer clinical trials, with 39% of the global total. The only way to stay ahead is by cementing the U.S. as the world's most attractive biopharmaceutical research and investment country. The biopharmaceutical sector is one of the most research-intensive industries in the United States, spending more than 100 billion every year researching and developing new medicines for patients despite only a 12% successfully achieving FDA approval. Even as the industries commit massive resources to this R&D, the industry ranks in the middle of the pack for annual issued patents compared to other high IP industries, affirming that the industry's patenting behavior is not an outlier. By any measure, America's IP framework has been a resounding success. Despite the long odds, biopharmaceutical companies have launched nearly 900 new medicines since 2000, resulting in significant progress against some of the most costly and challenging diseases. And many of these have been due to biologic medicines. For example, CAR-T therapies are curing advanced childhood leukemia, while checkpoint inhibitors are transforming cancer care, contributing to a 33% drop in cancer death rates. Since the 1990s, biologics have dramatically improved outcomes in daily functioning for patients with autoimmune conditions like rheumatoid arthritis, Crohn's, and psoriasis, and genome edited therapy offers a potential cure for sickle cell disease, showcasing how these therapies could replace costly chronic care with one-time treatments. Importantly, our IP system not only incentivizes development of new medicine, it spurs competition that lowers health

care costs. Many companies can research the same disease, and the brand-to-brand competition that results when companies seek to develop the most effective treatments for patients drives choice, and it decreases net prices by as much as 60%. Post-approval R&D further expands treatment options and IP protections on those advances do not prevent the approval of generic copies or biosimilars of earlier versions. Today, in fact, as was mentioned earlier, 90% of prescriptions in the U.S. are filled with generic and biosimilar medicines, which are 33% cheaper on average than in other OECD countries. On average, also as we talked about earlier, a small molecule drug is on the market only 13 years before facing competition from generics, which can cost over 80% less than the brand. Patent settlements have accelerated patient access to generic and biosimilar medicines to market by, on average, more than five years before patent expiration, and since 2013 have resulted in $423 billion in savings to the health care system. This framework--framework is what makes the marketplace for medicines unique. Similar cost containment mechanisms do not exist for any other part of the healthcare system. Medicines are the only part where prices go down over time, but there are real challenges to getting more affordable options to patients. Insurance companies and their PBMs control which medicines are covered, how much patients pay, and what barriers they face to access prescribed treatments. Today, as Julie mentioned, three PBMs control nearly 80% of the market and are vertically integrated with insurers, pharmacies and provider groups, significantly impacting whether patients can benefit from this innovation and competition. PBMs inflate costs by marking up medicines dispensed through their own pharmacies, often by hundreds or even thousands of percent. And over the last five years, PBMs have increasingly excluded biosimilars from their commercial formularies. PBMs aren't the only intermediaries that are profiting at patients' expense. The 340B program, created to help underserved patients, often benefits hospitals instead. 340B hospitals are more likely to prescribe costly drugs, and biosimilar adoption is 23 percentage points lower among commercially insured patients at 340B hospitals compared to non-340B hospitals. Policymakers should be focused today on advancing policies where competition could be enhanced without undermining the very foundation of the industry's ability to innovate, and this includes addressing the misaligned incentives in the PBM market, fixing the 340B hospital markup program, as well as making foreign countries pay their fair share for innovation. Thank you very much and look forward to the discussion.

Moderator Jill Maguire:

Our next question is for Mr. Gelfand. Biologics have provided important advances in treating serious medical conditions, but in addition to the cost to patients, these treatments can be extremely expensive for employers. Biosimilars have the potential to reduce those costs. What challenges do employers face when trying to incorporate biosimilars into their health plans, and what changes could mitigate those challenges?

Speaker James Gelfand:

Thank you for the opportunity to be here. As Jill mentioned, I'm the president and CEO of the ERISA Industry Committee. ERIC is a--represents large employers in their capacity as sponsors of employee benefit plans. More than 160 million Americans get benefits--health benefits through an employer, and large employers pay more than 80% of health care costs for employees and families. But that's increasingly difficult today in today's prescription drug market, due to extreme anti-competitive conduct that takes place. Anticompetitive practices amount to a massive tax on employers, translating to fewer jobs and less take-home pay for hard working Americans. In my remarks today, I will outline concerns that employers have regarding pharmacy benefit managers, gaming of the patent system, and unacceptable regulatory barriers. First, PBMs. You've heard several times now that three PBMs control over 80% of the prescription drug market. PBMs are extremely secretive, often hiding an employer's own claims data and the prices that the employer pays for drugs or holding that data hostage for incredibly high fees. They routinely refuse to allow employers to compare the net prices of drugs and obfuscate about their compensation. Let me give you a powerful example, which is the launch of the Humira biosimilars. Humira is the highest grossing drug ever, and thus a major cost to employers. We had very high hopes for biosimilar products entering the market to start competing, and we knew that this was a make-or-break moment for a successful biosimilars market. Humira' list price was about $6,700. Its biosimilars launched at around $1,000, so even accounting for rebates, the biosimilars net cost was still over $1,000 less than the brand. But after biosimilars became available, PBMs still pushed the higher price branded products. Why? Because PBM compensation is not based on getting the lowest net price. Instead, they profit from big rebates and they charge fees to drug manufacturers through the PBMs' overseas group purchasing organizations. Those fees are a percentage of the list price, so 5% of $6,700 is far more than 5% of $1,000. These fees also create a major ethical problem for these middlemen, who employers are hiring to negotiate the lowest possible costs for working families. One PBM we are--

we are aware of even imposed a try first requirement, where a patient would have to try the branded drug and fail before they could get the cheaper biosimilar drug. Employers want the lowest net cost options, but PBMs often present misleading data, focusing only on rebate percentages or telling plans that rebates are bundled across a pharma manufacturer's entire product portfolio. This is not a free market, it's a distorted one where employers can't get basic pricing information, and PBMs forbid biosimilar manufacturers from sharing net pricing details with employers. And if an informed employer--and an informed employer may still have no recourse, as PBM contracts generally prohibit carving out drugs from the PBM's formulary or extract prohibitive fees from an employer seeking to do so. Even worse, PBMs now create private label biosimilars under the auspices of their own "drug companies," and I'm putting quotes because those companies do not produce drugs. They partner with manufacturers and hike up the cost, sometimes charging a 200% or higher markup and then sell it to patients under their own brands. These--these private label drugs are often slightly cheaper than the brand name drug, but vastly more expensive than competing biosimilars. This manipulation undercuts biosimilar sustainability, and that's not the only obstacle to competition. Patent thickets are another major problem where brand name manufacturers patent the same invention multiple times using slightly different language. Look at any new drugs patents in the United States. Chances are that you will see they have many more patents in the United States than they do overseas. To get on the market and to compete, the biosimilar companies have to spend millions of dollars trying to invalidate each of these individual patents. These tactics delay competition. They keep prices high. ERIC supports legislation by Congressman Jodey Arrington, which would crack down on this abuse, but it shouldn't be needed, as this kind of anticompetitive gaming of the patent system shouldn't be tolerated. Finally, I want to address a major regulatory barrier, the supposed need for interchangeability designations before pharmacists can substitute biosimilars. There is no clinical difference between biosimilars and their reference products, and obtaining this designation requires hundreds of millions of dollars and years of lost market share while conducting studies. A misinformation campaign was used to pass laws in many states preventing substitution of biosimilars without that interchangeability designation. The FDA has gone to great lengths to correct the record, but the damage persists. ERIC supports legislation by Senator Mike Lee which would negate this anticompetitive tactic. In conclusion, employers believe change is needed to restore competition. PBM practices like rebate walls, private labeling and pricing opacity hurt patients and drive up costs for employers. Patent games and requirements for unnecessary studies increase the barriers to entry for biosimilars into the U.S. market and

inappropriately increase exclusivity for branded drugs, costing employers and working families many billions of dollars. We appreciate the opportunity to be here and contribute to this discussion, and I look forward to working with you to bring accountability and reform to the prescription drug marketplace.

Moderator Kara Monahan:

Our next question is for Professor Carrier. Consumers depend on pharmaceutical manufacturers to develop new drug products to improve treatment options. But sometimes manufacturers make what seem to be minor therapeutic changes to their products and then take steps to switch patients to the new product, which can ultimately impede generic competition. Can you give some background on product hopping cases and address recent developments with pharmacy benefit managers?

Speaker Michael Carrier:

Sure. So thank you for the question and thank you for holding this really important event. Product hopping is nuanced because it involves the intersection of antitrust law, patent law, the federal Hatch-Waxman Act, state drug product substitution laws. It also involves markets that are unique because you have the decider, the doctor, who is different from the payer, the insurance company or the patient. And so you have lots of room for anti-competitive behavior. By product hopping, Steve Shadowen and I have defined it as reformulating the version of the drug so that the generic is not substitutable on the first hand, and then also encouraging doctors to write scripts for their reformulated version. So if you are expanding the prescription base, that is fine. If you're migrating it over to impair competition, that is less fine. And also it avoids state substitution laws. So state substitution laws require that the drug be bioequivalent, therapeutically equivalent. These small changes are enough to get out of those substitution laws. And so that is a real problem with what's going on. So a really quick recap of five leading product hopping cases just in terms of the facts. First, we have the Tricor case. That was a hard switch. That's where the brand company pulls the old version from the market and the market is just left with the new version. That is what happened in Tricor. Second is the Walgreen's case, which was a soft switch from Prilosec to Nexium. Soft means that Prilosec remained on the market. Third was the Suboxone case, where the brand firm raised the original price. It also disparaged the original. It warned of false safety concerns. Fourth is the Doryx case, which was a hard switch where the brand company bought back and destroyed capsules. And fifth was the Namenda case, where the brand version removed the original even before that announced the discontinuance. That is all unilateral conduct. And what I'd like to talk

about now is the intersection of product hopping and PBMs. Now, this might look like collusion. It might look like the folks on this side of the--of the panel have all been talking about PBMs, even though this is not the session for PBMs. It might even look like collusion among us. And I would hope that this would not be per se illegal. But maybe under the rule of reason, we have some good reasons to talk about that. I hope that the court would consider that. But what I'd like to offer as a big picture approach here is it's not just blame the other side. Sometimes you hear pharma says it's not us, it's PBMs. And PBMs say it's not us, it's pharma. Maybe it's all of the above. Maybe there is enough blame to go around so that it's more than just one simple bad actor here. So in terms of PBMs, I don't have to repeat all that's been said so far, but--but clearly it's in the interest of both parties here. So the manufacturer benefits when it gets its drug placed on the formulary. That is a true benefit because that means it's available to the patient. The PBM benefits because the PBM gets a large rebate, doesn't always pass it on to the ultimate payer. And so there's a lot of benefit for both sides here. Let me offer a couple of examples. Victoria Field and I have written about four examples. The first example is Humira. Again, I feel like on this panel we all have to talk about Humira. But let me just mention the formulary placement issue in terms of the money. So you have a very expensive drug that is included on the formulary. Basically, what Humira did here is it switched in 2019 to next gen therapies like Skyrizi taken a few times a year, Rinvoq taken daily, even though in early 2020 for biosimilar uptake was 400% higher, the prescription fill volume went down because of all this product hopping. So again, you had Skyrizi which--which had a $21,000 list price that was on the same tier as drugs that were a third of that. You had inexpensive drugs, only $1,000, that were excluded from the formulary. Big picture, formulary placement makes a big deal, and the PBM and the manufacturer can work together to engage in product upping. And my final example is Copaxone. That involves tying--tying rebates to the inclusion of a new drug. So here, Teva is switching from a 20-milligram dose of MS-treating Copaxone to a 40-milligram dose. The clinical trials failed to show that the 40-milligram dose was superior, the internal presentation said that, quote, the data is not going to support the higher doses. The scientific team was strongly against it, but the life cycle management team said there's business value here. When you bring it over to the PBMs--Teva pressured the PBMs by tying the rebates on the 20 to the inclusion of the 40. In other words, PBMs, if you want to have the 20 there, you also have to include the 40. So there is one PBM that forfeited its rebate because it didn't include the 40. The next year, it came back and included the 40. This had a real effect. Copaxone 40 had 77% of the market within two years. And according to one empirical analysis, the strategy cost the U.S. health care system $4 to $6 billion in additional

expenditures over a two-year period. So in short, product hopping and PBMs--manufacturers and PBMs can work together to engage in product hopping. Thank you.

Moderator Jill Maguire:

Our next question is back to Mr. Brill. Certain diseases only impact a relatively small patient population, which limits the potential market size for drugs targeting those rare conditions and may affect incentives for biosimilar development. Are there any specific regulatory reforms or other initiatives that could promote biosimilar development for smaller drug markets?

Speaker Alex Brill:

Sure. Thanks for the question. So I think in two parts, one could think generally about regulatory reforms that would not be targeted towards--towards small market products or population products that would have benefits for those orphan market products. So a broad reform, say, elimination of a requirement for switching studies or something of that nature would--would--would benefit all biosimilars, including those smaller products. Or, and/or I should say, policy makers could think about narrower, targeted incentives to encourage the development of competitive products for these smaller market products. You'd have to, you know, balance that in a--in a clinical context. You'd want to preserve the clinical integrity of the biosimilar development, but one could develop ideas related to exclusivities for biosimilars, for those smaller products. I think one thing that would be important to recognize is that expectations for the degree of competition in those markets would be less than in, say, the example that--now I've also acknowledged the Humira environment, now we've all said it, where there are, you know, ten or more biosimilars. So you would get a less dynamic, a less competitive marketplace but--in the smaller product, but you should still consider policies to create competition there as well.

Moderator Kara Monahan:

Our next question is for Ms. Reed. Rebating strategies that favor high list prices and high rebates may hinder competition from biosimilar products trying to launch at lower list prices. What changes would you like to see regarding formulary access and rebating practices to better support competition from biosimilars?

Speaker Juliana Reed:

Thank you. Really, PBM reform needs to happen and not just what is being proposed as today. We need transparency, transparency, but that transparency is only going to give policymakers what has happened--what we all know is happening. It does not move that the PBMs are forced to accept or promote lower cost products like the small molecules. We need delinking. We need pass-through rebates. We need to get PBMs to provide access to lower cost biosimilars. We also need Medicare, CMS, to remove their no interference clause between them and the PBMs. The--CMS and Medicare as one of the largest insurers in this country cannot tell the PBMs we want the lower cost biosimilar. As a future Medicare patient and beneficiary, I kind of want the lower cost biosimilar. So those things. But I'm going to also--I'm going to steal your question a little bit more and tell you that we will give you, as industry, very specific things that could happen at the FDA after 15 years. It's time to evolve the FDA. We need to get rid of interchangeability. As was said by one of the other speakers, that was put in the original bill as a misinformation, as a barrier, creating a false second standard for biosimilars. We need to get rid of it. We need to increase the efficiencies at the FDA. We need to give the OTBB the ability to review and add their signature to a biosimilar application. They don't have that, but they're the experts in the science of biosimilars. We need to eliminate the FDA's over-conservative--I'm sorry I ignored your one minute--the over-conservative approach to biosimilars three-way PK studies. Right now, the FDA routinely requires the biosimilar manufacturer to prove that the reference product brought in--bought in Europe is the same as the reference product in the U.S., even though publicly they are. We have to do a very expensive three-way, public--three-way P--PK studies. We need to eliminate the crazy biosimilar suffix. No one uses it. All right? It was--it was created so that you knew the biosimilar had a safety single. We have ten years of FDA research that shows no biosimilars had a safety single. Get rid of the FDA--of the--of the suffix. No one uses it. And let's give the time back to the FDA people who are looking at suffixes or applying suffixes to do real work. We need to provide greater, as--as Alex said, greater efficiencies at the agency. Let the agency use their 15 years of experience to improve biosimilars development and evaluation. We know that if we can get these things done, if all of us could get PBM stuff done, if all of us could get stability in physicians' reimbursement, if we can improve the FDA process, we will go after the products that are in the void. But we can't continue to take 7 to 9 years, 7 to 9 years, and hundreds of millions of dollars to develop a biosimilar after 15 years. So I just continue to tell you all, if you want this industry here in ten years, I can't--we cannot be the only people doing this stuff. So thank you. And thank you for giving me more time.

Moderator Jill Maguire:

Our next question is for Ms. Ulrich. What are some steps that PhRMA and its members are taking to support access to lower-cost drug products?

Speaker Jocelyn Ulrich:

Thanks. So, you know, similar to some of the things that Julie talked about, you know, I think critically important is advancing reforms on the PBM agenda, making sure that compensation for PBMs is being tied not to the--or that copay for patients is not being tied to the list price, that we're sharing the savings. We're looking at those incentives and also, importantly, looking at the growing trend towards all the vertical integration. I think we also really believe that 340B reform would be critically important, as I mentioned in my opening remarks. And then, you know, really, as I said, in the end, you know, we've increasingly been discussing the fact that patients here are paying a premium on prices because other countries are not paying their fair share of innovation. There are certainly things that, through trade agreements and other things that Congress could do to ensure that countries are paying a more fair share towards innovation, that they are increasing their healthcare budgets, and, in particular, for innovative medicines. And that would certainly relieve some of the pressure here. And I think all those things together, I think, would make a big difference.

Moderator Kara Monahan:

Our next question is for Professor Carrier. Product hopping has received attention from both the courts and Congress, where bipartisan legislation was introduced to prohibit manufacturers from engaging in product hopping. How do congressional and court approaches to product hopping compare, and what are key considerations for stakeholders trying to address this problem?

Speaker Michael Carrier:

Thank you. So one concern is that courts don't always fully appreciate the harms from product hopping. That's especially the case with soft switches where the old drug remains on the market. So for example, you look at the Walgreens case, the court said the old version's on the market, you're adding choices. The market will determine which is superior. That is a bit simplistic. There are allegations in that case that of the dozens of options, this was the worst for consumers. A government official said doctors should be embarrassed if they prescribe the drug. The CEO said if this was left to R&D, there would not be Nexium. This was driven by marketing. There were

negative false claims. So there is tons of evidence there that this was a concerning product hop. If you just focus on the fact that it was a soft switch, therefore it's per se legal, that doesn't capture it. Similarly, in the Doryx case, lots of concerning examples here of hard switches. Nonetheless, the court said this is not David versus Goliath. Milan was a victim of its own business strategy. These are approaches that are very concerning. And so there is legislation that has been introduced in the past several Congresses, from Senators Blumenthal and Cornyn that would address these issues, that would address soft switches as well, tons of protection for brand firms in there. The legislation limits the conduct to a particular window in time in which generic entry is expected. There are exclusions based on marketing. There are justifications. So if the brand firm would have made this change, regardless of the effect on generic competition, then automatically it's fine. This is the no economic sense test. It's conservative a test as you'll find in the case law. And so that is--that's legislation that is worth a careful look. Sometimes we hear that we can't do anything on product hopping because that would harm innovation. I think to the contrary, if you remove antitrust legislation here, then that is a problem. I've written about examples like Tricor and Neurontin and Namenda, where the brand firm had the innovation and sat on it for years until the generic was about to enter the market. And so we need to have robust competition here through legislation and the courts. And then one final point is we've heard today about patents, and we don't know the number of patents that are the issue. Two quick responses on that, Sean Tu and I engaged in an empirical analysis of patents in the pharmaceutical industry versus those in the high-tech industry. And we showed that the patents are used differently, obviously, more cross-licensing in the high-tech industry. We looked at continuations. It's very different. Just because it's okay in high tech doesn't mean it's okay in pharma. And then finally, you--you look at the Humira example, it's not the number of patents. It's what was done with the patents. The district court there said that AbbVie listed nine formulation patents with ingredients not in the biosimilar or Humira, quote, in other words, they were objectively baseless to assert. The court didn't follow that since Seventh Circuit brushed that under the rug. If this is objectively baseless to assert, that's the sham exception to Noerr-Pennington. And so let's look at the facts before we jump to these overall legal conclusions. Thank you.

Moderator Jill Maguire:

Our next question is Mr. Gelfand, and you've already touched on this topic, as has another panelist. But just to go back to it and dig deeper, small molecule generics are typically substituted for brand prescriptions at the pharmacy counter. In the biologic space, there are biosimilars and

interchangeable biosimilars. What is the significance of the interchangeable designation--designation, and how does it impact biosimilar access and affordability?

Speaker James Gelfand:

Thank you. I think if we're going to talk about interchangeability, we should start by acknowledging that the very existence of this designation was a poison pill added to legislation 15 years ago. This is a designation that does not exist in Europe or elsewhere because it is duplicative. If the FDA approves a product as a safe and effective biosimilar for a given reference drug, then by definition, it is already interchangeable. The only reason to require further study is to slow down the ability to substitute, and it is widely known that substitution was the key to unlocking savings from generics in the small molecule market. And if we can't substitute in the large molecule market, we're not going to capture the savings that we did. So FDA has repeatedly sought to dispel the notion that there's any difference between biosimilars, with or without the interchangeability designation, but stakeholders who are defending the status quo continue to publish misinformation. The effect of this misinformation is to confuse providers, right, so they're not prescribing biosimilars. It's to scare patients and make them think that there's secret, unknown ingredients or health consequences for switching to a biosimilar. And ultimately to block access so that patients aren't getting these drugs, which means that they're paying out of pocket and the employers are paying the--for the much more expensive branded drugs. So what DOJ and FTC should explore is whether some of the statements and actions by branded manufacturers or their associations or their proxies are falsely--falsely challenge the safety or effectiveness of biosimilars as a substitute for their reference product.

Moderator Kara Monahan:

So for our final question to all ten panelists, we are going to do a lightning round where we are going to ask you for your 30 second response to what do you think would be the biggest change that would make the most impact in deterring anticompetitive conduct by pharmaceutical companies? So we're going to start with Professor Carrier, and we'll work our way around the panel ending with Dr.--Dr. Schondelmeyer, excuse me.

Speaker Michael Carrier:

So I think in terms of this side of the panel, product hopping is a concern. And you need to think broadly about who is engaging in it, the brand manufacturers as well as the PBMs. And then in

terms of delay, pay for delay settlements are still an issue. Even though it's getting more and more nuanced, it's still worth attention.

Speaker James Gelfand:
We need PBM reform. We need--we need to crack down on duplicative, unnecessary patents by passing the Arrington legislation.

Speaker Juliana Reed:
I would say PBM reform requiring PBMs to share savings with medicines directly with patients at the counter and fix the misaligned incentives, and fixing the 340B hospital market program to prevent hospitals from using it as a profit center.

Speaker Jocelyn Ulrich:
PBM reform. Preferring lower cost biosimilars, improving the FDA, getting rid of interchangeability in the suffix, and also improving the IP system. Thank you.

Speaker Alex Brill:
Recognizing it's the collective effect of a myriad of strategies that are delaying or discouraging biosimilar development. Taking a holistic approach to this issue, I think, is critically important. And as I noted in my earlier--in my opening remark, I--the concerns around the price negotiations from the IRA can--is one of--one example of a policy that can have that kind of chilling effect.

Speaker Shashank Upadhye:
So recognizing that at the end of the day, there's no single answer to this and that it is not monolithic in its answers and recog--it's a holistic approach. And my advocacy would be that the agencies and the FDA and the court systems take a surgical look at various practices, pick your best case, you know, win it, and then that will make everybody else fall in line, you know, because nobody wants the future liability. But thinking that it can be done in one fell swoop is never going to happen.

Speaker Sneha Dave:
I agree with all the multifactorial solutions, but I think that we can start with stopping to grant bad patents, and I understand it might be done in other industries, but these are prescription drugs. These are not, respectfully, golf balls or other products. These are things that impact patient lives,

day to day life or death for patients. So we need to be looking at prescription drugs as a crucial issue versus the way that other systems work. Because again, these are products that patients often don't choose to be on but have to be on for the rest of our lives.

Speaker Hans Sauer:
Policymakers need to engage more with data and less with narratives. There's too much generalization from examples that, you know, are amenable to too many descriptions. We have to find a way to unburden patients and sharing in the savings. And that presupposes PBM reform first and foremost. Thank you.

Speaker Markus Meier:
I feel like everybody else was told we were going to be asked this, so I didn't really think too much about it, but I wasn't told. But here I go. I said 10% of prescriptions, 80% of spend, branded drugs, high drug prices that people are mostly complaining about has to do with branded drugs. They're just damned expensive. And one of the reasons they're expensive in defense of the industry is that there's clinical trials that are super expensive to conduct. I'd like to see, and this reform has nothing to do with the FTC or DOJ, but I'd like to see some experimentation with the public finance of clinical trials and in return, a shortened patent term or a shortened period of exclusivity, and see how well that would work.

Speaker Stephen Schondelmeyer:
Reform again is one method that's needed. But there are a lot of aspects to how you reform PBMs and what you do with those. And even PBM reform is not a single shot. It's got multiple arms and legs. I do think we need to revisit the safe harbor rule that says rebates are not kickbacks. Yes, they are, and they behave like that. I think this market is rife with reverse, perverse economics. What looks like reverse payments on pay for delay, reverse payments of rebates, you know, PBMs making decisions because they make more money at a higher price than a lower price. Doctors prescribing part B drugs because they make more money on one drug versus another, even though they may be similar. There are all kinds of reverse, perverse economics in this market that need to be sorted out. I believe in markets. Markets work, but we have to also understand the structure of the pharmaceutical market space is not a normal market to begin with. We require that permission slip from the doctor, and the PBM is making the decisions. The insurer or employer is paying for it. The consumer gets caught in the crossfire. This market isn't normal. And we have to understand all of

those distortions in the structure of the market to begin with, to understand what kinds of behaviors we'll get out at the end after we do reform.

Speaker Principal Deputy Assistant Attorney General Roger Alford:
I love that final comment. This market is not normal, and it's--what's amazing, we've like this collective wisdom here of all the people in this room. We just have so much knowledge here in this room. This is our very first session with only the first ten people. And it's shocking to me how many different problems have been identified. I mean, usually when we have a giant antitrust case, we can get to the nub of the problem relatively quickly. But what I'm hearing is there's a myriad of different problems, and that we need to try to do as much as we can to sort of tackle them. Thankfully, we have an executive order that mandates that we address these problems. So there is a will, there's a--there's willingness to do it, I think at the very top and a mandate that we all look at it, so we can look at regulatory reform and we can look at antitrust litigation. This has been great. I mean, both--both of our interlocutors have been phenomenal. The experts have been great. So I'm glad that we had the first listening session. It's obviously being recorded and will be posted. And this is only focusing on generics and biosimilars. You know, like the other sessions, we're going to be focusing on other things as well. So our next listening session is July 24th. And I don't know the details on it, but it's on the event page. Is it going to be in this room as well or is it going to be the FTC? Do we know Markus, where it's going to be? It'll be at the FTC on July 24th. And then obviously we welcome public comments. We welcome further discussion on the event page. If you just like--if you just Google listening sessions for DOJ and FTC, you can find the event pages for this. So thank you. Thank you, Markus. Thank you all of the experts here in the room. We're adjourned.