Synda Mark:

One minute, so if everyone could take their seats and we will get our program started. Thank you so much.

Kara Monahan:

Good afternoon. My name is Kara Monahan. Before we get started today with our substantive program, I'm just going to review some administrative details. Please silence any mobile phones or other electronic devices. Please be aware that if you leave the Constitution Center building for any reason during the workshop, you'll have to go back through security screening again, so please keep this in mind, especially if you're participating on a panel. Restrooms are located in the hallway just outside of the auditorium here. Most of you received a lanyard with an FTC event security badge. We use these for multiple events, so when you leave for the day, please return your badge to security. If an emergency occurs that requires you to leave Constitution Center but remain in the building, follow the instructions provided over the Building PA system. This event is being photographed, recorded, and live-streamed. By participating in this event, you are agreeing that your image and anything you say or submit may be posted on ftc.gov and one of the Commission's publicly available social media sites. I am now pleased to invite FTC Chairman Andrew Ferguson to provide opening remarks.

FTC Chairman Andrew Ferguson:

Thank you, Kara. Good afternoon everyone. My name is Andrew Ferguson and I'm the Chairman of the Federal Trade Commission. Today my agency together with the Department of Justice and the Department of Commerce is hosting the second of three public listening sessions on potential anticompetitive behavior in the pharmaceutical industry. In keeping with his commitment to lower drug prices for everyday Americans, President Donald J. Trump has tasked the Department of Health and Human Services and us with conducting these listening sessions and with issuing a report containing recommendations for combating potentially anticompetitive practices that raise the cost of prescription drugs. To that end, I also want to welcome representatives from the Food and Drug Administration and the U.S. Patent and Trademark Office, each of whom is an important collaborator in this effort. In our last listening session, we focused on potentially anticompetitive practices that raise

the cost of prescription drugs by impeding the introduction of generic or biosimilar competitors to brand name drugs.

In today's session, we will focus on three potential causes of reduced competition and higher costs in the drug market. One, the business relationship between pharmacy benefit managers and drug manufacturers, the misuse of the FDA's Orange Book and drug safety programs and government regulations that disincentivize competition on price and product quality. FTC leadership and staff have taken an aggressive approach to combating these kinds of anticompetitive practices in the prescription drug market. Just last month, we sent warning letters to pharmaceutical companies that disputed the propriety of over 200 patent listings in the FDA's Orange Book across 17 different name brand drug products. By listing patents in the Orange Book that do not actually cover their products, drug manufacturers can trigger automatic delays in the introduction of generic alternatives which impede competition and raise drug costs for Americans. The FTC has long considered improper listings of patents in the Orange Book to be a potential violation of Section 5 of the FTC Act, which prohibits unfair methods of competition, and we will not hesitate to exercise our enforcement authority to prevent this industry practice.

Likewise, the FTC is in the midst of an intensive industry study to learn whether the business practices of our nation's largest pharmacy benefit managers are negatively impacting the accessibility and affordability of prescription drugs. Compelling these companies to provide information to the FTC is giving us insight into their rebate agreements with drug manufacturers, as well as the methods for determining reimbursements, audits, and fees for different pharmacies. We can take what we will learn and fulfill one of the most important duties with which Congress has entrusted us: To inform the public and Congress about the FTC's understanding of these markets. Doing so can lay the groundwork for legislative action as well as for potential, future enforcement actions aimed at combating anticompetitive conduct in the prescription drug markets. The Biden administration failed to provide the resources necessary to complete this study. Under President Trump, we will get this done.

I'd also like to highlight that both in the case of manufacturers' misuse of the Orange Book and PBMs' rebate and pricing methods, incumbents appear to use government laws and regulations which were designed to promote competition and reduce costs to shield themselves from competitive pressure imposed by rival firms, which result in higher costs for consumers. Rather than increasing one's market share through genuine innovation resulting in lower prices or better-quality products, incumbents engage in regulatory arbitrage or lawfare to edge out rivals. But lawmakers and regulators intended to incentivize competition on price and product quality, not competition in rent-seeking. To promote competitive pharmaceutical markets, we need to identify and eliminate all forms of rent-seeking activity that allow companies to reap financial rewards that are entirely out of proportion to their contribution to genuine innovation in pharmaceuticals.

In today's listening session, we will hear from a variety of experts and scholars on these issues, which will undoubtedly inform our final report and its recommendations to the president. I'm very grateful to our dedicated staff for organizing this event as well as to each of our panelists for lending us their time and expertise. I hope this conversation will provide us with some fresh perspectives on how lawmakers and regulators can promote a competitive marketplace for pharmaceuticals that yields substantial benefits for all participants, but most importantly for the ordinary Americans whose personal and financial livelihood depends on ready, safe, and effective access to prescription drugs. With that, I'll turn it back over to Kara, our Deputy Assistant Director of the FTC's Health Care Division, who will kick off our panel today. Thank you.

Kara Monahan:

Thank you, Chairman Ferguson. I will be one of the moderators for today's session along with my colleague Markus Brazill from DOJ's Antitrust Division. We will have two one-hour panel discussions today. Upon the conclusion of the first panel on formulary and benefit practices, we will take a short break before the second panel. 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.

Markus Brazill:

Hello, my name is Markus Brazill and I'm Counsel to Assistant Attorney General Abigail Slater at the Department of Justice's Antitrust Division. Let's introduce the members of our first panel who will speak about formulary and benefit practices and the relationships between drug companies, PBMs, and pharmacies.

Cheryl Damberg is the director of the RAND Center of Excellence on Health System performance, the RAND Distinguished Chair in health care payment policy, and a principal senior economist at the RAND. Her research has explored the impact of strategies to drive cost and quality improvements in health care delivery and the effects of health care consolidation on health care spending and quality performance. She regularly advises Congress, federal agencies, and state governments on these and other key policy issues. Dr. Damberg currently serves as a commissioner on the Medicare Payment Advisory Commission, which is a bipartisan commission advising Congress on Medicare policy.

Kara Monahan:

Tim Dube is the Senior Vice President for Policy and Regulatory Insights at PCMA, a trade association representing the interests of pharmacy benefit managers, where he oversees internal work and external engagement with federal regulators, policymakers, and researchers. Before joining PCMA, Tim worked as a senior policy analyst with the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, and for Genentech in various roles spanning from drug development to commercialization to state and federal policy.

Markus Brazill:

Stacie Dusetzina is a professor of Health Policy and an Ingram professor of cancer research at Vanderbilt University School of Medicine, Department of Health Policy. She is a health services researcher focusing on the intersection between health policy, epidemiology, and economics related to prescription drugs. She has been recognized for her work at a national level advising congressional committees and multiple government agencies on prescription drug legislation and serves as a Commissioner on the Medicare Payment Advisory Commission.

Kara Monahan:

Kathleen Jaeger is the president and CEO of Medsecurean, a consulting firm, and is also the Founder and CEO of the Center for American Medicine Resiliency. She previously served as Executive Vice President at the National Association of Chain Drug Stores, as well as the President and CEO of the Generic Pharmaceutical Association, now AAM. Ms. Jaeger helped advance two landmark pieces of legislation, the Hatch-Waxman reforms, and the Medicare Modernization Act of 2003, and the Biologics Price Competition and Innovation Act.

Markus Brazill:

And finally, Joe Shields is the founder and President of Transparency-Rx, a coalition of companies committed to pass-through transparent pharmacy benefit management and a resilient American supply chain. Transparency-Rx represents more than 22 million covered lives with members operating in all 50 states, serving a wide range of national and local employers and plans. Joe has served under three governors, has been appointed as a chief executive and spearheaded major initiatives spanning law enforcement, behavioral health, and community development.

Kara Monahan:

Our first question is going to be for Mr. Dube. The first PBMs emerged decades ago to facilitate the flow of claims processing and reimbursements between insurers and pharmacies. How have PBMs evolved and what services do they provide today?

Tim Dube:

Thank you, Kara, for the question. I'm glad to be here to provide the broad PBM industry perspective on the questions being asked today. PBMs are the only part of the drug supply chain that is in your corner working hard to save you money. As we'll talk about throughout this panel, PBMs are hired by plan sponsors to do many things to control the cost of drugs. Any argument that PBMs do the opposite and raise drug costs is simply implausible. If it were true, no one would hire a PBM. PBMs and the services they offer today emerged as a direct response to rising drug spending and anticompetitive behavior on the part of drug companies. For years, drug companies have leveraged their monopoly pricing power for brand-name drugs to set high prices and block generic and biosimilar competition. Plan sponsors, meaning employers, unions, state and federal programs like Medicare Part D, could negotiate directly with drug companies and pay the price each pharmacy charges.

Almost all would lack the clinical expertise, and the specialized knowledge needed to do so. Instead, nearly all of them hire a PBM, and the industry provides drug benefits for 289 million Americans. These efforts generate more than $1.2 trillion in savings for their clients and taxpayers over the next 10 years, equating to about $1,150 per person per year. In the 1990s and 2000s as you referenced, Kara, PBMs developed comprehensive formularies to ensure the most clinically appropriate drugs were used rather than the most advertised ones. PBMs also responded to other blockbuster drug launches by creating pharmacy networks, so that their clients could get better retail pricing for those drugs without competition. Over the last decade, specialty drug spending has overtaken spending for all other categories of drugs. PBMs have responded by bringing specialty pharmacy services in-house and by forming GPOs to bring greater scale to bear against drug companies in their ongoing negotiations.

The more lives a PBM contract covers or the more units a specialty pharmacy is purchasing, the lower the prices they can secure for their clients. Any argument to the contrary is impossible. PBMs compete fiercely for these clients. There are more than 70 full-service PBMs operating in the U.S. today with new entrants each year. They all offer different types of services to their customers through which the PBMs compete for business. Some clients prefer larger integrated companies to go heavier on care coordination for their employees to control costs. Some clients want customized information on enrolled utilization and spending. Some clients want to customize their plan's formularies. And some clients want to customize pharmacy networks to further drive savings. Let me give you an example on how PBM negotiations have provided direct savings for clients and clinical benefit for patients.

Going back to 2013, the first cure for hepatitis C was priced by its manufacturer at $84,000 a year. That was a big number back then. Within a year, new products were approved by the FDA and they all fiercely competed for coverage on PBM formularies. Between 2014 and 2019, the average price of hepatitis C treatment fell from $55,000 to $14,000 per year. More than a million people were treated and most of them were cured. The total number of patients in the U.S. with this terrible disease has been significantly reduced as an effort of those negotiations. PBMs are also at the forefront of

improving access to generics and biosimilars and making them more affordable. Today, 91% of prescriptions filled are for generic drugs, not brands because PBMs have successfully moved the healthcare dollar to the lowest cost therapies. Through PBM efforts, biosimilars have also chipped away at Humira spending as one example. Finally, through new entrants including private label biosimilars, a growing share of new prescriptions are for these biosimilars, generating savings for clients and patients.

Any argument that PBMs prefer brands over generics is just not true. Today, big pharma determines the price of drugs, when to increase their prices, they block competition to keep prices high, and they spend billions of dollars each year advertising to prescribers and consumers and on attack ads aimed at redirecting attention away from these anticompetitive actions. The prices of newly launched drugs are higher and higher each year. PBMs are the sole counterweight to drug company pricing power. So-called PBM reforms are driven in large part by the drug companies, and they will only drive costs higher for plan sponsors and consumers. Policy makers, including the Department of Justice and the FTC should stay laser-focused on the primary driver of high prescription drug costs, these anticompetitive practices taken by drug companies to maintain their monopolies and keep prices high. PCMA looks forward to working collaboratively with the administration and other stakeholders on these matters. Thank you for including me today, and I look forward to the rest of the discussion.

Markus Brazill:

Thank you. Dr. Dusetzina, PBMs develop formularies that specify which drugs are covered by insurance, set the terms of that coverage, and also contract with pharmacies to build networks for health plans and employers. How does PBMs' role at the center of prescription drug supply chains impact drug access and cost?

Stacie Dusetzina:

Thank you very much for the opportunity to be here today. One quick disclaimer before I go is that while I'm a current commissioner for MedPAC, I do not represent the official position of MedPAC nor my employer. My views are based on my own research and as an expert in this space.

So, pharmacy benefits managers have historically played a very important role in drug price negotiation and formulary benefit design on behalf of health plan employers, so their value for that role is quite clear. Without PBMs, it is likely Americans would pay more for their medications than they currently do, but there are policies, and trying to fix this is challenging because if you create policies that mandate coverage of specific drugs or mandate fixed cost sharing for example, that can actually harm the ability of PBMs to negotiate successfully for prescription drugs. So balancing access for patients and cost can be challenging in this space.

Despite the benefits that PBMs bring, there are some interventions likely that are needed in this area to address specific behaviors that are harmful for patients, taxpayers, and pharmacies. These behaviors include PBMs charging more for drugs than the prices that they have negotiated with manufacturers, them paying less money to the pharmacy than the acquisition cost for that pharmacy to obtain the drug and dispense it, and then PBMs preferring some drugs with higher list prices and large rebates relative to drugs with lower list prices and maybe smaller rebates. So, overpayments from plans to PBMs and underpayments from PBMs to pharmacies can lead to profits for PBMs, but that can harm other actors in the supply chain. Plans will pass these costs along to policyholders, that's taxpayers, patients, and employers. Meanwhile, pharmacies could also be losing money on many transactions and that could cause them to both refuse to carry specific drugs or to be forced to close due to underpayments.

The current system that we have is opaque, and the extent to which these overpayments are occurring is not well known. But there are some areas where you can get some key insights. For example, many Americans have experienced going to pay with coupons or through a discounted website where they don't use their health insurance benefits because doing so would cost them more than if they paid cash outside of their health insurance product. In research that I've conducted and in prior FTC investigations into PBM practices, specialty generic drugs including the drug imatinib are a very good example of these overpayments. For example, for Medicare beneficiaries in 2023, the median reimbursed amount through pharmacies was $1,600. This would cost a Medicare beneficiary about $400. At the same time, they could have gone and paid cash at a discount pharmacy and paid 10% of that price without using their Part D benefits. This is why you don't staple the pages.

So finally, I want to mention the issues associated with PBMs preferring drugs with high rebates over those with lower rebates. It's important to recognize that rebates do lower overall spending on prescription drugs, so we should value rebates that are negotiated, but they also can result in patients paying higher amounts than they should. In particular, patients who are being asked to pay a deductible or co-insurance, a percentage of the drug's price, are forced to pay that off of the list price of the drug so they don't get to benefit directly from those rebates. We should want PBMs to select the drug with the lowest net price, including rebates, but we need to make sure that when they do so that they are not harming patients by having them overpay their share of the bill.

I would encourage the following actions to be taken to address drug spending and lower drug spending for patients. First is to consider and pass legislation that mandates transparency in the financial flows within the drug supply chain and target further legislation as needed once those financial flows are well understood. It's important to make sure that PBMs are fairly compensated for the services that they provide, but not overcompensated for their role. Second is to establish payment models that reimburse pharmacies as a function of drug acquisition costs, plus a reasonable dispensing fee. Prior legislation and some Medicaid programs use models like the National Average Drug Acquisition Cost, the NADAC, and this is a useful model. However, if NADAC is used, the survey needs to be mandatory, include all pharmacies, and include specialty pharmacies in that measure. And finally, we should encourage plans to prioritize coverage of and access to drugs with the lowest net price. But when doing so, those should be available via co-pays or flat fees rather than a percentage of the drug's price. Thank you very much.

Kara Monahan:

Thank you. Our next question is for Dr. Damberg. In recent years, consolidation has resulted in a few very large vertically integrated healthcare companies that operate health insurers, PBMs, specialty and mail order pharmacy businesses, and provider groups. What in your view has driven this consolidation and what effects does it have on these companies' incentives and the affordability of drugs?

Cheryl Damberg:

Thank you for the opportunity to participate. I too will provide my disclaimer that the comments I provide today represent my expert opinion and do not reflect the official position of the Medicare Payment Advisory Commission. Excuse me. Vertical integration, the topic I was asked to speak to in the healthcare sector is at the top of the policy agenda, given the substantial and continued growth of vertical consolidation among the different actors in the healthcare ecosystem and growing concerns that greater consolidation is leading to harms. The PBM market has greatly evolved since its inception in the 1960s, both through horizontal integration, reducing the number of PBMs, and in recent years, vertical integration of PBMs and pharmacies with insurers leading to a handful of large firms with significant market power. Five of the six largest PBMs are vertically integrated with insurers, specialty

pharmacies, mail order pharmacies, and retail pharmacies, setting the stage for potential conflicts of interest and the ability to generate large profits for the insurer parent organization.

The high degree of consolidation and associated market power improves the ability of PBMs to negotiate better prices with drug manufacturers who themselves have market power. And this negotiating clout is a key reason why insurers contract with PBMs. Insurers are vertically integrating with other providers of healthcare services for several reasons. But a primary reason is to maximize revenues. And a substantial share of revenue and revenue growth and profits for insurers is generated from their vertically integrated subsidiaries, particularly the PBM pharmacy arm of their business. For example, in 2025, OptumRx will constitute approximately 25% of earned revenue for the United Health Group. More generally, the reasons for insurer vertical integration include to gain access to markets to increase revenue, to drive traffic to own providers to generate downstream profits, to gain access to data which has high value, and to align the delivery of healthcare to achieve better coordination of care, better clinical outcomes, and to deliver care more efficiently.

However, on this last point, the broader evidence on the effects of vertical integration in healthcare shows that after vertical integration, prices are higher, spending increases, payment rates are higher for owned providers, and there are either no improvements in quality or declines. At this point in time, the empirical evidence on the welfare impacts of vertical integration of PBMs and pharmacies with insurers is sparse. This is due in large measure to lack of transparent data on contracting arrangements, negotiated prices, prescription drug rebates and pass-throughs, fees, drug acquisition costs and reimbursement to pharmacies, and prices paid by insurers and consumers. However, two recent studies that are not yet published find that after implementation of the medical loss ratio regulations that cap the percentage of the premium dollar that the insurer could receive to cover profit and administrative costs to somewhere between 15 to 20%, the prices paid by insurers to their own pharmacies were between 5 and 7% higher than prices paid at non-owned pharmacies, and the researchers hypothesize that vertically integrated firms pay higher prices to their own pharmacies to skirt medical loss ratio limits on earning profits.

And to that point, a significant driver of vertical integration of PBMs and pharmacies with insurers is the ability to get around the medical loss ratio rule. The MLR creates incentives for vertical integration because insurers can capture a greater share of the healthcare premium dollar through their subsidiary firms using a tax accounting technique called intercompany elimination. Intercompany eliminations are a workaround to the MLR because they enable the insurer to expense the cost of providing services by their own subsidiaries and move the profits earned by subsidiaries up to the parent entity, thereby earning more than the 15 to 20% that the MLR allows. And this is a significant arbitrage opportunity to garner more of the healthcare dollar. Intercompany eliminations represent a significant source of revenue for vertically integrated firms, and again, for example, in 2024, United Health Group had $151 billion in intercompany eliminations.

I realize we're short on time, so I'm going to cut to the chase in terms of some recommendations. You all have my full set of remarks, but I will echo Stacie's comment. I think we lack a lot of information in this space that requires transparency of information. And I think the complexity of purchasing and contractual arrangements and payments made between the various actors obfuscates the ability to determine whether and where anticompetitive practices may be occurring, where the healthcare dollars are going, and what types of regulatory actions should be taken. And then lastly, this is a bigger issue than just PBMs. And so attention needs to be paid to the other players in the prescription drug ecosystem that contribute to high prescription drug costs, including drug manufacturers, drug wholesalers, group purchasing organizations, and pharmacies. Thank you.

Markus Brazill:

Thank you. Ms. Jaeger, PBMs are creating or affiliating with group purchasing organizations. Why do large PBMs create or affiliate with these group purchasing organizations? And do PBM-owned GPOs present any competitive concerns?

Kathleen Jaeger:

Thank you for the question and thank you for the opportunity to be here on this panel today. For context as you all heard, generics actually represent about 90% of the prescriptions that dispense in the United States but only account for 14% of the total drug spent. And over the last decade, they have provided over $3 trillion in healthcare savings. And that's actually extraordinary value, right, for families, working families, patients, employers, and taxpayers. So today we see six PBMs now controlling about 94% of the U.S. prescription transactions, while the top three control about 80%. Through horizontal consolidation and vertical integration, PBMs are no longer just intermediaries. They are major decision-making entities. They're huge profit centers and they're relentless gatekeepers all rolled into one. PBMs claim that they're stewards of cost, but in reality, they often skew the system towards expensive brand products through unfair strategies such as spread pricing, preferred rebate deals, and opaque fee structures.

These tactics favor their corporate bottom line, not the interest of patients, and certainly not the preservation of a competitive, affordable healthcare system. A recent Avalere study found that in Medicare Part D, 57% of the covered generics were excluded from generic tier. That means the majority of the generics were not placed on the lowest tier despite being the most affordable option. Instead, brands were favored because of the rebates and the other pricing schemes that enrich both the PBMs and the brand industry. And now what we're doing is we're witnessing PBMs steering their formularies towards their own private labeled products and granting them favorable treatment as well. These practices present major antitrust concerns, conflicts of interest, and certainly have real world consequences. Inflated drug cost to consumers, limited patient access to affordable medicine, and discouraging drug investment. But PBMs are only half the story. Another powerful gatekeeper are GPOs, group purchasing organizations who are made up of affiliates.

The top three GPOs are WeBad, Red Oak, Clarus One that control over 90% of the U.S. generic purchasing, exerting immense power over generic manufacturers. Here again we see the middlemen pursuing their own profits at the expense of public goods. GPOs engage in predatory practices. They underpay, they overcharge generic manufacturers, and they actually impose punitive contractual arrangements that manufacturers would never agree to in a competitive marketplace. And while GPOs are technically subject to our 3% administration cap, they circumvent this rule. Demanding fees that can go up to a total of 30% of the drug price by creating artificial menu of baseless fees. So as a result, we're seeing drug shortages driven by economics. We're seeing a generic drug industry very unsustainable each and every passing year. Now, meanwhile, GPOs and PBMs are capturing an enormous amount of the pharmaceutical revenue of that channel at the expense of the actual manufacturers who make the drug products.

A recent Berkeley research group study reported the total spend of both brand and generic medicines reached $803.6 billion in 2023. The brand industry received about 42% of that total, the generic industry received 8.8% of that total, despite being 90% of the prescriptions, and the remaining 50% went to the middlemen. Now, the good news is that the antitrust laws provide both FTC and DOJ with the tools to correct the antitrust conduct of these entities, reassess where their brand PBM rebates actually violate the anti-kickback statute, and restore competition in the marketplace. And along with these targeted actions, we also need meaningful reform.

We need to restore the balance of Hatch-Waxman and close all the loopholes that we are seeing today. We need to ensure fair procurement reimbursement for generics. We need to implement a generic-first policy across all federal programs to drive efficiency. And we need to create an enduring system, a framework built on principles of transparency, balance of innovation and access, competition, affordability, and sustainability. So with that, I thank you very much and I'll be providing more detailed remarks in written comments. Thank you.

Kara Monahan:

Thank you. Mr. Shields, employers play an important role in healthcare by contracting with PBMs to manage prescription drug benefits for their employees with the goal of controlling costs and increasing access to drugs. What challenges do employers face in comparing the PBM options available to them for providing prescription drug coverage?

Mr. Shields:

Thank you again for this opportunity. I appreciate the attention that the Department of Justice and the FTC is putting to these critical issues within the supply chain and sort of engineering a civil discourse, which, given the times, is important enough. So, thank you for your efforts in that.

I'd like to focus and take a note from the first listening session on something pretty concrete related to the supply chain and the anticompetitive behavior. Often under-examined in terms of the pharmacy benefit, the vertical integration of third-party administrators by large insurance conglomerates, not just the PBMs, but how they restrict employer choice and block market entry and advance rent-seeking. We all know that the three PBMs process nearly four out of five prescriptions that has been stated here. Equally important is how they maintain their dominance. They own or control third-party administrators and networks that employers must use to access broader health plan services. That integration often precludes fair competition. United Health Group owns OptumRx and UMR, the largest third-party administration in the country, and I could put third-party in quotes there. CVS via Aetna and Caremark operates one of the largest PBMs and a leading TPA platform. Cigna owns Express Scripts, both a PBM and an administrative gatekeeper. Elevance, formerly Anthem, runs its own TPA.

These are not incidental structures, they're how exclusion is enforced. Let me give you a specific example. Milano International, a pizzeria chain in California with just 85 employees, chose United Health Care for medical coverage and then tried to shop for PBMs. As reported in the New York Times, United Health Care told them they couldn't use OptumRx. The rationale was "housing both services under one roof manages the experience." What was really managed was the employer's access to fair market options. The employer wanted to shop, and this scenario raises a critical and often hard question. When a plan is in a vertical relationship, how does it ever, ever freely get out of it? The scenario is far from isolated.

TPAs often reinforce in advanced marketing concentration acutely at the local level. Small and mid-sized, self-funded local employers, and in my remarks are specifically focused to the commercial markets, job creators that attempt to have a PBM carve out to address out-of-control drug prices often face financial pay penalties or higher administrative fees, denial of access to integrated medical networks, supplemental carve-out fees, backfilling loss rebate spreads, integration "value loss fines" for independent PBMs, offset by "medical rebate credits" for in-house PBMs. Medical prioritization reviews embedded in the pharmacy bids.

These closed systems disadvantage transparent PBMs, distort procurement, and frustrate competition and can be distinguished from how transparent pass-through models routinely share and facilitate actionable data and reduce drug pricing. Transparent PBMs report losing 40 to 75% of potential RFPs

due to these structural barriers, and it explains how the largest PBMs and their competitors report Soviet-level retention rates of nearly 96 to 98% despite widespread public scrutiny led by President Trump, Congress, nearly every governor and legislative body in the nation, as well as well-documented dissatisfaction by employers who routinely express a desire to truly shop or carve out benefits.

Brokers often financially aligned with large PBMs and TPAs reinforce the status quo through narrow RFPs and controlled information. This pattern mirrors practices the DOJ and the FTC is already examining in the technology sector and other industries where intermediaries lock in incumbent dominance through sustaining and ongoing revenue streams. As a legal matter, these tying arrangements and exclusive contracting provisions raise serious questions under the Sherman Act, the Clayton Act, may violate state procurement and competition laws, and conflict with FTC's-DOJ's healthcare antitrust statements, which warn that vertical integration that raises rival costs or limits consumer choice merits scrutiny. Earlier this year the FTC issued a unanimous consent against a real estate contractor for using restrictive covenants to lock up employer and labor markets recognizing such restrictions are violations for economic liberty. That was the same logic that's informative here, to address fundamental restraints on commerce and competition. Self-insured employees now covering roughly two-thirds of privately insured lives, serve as a risk of fiduciaries and have a duty to select based on value. When TPAs block PBM choice or impose non-transparent penalties, that fiduciary right is undermined. The market impact is clear. Per capita drug costs have doubled in 20 years. PBM revenues now exceed over $400 billion annually and premium sectors across the board, premiums are going up.

What can we do about these exclusionary practices? Well, we can demand targeted enforcement and policy remedies. The FTC can prohibit tying of PBM services to TPAs or networks, ban retaliatory fees and data withholdings that deter PBM carve-outs, and scrutinize rebate-based exclusionary contracts as potential antitrust violations. Thank you and we look forward to a continued dialogue.

Markus Brazill:

All right, now we've concluded the opening remarks. I'm going to provide the panelists with two minutes each to respond to any other comments provided by the other panelists. Does anyone want to start?

Tim Dube:

I'll start by just responding to the claims that the bigger PBMs aren't transparent. Our association represents 21 different PBMs out of the 73 or so that are in the United States today. They run the gamut from those that work with specifically small employers in the self-insured market who are choosing not to go into the larger fully insured lines of business. And they are growing. We have more PBMs now than we've had over the last five years today. This is not a dwindling market, this is a healthy market of competition for PBMs.

Cheryl Damberg:

I'm just going to make a comment about some of these exclusionary practices. I think if you look at the way in which these vertically integrated organizations have set up their networks, there's clearly steering going on to their owned entities. And that comes often at a high cost to the consumer as well as the employer or taxpayers. And those steering practices, and this is through the construction of their networks of, say, pharmacies that a consumer can use, really disadvantages their rivals. And so, if you look at some communities, the independent pharmacist is sort of the last actor in town. And this creates a big risk exposure, particularly in rural areas. And we have to look at pharmacies as providing a broader set of services than just filling prescriptions.

Mr. Shields:

Yeah, I just wanted to comment on the GPO reflections that were made with most of which I felt were wholly accurate and really informative. The GPOs in the PBM space is sort of specifically distinct from other GPOs in the marketplace as was alluded to, and don't follow what are considered either best practices or industry standards in other parts of healthcare, including a baseline of a 4% fee. And look, the track record is that the GPOs that have been created came as a result of, or in response to, the rebate rule that was promulgated by President Trump in his first term. And in response to that, the largest PBMs created new GPO structures under their own parent companies that are now offshore, primarily in places like Switzerland and Ireland, that negotiate rebates on behalf of almost every patient in the country, at least in commercial markets.

That's not reform, that's not meaningful transparency or market integrity. And certainly, we've been pretty forthright of sort of asking Congress and other stakeholders to examine the role of GPOs and to ensure that consistent with President Trump's recent executive order that there's going to be open competition and meaningful reform in the group purchasing markets.

Kara Monahan:

Thank you. Our next question is going to be for Mr. Dube and Ms. Jaeger. Biologics have provided important advances in treating serious medical conditions, but they can be expensive and represent an increasingly large percentage of drug spend in the United States. Despite an increasing number of biosimilars entering the market, the use of some of these lower priced products has been limited. What factors contribute to low biosimilar uptake and what can be done to support biosimilar competition?

Tim Dube:

So many people who take biosimilars or biologics are on them for life or for a long period of time. A lot of what you see is that people are pretty sticky on the brands. And it would seem to be a lot of parts of the prescription drug supply chain would be involved in getting people off of the biologics and moving on to the biosimilars. Prescribers and patients have both shown hesitancy in surveys on switching to biosimilars from the reference products. Some of this is honestly effective messaging by the brand drug industry about the safety issues related to the biosimilars, which is just not true. Some of it is regulatory. The FDA interchangeability designation in the BPCIA is an unnecessarily high barrier. Many biosimilar makers just don't bother to achieve that designation. They're just trying to get on the market to compete and they don't pursue it. However, as I noted in my remarks, new starts for adalimumab, for example, they are increasingly occurring on the biosimilars rather than on the branded product.

There are other actions that could be taken. We've been working with CMS on rules in Medicare Part D and in the ACA exchanges to allow for more prompt formulary switching and substitution within those markets, as well.

Kathleen Jaeger:

See, I would agree that a lot of this is actually misinformation and more of a scare campaign than anything else. And really what happened during, when we actually passed the biosimilar law back in 2010, the brand industry did a very good job, the Bio in particular did a really good job of actually placing in this interchangeability provision. Right now, it takes, it really costs quite a bit to bring a biosimilar to market much more than a small molecule. So, you're looking at upwards of $300 million over a six to nine year period. And what happened here is on the generic small molecule side, we used state substitution laws, basically, to drive generic utilization. And so that means therapeutic equivalence is determined by FDA.

Here, what happened in 2010, Bio actually put in a provision, which we can call a poison pill or we also know it was a huge, really a huge bump in the road. It was going to be really a huge challenge to address, but we thought it was actually worthwhile to actually put the bill in play, and the executive committee of the generic industry thought it was much better to put it in play and try to reverse it later. Now we have a situation where FDA approves biosimilars that are safe and effective, they should be interchanged. The pill basically was just this huge hurdle to overcome and basically was just a waste of taxpayer money, manufacturers' money, and everyone else.

Ultimately what needs to happen is that interchangeability needs to be reformed. There are legislation on the hill right now and what that reform needs to do is be pure and clean and free of bio and pharma edits. If we can do that, we will see a lot of great uptake across the United States. I also would suggest that you can also, in the federal programs, also design programs whereby you actually incentivize the insurers and all the different entities to drive for biosimilar uptake. So, it can be star ratings and can be so many different creative solutions that can be utilized. But there are a lot that can be done. But this is really a scare tactic more than anything else.

And I think one last point I want to make is, stop and think of why do we have 118 bioproducts out there today that only have less than 10% of the competition coming in? It's because the hurdles are so high and the market is not there. We're not going to get the cost savings unless we fix the system. And it's been 15 years, it shouldn't take another five, ten years. It really should be done now.

Markus Brazill:

So, there are other types of PBMs in the market that give consumers an alternative to the traditional model offered. And for example, they offer low-cost cash prices for certain drugs. How successful have alternative business models been in competing with the established PBMs? And are there any obstacles to their growth? Let's start with Mr. Shields.

Mr. Shields:

I'll reserve my comments on the obstacles to growth. I think I sort of articulated those in the beginning comments. But in terms of the alternative approaches or paths to transparent approaches, I think there's some misnomer that these are new creations. The truth is a lot of transparent PBMs have been in the market for some time growing out of often enough relationships and led by independent pharmacies who were seeing the writing on the wall related to what was happening in their own marketplaces by traditional PBMs. And so, they created pass-through PBMs as their own inventions and innovation within the marketplace. Just some data points on that in terms of the approach that pass-through PBMs take which rely on flat fees disclosed to the client as a sole or a primary source of revenue, in terms of the approach that they take distinguished from spread pricing models that I think have been articulated here.

The data shows that when self-insured employers, and this is from a Johns Hopkins study, adopt waste-free formularies associated with transparent PBMs, they cut drug spends to 9 to 15%, slash cost 53 to 60% in targeted classes of drugs, and swapped out 95% of flagged drugs for clinically equivalent lower-cost options. Employers moving to transparent PBMs, pass-through PBMs see 15 to 13% first-year savings, cash or pass-through channels beat legacy PBM prices on common generics by 50 to 90%. Lower predictable prices translate into higher script rates and better adherence, especially for chronic medicines where a $10 swing can decide whether a patient stays on the medicine or walks away.

Just as important, these PBMs hand employers full auditable claims, rebate files in real time, and let them spot formulary games and waste. Let me give you three examples since the Humira examples came up explicitly and I would distinguish the Humira examples I'm giving from a traditional PBM model that might offshore our GPO in, let's say, the Cayman Islands and take an interest and development of their products. Our members' products associated with members shifted 90% of Humira claims to a

biosimilar in 2024, delivering 90% ingredient cost cuts and over $40 million in autoimmune savings after launching.

Another one saved similar savings for roughly three approaches to the market at $5 to $1,000 per a thirty-day supply in typical savings with 34%. The common threads here are fee-based revenue, aligned incentives, formulary prioritizing true lowest cost, and pricing made simple so the CFO or a patient can understand it and it's accessible. Thank you.

Markus Brazill:

Mr. Dube.

Tim Dube:

Yeah, thank you. It is true. Many self-insured, most of the self-insured market has moved toward transparent and pass-through type models over the past 10 years because these are offered by all PBMs in the market in the RFP process. There is no difference between the PBMs in Joe's Association and the PBMs at PCMA. They all offer these to clients. The clients choose based on the best price and the best option for them.

In talking about the discount cards, which you raised in your question, also, essentially all of the PBMs are partnering with one discount card provider or another or more than one, and they're able to pull through lower prices at the point of sale if that's what the client has chosen to do. It's all based on what it is that the employer or the union or the government program wants to pull through to the point of sale for the enrollee in their plan. PBMs across the market are partnering on ways to drive savings for consumers.

Just one little example here is that one member company of ours is the fulfilling pharmacy for Mark Cuban Cost Plus Drug Company, which is obviously a cash pay option available to anybody who wants to use that.

Kara Monahan:

There's a complex flow of fees, rebates, and other costs between PBMs and the various entities in the pharmaceutical supply chain. What impacts the prices that pharmacies, payers, and patients ultimately pay for a drug? We'll start with Ms. Jaeger and then hear from Dr. Dusetzina.

Kathleen Jaeger:

Yeah, I think today, as we heard, the whole system's quite opaque and we really need to look at every cents. Where does that cents, where's it coming from, where's the dollar going from and from whom and why? Because at the end of the day, whether we're talking about a pharmacy with the PBM, or we're talking about GPOs and generic manufacturers, what we see is all these fees that are there that are baseless fees. They're made up arbitrary fees, they're kind of like a shifting game in a menu approach. When one gets closed down, another one pops up. Ultimately, these fees actually have a dramatic impact on the entities. With the pharmacies, maybe we heard sometimes they won't stock a product, sometimes they actually lose money and go out of business and close their doors. On the generic side, what happens there is that they can't produce that product any longer and they basically take a step back and say, "I can't provide this because of economics." Who actually is hurt here is the American consumer and the patient. We need to ensure that patients can have access to affordable medicine and they can get it in their communities from their pharmacists of choice. Now on the GPO side, what I mentioned was that you have all these prices here and you've got prices that should really be banned. They're called source program fees, distribution fees, commercial product fees, financial management fees, stocking allowance fees. They're all baseless. Why? Because there's no bonafide value attached to that fee. Really, it's just a transfer of money from the generic manufacturer to the

GPO or to a wholesaler in terms of a chargeback. So, ultimately, we've got to get true transparency in all the different arrangements. We need to look at opportunities to, on the fees, on the 3% fees, make sure they're on net pricing, not on WAC. And then two, also, look at opportunities to ban all these pieces and really drive what I'm going to call accessibility and affordability and making sure that we have an enduring sector. Because ultimately, without generics, we don't have brand rebates and we don't have lower costs. So we need to make sure we have accessibility and sustainability of the generic industry.

Stacie Dusetzina:

Thank you very much for this question. We all pay for our benefits, right, so premiums and cost sharing are all on the consumer. So whether it comes through your employer sponsored health insurance where they're paying a bigger share of the load or maybe you're not getting a pay increase because their premiums are going up and you're not seeing it through your benefits, you're seeing it in some other way. It all comes back down to taxpayers, patients, and employees, employers, it's all of us. So when we talk about spending on prescription drugs and the spending in the supply chain, those additional dollars spent in the supply chain are coming out of all of our pockets in some way or another as insured individuals.

So I think it's really important to say, "Okay, you know, what is a reasonable amount of money to be coming to these entities that are doing real work and important work in negotiating for drug prices, setting benefit designs?" I don't know about you, but maybe my specific employer wouldn't be great at doing all of that and keeping up with all of that in addition to the work that we're doing. So, you know, we want to pay for those services. We want to get our dollars worth and we want to make sure that people have the best access they can to prescription drugs.

Now, as others have mentioned, one of the key issues that harms consumers specifically here is the use of list prices for charging patients co-insurance or deductibles where they pay an inflated amount that their health plan is not ultimately paying, that is harmful for patients and it is driving up their cost, potentially to the benefit to the other people on the plan. But this is one of the practices that I think we have to keep our eyes on. But it all comes down to us. The more we spend in the supply chain, the less money we have to spend on other things.

Markus Brazill:

We've talked today about the roles that PBMs play in developing and managing drug formularies and pharmacy networks. Seniors typically receive prescription drug coverage through Medicare Part D plans or through their Medicare Advantage health insurance plan. What trends do you see in these Medicare plans that impact choice and the affordability of drugs for seniors? I'll start with Dr. Damberg.

Cheryl Damberg:

There we go. So if you look at the Medicare Advantage market as well as the freestanding, standalone prescription drug plans, you've essentially seen a decline in the number of the freestanding plans in the marketplace. And consumers are increasingly shifting out of the freestanding market. So traditional Medicare combined with a standalone Part D plan into Medicare Advantage plans, and Medicare Advantage plans with prescription drug coverage. And the significant decline in the number of these standalone plans, I think signals a worrisome sign and something that policymakers need to be paying attention to. And I think some of the factors that are leading to this is that we have a very unleveled playing field in the market. Medicare advantage plans have significant advantages both over traditional Medicare as well as these standalone plans.

The Medicare Advantage plans have rebates that they can use to buy down premiums and to offer potentially more generous benefits. And the standalone Part D plans do not have access to rebates. And so when you look at the marketplace as a consumer, it's far more costly to enroll in a standalone plan. And as someone who has run the Medicare MA and Part D disenrollment survey for years, the major reason why people switch plans is due to financial reasons, and generally they're shopping for a lower cost plan.

Markus Brazill:

Dr. Dusetzina.

Stacie Dusetzina:

Yeah, echoing Cheryl's points, the market is not a level playing field. So if you were a person shopping for your prescription drug plan for Medicare, your average premiums last year in Medicare Part D for the standalone market would've been north of $40 per month for your drug benefit alone. And then in the Medicare Advantage market, it's closer to $8 with many plans being $0 premium plans. So if you don't fully understand all of the trade-offs that you're making when you're selecting between Medicare Advantage versus traditional Medicare as far as your network or providers and these sorts of things, why would you not pick the $0 plan? It's free and it's got the same drug coverage. So there's a lot of information asymmetry. People don't really understand it fully. The decisions that they're making when they're enrolling into the Medicare benefit and how consequential those decisions are for their ability to maybe go back into traditional Medicare if they start with MA. I think this does make it much more difficult than for people to stay in traditional Medicare or pick traditional Medicare.

I think the other thing that makes it complicated is just incentives for these plans. So if you're offering a pharmacy benefit for traditional Medicare, there are rules about what has to be covered, but your medical spending doesn't affect you. If you're the private plan offering the standalone part D plan, you are not responsible for medical spending, whereas the Medicare Advantage plan is responsible for both drugs and medical spending. So it creates some other incentives, I think, for thinking about how you design your benefit and how coverage is or is not accessible to patients. I think, in general, the market is shrinking and we are seeing much more upward pressure on premiums in the standalone market, and those are likely to need more intervention in the future.

Kara Monahan:

Our last question for this panel is a lightning round. We'd like to hear from all panelists on what one change in formulary and benefit practices would you recommend to increase competition and lower drug prices for Americans? We will start with Dr. Damberg and move down the line for your 30-second response. Thank you.

Cheryl Damberg:

I'm going to double down on transparency related to all aspects of transactions happening in this market. And I think with transparent information that's made available to, you know, a wide group of people in the marketplace, I think that will help put downward pressure among the actors. And so that's number one.

And then I guess my number two is I think as we think about this from a policy perspective, we need to be looking for ways to simplify the marketplace. So the drug negotiations that are happening in the context of the Inflation Reduction Act, that strikes me as an opportunity to learn from that to determine whether that starts to achieve the same kinds of savings, maybe better than what PBMs are offering, maybe with some reduced complexity in the market.

Tim Dube:

Thank you. So first, I'd like to associate myself with Kathleen's excellent, eloquent remarks on the interchangeability designation and the folly of that thing's existence. That needs to go, number one.

Number two, the administration should leverage its existing authority where it has it to address drug company anticompetitive practices. This is your second panel today. We'll hear all about that. So that more drugs come to the market and allow PBMs to do what they do best, which is save money for their clients. Congress should also pick up the ball here. They need to reform patent laws and regulations to accelerate the market entry of competitors. They need to ensure market exclusivity is used to incentivize innovative drug research at appropriate intervals for market exclusivity, and they need to penalize drug manufacturers abuse of the citizen petition process.

Stacie Dusetzina:

See how many things I can recommend in 30 seconds? Just kidding. So I think the first thing in my mind is to establish a reimbursement model that gets patients drugs based on the acquisition cost plus a dispensing fee or work in that direction to make it much more transparent how that pricing is set up and try to preserve access to pharmacies. That will mean improving some of those measures to get all of the reporting in, and then doubling or tripling down on Cheryl's point, we need transparency. You cannot regulate this system as it is with the lack of transparency. You need full information on financial flows, including wholesalers, GPOs, and other members in this supply chain.

Kathleen Jaeger:

Transparency, transparency, transparency. And I would agree with everyone else's initiatives here, too, but I also would say that you also need to stop and be mindful of looking at the balance between innovation and access and don't let that slip away. We've actually, it's been slipping away for the last 10 years. We need the balance back. And so reforms are absolutely necessary in this world. But here again, we also have an opportunity to do something that's near and dear to FTC and DOJ; really take on enforcement action that also will dampen a lot of activity right now. And there's a lot of you've heard tonight, there's a lot to be looking at and analyzing. Thank you.

Mr. Shields:

Yeah, I'll stand by my comments of what I said around third party administration and helping scale innovative PBMs and transparent PBMs so that they go to market in an open competitive fashion. My other point is a note of sort of discernment or observation. A few months back, the largest PBM CEOs testified before Congress and they repeatedly said that they passed through one hundred percent of their rebates, one hundred percent of their rebates to the plans that they administer. Literally, the next day, in a “I can't make this up” moment, CVS settled a lawsuit to the tune of $45 million for not passing through the rebates that were relatively hidden and housed under their group purchasing organization in Ireland. So, I would just suggest to the stakeholders in this area to take hard looks at the areas of concern and understand the relationships in place that ultimately protect opaque practices and keep drug prices too high. Thank you.

Markus Brazill:

So, thank you to all of our panelists for contributing your insights. We're going to take a very short break so that we can switch to the second panel. Thank you so much.

Kara Monahan:

Started with panel two, so if I could ask everybody to take their seats.

Markus Brazill:

All right. Welcome back. Our second panel will focus on regulatory abuse by pharmaceutical companies that impedes competition. Again, I would ask that all panelists be mindful of time constraints when responding to questions. Our listening session today will conclude promptly at 4 p.m. Now let's introduce the members of our panel.

Sarah D'Orsie is a Senior Vice President at Fresenius Kabi Biopharmaceuticals, a biosimilar manufacturer, and there she oversees Global Government Affairs, Policy and Health Economics, as well as Outcomes Research. Before joining Fresenius Kabi, Sarah worked for several branded biopharmaceutical companies, the American Academy of Physical Medicine and Rehabilitation, and the Brain Injury Association of America. Sarah spent the first part of her career as professional staff and the deputy parliamentarian at the House Oversight and Government Reform Committee under Chairman Tom Davis.

Kara Monahan:

Adam Mossoff is a law professor at the Antonin Scalia Law School at George Mason University. His scholarship on patent law and innovation policy has been relied on by the U.S. Supreme Court, the Federal Circuit, and by many federal agencies including the USPTO, FTC, DOJ, and NIST. He has been invited several times to testify before the U.S. Congress on patent legislation. Professor Mossoff is also a director and senior fellow at several academic centers, think tanks, and policy organizations.

Markus Brazill:

Maryll Toufanian is Senior Vice President for Regulatory Strategy and Government Affairs at Amneal Pharmaceuticals where she leads the company's efforts to support the approval and commercialization of key products across the specialty branded biosimilar and generic portfolios. She also leads Amneal's government relations and public policy interface with state and federal policy makers in the legislative and executive branches.

Prior to joining Amneal, Maryll was the Director of the Office of Generic Drug Policy at FDA's Center for Drug Evaluation and Research. At FDA, she oversaw all regulatory and policy matters in the Office of Generic Drugs and publication of the Orange Book. And she also directed agency efforts on the Commission's Drug Competition Action Plan.

Kara Monahan:

Sarah Yim is the Director of the Office of Therapeutic Biologics and Biosimilars in the Office of New Drugs at FDA's Center for Drug Evaluation and Research. She has been with FDA since 2005 in various roles including two years as Director of the Division of Clinical Review in the Office of Generic Drugs and 11 years in various roles in rheumatology regulatory review. Dr. Yim is a rheumatologist and has completed a postdoctoral fellowship in rheumatology at the National Institute of Arthritis and Musculoskeletal and Skin Diseases at the National Institutes of Health.

Markus Brazill:

The first question will be for Ms. Toufanian. Ms. Toufanian, under the Hatch-Waxman Act, branded drug companies must list certain patents in an FDA publication commonly referred to as the Orange Book,

but may not list all patents relating to a particular product. How can Orange Book patent listings impact competition from generic drugs?

Maryll Toufanian:

Thank you. Good afternoon and deep thanks to the FTC and DOJ for the opportunity to discuss these vitally important topics. By way of housekeeping, I'm here in my personal expert capacity and not on behalf of Amneal Pharmaceuticals. Before I dive in today's remarks, I've been asked to provide a brief background on the Orange Book and patent listings. The Orange Book is the cornerstone publication of U.S. drug regulation and contains an extensive amount of information including statutorily required information related to certain patents on brand drug products. What patents are we talking about? Well, the 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act establish the modern generic pathway and a mechanism by which patents related to brand products could be litigated prior to generic approval to facilitate generic access.

Under this process, a brand applicant and sponsor must provide to FDA information on each patent that it thinks claims the drug for which approval is sought, that is drug substance or active ingredient, a drug product formulation or composition patent, or a patent that claims a method of use for such drug for which approval was sought. FDA then publishes or lists this information in the Orange Book and generic applicants in turn must file one of four certifications to those listed patents, which can include what's referred to as a paragraph IV certification in which the generic applicant asserts that the listed patent is invalid or not infringed.

A generic applicant also can submit what is referred to as a Section 8 statement, providing that the applicant is carving out or not seeking approval for an approved method of use covered by a listed patent. If a generic applicant submits a paragraph IV certification, the brand holder can initiate patent infringement litigation and obtain a 30-month stay of generic approval.

So short story long, the listing of patents can cause a thirty-month delay in generic competition after the application is otherwise ready from a scientific perspective to enter the market. And for products that can make millions of dollars a day, every day of delay is a boon for brands. Now important to keep in mind, FDA takes a ministerial role with respect to patent information submitted to the agency and does not independently evaluate the representations reflected therein.

This is appropriate because among other reasons, FDA's expertise lays in drug regulation and not in patent law, but that does mean there's no direct or upfront arbiter of patent listings. The questions today are if and how brand companies use this complex system to delay competition beyond that contemplated by Congress. And the answer firmly is yes, as demonstrated by the significant activities of the executive legislative and judicial branches in response to brands that over the past 40 years have been pushing to obtain and list as many patents as possible.

From my perch, the system only works to achieve the Hatch-Waxman balance if the brand sponsor only lists patents contemplated by Congress and lists them accurately. I'll go through some of that history so we can know what I'm talking about. Early on, FDA determined that process or manufacturing patents were not listable and that's pretty, I think, non-controvertible these days.

In 2003, Congress established a right for a generic applicant to bring a counterclaim in the paragraph IV litigation to require the brand to revise its patent listing information. In 2016, FDA issued a major revisions to its regulations to provide clarity and streamline the patent information and certification processes. In 2020, under the FDA's Drug Competition Action Plan, the agency asked for comment on patent listings and partnered with the PTO to identify avenues for collaboration to ensure the Hatch-Waxman balance is maintained.

In 2021, Congress enacted the Orange Book Transparency Act, which revised the FD&C Act to expressly provide more detail on the scope of listable patents and prohibited patent listing that did not fall within this language. And there's more to come on CDER's FDA Guidance Agenda for this year. There are several relevant guidances we are anticipating, including the information related to submission of patent information for listing in the Orange Book.

With respect to device patents, in particular, as Commissioner Ferguson mentioned. Excuse me, in '23, '24, and 2025, under both presidents, the FTC issued statements of policy and sent letters to companies with certain Orange Book listed patents demanding the companies delist the patent and instituted patent listing dispute proceedings under FDA's regulation. In response, numerous but not all patents have been delisted.

In addition, the Federal Circuit in *Amneal v. Teva* directly considered the listing of several device patents that had claims to dose counter and canister parts of a metered dose inhaler, but did not explicitly require the presence of an active drug. The appellate court concluded that quote, "To qualify for listing a patent must claim at least what made the product approvable as a drug in the first place. Its active ingredient."

The listing of method of use patents has provided fertile grounds for brands as well. As I described above, the statute expressly provides that a generic applicant can carve out certain protected methods of use. This is often referred to as skinny labeling. And federal appellate courts for decades reinforced the propriety of carve-outs. Two recent litigations, however, have brought the viability of skinny labeling directly into question.

In *Teva v. GSK* and *Amarin v. Hikma*, the Federal Circuit held that a generic company with an FDA-approved skinny labeling can be held liable for infringing a patent by publicly describing its product as equivalent to the brand. Uncertainty generated by these decisions puts significant savings at risk. To be clear, a recent AGMC report determined that from 2015 to 2020, 15 skinny labelings alone say it generated $14.6 billion in savings for Medicare.

Legislation has been introduced in the Senate to create a safe harbor. My position is this passage of this legislation is essential to ensure savings contemplated and achieved by the now 41-year-old statute the savings are achieved. Patent listings is just one stopping point on the broad topography of Hatch-Waxman at which brand companies have tried to stretch or abuse the regulatory scheme. I look forward to my comments from my fellow panelists.

Kara Monahan:

Professor Mossoff, innovation in the pharmaceutical industry can lead to new treatment options for patients. Patents can support pharmaceutical innovations along with regulations and statutes such as the Hatch-Waxman Act. At the same time, patents can be misused in a way that harms competition. What is your view of pharmaceutical patents and their impact on competition and innovation?

Adam Mossoff:

Thanks for the question. Thank you for the question and thank you for the invitation to speak. I think my phone, I have my timer set here so that I don't need talk too long. My answer to the question and all the follow-on questions in our discussion today can be easily summarized as the FTC and other agencies should always follow the fundamental principle of good governance and engage in evidence-based policymaking.

Now applying this principle to this first question, I'm going to make two general framing points and then I look forward to digging into more details with the other panelists and with our interlocutors. First, the

systemic economic evidence demonstrates a patent system is key as a driver of innovation in new drugs and that the Hatch-Waxman Act has been massively successful in creating a generic drug industry that benefits all patients.

And then second, given these undeniable facts, the evidentiary burden then is on those making contradictory claims about patents and the Hatch-Waxman Act. And unfortunately, these arguments are largely based on rhetoric and policy-based evidence making not rigorous legal and economic data.

Alright, so the first point, the patent system has been a key driver of the U.S. innovation economy for over 200 years. Economists, historians, legal scholars recognize that patent system is secure, reliable, and effective property rights to inventors consistently and strongly correlate with growing innovation economies that benefit everyone, innovators and consumers alike. And the biopharmaceutical sector dramatically confirms this general empirical truth about patents and innovation.

The biotech revolution began in the United States in the early 1980s because the United States was the first country to secure patent protections in biotech-created drugs. The U.S. remains to this day a global leader in creation of new drugs. More than one half of all new drugs are invented in the United States to this day. Now this is the result of an innovation ecosystem that was built on this platform of property rights: patents.

For instance, prompting research and development investments by private companies to a tune of almost $130 billion annually. By the way, this is more than four times the amount of public funding provided by the National Institutes of Health for basic upstream research. And in fact, pharmaceutical companies invest significantly more R&D per granted patent than any other company in the U.S. innovation economy, including in the high-tech and cellular industries, which are some of the most patent-intensive sectors of the U.S. innovation economy.

Now, the Hatch-Waxman Act has also succeeded in its goal of growing the generic drug industry and prompting greater availability of generic drugs. Now, of course, no law or institution functions with 100% efficiency, but the systemic economic evidence and data confirm that the information disclosing function of the Orange Book and the dispute resolution system of the Hatch-Waxman regime had been successful.

How do we know this? Well, before the Hatch-Waxman Act, the generic drug industry had total sales in only hundreds of millions. Today, we would say only in the hundreds of millions. Well, now today, the generic drug industry has sales in the hundreds of billions. Now, economists have long recognized that massive economic growth like that from millions to billions, right, does not occur if there is a systemic lack of clarity in property rights. If information to invest or transact is uncertain or unavailable or if there's systemic abuse of a legal system. The Orange Book has in fact facilitated generic drugs in becoming the dominant drugs prescribed to patients today. 90% of all prescription drugs that are prescribed are generic drugs. That is a dramatic increase from only 13% in 1984 before the Hatch-Waxman Act was enacted.

Moreover, contrary to claims of evergreening, many rigorous empirical studies over the past 15 years using different methodologies have consistently reached the same conclusion that the average market exclusivity for drug innovators is only about 13 years, less than the 20-year patent term. In sum, the empirical data of the past 40 years demonstrates new healthcare innovations and new drugs and massively expanded availability of generic drugs.

Now, unfortunately, the policy debates today are dominated not by that data and that evidence, but by rhetoric and unreliable and unconfirmed numbers of patents, mostly based in splashy pamphlets published by activist organizations like I-MAK. Now, the USPTO in the past year has engaged in several

studies, both of patent tickets, of market exclusivity, and of drug patents, and they have been unable to confirm any of I-MAK's numbers.

Now, to give you just one quick example, so the Lyrica capsule: I-MAK says that there are 68 patents that cover this drug product. The Orange Book says there are three. I-MAK says there's 32 years of market exclusivity. The actual market exclusivity before generic entry was 14.6. Now in a letter to Senator Thom Tillis, CEO of I-MAK, Tahir Amin said that, "Well, the reason why you have these differences is because drug innovators" or he just said drug companies, "don't identify all the relevant patents. They don't list them."

Yet other commentators, including the FTC, have taken the exact opposite position that drug innovators are listing too many patents. Well, which is it? These two contradictory claims can't both be true at the same time. Yet both claims are being asserted in the policy debates with bills and regulatory actions being taken on the basis of both of them despite this inherent contradiction.

So, in closing, FTC should follow the principle of evidence-based policymaking and avoid the clarion call of rhetoric or worse claims from policy-based evidence making that patents are a cause of higher drug prices or that the Hatch-Waxman Act and its important dispute resolution mechanism and in the Orange Book are not actually serving their functions in which they have in the past 40 years. Thank you.

Markus Brazill:

Ms. D'Orsie, 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 incumbent brand drugs. What are some challenges that biosimilar manufacturers, like your employer, face in entering the market and competing?

Sarah D'Orsie:

Thank you for the question and thank you for having me. First, I wanted to say something about the 90% statistic of all prescriptions in the U.S. Typically, most of the spend in the U.S. is in the specialty tier and that 90% of what everybody is getting generics for that is very inexpensive is underneath that specialty tier. When I'm talking about biosimilars today, I'm going to be talking about that very high spend category where there isn't as much generic and biosimilar adoption.

The specialty generics and biosimilars industries are the most overlooked solutions for high drug costs in the U.S. As such, the administration should focus on addressing the root causes that drive market forces such as patent thickets rather than symptom control. The U.S. is often the last country where patents are cleared, which allows other developed countries, including the EU to have low-cost competition years earlier.

This causes the price differential that the Trump administration is trying to correct. Biosimilars are eager to compete and bring down prices, but they're hindered by loopholes in the U.S. patent system. This country sees more patents asserted. Asserted, this is when the brand is deciding to sue a biosimilar company, not just listed like what we talked about with the I-MAK report.

So, the U.S. is an outlier in the number of patents asserted against the same 30 biosimilars with nearly eight times the number of patents compared to the UK and Canada. This increased number of assertions correlates with delayed biosimilar launches here compared to abroad. The difference between the countries is not that the U.S. has more incremental improvements to old drugs. In fact, Europe also grants patents covering incremental improvements.

Rather, the difference lies in policies addressing double patenting, which calls into question not only the number of U.S. patents but also their quality. Everywhere in the world, patent applications are

rejected when claims are not patentably distinct from each other. Only in the U.S. can this rejection be overcome by filing a terminal disclaimer. This allows the patent to grant by aligning its expiry date with the earlier patents to which it's tied.

When I say non-patentably distinct and you'll see over here, here is what I mean [pointing to demonstrative]. This first example is an example of two patents in the same patent family. The invention is the same. It's a 40-milligram dose of the same drug once every two weeks. However, patent one describes this dose as treating rheumatoid arthritis in a human subject. Patent two describes this dose, same dose, as reducing signs and symptoms of rheumatoid arthritis in a patient.

Many of the patents asserted in the U.S. and the pharmaceutical sector look like that example. They do not represent incremental improvements as the branded industry claims. Further, the USPTO report that my colleague mentioned issued this year contends that terminally disclaimed patents do not extend monopolies because each patent expires at the same time as the original, implying that these patents are harmless. However, this is an oversimplification.

Some incremental inventive features are novel, some are not. Therefore, biosimilar manufacturers may discover that some of these features, these secondary inventions, existed in the public domain years before they were claimed and can invalidate the patent in court. In the EU for example, invalidating a patent means biosimilars may be able to launch their products.

However, in the U.S. invalidating only one patent means that its duplicates, the ones we looked at, can be asserted in a lengthy litigation one by one by one. In no other country do patent owners have multiple chances to defend the exact same feature. Therefore, in the case that a patent is found invalid, going back to the USPTO report, the expiry date of the duplicates are not relevant.

While generic and biosimilar makers are sitting on the market sidelines litigating the patent, referencing the patient after they've invalidated the patent, referencing the human subject for example, biosimilars are launching abroad. However, there is a solution. The bipartisan Bicameral Ethic Act introduced in both the House and the Senate would allow brands to assert one patent per terminally-disclaimed group against a biosimilar generic manufacturer.

This approach would reward innovation including incremental improvements. It would protect those to old drugs but would stop the gamesmanship that is inappropriately delaying competition and is nuanced to balance patent quality and quantity. I'd like to conclude with a comparative example of three costly specialty drugs and illustrate the relationship between terminal disclaimer practice and drug pricing.

Tecfidera, a specialty MS drug, Revlimid a drug treating multiple myeloma, and Imbruvica a treatment for leukemia. The Tecfidera litigation involved one patent. The generic manufacturer invalidated that patent, found it was weak, it shouldn't have been granted, and launched at risk immediately and caused 90% price erosion overnight. The Revlimid litigation involved nine patents with at least 50% of them being terminally-disclaimed. This litigation ended in a limited volume patent settlement, no doubt including contractual terms that a generic challenger would not accept if not facing crippling leverage, inconsistent with the quality of the remaining patents.

This delayed price erosion by delaying full competition. Finally, the Imbruvica litigation involved 41 patents with 75% of them being terminally-disclaimed. Using the leverage gained by the thicket, the originator potentially delayed competition until 2036. Medicare negotiated a price for this drug that was 38% off the current list price scheduled to apply next year. This discount is significantly less than what occurred with Tecfidera and will not give relief to the commercial market.

In summary, a higher percentage of terminally-disclaimed patents results in longer wait times for lower-priced medicines. The ETHIC Act would ensure that more specialty drugs follow the Tecfidera path where

innovation and competition provided the best outcomes for Americans. Therefore, it's crucial for the FTC and DOJ to support this policy to curb anticompetitive behavior and restore efficient market forces.

Kara Monahan:

Thank you. Our next question is for Dr. Yim. Although the FDA requires biosimilars to be highly similar to biologics with no clinically meaningful differences, this distinction between biologics, biosimilars and interchangeable biosimilars has created confusion. There have been concerns that this confusion can be leveraged to imply that biosimilars are not safe or effective substitutes. What are these concerns and what steps has the FDA taken to address biosimilar disparagement?

Sarah Yim:

Thank you for the opportunity to participate here with you today. The introduction of a new approval pathway for biosimilar biological products via the Biologics Price Competition and Innovation Act in 2010 ushered in the potential for increased competition and increased patient access to biologics, but also brought the complex science underlying biologics and biotechnology to the forefront.

Add to that the two designations of biosimilar and interchangeable biosimilar, which other countries did not employ, and it was clear that the new pathway also brought with it a large potential for confusion. Even early on in the pathway's implementation, FDA was made aware of the existence of written materials that could undermine understanding and confidence in biosimilars and foment confusion about what biosimilar and interchangeable designations meant.

FDA has also done multiple rounds of focus group testing and interviews of healthcare providers and patients over the years in order to identify misperceptions and confusing key concepts, including specifically interchangeability and to create materials to help address those confusing aspects. To the average person and even to other health regulatory agencies around the world who do not have multiple statutorily defined designations, the term interchangeable has a common meaning, i.e. it's something that is substitutable or can be used in place of a particular other thing. But in the U.S., our law provides for two such categories, biosimilars, which can be used in place of their reference product with the expectation that there will be no clinically meaningful differences and interchangeable biosimilars, which can be used in place of their reference product without intervention by the prescriber.

For example, needing a new prescription, also known as pharmacy level substitution, which was I think intended to mimic the context in which small molecule generics are used. These two designations are tied to very specific criteria requirements in the BPCI Act, but if one were just to use the term interchangeable colloquially, then both biosimilars and interchangeable biosimilars would indeed be interchangeable because they both can be used in place of the reference product with the expectation of similar safety and efficacy.

You can imagine how confusing this would be for the average healthcare provider or patient who's not steeped in regulatory terminology or particulars of biotechnology. In response, FDA has developed and continues to update and add to a comprehensive portfolio of multimedia educational materials to improve understanding of these basic concepts about biosimilar and interchangeable products, to emphasize that biosimilars and interchangeables have the same high level of similarity and quality, how they both can be used in place of the reference product, and how people do not need to wait for a biosimilar to be approved as an interchangeable before using it in place of the reference product.

Our portfolio of educational materials includes a healthcare provider curriculum, continuing education pieces, including videos and articles and fact sheets. There are also public service announcement ads

and videos which play in waiting rooms and on social media. These efforts have reached tens of thousands of patients and healthcare providers already, and we hope to keep the momentum going. Again, thanks for the opportunity to participate in these important discussions.

Kara Monahan:

Thank you. Our next question is going to be for Professor Mossoff and Ms. D'Orsie. Generic and biosimilar competitors often face patent infringement litigation, which can involve many patents. What are your views on the number of patents asserted against generic and biosimilar competitors and whether this raises competitive concerns? We'll start with Professor Mossoff.

Adam Mossoff:

All right. Sorry, I thought you were going to start with Ms. D'Orsie first, but that's all right. So it's a very good question, and whenever someone says a lot of something, a lot of patents or a lot of property or a lot of contracts, the question is always by reference to what? By what standard? As compared to what? Because the fact of the matter is that the actual number of patents that are you see in litigation in the biopharma context is actually fairly small compared to other areas of patent litigation. For instance, in the high-tech space, in the cellular space, you have patent lawsuits involving tens if not hundreds of patents that are alleged to be infringed, especially involving standard essential patents, which can sometimes involve thousands of patents. And in fact, hundreds of thousands of patents are alleged to cover the single device right here [holding up a smartphone], and yet we are complaining about five or six patents covering this and potentially being asserted.

Moreover, you have another unique aspect to the biopharma space that you don't have in any other area of the patent law, which is because of the dispute resolution mechanism that was created in the Hatch-Waxman Act, there's going to be infringement litigation between the drug innovator and the generic. That is part of the mechanism that has to happen. It prompts litigation in a way that you don't have litigation prompted in other areas of the economy. And so we have to hold these points in context, especially when the allegation is made, that it's the litigation that is leading to higher prices and to harm to consumers and to patients. And I'm looking for my quote now, I apologize. I can't find it. Where in the recent litigation over Humira, which we've heard a lot about and is often the go-to example for a lot of patents, the City of Baltimore brought antitrust claim saying, "You have a lot of patents and this is a patent thicket, and this is causing high costs in both litigation and in preventing generic competition."

And Judge Easterbrook soundly rejected the claim because he recognized that, while identifying that there were a lot of patents, they did not actually explain that this was causally connected to any increase in prices, in fact zero, and essentially reduced down to an allegation that they had a lot of patents. And he said, "You know who also has a lot of patents?" As I was looking for the quote, he says, "Cisco and Apple and Samsung have thousands more patents than AbbVie does." He says, "Even Thomas Edison had over 1,000 patents, and yet those are not being accused in this context of upholding innovation, and we shouldn't do the same in the biopharma context."

Sarah D'Orsie:

So I'm going to go off script and just respond to that. So the way that other industries use patents aren't the same as the pharmaceutical industry. If you have a golf ball that has 50 patents on it, that is not the same as a pharmaceutical product. Golf ball manufacturers or cell phone manufacturers are using patents to cross license, and so they are able to still launch their product when they are maybe infringing some different features of each product. For generics and biosimilars, we are statutorily and

regulatorily, we have to be the same as the brand. And so you can see that you can block competition with less patents. It's just not the same.

And in fact, I'd like to address a few statistics also raised during the first panel regarding the number of pharmaceutical patents and their growth over time. The panelists referred to numbers of patents only without the mention of the nature of those patents, so it's not just numbers. The claim is that about four to six small molecule patents are litigated and about a dozen biologic patents are litigated. The argument is that this is a stable and reasonable number of patents. It hasn't increased substantially over time. However, if you consider the increase in the number of double patenting and terminal disclaimers, the results look very different.

So you can see here in 2023 [referencing her demonstrative], this is not narrative, JAMA-published data showing 68% increase in the number of FDA-listed patents per drug from 2000 to 2015, which sounds reasonable. However, while the number of novel patents increased by just 15%, the number of terminally disclaimed patents increased by 200%. These findings suggest that the growth of patenting innovation is slowing while the frequency of double patenting is exploding, likely delaying or deterring competition. Therefore, while the number of patents looks stable, the ratio of duplicates to novel patents has turned upside down, proving that the number alone does not tell the story.

So, further, this is my favorite, a JAMA-published article in 2023 considered when these duplicative patents are granted. And, surprise, year 12, when the innovator is coming off of their data exclusivity and biosimilars are getting ready to launch, you see the huge spike in duplicates to try to force us to a settlement with inappropriate leverage or say, "Look, we don't have the money to litigate these patents even if they're weak."

Finally, I would like to address the claim that generics and biosimilars industries are ignoring what patients think about the value of secondary innovation to their quality of life. My mom, who was diagnosed with multiple myeloma in 2015, was treated with Revlimid for many years. I read to her the claims of two terminally disclaimed patents in the Revlimid patent family. I explained that in both patents, the invention described a method of allowing a prescription for Revlimid to be issued to a patient only after the patient understood and agreed to preventing birth defects by using the medication properly.

Both patents claim an eight-step method for giving the patient the warning. These eight steps are identically worded, and I won't go through what they were. They're identically worded. Only one of the patents, the `566 patent, mentions one additional step of providing the prescription for the drug to the patient, which is not mentioned in the `886 patent. My mom listened carefully, looked confused when I didn't go on after describing this, like she was waiting for the punch line. And when I asked her if she thought the `566 patent represented a meaningful improvement from the `886, she said, "Sarah, that is ridiculous."

Markus Brazill:

Ms. Toufanian, one avenue for anticompetitive behavior is the misuse of regulatory processes in a way that harms competition from generic or biosimilar products. This can include sham petitioning to the FDA and sham and serial patent litigation among other things. How does this type of regulatory abuse harm competition from generics or biosimilars?

Maryll Toufanian:

Yes. Thank you for the question, and I can speak to citizen petitions in particular. So, taking a step back, petitioning the government has constitutional protections and it's appropriate, and I would say necessary, for parties external to an agency like FDA or otherwise to have a transparent mechanism to

bring issues before the agency. The challenge becomes when those efforts are designed to slow the ultimate approval of a generic product. So, I am full in favor of petitioning the government, but it needs to be done in a way that is not abusive of a system that was contemplated to bring generic drugs to market.

It's indisputable that the citizen petition process has been abused by brands trying to improperly extend their monopolies. I actually lived it firsthand in the form of an 86-page single-spaced petition response that dispensed of 46 petitions or petition supplements, numerous public comments, multiple litigations needed to address tactics trying to forestall generic competition for Vancocin capsules.

Now, that was now almost two decades ago, and things are better post enactment of Section 505(q) of the FD&C Act, which was specifically designed to balance the importance of petitioning the government without allowing brands to use the petition process, to use up time and resources when each day they are extending their monopoly and making hundreds of thousands if not millions of dollars. In addition, I think the parameters set forth in Section 505(q) are important. They essentially guide how FDA responds to these petitions, particularly those seeking to block approvals, and by FDA's related guidance that sets up criteria the agency will apply in evaluating delaying tactics.

Now, FDA can and does refer citizen petition abuse of matters to the FTC when the agency finds that the petition was submitted with a primary purpose of delaying approval, but that standard is high. And in addition, and maybe even more importantly, resources from all of these petitions take vital bandwidth away from the experts within FDA who are otherwise supporting generic drug approvals. So there is not only a direct implication, but a secondary implication in that the same small cadre of experts who are working on generic drug development have to put their resources into the ultimately unsuccessful citizen petitions.

I will say there's also an issue with respect to serial petitions. More recently, and in a 2024, 46 page, oh, excuse me. Yes, I'm sorry. I'm going to take a step back. Notwithstanding 505(q), petitions continue to be slowing or preventing generic competition. For example, in 2024, in a 46-page response, FDA denied Novartis's citizen petition asking FDA to refrain from approving generic applications for Entresto that sought to carve out information related to a three-year exclusivity and certain methods of use patents, which decision by FDA was held up by the district court under *Loper Bright*. As for serial petitioning, it doesn't happen as much, but I still think it's a real issue for those patients who need access to products. For example, I know a number of folks who are tracking an extensive number of submissions of petitions and other comments related to iron drug products recently submitted by brand sponsors or related entities. And I think the key is that although it may not be broad, when serial petitioning or petition blocking petitions is happening, it is blocking, it is slowing access to patients to those generic medicines.

Markus Brazill:

Thank you. Dr. Yim, the FDA has proposed regulatory changes relating to biosimilar interchangeability, including the need for switching studies. What are these proposed changes and the impact they may have on biosimilar approval and uptake?

Sarah Yim:

Yeah, thank you for that question. FDA's regulatory expectations have evolved over time with increasing experience and increasing scientific knowledge, allowing for streamlining of the original expectations. This, we anticipate, will reduce barriers to biosimilar development and ultimately encourage more competition for biologic products and increase access for patients. This has included reducing or eliminating elements that were considered scientifically unnecessary, like routine or default switching studies to support interchangeability or routine or default expectations for comparative efficacy studies.

If I were going to choose one word to describe what would be helpful on the pre-market side of the equation, I would choose the word simplify. Just because the underlying science is complex does not mean that the regulatory expectations have to be complex. Science can be complex in predictable ways, and that is what we're dealing with most of the time. In its FY25 and FY26 legislative proposals, FDA has proposed to eliminate the statutory distinction between biosimilar and interchangeable products and to deem all approved biosimilars to be interchangeable with their respective reference products. But the intent here would be not to add additional expectations in order to be approved as a biosimilar. The biosimilarity standard is already high. Simply, the early rationale for having two designations has not been borne out as a real need in our experience. So that's how we would propose to help lower the barriers on the pre-market side.

Kara Monahan:

Biosimilars are important to a competitive marketplace, but development and approval can be expensive and time-consuming. Can the regulatory process for getting biosimilar approval be streamlined? And can incumbent biologics engage in conduct that complicates the process? Let's hear from Ms. D'Orsie first, and then Dr. Yim.

Sarah D'Orsie:

Actually, yes, we've been very encouraged by the recent statements made by Commissioner Makary on this topic. Namely, on waiving phase three clinical trials for biosimilars which are unnecessary and supporting deeming biosimilars interchangeable upon approval of a biosimilar to the reference. However, recently there have been attempts by the branded industry to insert a rule of construction into the current interchangeability legislation in the House that would allow them to challenge FDA's determinations of the biosimilarity standard under *Loper Bright* using things like citizen petitions like Maryll talked about, and litigation.

By adding into statute that FDA should not limit information that may be necessary to prove biosimilarity, which sounds reasonable, they give themselves an avenue to import the interchangeability standard, which the Trump administration and the scientific community would like to discontinue into a new standard for biosimilarity. So instead of getting rid of red tape, they want to insert more to delay biosimilar launches instead of accelerating them.

Sarah Yim:

I hope that doesn't end up being the case. Biologics manufacturing itself is an expensive and difficult process, so we don't want to add unnecessary regulatory expectations that would increase the difficulty further. Much of the clinical data historically requested lacks sensitivity to change, and the comparative analytics must meet the highly similar standard for a biosimilar to be approved, so the differences observed are much smaller than would be evident in a clinical study. Thus, clinical studies are ripe for streamlining. However, healthcare providers and patients are used to clinical data, so we need to provide, and continue to provide, supportive education that explains the basis for biosimilarity.

I think this panel and the previous panels have really mentioned a lot of important tactics that biologic sponsors can potentially use to impede competition. And there are many, so you guys have a hard job in front of you to help combat all of these potential avenues, but we will try to do our part on the pre-market side.

Markus Brazill:

The next question is for Professor Mossoff and Ms. Toufanian. Drug companies have to work with a variety of statutory and regulatory frameworks overseen by several different government agencies including FDA, CMS, USPTO, DOJ, and FTC. Does the shared government oversight in the pharmaceutical sector create opportunities for incumbent brand companies to harm competition or any additional challenges for enforcers?

Adam Mossoff:

Who's going first? Thank you. So I'm interpreting this question as an inquiry about whether you have, which is a common claim, and there's some bills that entailed FDA-USPTO collaboration about information sharing given allegations about saying one thing to one agency and not to another. And it's notable that actually in the past 30 or 40 years, if you're going to have a bill that is going to establish a systemic change to a system or mandated defenses or additional documentation production at the USPTO during the patent prosecution process, that there was actually evidence that shows a systemic problem.

And then in 30 or 40 years, you actually have two cases in which there was an allegation proven that there was something that was said to one agency and not to the other. One didn't involve a drug, one was a medical device. And the other did involve a drug, but the patent was ultimately deemed to be unenforceable because they were found under pre-existing law to have violated the conditions under committing a fraud at the Patent Office.

And so I don't see, actually, again, going back to evidence-based policymaking, I don't see an established basis for arguing for systemic changes to impose additional costs on innovators to create additional ways in which patents can be undermined and be made even further unreliable given two instances in 30 or 40 years in which this has happened in which both of those were addressed. Because otherwise then what you have is similar to I-MAK-type style allegations, which you just have allegations being made or colorful anecdotes being shared, but you don't actually have the actual evidentiary foundation for systemic change to the system that you should establish in order to make that change.

Markus Brazill:

Ms. Toufanian?

Maryll Toufanian:

Thank you. And just in response, I'll say one thing. And that is I vehemently agree about data-based policy, but I think that with what your observation related to, I don't know there's a mechanism to actually currently police it, so I would be very interested in diving into that issue a little bit deeper. And to answer the more general question, yes, there are potential to harm competition due to the complexity of the various parts of the administration that work on our issues, but not for the reasons most might anticipate, I discuss. And the role of different agencies may ultimately enhance policy development.

As is very clear, I think from today's discussion, pharmaceutical regulation by FDA, CMS, and PTO, enforcement by DOJ and FTC, are some of the most complex and specialized regimes in the federal law. But there is crossover and it is essential that sister agencies and departments develop and maintain understandings of each other's statutory schemes and policy priorities. Otherwise, you risk uninformed policy decisions, litigation positions, and technical assistance provided to The Hill, and brands can exploit any gaps in a sister agency's knowledge to use to their advantage.

But even without the role or persuasion of a brand, you don't want an FDA regulatory expert opining to the White House or The Hill on matters at the intersection of FDA and PTO law without some

understanding and acknowledgement of how PTO works and the mission and the authorities underlying it. And I was thinking, you certainly don't want to ask a DOJ attorney to, you know, pick up a brief and argue something about carve outs, reissued patents, and exclusivities without some background. I think that would be just plain mean.

On the flip side, if you establish and maintain avenues of education, communication, and growing expertise, you'll have well-informed litigation and policy positions across the government that will be able to, yes, identify and push back any untoward influence from a party trying to push for policies by exploiting the number of agencies. And more importantly, you'll develop well-rounded positions that balance the interests of these important and separate regulatory regimes. I firsthand as a public and private litigant, as a private and public policymaker, I've experienced firsthand the value such structures can bring to public health and the risk to sound policy and legal positions that occur if that doesn't exist.

Kara Monahan:

Our last question for this panel is going to be a lightning round where we'd like to hear a 30-second response from each of you on this question: Whether in the context of small molecule drugs or biologics, statutes and regulations have sought to strike a balance between incentivizing the development of new drug products while also promoting competition from lower-priced generics or biosimilars. Is the balance struck in the right place? What one change would you make that would be most impactful? Let's start with Ms. D'Orsie.

Sarah D'Orsie:

So, obviously, the first change that I would suggest is, look, double patenting is not innovation. Pass the ETHIC Act.

Secondly, I'm going to use the rest of my time to talk a little bit about the FDA-PTO coordination. So, actually, what is happening here is you have the inequitable conduct defense to infringement, and that is what these cases are using to try to prove that an originator disclosed something to the FDA and then only disclosed half of that invention at the time to the PTO. And, so, then they're holding back the other part of the invention as a trade secret to the FDA and filing it later.

So when you go to in court later, the only way to prove this is that you have to prove that the person who filed the patent is the same person who filed the BLA or NDA, whatever, and it's very easy to get away with that by just putting up these walls. And so, of course, also the bill that you were discussing, there's nothing on the FDA. The patent holder is responsible for giving the information.

Maryll Toufanian:

So, rather than one particular change, I would offer the most impactful thing in maintaining the balance between innovation and access would be, for new policies, or repairing old policies, would be for policy makers to keep front and center a quote from a judge's decision in an FDA case that was actually an Orange Book decision, and that was, quote, "Reality matters." In other words, crafting policy that will operate to achieve policy goals in the real and complex world where data matters. For example, policies that might seem reasonable in the context of one drug application must be operationalizable by FDA for hundreds of brand drugs and thousands of generic drugs each year, and they must ensure that similar actors treat similarly situated folks the same. I used to call this, "Can you just do that for my application?" And the answer is no. And I think in addition to operationalizing it, you have to make sure that the agency has the actual human and IT resources to do it.

On the flip side, the real world extends to the private sector as well. Policies that might make sense in the context of one patent or patent case might not achieve the underlying goal. If one fails to recognize that, for example, each generic company is managing tens, if not more, pending applications and related

patent litigations involving hundreds of patents on a fixed litigation budget, limited by the market dynamics that we've discussed previously. And for every successful innovative product from the brand manufacturers, many more do not make it across the finish line. If we continue to ask ourselves, "Will this work for the system rather than for one set of facts?" the balance will be best fostered.

Adam Mossoff:

So, as it was I think very clear from the very first panel that there are an incredible number of influences and various factors that at play within the U.S. health care system and within the broader legal and regulatory system, and so there's lots of friction points in the system. And to reduce it down to just patents as is foolishly simplistic and reductionist. And so, in fact, I think the first panel made very clear that the type of reform that should be made is at the PBM stage. There you can actually achieve, I think, some real efficiencies in the system and eliminate actual harms that are being created that are linked to actual harms of increased prices. But until then, what we have with respect to patents is primarily colorful anecdotes and lack of actual correct comparisons to actually what's happening in the real world because reality matters. I appreciate that quote.

Sarah Yim:

Short answer to the question of, is the balance struck in the right place? I would say that maybe not quite yet. FDA needs to reduce barriers to development and approval while still ensuring approval of high quality, safe, and effective biosimilars. So we will continue to streamline expectations to facilitate competition, but there are many challenges in the U.S. health care ecosystem that are making it difficult for biosimilars, and hopefully we'll be able to find some solutions for those.

Kara Monahan:

Thank you. It's my pleasure to invite Taylor Hoogendoorn, Deputy Director of the FTC's Bureau of Competition to provide closing remarks.

Taylor Hoogendoorn:

Thank you, Kara. As Kara said, I'm Taylor Hoogendoorn, Deputy Director of the FTC's Bureau of Competition. There I have the distinct pleasure of working closely with our terrific healthcare attorneys like Kara, on a variety of interesting cases every day. I also have the distinct pleasure of standing between you and the conclusion of a two-hour listening session, so I'll be brief.

The American people elected President Trump to fight against rising inflation and to revive a stagnating economy. As President Trump's executive orders make clear, restoring competition to lower drug and healthcare prices for the American people is a key priority of the Trump-Vance FTC. The Chairman described several of our efforts earlier today, and there are many, many more. Our healthcare division is currently challenging a provider roll-up scheme that skyrocketed anesthesia prices in my home state of Texas. And very relevant today, it also serves as complaint counsel challenging the big three PBM's formulary practices for insulin, which became unaffordable for many Americans. This listening session is just another example of that practice.

Thank you to Kara, to Markus, and to the many dedicated public servants at the FTC and our sister agencies, whose efforts made today's event possible. As these listening sessions demonstrate, the healthcare industry is rife with misaligned incentives, dominant oligopolies, and market structures that are opaque by design. Americans can see that our pharmaceutical supply chain is deeply flawed almost every time they fill a prescription or they pay an insurance premium. It doesn't take a PhD, a JD, or a

career in medicine to see the problem, but these forms of expertise can help analyze the problem and hopefully solve it.

So, on behalf of the FTC, thank you to all of our distinguished panel participants who have volunteered their time and talents here today. This was, in my view, a truly substantive and insightful discussion, and we're very grateful for your time. Our final listening session on Lowering Americans' Drug Prices Through Competition is set for August 4th. It will focus on turning insights into action to reduce drug prices and will serve as a capstone for the series of listening sessions. The public is invited to continue to submit questions and comments through links on the FTC and DOJ's event pages. Thank you