Listening Sessions on Lowering Americans' Drug Prices Through Competition: Third Listening Session Transcript

August 4, 2025 | Commerce Research Library

0:10

Jason Clark

All right! Good afternoon. On behalf of the United States Patent and Trademark Office and the United States Department of Commerce, I'd like to welcome you to the historic Commerce Research Library. Today is the third in a series of listening sessions that have been held in accordance with President Trump's Executive Order number 14273, lowering drug prices by once again putting Americans first.

0:33

Section 13 of this executive order asks us to hold listening sessions and later make recommendations to reduce anti-competitive behavior in the pharmaceutical sector. I'd like to especially thank our partners in this process, the Federal Trade Commission, the Department of Justice, and the Department of Health and Human Services for making today possible.

0:54

A few housekeeping items before we begin today's program. Today's session will be live streamed and video recorded. A copy of the video and the transcript for today will be available on the event page online. For those of you who are participating in the panel today, you'll notice there's a little button on your microphone. Make sure you press it. You should see a green light and that will turn your microphone on. Please remember to silence your cell phones or put them on vibrate.

1:23

There are water and cookies in the back. Please help me eat the cookies; otherwise, I will have to eat them all myself afterwards and I can't afford to buy a new suit. The restrooms are located in the back, straight back by the exit but before you leave, just to the left and the nearest exit of course is straight to the left. Or in an emergency, you can also exit out here to my right.

1:46

Today we are holding our listening session in historic Herbert C. Hoover Federal Building. When this building opened in 1932, this section of the building was home to the United States Patent and Trademark Office's examining core. This very room was home to the Patent Office Library, which was known as one of the finest scientific book collections in the world. The USPTO outgrew this space long ago, and while we are no longer here, the spirit of innovation and progress continues to inspire us in this room today.

2:19

It is now my distinct pleasure to introduce the Acting Under Secretary of Commerce for Intellectual

Property and the Acting Director of the United States Patent and Trademark Office, Ms. Coke Morgan Stewart.

2:40
Acting Undersecretary of Commerce, Coke M. Stewart
Thank you so much, Jason. Good afternoon, everyone.

2:45
Today, the Department of Commerce, together with the Department of Justice and the Federal Trade Commission, is hosting the third of three public listening sessions on how to lower drug prices through competition.

2:58
These sessions take place at the direction of our President, Donald J Trump. He will ensure that drugs remain not only safe and effective, but also reasonably priced. For too long, the United States has paid more than its fair share for drugs.

3:13
President Trump and Secretary of Commerce Howard Lutnick will ensure that this ends by not only by ensuring fair competition in the United States, but also by ensuring fair competition throughout the world.

3:26
The United States is the most innovative country on earth. United States companies spend more on research and development for drugs than companies from any other country, and they invent more drugs than any other country, drugs that save the lives of our mothers and fathers, sons and daughters, and our loved ones. Why is that? One answer lies in the U.S. Constitution.

3:50
Our founding fathers have the vision to include the protection of intellectual property there. It's in Article 1, Section 8, Clause 8, which grants Congress the power to promote the progress of science and the useful arts by securing, for limited times, to authors and inventors the exclusive right to their respective writings and discoveries. Relying on our Intellectual Property Clause, Congress has protected patent rights since 1790.

4:19
These rights provide incentives that individuals, small businesses, and large companies need to spend the time and money to develop technological inventions, knowing in turn that those inventions can be licensed and or commercialized. Without those rights, without incentives to create and discover, innovation as we know it would cease. How do we know that?

4:43
One way is through work that led to the bipartisan Bayh-Dole Act. Before the Bayh-Dole Act, the federal government would fund research. The research would result in inventions and the inventions would sit on shelves and would never be brought to market.

4:57
The government funded entities did not have the ability to develop, manufacture, sell, and distribute their inventions. At the same time, no one wanted to invest in government owned inventions because then their competitors could easily manufacture and distribute the same products, putting the entire endeavor at risk.

5:15
This is why a world with fewer patents may look like a utopia of open markets and free access to innovations, when in reality, it would destroy the very incentives that promote competition and access to medicines.

5:29
I love to use the example of Shark Tank. What is one of the first questions the Sharks ask inventors and small businesses who appear before them? Do you have a patent? Why is that?

5:42
Because the exclusive right for a limited period of time to manufacture and sell an invention is what creates the incentive for investors. The IP clause of the U.S. Constitution thus reflects an economic philosophy that encouraging individual effort through financial gain is the best way to advance public welfare through the talents of our nation's inventors.

6:05
As we heard in previous listening sessions, commercially viable drugs require more than a decade of preclinical testing, clinical trials, and U.S. regulatory approval. All of this is required before they make it to market. On average, companies invest $1.4 billion of their own costs and then another $2.6 billion to bring a single FDA approved drug to market.

6:30
And only 12% of drugs that begin clinical testing result in FDA approval. Without the protection provided by patents, investors, companies, universities, and individuals would not have the means to spend the required billions of dollars on a new drug, a drug needed for the good of everyone.

6:51
But patents are not just for a drug compound. Patents are for innovations that make the compound safer, more effective, and more convenient to administer. This in turn lowers the price of healthcare and improves outcomes. Patents are also for new uses of existing compounds.

7:10
A drug once patented to treat heart disease may, through additional research and trials, be discovered to treat breast cancer and then patented for that use. Without the incentive to do that follow-up research, these new uses would never be discovered. Even though patents are critical to innovation, this does not mean that the patent system cannot be improved.

7:32
Through the leadership of Secretary Lutnick, the USPTO is spending more time and money on patent quality than any other administration in history. This includes everything from AI tools that help patent examiners find prior art, to tools that help examiners navigate the complex legal and regulatory requirements to obtain a patent. Excellent searches and examination are critical so that the patents the USPTO issues are for drugs and drug-related inventions that are truly new and non-obvious.

8:05
Patent laws also require that inventions are supported by adequate written disclosure that enable others to make and use the invention when it is off-patent. That's the quid pro quo of the patent system. Exclusive rights for a limited time in exchange for sharing knowledge.

8:23
And it's working. 90% of drugs prescribed in the United States are generic drugs that are off-patent.

These generic drugs are brought to market almost entirely by the earlier research, testing, and patent disclosures of branded drug manufacturers.

8:39
In addition to improving the quality of issued patents, the USPTO, again through the leadership of Secretary Lutnick, is working to ensure that once a patent is issued, it is stable and can be relied on for investment.

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We do not want patent applicants to spend their time on research and development, and we don't want patent owners and their investors to commercialize products while at the same time imposing a constant threat of loss of patent rights through administrative challenges, not to mention imposing layers and layers of additional laws and regulations.

9:15
Let's remember the least expensive drug is the drug that is never brought to market. It costs nothing and helps no one. While we work together to ensure that we have lower drug prices, we must ensure that those efforts do not damage the very system enshrined in the Constitution that makes the United States the most innovative place on earth.

9:37
That said, now is the time that we, the U.S. government, Congress, and industry deliver on the President's directive to lower drug prices for all Americans. The United States provides the medical innovations that improve health for the world. It is imperative that other countries step up now and pay their fair share.

9:59
In closing, a strong intellectual property system increases competition. It lowers drug prices and health costs, and it ensures that we have the best medical care for generations to come. Thank you for being here today to be part of the solution.

10:15
And with that, I'll turn it over to the moderators of today's session, Isabela McGinniss from the U.S. Department of Justice, and Kelse Moen of the Federal Trade Commission. Thank you so much.

11:14
Isabela McGinniss
Thank you, Under Secretary Stewart. My name is Isabela McGinniss. I'm counsel to Assistant Attorney General Gail Slater at the Department of Justice's Antitrust Division, and I'll be one of the moderators for today's session along with my colleague Kelse Moen from the FTC.

11:31
We'll have one panel discussion for this last session. Today, we're focusing on turning insights into action to reduce drug prices.

11:41
The panel is comprised of some of the leading voices on Capitol Hill working on the nexus of healthcare, pharmaceuticals, intellectual property, and other pressing public policy issues. They will share their views on the issues impacting drug affordability and accessibility and identify possible solutions to reduce drug prices.

12:03
We have a lot to cover today, 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 speaking. My co-worker, Markus, will have time cards right there so you can glance at him if you're wondering how much time you have left.

12:21
Kelse Moen
Thank you, Isabela. My name is Kelse Moen and I'm a deputy director in the Federal Trade Commission's Bureau of Competition. So let's start by introducing the members of our panel.

12:31
Franci Rooney Becker is Chief Counsel to Senator Cornyn on the Senate Judiciary Committee. A graduate of the University of Notre Dame and Georgetown University Law Center, she clerked for Judge Terrence Boyle in the Eastern District of North Carolina before joining the senator's judiciary staff. She grew up in Dallas, Texas.

12:53
Isabela McGinniss
Thomas DeMatteo is Chief Counsel of on the Senate Judiciary Committee to Senator Mike Lee. He previously served as counsel to the Assistant Attorney General of the Department of Justice's Antitrust Division, where he worked on civil merger and non-merger matters across numerous industries, including large technology platforms, defense, and consumer products. Mr. DeMatteo is a graduate of Washington and Lee University School of Law and the University of Rochester.

13:25
Kelse Moen
Jay John Lee is the Chief Counsel for Intellectual Property of the House Judiciary Committee, where he is a principal advisor on IP and AI issues and helms the Subcommittee on Courts, Intellectual Property, Artificial Intelligence, and the Internet. Prior to joining Congress, Mr. Lee was a Lead Administrative Patent Judge on the Patent Trial and Appeal Board at the U.S. Patent and Trademark Office. Before his judicial appointment, he was a partner at Kirkland and Ellis LLP. Mr. Lee also served as a law clerk to Chief Judge Paul R. Michel of the U.S. Court of Appeals for the Federal Circuit. He is a graduate of the University of Pennsylvania Law School and also holds degrees in bioengineering and neuroscience from the University of Pennsylvania.

14:12
Isabela McGinniss
Peter-Anthony Pappas serves as the Director of Intellectual Property Policy for the U.S. Senate Committee on the Judiciary under Senator Thom Tillis, Chairman of the Subcommittee on IP, to whom he advises on all IP matters. Prior to working in the U.S. Senate, Mr. Pappas served as the Special Advisor Detailee to the Under Secretary of Commerce for IP and Director of the USPTO, Andrei Iancu. Mr. Pappas received a Bachelor of Science in Computer Engineering from the Georgia Institute of Technology and received an Executive Certificate in Public Leadership from the Harvard Kennedy School.

14:55
Kelse Moen
Nicholas Pottebaum serves as health policy advisor to Iowa Senator Chuck Grassley, who is Chairman of the Senate Judiciary Committee and a senior member of the Senate Finance and Budget Committees. Mr. Pottebaum is a native Iowan and a graduate of the University of Iowa.

15:14
Isabela McGinniss
Peter Stein serves as Senior Policy Advisor to U.S. Representative Diana Harshbarger, a career pharmacist and a member of the House Energy and Commerce Committee. Mr. Stein has more than 12 years of experience working on Capitol Hill, previously serving as Policy Advisor to U.S. Senator Rick Santorum, where his chief projects included helping to craft the Medicare Prescription Drug Benefit Part D and introducing legislation that led to enactment of the Combating Autism Act. Peter is a graduate of Georgetown University and received a master's degree from George Washington University.

16:02
Today's panelists have extensive experience working on healthcare policy issues. We've asked them to tell us about an issue impacting drug affordability and accessibility and possible solutions to address it.

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Let's start with Senator Lee's Chief Counsel on the Senate Judiciary Committee, Mr. DeMatteo.

16:21
Senator Lee currently serves as the Chairman of the Judiciary Committee's Subcommittee on Antitrust, Competition, Policy, and Consumer Rights, where he has long been a leader in promoting competition roles that work for American consumers.

16:36
So Mr. DeMatteo, what are some issues from your perspective impacting drug affordability and accessibility?

16:44
Thomas DeMatteo
Thank you. First, I'd like to thank President Trump and his teams at the Department of Justice, the Federal Trade Commission, the PTO, and the Department of Commerce for their leadership on this issue of critical importance to millions of Americans who rely on life saving medications.

17:01
Our healthcare system needs regulatory reform. It is one of the most heavily regulated sectors in the economy, burdened by layers of regulatory red tape that often shield incumbents from competition. While regulation has long been a feature of healthcare, the Affordable Care Act has intensified these effects.

17:18
A recent Senate Judiciary Subcommittee on Antitrust hearing underscored how rules meant to protect patient safety are now being used to deter entrants and stifle competition. From my perspective, price transparency and competition are lacking across the entire healthcare industry. From services and procedures to prescription drugs, patients often have little or no information about costs.

17:44
This problem is compounded by the labyrinth of regulations and a web of intermediaries, such as insurance companies, PBMs, drug wholesalers, and pharmacies, all taking a cut at various stages of the supply chain. The result is a system where patients, understandably, feel as though everyone has a hand in their pocket. When functioning as intended,

18:07
PBMs serve an essential role by aggregating purchasing power across millions of covered lives they can negotiate substantial rebates and discounts from drug manufacturers that individual insurers or pharmacies alone could not obtain. In 2023, PBMs reported securing an average discount and rebates of about 50% off the list price of brand name drugs.

18:31
They also help manage formularies that favor lower cost generics and biosimilars, run adherence programs, and promote generic substitutions, all of which can improve health outcomes and reduce overall costs. In principle, this scale could help reduce system wide drug prices and expand access especially to high cost, specialty medications.

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PBMs have the potential to counterbalance pharmaceutical pricing power and deliver value, but they also risk becoming mere toll collectors along the drug supply chain. PBMs' compensation structures can at times create perverse incentives.

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One notable example is the so-called rebate trap, where low-cost generics may be less attractive to PBMs because they generate minimal rebate revenue. Consequently, PBMs may steer patients towards higher priced branded drugs that provide greater rebates even when equally effective lower cost generics are available.

19:33
The complex, overlapping patchwork of state and federal regulations has contributed to increase consolidation and vertical integration across insurers, PBMs, and pharmacies. While vertical integration can bring efficiencies and more coordinated, holistic care, it doesn't always yield lower prices or better outcomes.

19:53
With three vertically integrated PBMs controlling 80% of the market, regulations, such as the Affordable Healthcare's medical ratio in place, the benefits of scale often fail to reach patients. The FTC has recently sued PBMs that have allegedly used anticompetitive practices, particularly in rebate arrangements, to artificially inflate the list price of essential drugs such as insulin.

20:21
Another critical issue is the pricing and availability of prescription drugs. Pharmaceutical companies invest billions in research and development and rely on patent protections to recoup those investments.

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While patents are essential to incentivize innovation, they also create temporary monopolies that allow companies to charge higher prices. Biosimilars are beginning to ease the burden of high-cost biologics, although their initial price discounts tend to be more modest due to higher development costs and regulatory barriers. Even so, biosimilars have saved the U.S. healthcare system an estimated $21 billion over the past five years. Senator Lee has championed two bills that would bring reform in this area.

21:01
First, the Biosimilar Red Tape Elimination Act would streamline access by making FDA-approved biosimilars automatically interchangeable once deemed safe and effective. Given that modest

increases in biosimilar uptake are projected to save tens of billions of dollars, this is a common-sense reform to accelerate access to affordable therapies.

21:24
Second, the Short on Competition Act would empower the Secretary of Health and Human Services to expedite reviews, inspections, and temporary importation in the event of a drug shortage. The bill would also allow for expedited review and importation of drugs approved for more than 10 years that have fewer than five suppliers in the market.

21:46
Finally, is also essential to recognize the role in government creating artificial market constraints. When Medicare sets reimbursement rates below market value, hospital and pharmacies are forced to shift costs to privately insured patients, thereby raising prices across the board.

22:02
True reform lies in removing government imposed regulatory barriers and in aligning incentives to unleash market forces that reward innovation, efficiency, and competition. Thank you.

22:18
Kelse Moen
Thank you, Mr. DeMatteo. Now let's hear from Representative Harshbarger's Senior Policy Advisor, Mr. Stein.

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Now, Mr. Stein, Representative Harshbarger has a unique distinction of being one of the only representatives in Congress to have previously worked as a pharmacist. Since coming to Congress in 2021, she has already taken the lead on several bills to improve prescription drug affordability and accessibility.

22:41
So Mr. Stein, I'll leave you with the same question. What are some of the important issues of drug affordability and accessibility from your perspective? And what do you view as some potential solutions?

22:55
Peter Stein
Oh, thank you for the invitation and thank you for the questions.

22:58
And Representative Harshbarger certainly applauds President Trump's dedication and leadership to this issue. It's one which we hear so much about from so many of our constituents across the country.

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As was mentioned, Representative Harshbarger is one of two pharmacists in Congress. For 35 years she served as a pharmacist. And so these issues of enhancing affordability and accessibility of prescription drugs is very near and dear to her.

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Representative Harshbarger also serves on the Republican Doctors Caucus. She's Co-Chair of the Congressional Bipartisan Rural Health Caucus and she was recently named Vice Chair to the Energy and Commerce Health Subcommittee.

23:42
I think Representative Harshbarger sees these issues that I won't go into all the derivations of these, they're multifaceted, but she sees a lot of these issues that of different components that add to this equation. Some have to do with patent reform, she believes, others have to do with increased price transparency, as was alluded to earlier, and others she's very dedicated to. And one of her top legislative priorities is pharmacy benefit manager PBM reform.

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And Representative Harshbarger has been so inspired by and, and, and fortunate to stand on the shoulders of so many great thought leaders, lawmakers here in Congress, notably Senators Cornyn, Senators Grassley, Senator Lee.

24:29
And I think some of her ideas she brings to the table that I'll mention briefly build on a lot of what they have been working on in the past. With regard to patent reform of pharmaceuticals,

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Representative Harshbarger has been working on bipartisan legislation with Senator Hassan from New Hampshire that was recently introduced late last week.

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The issue being brand name manufacturers can at times be able to game the drug approval and patent system by telling one story to the FDA about their new drug and telling another story to the Patent and Trademark Office, the PTO.

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Although FDA and PTO receive the basic information about a drug—chemistry, manufacturing, etcetera—manufacturers can exploit the lack of coordination between FDA and PTO and hold back information from the Patent and Trademark Office so they can seek secondary patents years later.

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This can lead to patent thickets that unfairly extend the product's market exclusivity, blocking biosimilar and other generic drugs from market entry years after an initial product's patent has expired.

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Representative Harshbarger is working on the bipartisan Medicaid Medication Affordability and Patent Integrity Act that would be that would put in place some simple reforms: require manufacturers to certify that when they submit initial info to the FDA and the PTO, they are not knowingly submitting conflicting or incomplete information.

26:03
Failure to comply with this act, the attestation, or information disclosure requirement under the legislation, could render a patent unenforceable if the patentee is found to have acted improperly in later litigation.

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The nonpartisan Congressional Budget Office has estimated this will unlock more generic competition, saving taxpayers some $100 million over a decade and likely with more out of pocket savings for patients as well.

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With respect to the greater transparency, Representative Harshbarger was proud to work with the Energy and Commerce Committee in a bipartisan fashion on a number of elements of the Lower Cost More Transparency Act, which passed the House of Representatives last session of Congress with strong bipartisan support.

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One of the areas Representative Harshbarger has been concerned about is the growing vertical integration of healthcare entities in Medicare and other places.

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Representative Harshbarger has been championing and will be reintroducing somewhat soon, Promoting Transparency and Healthy Competition in Medicare Act.

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The bill would require greater public data reporting and transparency into how vertically integrated companies such as insurers that own providers, PBMs, and pharmacies interact with one another compared to when vertically integrated companies interact with independent physicians, pharmacies, and other entities not owned by the insurance company or PBM.

27:29
This in Representative Harshbarger's view will allow policy makers to better understand the impacts of these arrangements may have on the delivery of healthcare.

27:38
I want to mention in the in the realm of pharmacy benefit manager reform, PBMs, which is again one of Representative Harshbarger's top legislative priorities. She's proud to join forces with a number of bipartisan members—her fellow pharmacist Representative Buddy Carter—to have recently co-led introduction of the PBM Reform Act.

27:59
This includes all of the PBM reforms that were included in the original continuing resolution package toward the end of last year in December of 2024 that were negotiated on a bipartisan, bicameral basis.

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And a number of these key provisions would ban spread pricing and Medicaid and ensure pharmacies are fairly and adequately reimbursed for serving Medicaid beneficiaries.

28:25
It would also establish new requirements for the PBMs under Medicare Part D, including the policy to delink PBM compensation from the cost of medications and increase transparency.

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There's another section to promote price transparency for prescription drugs purchased by employer health plans by ensuring PBMs provide group health plans and insurers with greater with detailed data on prescription drug spending at least semi-annually.

28:53
And a requirement for the Centers for Medicare and Medicaid Services to define and enforce reasonable and relevant Medicare Part D contract terms from PBM insurer to pharmacy, including reimbursement.

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Very briefly, I'll wrap up with one of the other major issues or major bills that Representative Harshbarger has been working on looking to reintroduce soon with her bipartisan partners, Senators Elizabeth Warren and Hawley in the Senate and Representative Auchincloss.

29:27
And due to the conflicts of interest that have accrued in the PBM insurance industry, where PBMs are no longer just PBMs, they own providers, they own their own pharmacies.

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They have tremendous ability to steer business toward their own entities.

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Representative Harshbarger has championed last session the Patients Before Monopolies Act, which will address these conflicts of interest, prohibit a parent company of a PBM or an insurer from owning a pharmacy business and requires that a parent company, in violation of the PBM Act, to divest its pharmacy business within one year of the bill's enactment.

30:07
There are a number of other provisions that would seek to prevent these vertically integrated healthcare entities from seeking to game the system or get around the letter or spirit of the legislation. Very, very quickly—

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there is there is clear presence for government prohibitions on joint ownership to protect consumers and enhance competition, including in the railroad and banking industries.

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Following introduction of this bill, in the 118th Congress, the state of Arkansas enacted a state law to structurally separate PBMs from pharmacies and 39 state and territory attorneys generals recently urged Congress to take federal action to break apart PBMs from pharmacies as the PBM Act would. Thank you very much for this opportunity.

30:53
Isabela McGinniss
Thank you, Mr. Stein.

30:55
We'll now turn to Mr. Pottebaum, Health Policy Advisor to Senator Chuck Grassley, the Chairman of the Senate Judiciary Committee. In over four decades in the Senate, Senator Grassley has been an advocate of drug affordability and accessibility, with particular attention to the issues of rural communities like his native Iowa.

31:17
So Mr. Pottebaum, what are some issues impacting drug affordability and accessibility that you'd like to discuss today?

31:25
Nic Pottebaum
Great. Thank you for that question and thank you for the opportunity to provide comments today.

31:36
The issue of lowering prescription drug prices is a top priority for Senator Grassley. Today, approximately 47% of Americans used one or more prescription drugs in the past 30 days and this is roughly in line with utilization over the past two decades.

31:52
More Americans have access to prescription drug coverage than ever before with the advent of the Part D law and other health insurance policies in the past two decades. The growing availability of generic drugs and biosimilars in the recent decades has also resulted in higher utilization of lower cost treatments.

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However, Americans are spending more out of pocket on prescription drugs today and have serious issues and growing issues about accessing a local pharmacist. Today, we have fewer or we have 30% fewer retail pharmacies than we had a decade ago, and we have fewer rural and independent pharmacies, including in Senator Grassley's home state of Iowa.

32:30
I can point out several reasons from Senator Grassley's perspective about the high cost of prescription drugs and how it impacts reduce access, namely the lack of competition and abusive practices that we've already heard a little bit about in the pharmaceutical supply chain. The lack of transparency on prescription drug prices as well as opaque and powerful prescription drug pharmacy benefit managers we all call PBMs.

32:53
To establish more competition in the prescription supply chain, the Senate Judiciary Committee under Chairman Grassley's leadership this Congress has marked up and passed reforms to end pay-for-delay deals, curb the use of sham citizen petitions, deter product hopping, crackdown on patent abuse system, as well as improve coordination between the Patent and Trademark Office, Patent and Trademark Office and the FDA.

33:18
Senator Grassley, along with Senator Durbin of Illinois, have also worked to advance price transparency requirements and prescription drug ads. That has bipartisan support and support of the President, Vice President, and Health and Human Services Secretary.

33:31
I do want to spend most of my time discussing PBMs and their role in driving up healthcare costs along with some solutions. PBMs play a significant role in this prescription drug supply chain. They decide which prescription drugs you can access under your health plan, how much consumers will pay out of pocket, where you can get that drug, and how much the pharmacy gets paid.

33:51
PBMs are steering more patients away from their local pharmacy through low reimbursement mail order requirements as well as limiting patient choice. And as has been noted by Peter, PBMs have also become consolidated with the three major PBMs controlling roughly 80% of the PBM market and many are vertically integrated with insurance companies, providers, specialty and mail pharmacies, group purchasing organizations, offshore rebate aggregators, and more.

34:19
Nearly half of our nation's healthcare spending comes from state, local, and federal government. So as

policy makers, we need to be asking the question, are we getting the best, most efficient deal at the cheapest price for prescription drugs? Higher patient costs, reduced access, reduced competition and greater consolidation suggest we are not. Sunshine on PBMs has played a greater role in people understanding their frankly existence and becoming aware of PBMs and their power.

34:46
In 2021, Senator Grassley released the findings of a two-year bipartisan investigation with Senator Wyden on the Finance Committee into insulin price gouging. The investigation found many things, but it specifically found that PBMs encourage drug makers to spike the drugs list price in order to offer greater rebate. This in turn has allowed manufacturers to secure priority placement on covered medication all at the expense of the patient.

35:14
PBMs use the exclusion list that has put more pressure on companies to increase the size of the rebate, but have done little to reduce the price of insulin. This demonstrates the powerful role PBMs play in insulin price gouging.

35:28
Given the known problems that PBMs are causing, Senator Grassley has taken a multi-faceted approach with his colleagues in the Senate to lower prescription drug prices and hold PBMs accountable. It's critical that PBM legislation, the evidence based, promote robust transparency and accountability and take a comprehensive approach across the health insurance sector.

35:49
In 2018, Senator Grassley requested the FTC to assess consolidation in the pharmaceutical supply chain and its impact on drug prices. Senator Grassley appreciates that the FTC acted in 2022 and began their 6(b) study on the impacts of PBMs and the affordability of medicine. Since then, the FTC's two interim staff reports certainly have been helpful, but we're eager to get a full study, complete with legislative recommendations.

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That's why the Senate Judiciary Committee recently passed in April the Bipartisan Prescription Pricing for the People Act without opposition, which would require the FTC to produce its PBM study in a timely manner. While this timely report on PBMs is certainly critical,

36:30
we can stop some known anticompetitive PBM behavior today. Senator Grassley has introduced the Bipartisan PBM Transparency Act, which directs the FTC to stop deceptive and unfair pricing schemes like spread pricing, as we've seen with the Ohio Medicaid Managed Care program, prohibit arbitrary claw backs of payments made to pharmacies as we've seen under Medicare Part D with DIR fee claw backs, as well as require PBMs to report to the FTC how much money they're making through spread pricing and pharmacy fees.

36:59
We can certainly learn a lot about the effectiveness of state transparency laws in this space, as some have been more effective and less gamed by PBMs than others. Senator Grassley has also worked on and supported the Finance Committee's as well as the HELP Committee's PBM legislation last Congress in the 118th Congress, which in the 118th Congress, 68 Senators at one point co-sponsored or supported PBM reform legislation in committee.

37:24
A portion of Senator Grassley's committee work on the Finance Committee as I mentioned includes—

or not, not as I mentioned, I will talk about—is ensuring that there is fair assessment of pharmacy performance fees as well as quality metrics under Part D preventing spread pricing, preventing conflict of interest by PBMs at the expense of patients similar to standards we already apply at drug companies on P&T committees as well as price transparency through the Medicare and Medicaid program.

37:51
Certainly there are other common-sense evidence-based solutions that have been discussed and probably will continue to be discussed during this listening session, including de-linking compensation under Part D, empowering self-insured health plans with data from PBMs, as well as establishing fiduciary or duty of care standards that at least a half dozen states have established.

38:11
Iowans are certainly fed up with the skyrocketing cost of prescription drugs and reduced access; patients, rural pharmacies, and taxpayers certainly expect more. Thank you for giving me the opportunity to discuss some of Senator Grassley's PBM reform efforts and happy to submit my comments in writing.

38:28
Kelse Moen
Thank you for those comments, Mr. Pottebaum.

38:31
Now let's hear from Senator Cornyn's Chief Counsel on the Senate Judiciary Committee, Ms. Rooney Becker.

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Senator Cornyn, who is a senior member of the Judiciary Committee, has also sponsored several bills to promote lower prices through drug competition.

38:46
So, Ms. Rooney Becker, what are some issues impacting drug affordability and accessibility and possible solutions from your perspective?

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Franci Rooney Becker
Thank you so much, Kelse.

38:54
And I want to say thank you to President Trump and everyone in this room for your sincere attention to this important issue. Senator Cornyn is grateful to be included in this conversation. Innovation and competition are the two most important things about drug pricing going forward in this environment.

39:13
Pharmaceutical development is an incredibly complex system. There are multiple opportunities for arbitrage and misuse and bad behavior. It's important to protect intellectual property and incentivize development. But the cost of drug pricing is an issue that's felt in every household. And in Senator Cornyn's opinion, the number one way to solve this is to increase generic and biosimilar access into the market.

39:38
The speed of competitive drugs coming to the market and the ability to have pharmacy level

substitutability and interchangeability as soon as possible within the within a framework that still functions and protects innovation and intellectual property, right? The arrangement where if you get a patent, you get a term of exclusivity. That's the foundation for the kind of financial development that makes the United States the crown jewel of pharmaceutical development worldwide. And so it can't be appropriate to disrupt that.

40:12
But everything that we can do to solve those technical problems we're seeing in the current system that harms the availability of generics and biosimilars to come to market would have redounded benefits nationwide. And so in an attempt to try to improve that, the Senator has two bills introduced that were both reported unanimously out of the Senate Judiciary Committee earlier this year and have been for multiple Congresses that would tackle two particular bad behaviors that in the Senator's view, impede this increased access to generics and biosimilars.

40:49
The first is the Affordable Prescriptions for Patients Act, which would target the use of patent thickets in the patent dance. And I'm being very precise with my language there by referencing the patent dance because I think sometimes discussions around patent thickets can get a little bit messy. Because if you and, and granted, right, like every patent should be validly created and, and the Senator believes that there's an appropriate role for post grant review and that it's fair sometimes to administratively challenge patents.

41:18
But at the same time, if the fact that this is your 14th patent added to a particular pharmaceutical combination doesn't mean per se that that particular patent is improperly granted, right? Like if a patent can stand on its own, it will stand on its own when it's the 15th patent. And I do think that can get kind of lost in conversations around patent thickets because sometime if a patent is a true new non-obvious development, then it is appropriate for that patent to be granted, even if there are many patents on one particular drug.

41:46
That is why what Affordable Prescriptions for Patients does is addresses patent thickets in the context of the patent dance. The patent dance was passed in BPCIA—I believe it's a part of the Patient Protection and Affordable Care Act back in 2010—and the patent dance tried to create a framework for biosimilars similar to Hatch-Waxman, to increase the resolution of intellectual property prior to the launching of a drug competitor at the end of a patent term.

42:14
The patent dance is a voluntary pathway and over the course of the last 15 years, it has not functioned as intended. Part of this is because it has not created the efficiencies that were intended in terms of litigating the patents at issue.

42:32
So what Affordable Prescriptions for Patients does is it says, if you participate voluntarily in this patent dance, then the number of patents to be litigated are limited to kind of the foundational patents, the ones that really have to be litigated, the ones that are like about the actual molecular structure and so on.

42:48
And then, in return, the reference product sponsor has to provide all of the information that they have about the drug's manufacturer. This was what we see as a problem in the patent dance. You had two

parties who didn't really trust each other. And because it was a voluntary pathway, you had a kind of "I'll show you mine, you show me yours," issue.

43:05
So you had a failure of information and then huge amounts of patents need to be litigated. Intellectual property litigation, as everybody knows, is incredibly expensive. And so you just did not have the efficiencies created in the system that you were hoping for. So that's what Affordable Prescriptions for Patients does is it sets a cap on the number of patents that are litigated if the parties do voluntarily participate in the patent dance.

43:27
I think going back to my comments about patent thickets in general, I think that's a very important comment. I think that attempts to address patent thickets can run into real problems when they're dealing with actual validity enforcement of a particular patent and can implicate like larger property rights issues that are worthy of discussion, but maybe not solvable in a two-page bill. And that's why this bill tackles the patent thickets specifically as to the patent dance, again, bringing further biosimilar entrance to the market faster with more certainty.

43:59
And then we can get that competition and that is what is going to bring prices down for people, especially as biosimilars are going to become even—biosimilars and large molecules, right, are we're transitioning from a small molecule world to a large molecule world, more infusions—and so it's really important to make sure that that system functions 'cause we're going to see more and more of it going forward.

44:21
The second bill that Senator Cornyn has is the Drug Competition Enhancement Act. This bill addresses another particular behavioral issue. This is an antitrust issue called product hopping. Product hopping occurs when a manufacturer creates a follow-on product, a new, a new product that is treating the same condition but is an improvement in some way, extended-release tablets, things of this nature.

44:50
But the problem is, is that their new product is facing many more years of exclusivity and their old product which is still approved and still functional, right, can be close to coming off exclusivity. The generics are kind of coming down the pike.

45:06
And so sometimes a manufacturer will behave in an anticompetitive manner as to the original product, as to the old drug that is coming off exclusivity. This is a very important point because the follow-on products—innovation, development, growth—is good. We want to incentivize that.

45:22
We would never want to create a situation where people do not want to create new drugs, but just because you have a new drug does not mean you can make misrepresentations or otherwise behave in an anticompetitive manner as to your original product.

45:36
So those are the Senator's two bills that he has in the space. We've moved them out of the committee multiple times before. We're hoping to move them out of the Senate this year. And Senator Cornyn is grateful to be here to discuss these important issues. Thank you.

45:48
Isabela McGinniss
Thank you, Ms. Rooney Becker.

45:54
We'll now turn to Mr. Pappas, who serves as Director of Intellectual Property Policy for the U.S. Senate Committee on the Judiciary under Senator Thom Tillis. Senator Tillis is a leader on intellectual property issues and patent reform, currently serving as Chairman of the Judiciary Committee's Subcommittee on Intellectual Property.

46:17
Mr. Pappas, same question to you. What are some issues impacting drug affordability and accessibility and possible solutions?

46:27
Peter-Anthony Pappas
Well, thank you for inviting Senator Tillis' office to participate in this listening session. I appreciate the opportunity to share some thoughts.

46:33
America's robust intellectual property framework, most notably our patent system, is essential to fostering investments in pharmaceutical innovation and to ensuring accessibility to those medicines to benefit patients and society, both in the short and long terms. Concerns regarding drug affordability are important, as are the efforts to strengthen the patent system to ensure continued innovation now and well into the future.

46:54
Let's not forget Article 1, Section 8, Clause 8 of the U.S. Constitution grants Congress the enumerated power to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries."

47:09
How many other countries had the foresight to embed IP into their very founding? The U.S. leads the world in pharmaceutical innovation, and this leadership is indeed built upon the strength of our patent system, which has enabled countless new medicines to transform the health of Americans and fuel tremendous contributions to the economy.

47:25
This is no mistake. American exceptionalism when it comes to biomedical innovation has been facilitated by carefully crafted policies that sought to achieve this outcome, and by all accounts, they have proven a remarkable success.

47:37
Given the success, any proposed changes to the patent system or restrictions on its use should be based on demonstrated need and robust and reliable data and facts. In the pharmaceutical area, those calling for such change have not met that heavy burden. Allegations regarding so-called patent thickets and evergreening have invariably been based on misleading data that have been thoroughly debunked.

47:56
Yet, this unreliable data continues to be cited and harmfully influence the policy debates surrounding

drug pricing. Concerned with this trend, beginning in 2022, Senator Tillis sent multiple letters to the USPTO and the FDA that raised questions regarding plain errors and data published, for example, by the group I-MAK.

48:14
For years, I-MAK and affiliated groups, including certain commonly funded academics, have claimed in the reports and writings that most medicines are covered by dozens or hundreds of patents each allegedly resulting in exclusivity periods that last 30 or more years. It was evident, however, that many of the examples cited in such sources had already gone generic shortly after or, in some cases, even before they were published, emphasizing the importance of reliable evidence.

48:38
Senator Tillis therefore requested the FDA and the USPTO conduct a study regarding whether this data is reliable, as it underlies many of the legislative and policy proposals in this area. In June 2024, the USPTO, alongside the FDA, published a report that countered the approach and conclusions raised by these groups.

48:55
The study refuted various claims by such groups, including acknowledging the cycle of innovation and confirming that the number of patents may not be predictive of the timing of generic entry. The study also concluded that the number of patents claimed by I-MAK were erroneous because it was not appropriate to include abandoned applications in the number of patents as they do not pose a barrier to competition and that a total of all pending and abandoned applications is not a meaningful metric.

49:19
With respect to exclusivity periods, the report concluded that the timing of generic competition is not fully reflected by a computation of patents and exclusivities, as it can be affected by other factors. Both academics and innovators whose products appeared in such reports have also refuted the number of patents published by I-MAK, as well as the inference that the expiration date of patents is necessarily or even commonly an indicator for when generic drugs enter the market.

49:44
Both the FDA and the USPTO in fact held listening sessions in January 2023, which consistent with the conclusions of the later 2024 report, show that the average effective exclusivity period of drugs is around 13 years. The testimony and docket in these listening sessions also showed that many of the medicines that I-MAK claimed as covered by thickets, in fact had patent numbers in the single digits and had already become generic.

50:07
Earlier this year, the USPTO presented additional analysis that showed that large patent families that many claim amount to so-called patent thickets may be an issue in other fields, but that they're not actually common in the pharmaceutical industry.

50:18
In addition to these troubling inaccuracies, those who target the patent system as a means to lower drug prices often disregard the careful balance that the system strikes between incentives for innovation and access to generic drugs and biosimilars. It is critical to keep these incentives in focus as that is what brings new and improved medicines to patients in the first place.

50:37
Simply put, we would not be having a conversation today regarding drug affordability and accessibility if it were not for the U.S. patent system which encouraged and enabled these drugs to

exist in the first place. There's a reason why the world looks to our country when it comes to strong patent rights.

50:51
Senator Tillis is a sponsor of a series of bills to restore and bolster American innovation and provide more certainty for patents.

50:57
One bill, PERA, would ensure that there's robust subject matter eligibility for patent production so that we continue to encourage American innovation so that we do not fall behind Europe and China in critical fields such as cutting-edge medicine.

51:08
Currently, filed patent applications on diagnostic tests, regardless of how useful, novel or non-obvious the technology might be, are essentially dead-on-arrival due to the current state of our laws. This is extremely detrimental as it holds the U.S. innovators back from developing the best diagnostic capabilities as was evident in our lag to develop testing compared to Europe and Asia during the COVID pandemic.

51:29
Another bill, the PREVAIL Act, is intended to bring back balance regarding Patent Trial and Appeal Board proceedings and to eliminate gamesmanship by bad actors at the PTAB. Other patent related bills that have been proposed, specifically, those that aim to address so-called patent thickets and evergreening, do not address competition concerns because, again, the evidence does not show that there are patent thickets or evergreening problems in the pharmaceutical space.

51:48
Further, these proposals reduce incentives for innovation for new medicines or R&D.

51:54
Another area that does not require further legislation is patent settlements. We should be encouraging patent settlements that lead to generic or biosimilar entry. In this area, the FTC and the DOJ already have authority to enforce the law under the Supreme Court guidance and already receive information regarding settlement agreements from companies.

52:09
We should be careful not to discourage pro-competitive settlements.

52:13
And then there's the area referred to as product hopping. There was discussion to address conduct in connection with improvements to medicine, regardless of whether the original product is still marketed.

52:21
The FTC has the authority to address unfair competition. It would be unwise to allow an antitrust cloud to be placed over improving medicines. It is also troubling to see proposed legislation aimed at eliminating the ability to enforce certain patents against generics or biosimilar companies merely because they have a terminal disclaimer or disclaimers.

52:39
A terminal disclaimer is a fundamental part of the patent system that is commonly used across

technologies. Prohibiting an innovator from enforcing more than one patent connected by a terminal disclaimer would negate the ability to enforce valid patents.

52:51
There's also been a reference to skinny labeling and creating a safe harbor against induced infringement. Induced infringement is a fact-based matter, it is not appropriate to encourage infringement by creating a safe harbor.

53:01
Looking ahead to the development of the FTC and the DOJ joint report on anticompetitive practices in the pharmaceutical markets, there's one consistent theme that has emerged across these listening sessions as disrupting the careful balance built into our IP system, and that is the role of pharmacy benefit managers in blocking access to generics and biosimilars, impeding efficient competition and access to pharmaceutical market.

53:22
As the agencies consider recommendations to improve the affordability of pharmaceuticals by increasing generic and biosimilar availability and promoting competition, reforms that address these misaligned incentives will be essential. Moving forward, we must take extreme care.

53:35
The Biden Administration unfortunately took the novel approach of simultaneously politicizing and weaponizing IP. It proposed a framework of exercising march-in rights under Bayh-Dole based on the price of medicines. Aside from being counter to the statute, such a framework would destabilize the innovation ecosystem for all technologies. Requests to misuse Section 1498 also would destabilize the innovation ecosystem across technologies.

53:57
IP rights are already under siege from foreign bad actors, and the last thing that the U.S. needs to do is subject itself from attacks from within.

54:05
In conclusion, the U.S. and its citizens should not be the ones to shoulder the burden of subsidizing the world's access to drugs and biologics. Nor should the U.S. patent system, the envy of the world, be made the scapegoat for the lack of lower drug costs domestically.

54:17
These drugs would simply not exist and thus, would not be the subject of discussion today if were not for the U.S. being the global innovation leader. Thank you.

54:30
Kelse Moen
Thank you, Mr. Pappas.

54:31
And now we'll hear from our final panelist, Mr. Lee, the Chief Counsel for Intellectual Property of the House Judiciary Committee.

54:39
Mr. Lee, you have you have had a front row seat to a lot of the issues we've discussed today, not only through your work on IP legislation in the House Judiciary Committee, but also in your previous job as

a patent judge on the Patent Trial and Appeal Board. So what are some of the issues of drug affordability and accessibility that you see and what are some potential solutions?

55:00
John Lee
All right, thank you very much. And first of all, thank you to the Department of Justice and to the Federal Trade Commission for holding this this event and for inviting me.

55:09
And I, you know, I'll start by joining the chorus and applauding the President for his leadership in addressing the critical issue of high drug prices and high healthcare costs in general. I think the issue that I wanted to speak most about is about balance. I think there's a lot of rhetoric going one way, going the other way, and I think really, the truth is somewhere in between. I think we all know that.

55:39
It is absolutely true that a critical part of the health of Americans is the availability of cutting-edge medicines. And in order to get cutting edge medicines, we need to have a healthy innovation ecosystem, of which the patent system is an important part. And we need to not kill the golden goose and make sure that stays the envy of the world. So that's, that's very important.

56:06
But at the same time, I think all of us can see that the balance and the status quo is not working; it's off-balance.

56:17
American consumers pay and American patients pay higher drug prices than any other people, inessentially the entire world, certainly in developed countries. There are many countries where the same medicines are available, they're just available cheaper. And why are American consumers disadvantaged?

56:37
So that, that's why the, the balance isn't quite working. So, you know, I, I do want to say that it's of course very important to note that there are a lot of factors that go into that.

56:50
So anyone who tries to distill it down to one thing, like you fix this one thing and drug prices will, will magically come down, I think that that person is, is being disingenuous to a lot of things that go into that.

57:01
You've heard about many of them today from my fellow panelists, heard about the role of PBMs, insurance companies, all the middle men. We've heard about a lot of things. There are a lot of regulatory burdens out there.

57:13
Obviously, unlike many other industries, the pharmaceutical and biotechnology industries are very heavily regulated. So that's another factor. There are trade aspects as well.

57:24
U.S. consumers are being disadvantaged by policies in other countries. And, and I would suggest that there are trade policies that could potentially address some of those disadvantages both for American consumers and for American pharmaceutical and biotechnology companies.

57:41
And this administration, of course, has been a leader, historic leader in using trade policy to try to help Americans and American businesses. But I do want to focus most of my, my discussion about patents, mainly because of course, that's, that's the work I'm most engaged in at the House Judiciary Committee.

57:59
It is, it is true that, you know, I, I think everyone on our committee, certainly Chairman Jordan and Chairman Issa of the IP Subcommittee, are very strongly behind clear, robust patent protections.

58:16
It's very important that if you are an innovator and you invent something new and non-obvious and all the other things that are required by the statute, that you and you get a patent issue issued to you that you can enforce that patent, and that patent is all, all the benefits of that patent are given to you so that you can recoup your investment, so that you can be incentivized to continue innovating. So that's, that's of course very important. And that is why the patent system is set up the way it is. That's why all the remedies that are available to a patentee are in the statute.

58:54
But that's not all that's in the statute.

58:57
Importantly, there are very, very clear limits on patents. You cannot get a patent if it is not novel, you cannot get a patent or should not get a patent if it is obvious. There are there are a number of limits in there and it's important that those also be enforced. And the reason is that while patents are an important incentive to innovate, they can also be anticompetitive and anti-innovation.

59:24
And we, the, Acting Director Stewart talked about the patent bargain in her opening remarks—that's very important—that in exchange for the government creating this property right for you as an innovator, there's the other part of the bargain that you provide transparency and disclosure, information so that follow-on innovations can occur.

59:46
If the limits of patents are not enforced, then all that follow-on innovation can potentially be co-opted and blocked as well. So it's important to both make sure that the remedies and strength of a patent that's in the in the Patent Act are enforced, but it's also all the limits to patent rights are also enforced.

1:00:11
And so there are a number of solutions that that we're looking at the House Judiciary Committee to address the, the balance of patent rights as part of, you know, solutions to, to the way drug prices are going.

1:00:27
Certainly we support the efforts of the Patent and Trademark Office in improving prosecution accuracy so that the patents issued by the PTO are properly scoped.

1:00:38
We're looking at litigation—the way that a lot of disputes across industries, but certainly in the

biopharmaceutical space between, you know, pharmaceutical innovator companies, branded companies, and generic and biosimilar companies, a lot of those disputes are handled in our courts.

1:00:58
And so the way patent litigation goes, how expensive it is, how long it takes, its complexity, these are some of the things that we're looking to address and that could, you know, benefit both generic and biosimilar companies as well as branded companies.

1:01:17
We're looking at preserving the ability that Congress has provided to challenge patents to ensure that patents that should not have been granted because they don't meet the requirements and they exceed the limits of the statute that such patents are being are able to be effectively challenged and if appropriate, gotten rid of.

1:01:40
And so, you know, that includes preserving the inter partes review process and the post-grant review process at the Patent Trial and Appeal Board.

1:01:51
As well, you know, we've, we've heard a lot about thickets, patent thickets. It's something we're looking at as well. A couple of pieces of legislation we're looking at there: the Affordable Prescriptions for Patients Act, which we've already heard about, as well as the ETHIC Act, which has to do with terminal disclaimers that my colleague just talked about.

1:02:08
And just a, just a moment on that, you know, a terminal disclaimer, at least the ones that are at issue in the ETHIC Act, these are situations where there has been a patent issued and then other patents issued that the Patent Office has determined to be not patentably distinct from the original patent.

1:02:27
So they're the same invention and our system is strange in that you're allowed to get more patents on the same thing. When that happens though that shouldn't that that shouldn't be abused in order to deter generic and biosimilar companies.

1:02:44
And the last thing I'll mention just to wrap up is the issue of skinny labeling, which has come to the fore in recent months. The ability for generic biosimilar companies to market generics and biosimilars where there are patents for branded drugs, but the patents don't cover all uses of that drug and that drug can be used off patent in other ways and instituting some reforms to make sure that's working properly. So those are some of the solutions that we're looking at.

1:03:20
Isabela McGinniss
Thank you, Mr. Lee, and thank you to all of our panelists here today. It was an insightful discussion.

1:03:29
And now we'll move to hear closing remarks from Daniel Guarnera, Director of the FTC's Bureau of Competition, and Dina Kallay, Deputy Assistant Attorney General for International Policy and Appellate at DOJ's Antitrust Division.

1:04:09
Director Daniel Guarnera

Thank you so much. Good afternoon. My name is Dan Guarnera, and I'm the Director of the Bureau of Competition at the FTC.

1:04:16
I'd like to thank our distinguished guests from Capitol Hill for taking the time to share their insights at this capstone listening session. It was extremely valuable to hear each of you discuss how Congress is working to tackle the high drug prices that President Trump's executive order asks federal agencies to address. These three listening sessions have been an important opportunity to bring together experts from across the country to learn, discuss, and begin to chart a path forward.

1:04:47
I am grateful for the participants in all three panels, experts in the competition introduced by generic drugs and biosimilars, and formulary and benefit practices, and in regulatory abuse in the pharma space, as well as, of course, our Hill staff here today.

1:05:03
Thank you also to the public, to the many concerned Americans who have submitted dozens and dozens of comments and questions in connection with these listening sessions.

1:05:12
Finally, I also want to thank the staffs of DOJ, the Department of Commerce, and the FTC for all the hard work that went into today's listening session, as well as the previous two.

1:05:24
As President Trump's executive order recognizes, unaffordable drug prices cause everyday Americans real financial hardship and can endanger people's health and even their lives. High prices cause too many Americans to face every day the choice between life sustaining medicine on the one hand and food, clothes, and the monthly rent or mortgage payment on the other.

1:05:49
For me, one of the big takeaways from these listening sessions is that lowering drug prices is going to require a dedicated and coordinated effort across many parts of the government, one that's informed by the best thinking on this issue from people in the federal agencies, in Congress, and those outside of government. The Trump-Vance FTC is committed to doing our part to address drug prices and other healthcare costs so families across our great country can flourish.

1:06:18
For example, as Mr. Pottebaum mentioned, we are in the midst of an in-depth market study of the PBM industry and we are hopeful that the reports that result from this study will bring needed transparency to pharmaceutical distribution and its effect on drug prices. FTC market studies have informed legislation in the past and so we encourage our Congressional partners to keep an eye out for that report.

1:06:42
We're also in the middle of litigating a case alleging that PBM pricing strategies drove up the price of insulin. And two months ago, we challenged the appropriateness of more than 200 products in the FDA Orange Book across 17 different brand name products.

1:06:58
This is on top of our work to drive down healthcare costs in other areas, including our active litigations against an anesthesiology provider roll up and a medical device merger.

1:07:09
These listening sessions make clear that the challenges to bringing down drug prices are significant, but so is the commitment by President Trump and those of us serving in his Administration, as well as our colleagues in Congress, to confront these challenges head on.

1:07:25
These listening sessions will help accelerate this process and shine a light on the path forward to lower pharmaceutical prices for the benefit of all American families. We at the FTC will carefully review the information, insights, and ideas generated in these three sessions and apply them to our work.

1:07:46
We look forward to working alongside our partner agencies and legislators in support of the Trump Administration's mission to make healthcare affordable for everyday Americans. My thanks again to everyone involved in this vitally important effort.

1:08:21
Deputy Assistant Attorney General Dina Kallay
On behalf of the Justice Department's Antitrust Division, I would like to extend my heartfelt gratitude to Tom DeMatteo, Peter Stein, Nic Pottebaum, Franci Rooney Becker, Peter-Anthony Pappas, and John Lee for all of your insightful remarks here today, and to our colleagues at the Department of Commerce and USPTO for hosting us here in this beautiful room today.

1:08:44
Today's hearing marks the conclusion of our three listening sessions on lowering drug prices through competition. We've heard from leading scholars, business experts, and congressional staffers dedicated to lowering drug prices for Americans. But our work under President Trump's executive orders to lower drug prices has only just begun.

1:09:05
Consistent with the President's directives, the Antitrust Division, under the leadership of Assistant Attorney General Gail Slater, is dedicated to enhancing competition and combating rent-seeking in healthcare.

1:09:19
In doing so, we're committed to promoting free enterprise competition that rewards productive economic activity and innovation while deterring economically repressive and inefficient practices. By combatting anticompetitive conduct and regulatory exploitation, we can make prescription drugs more affordable to American patients, employers, and taxpayers.

1:09:45
We disagree with those who say that our healthcare system is too complicated or dysfunctional for competition to make a difference and believe competition is key in this area.

1:09:57
To accomplish the Executive Order's goals, Assistant Attorney General Slater has prioritized vigorous enforcement of our antitrust laws in healthcare and the Antitrust Division's Anticompetitive Regulations Task Force is focusing on regulations at the federal, state, and local level that stimie competition and provide opportunities for gamesmanship.

1:10:20
We are also committed to working with partners across the Trump-Vance administration and

Congress to achieve the President's vision to the benefit of the American public. In executing our mission

1:10:32
at the Antitrust Division, we work for the American people, and we want to hear from you all. We encourage people affected by these drug and healthcare prices to reach out to the Antitrust Division directly or through our www.healthycompetition.gov complaint center. The Antitrust Division also recently launched a whistleblower program with the United States Postal Service that rewards tips resulting in criminal fines or other recoveries.

1:11:06
Let's get to work to make America healthier and more competitive again. Thank you.

1:11:21
Christopher Shipp
On behalf of the Department of Commerce and the USPTO, thank you to our partners from the DOJ and FTC for joining us and putting on this program. We also appreciate our friends from Capitol Hill for taking the time to speak with us. This concludes our event this afternoon. Please feel free to stick around and discuss. Thank you.